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Health Committee

Patient Safety

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Volume II

Oral and written evidence

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The Health Committee

The Health Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health and its associated bodies.

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The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the Internet at www.parliament.uk/healthcom

Committee staff
The current staff of the Committee are Dr David Harrison (Clerk), Adrian Jenner (Second Clerk), David Turner (Committee Specialist), Frances Allingham (Senior Committee Assistant), Julie Storey (Committee Assistant) and Gabrielle Henderson (Committee Support Assistant).

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Witnesses

Thursday 30 October 2008

Professor Sir Bruce Keogh, NHS Medical Director, Professor Dame Christine Beasley, Chief Nursing Officer, Department of Health, and Mr Martin Fletcher, Chief Executive, National Patient Safety Agency

Thursday 20 November 2008

Professor Richard Thomson, Professor of Epidemiology and Public Health, University of Newcastle, and Professor Alastair Gray, Professor of Health Economics and Director of the Health Economics Research Centre, University of Oxford

Mr Martin Bromiley, Chairman, Clinical Human Factors Group, Ms Josephine Ocloo, Patients for Patient Safety Champion, England, WHO, World Alliance for Patient Safety, and Mrs Clare Bowen

Thursday 15 January 2009

Professor Andy Adam, President, Royal College of Radiologists, Dr David Whitaker, Immediate Past President, Association of Anaesthetists of Great Britain and Ireland, and Professor Brian Toft, Professor of Patient Safety, Coventry University

Professor Mike Murphy, Consultant Haematologist, John Radcliffe Hospital, and Professor Bryony Dean Franklin, Centre for Medication Safety and Service Quality, Imperial College Healthcare NHS Trust, and Mr Roger Lamb, Healthcare Manager, GS1 UK

Thursday 22 January 2009

Mr John Black, President, Royal College of Surgeons of England, Rev Dr Pauline Pearson, Deputy Director, CETL4HealthNE: Centre for Excellence in Healthcare Professional Education, Newcastle University, and Professor David Webb, Professor of Therapeutics and Clinical Pharmacology, The University of Edinburgh

Ms Kathryn Fawkes, Senior Theatre Nurse, Great Ormond Street Hospital, London, Dr Susannah Long, Clinical Research Fellow, Clinical Safety Research Unit, Imperial College London, Mr Simon Kreckler, Clinical Research Fellow, Nuffield Department of Surgery, and Ms Sarah Dheansa, Matron for Surgical Care, Queen Victoria Hospital, East Grinstead
Thursday 5 February 2009

Dr Alison Holmes, Director of Infection Prevention and Control, and Consultant in Infectious Diseases, Imperial College Healthcare NHS Trust,
Professor Matt Griffiths, Visiting Professor of Prescribing and Medicines Management, Northampton University, and Professor Aneez Esmail, Professor of General Practice, The University of Manchester

Dr Jo Bibby, Director of Improvement Programmes, The Health Foundation, Dr Olga Kostopoulou, Medical Decision Making Research Group, The University of Birmingham, and Captain Guy Hirst, retired airline pilot, human factors trainer

Thursday 5 March 2009

Professor Sir Ian Kennedy, Chairman, Healthcare Commission,
Baroness Young of Old Scone, Chair, Care Quality Commission, and Dr Bill Moyes, Executive Chairman, Monitor

Mr Finlay Scott, Chief Executive, General Medical Council, and Mr Steve Walker, Chief Executive, NHS Litigation Authority

Mr Geoffrey Podger, Chief Executive, Health and Safety Executive, and Professor Kent Woods, Chief Executive, Medicines and Healthcare Products Regulatory Agency

Thursday 19 March 2009

Professor Sir Michael Rawlins, Chairman, National Institute for Health and Clinical Excellence, Lord Patel, Chairman, and Mr Martin Fletcher, Chief Executive, National Patient Safety Agency

Professor the Lord Darzi of Denham KBE, Parliamentary Under Secretary of State, Ann Keen MP, Parliamentary Under Secretary of State for Health Services, and Sir Liam Donaldson KB, Chief Medical Officer, Department of Health

Wednesday 3 June 2009

Dr Peter Daggett FRCP, Consultant Physician, Stafford Hospital, and Mr Howard Catton, Head of Policy and Implementation, Royal College of Nursing

Mr Ben Bradshaw MP, Minister of State for Health Services, Professor Sir Bruce Keogh, NHS Medical Director, and Mr David Flory, Director General, NHS Performance and Operations, Department of Health

Mr Eric Morton, Interim Chief Executive, Mid Staffordshire NHS Foundation Trust
**List of written evidence**

The following memoranda were published as *Patient Safety: Written evidence*, HC 1137, Session 2007–08

39 National Patient Safety Agency (NPSA)
40 Mind (National Association for Mental Health)
41 Care Quality Commission
42 UNISON
43 Medical Defence Union
44 Royal College of Nursing
45 ARHAI
46 British Institute of Radiology
47 Dr Liam O'Hara
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51 Hepatitis C Trust
52 Healthcare Commission
53 Adrian Delemore
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55 Royal College of Midwives
56 Action against Medical Accidents
57 National Institute for Health and Clinical Excellence
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60 Baxter Healthcare
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62 British Medical Association
63 Association of Anaesthetists of Great Britain and Ireland (AAGBI)
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65 Monitor
66 Royal College of Pathologists
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68 Royal College of Psychiatrists
69 Royal College of Surgeons of England
70 Royal College of Anaesthetists
71 Stuart Emslie and John Step
72 Council for Healthcare Regulatory Excellence
73 David Ringwood
74 Royal College of Physicians
75 Faculty of Occupational Medicine
List of further written evidence

The following written submissions were received after the publication of Patient Safety: Written evidence, HC 1137, Session 2007–08.

1. Department of Health (PS 01A) Ev 191
2. Department of Health (PS 01B) Ev 195
3. Department of Health (PS 01C) Ev 197
4. Correspondence between the Secretary of State for Health and the President of the Royal College of Surgeons of England (PS 01D) Ev 198
5. The Health Foundation (PS 21A) Ev 200
6. The Health Foundation (PS 21B) Ev 201
8. National Patient Safety Agency (NPSA) (PS 39B) Ev 204
9. Care Quality Commission (PS 41A) Ev 204
10. Royal College of Nursing (PS 44A) Ev 206
11. Royal College of Nursing (PS 44B) Ev 210
12. Royal College of Physicians (PS 47A) Ev 211
13. Patients Association (PS 50A) Ev 212
14. Healthcare Commission (PS 52A) Ev 218
15. Healthcare Commission (PS 52B) Ev 228
16. Action against Medical Accidents (AvMA) (PS 56A) Ev 229
17. Royal College of Psychiatrists (PS 68A) Ev 231
18. BASICS (British Association of Immediate Care) (PS 77) Ev 232
20. Royal Pharmaceutical Society of Great Britain (PS 78A) Ev 247
21. Mrs Clare Bowen (PS 79) Ev 251
22. Professor Richard Thomson (PS 80) Ev 255
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25. Professor Brian Toft (PS 83) Ev 266
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28. CORESS (Confidential Reporting System in Surgery) (PS 84) Ev 274
29. CORESS (Confidential Reporting System in Surgery) (PS 84A) Ev 276
30. National Association of Laryngectomees Clubs (PS 85) Ev 278
31. Professor Bryony Dean Franklin and Nick Barber (PS 86) Ev 281
32. Professor Mike Murphy (PS 87) Ev 285
33. Dr Susannah Long (PS 88) Ev 286
34. Professor David Webb (PS 89) Ev 287
35. Revd Dr Pauline Pearson, Amanda Howe, Aziz Sheikh, Darren Ashcroft, Pam Smith, Alison Steven on behalf of The Patient Safety Education Study Group (PS 90) Ev 292
36. Medicines and Healthcare Products Regulatory Agency (PS 91) Ev 295
37. General Medical Council (PS 92) Ev 298
List of unprinted evidence

The following memoranda have been reported to the House, but they have not been printed and copies have been placed in the House of Commons Library, where they may be inspected by Members. Other copies are in the Parliamentary Archives, and are available to the public for inspection. Requests for inspection should be addressed to The Parliamentary Archives, Houses of Parliament, London SW1A 0PW (tel. 020 7219 3074). Opening hours are from 9.30 am to 5.00 pm on Mondays to Fridays.

Patients Association (PS 50B)
Orde Levinson (PS 76 (Exhibits 1–5A and Appendices 1–3a))
Cure the NHS (PS 101A)
Dr Pradip Singh (PS 107 Annexes A to F)
Sufferers of iatrogenic Neglect (PS 109)
Oral evidence

Taken before the Health Committee
on Thursday 30 October 2008

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins          Dr Doug Naysmith
Sandra Gidley             Dr Howard Stoate
Stephen Hesford           Dr Richard Taylor

Witnesses: Professor Sir Bruce Keogh, NHS Medical Director, and Professor Dame Christine Beasley, Chief Nursing Officer, Department of Health, and Mr Martin Fletcher, Chief Executive, National Patient Safety Agency, gave evidence.

Q1 Chairman: Good morning. Could I welcome you to what is our first evidence session on our inquiry into patient safety? For your information, the written evidence that we have received has been published today, so it will be available for people to, I think “buy” is the right word, and read. I wonder if I could ask the witnesses if you could give us your name and the current position that you hold for the record, please?

Professor Dame Christine Beasley: Christine Beasley; I am the Chief Nursing Officer at the Department of Health.
Professor Sir Bruce Keogh: Bruce Keogh; I am the NHS Medical Director.
Mr Fletcher: Martin Fletcher; Chief Executive of National Patient Safety Agency.

Q2 Chairman: I have got a question to all of you that I would like to ask. How much harm is done to patients by the National Health Service overall, the primary care side and also the independent sector? Who would like to start?

Professor Sir Bruce Keogh: I am sorry; I did not hear the beginning of the question.

Q3 Chairman: I said how much harm is done to patients by those three organisations, the NHS overall, the primary care side and the independent sector? Who would like to start?

Professor Sir Bruce Keogh: I am sorry; I did not hear the beginning of the question.

Q4 Chairman: Do you have any views about that?
Professor Dame Christine Beasley: No. Obviously I agree with Martin. I think the whole issue of harm and safety covers the whole spectrum. I guess what I would add to that is that we look at the other end of the story. We ask acute patients what they think about their care, which includes safety and effectiveness as well as all the other things. Certainly the last Healthcare Commission report says that 92% of people say their care is very good, good or excellent. That is not just around patient safety but it includes that. So patients themselves tell us that a large amount of their care is very, very good.

Q5 Chairman: No views Bruce?

Professor Sir Bruce Keogh: I have nothing to add.

Q6 Chairman: Martin, you said that no harm has come to 66% of patients in the acute sector (583,000). How do you know that?

Mr Fletcher: What I said was of the 796,000, 583,000 relate to the acute sector. Of the total amount, 66% were reported as resulting in no harm to patients and around 1% of those incidents, which equates to about 10,000 reported incidents in that figure, were reported as being associated with either severe harm or death to patients.

Q7 Chairman: Who makes that judgment?

Mr Fletcher: That judgment is made at the local trust level, either by the person who is reporting or in consultation with the risk-management department who co-ordinate local reporting of incidents.
Q8 Chairman: Have you ever done any studies to show whether that reporting at that level by people immediately involved is sound?

Mr Fletcher: In terms of the harm outcome?

Q9 Chairman: In terms of the outcome in general: whether or not what they are saying is true.

Mr Fletcher: Yes, we do. For example, every incident where there is a report of serious harm or death of a patient we review individually. We have expert clinical reviewers who do that and, where we need to, we would go back to the trust also to get further information from them about the event and the investigation. I think it is quite a difficult thing to make an attribution about harm because we are often talking about people who are already quite sick and to exactly delineate what part the event played in terms of the overall outcome is not always an easy judgment to make but, as it relates to these reports related to death and serious injury, we review some 2,000 of those a month, and every one of those is reviewed individually to look at whether we need to take action from the point of view of national learning for the NHS.

Q10 Chairman: I was actually talking about the 66% that said there was no harm to the patient. Do you evaluate that as something that is correct? When someone reports that the patient has not suffered any harm, do you ever check to make sure that is the case as opposed to what is being said by somebody who may have a direct involvement in the patient’s situation?

Mr Fletcher: We have done that in particular topic areas. For example, one of the things that we would do is we might choose a topic, for example patient falls, and do a more in-depth study of those events. In those cases we would look in more detail at that. One of the things we think is that reporting of events associated with no harm is actually a good thing, because from the point of view of a safety culture, the more of those sorts of reports that we have the better opportunity there is for learning without anybody necessarily having been harmed. So we have seen the fact that there is that level of reporting as a very positive thing.

Q11 Chairman: I do agree with you. I am just questioning how definitely you know, when you say 66% of patients were not harmed, that it is the case that no harm came to them?

Mr Fletcher: That is what the NHS staff or the NHS organisation have told us.

Q12 Chairman: Why is it that reporting of patient safety incidents is not mandatory?

Mr Fletcher: It depends what you mean by mandatory. I think it would be fair to say that in every trust in the NHS there is an expectation that if an incident occurs that either could have, or did, harm patients that it is reported through the local risk-management system. In fact, one of the things that we have done over the past couple of years is worked with the Healthcare Commission to look at overall rates of reporting by a trust to see whether there are issues about under-reporting. If you are saying have we put out a rule and said everyone must report everything: that is not something we have done as an agency, but we have looked at other ways that this can be something that sends a very important responsibility and duty for staff in NHS organisations.

Q13 Chairman: Christine, do you have any views about this? I am quite interested. It is an expectation, for most things for 60 years in the National Health Service there has been an expectation, but why is it not mandatory?

Professor Dame Christine Beasley: I think we have to be. On the face of it, it can be very beguilingly simple to say: let us make everything mandatory, because you think if you do that that will give you all the data that you want, and often that is not the best way of doing it. Really the best way of doing it, I think, is setting expectations, and we do that in other ways too. For example, the Healthcare Commission looks at what it is that is going to be reported. We have seen the fact that there is that level of reporting and the annoyance about the under-reporting. There is a fine line to be drawn, I think, between where you put mandatory and where you really encourage the system to report.

Professor Sir Bruce Keogh: It seems a reasonable thing to do, on the face of it, but most, if not all, reports are voluntary. Often only the person that has made the error or the mistake knows that they have made an error or a mistake. So it relies on an individual’s personal, moral and professional responsibility to report it, and there is a tendency in trusts for reporting to be at both extremes of the spectrum. Very important and significant events tend to be reported and the annoying and irritating trivia are reported; it is the tranche in the middle that is poorly reported. There is a variety of reasons why they are poorly reported. Mainly because people do not recognise the value of reporting incidents like that because they do not perceive them as having really created much harm and they are not sure what influence they will have on the system, because they are unconvinced that the system will respond and, on the whole, historically, people have not had good feedback from the reporting of events. If this sort of thing were made mandatory, I think there is a risk that they could switch-off a slow and growing tendency to report the mid-range events. There is another issue, and that is that there are a lot of events out there. For example, at the Heart of England Trust I think there are 9,000 incidents a year reported, and that is in the face of known under reporting. We also know that some of the most effective reporting systems in other industries are based on voluntary nature and anonymity. So I
would much rather see this proceed with people continuing to report voluntarily because they believe that it is a good, professional thing to do and that it will help and, I think, in return for that, what we have got to try and do is make a system that is responsive to people when they do make reports.

Q14 Chairman: But we have to accept a level of known under reporting, from what you have just said. Do you think that is something that patients would feel comfortable with?

Professor Sir Bruce Keogh: I do not think anybody is comfortable with it, but by legislation I do not think you can force people to report incidents that they might report otherwise if they do not think they are that important: because there is quite a blurred area between when you think you have made a mistake and when you think you have not.

Q15 Dr Stoate: As usual, I would like to place on the record that I am a practising GP and also I chair the All-party Group on Patient Safety in this House. You talk about known under reporting, but surely that does not even begin to scratch the surface. I would like to pick up some points from Martin. The figures we have been given, estimated annual figures regarding adverse events in England in the NHS, given by the Department of Health and the National Patient Safety Agency; adverse events involving death per annum 34,000 (and that is preventable ones only). According to the NPSA, Seven Steps to Patient Safety (2004) that figure is 72,000 and yet Martin, when he announced some figures, which we have also got here, said that there were around about 10,000 severe harm and death reports. In fact, reported safety incidents in England by harm in the year 2007–08 only gives 3,200 deaths caused by patient safety incidents. Your own agency has estimated up to 72,000 deaths of which, as I say, 3,000 have been reported. That is not just under reporting, that is an extraordinary figure, surely.

Mr Fletcher: The figure I gave of 10,000, as you say, was for the period April 2007 to March 2008.

Q16 Dr Stoate: That is 10,000 severe harm and death. There are only 3,200 of those deaths. Your own agency has said there are 72,000 preventable deaths every year in the NHS, of which 3,000 have been reported?

Mr Fletcher: The data, to be clear, is 7,000 severe harm events and 3,283 deaths in that window.

Q17 Dr Stoate: That is right.

Mr Fletcher: One of the things to say is if you look at the overall trend in reporting, it is upwards. We are continuing to get more and more staff reporting and we are continuing to get more and more organisations regularly sending data to the NRLS. So, notwithstanding that we think there are issues around under reporting, and we have said that, for example, we need to do more around general practice reporting, which would be under represented in the data at the moment, the overall trend is upwards. As I say, the view we have taken is that higher reporting is a good thing, because it is associated with a more open, stronger safety culture, but I think also, as Bruce has said, there is no point collecting data if we do not do anything with it, and it is the response to that that is important in terms of action to improve patient safety.

Q18 Dr Stoate: I think, if the public realised that only between 5% to 10% of preventable deaths are being reported, they might have something to say about that.

Mr Fletcher: I think the issue is, as you know, depending on different approaches to how you measure these things you often get very different estimates of the deaths.

Q19 Dr Stoate: These are not my estimates, these are yours. Your organisation has estimated 72,000 deaths per annum of which you have said 3,000 are reported. So these are not my figures, they are your figures. Let me give you an example. If only 10% of airline crashes were reported, I think we would have some concerns?

Mr Fletcher: I take the point about the earlier estimate. I think the issue for me is that if you look at us in comparison to any other country, the comprehensiveness of the national system that we have got in place, the fact that as a national health service, on a monthly basis, we are now individually reviewing up to 2,000 reports of death and serious injury, I think, is a very comprehensive response. Could it be better? Yes. Is there more we need to do? Yes. But I think there is a very good basis from which to work. The other thing I would say is, although, obviously, the National Reporting System is the main engine room of how we identify areas that may need a national response, we are also looking at other sources of data as well, because we know that different data collections will give us different perspectives on issues. For example, in the past, when we did some work on issues around patients who were deteriorating and where there were safety concerns, we also looked at some of the data, on an anonymous basis, that the NHS Litigation Authority had, we would routinely be looking at data that the National Confidential Enquiries capture. A Serious Untoward Incident reporting system is in place, so I think part of what we are also trying to do here is build as complete a picture as possible from multiple sources of data.

Q20 Dr Stoate: Why are levels of reporting even lower in primary care, and what can we do about it?

Mr Fletcher: I think the reason that reporting is lower in primary care is because a lot of the focus of reporting and action on patient safety today has been in the acute care sector, and I think that in some ways has been inappropriate, because we know that some of the greatest risks to patient safety occur in the acute care sector because of the nature of the interventions that occur in hospitals, but I think there is recognition that we need to do much more now around engaging general practice in particular.
30 October 2008 Professor Sir Bruce Keogh, Professor Dame Christine Beasley and Mr Martin Fletcher

Q21 Dr Stoate: What effectively would you do?  
Mr Fletcher: The three things we have done recently is we have worked with the college to take the existing tradition in general practice of “significant event audit” and look at how we can build on that as an established, well respected part of how general practice reviews practice and make more of that; and at the recent College Scientific Congress we jointly launched new guidance on how to make the best of “significant event audit” with the College. We are also working with two strategic health authorities in the South West and also in the East Midlands to do some further work with general practice around a specially designed electronic reporting form for general practice: because I think one of the problem was that a lot of the data collection has been more focused on the acute care sector. What we need is a form that is easy to use, relevant to general practice, and so we are about to start that pilot in quite a large way in both those SHAs to actually provide a more bespoke reporting system for general practice and also working with primary care trusts as well. I think the third point, just to build on a point that Bruce also working with primary care trusts as well. I think the third point, just to build on a point that Bruce made, is that, of course, it is the feedback as well. People will report if they see a benefit in reporting, if they think it is going to improve patient care. So I think one of the problems that we have in the system is that I think people see events that they think are not that serious and they do not report them because they do not think they are that serious.

Q22 Dr Naysmith: I wonder if, Professor Keogh, I can pick up something you said earlier on. You talked about really severe incidents and trivial, at the end, and the ones in the middle that were rising slowly but were unreported. Presumably serious events are things that result in death and disability, and so on, but I am really interested in what you would call a trivial incident of which that lots are reported and what the mid-range type of things are that you are talking about.

Professor Sir Bruce Keogh: The trivial incidents that get reported in trusts range from things that people simply find annoying and irritating in their day to day work which do not necessarily—

Q23 Dr Naysmith: They are presumably safety?  
Professor Sir Bruce Keogh: No, not necessarily. I ran clinical governance quality and safety in a very big trust for about five years and the very first complaint I got when I took that post on was that someone wrote to me and said the scalpels were not sharp. I am a surgeon, so I know whether a scalpel is sharp or not.

Q24 Dr Naysmith: It could be quite serious if the scalpels are not sharp?  
Professor Sir Bruce Keogh: Yes, but it just was not true. These are the sorts of things which come across your desk. What I was particularly concerned about—in a sense when something goes seriously wrong the system has failed, and what we know from other systems is that when something seriously happens there have often been a series of other incidents which, if they were identified earlier, might have predicted that or other similar events and that with a number of events there are often common root causes. One way of getting to understand those root causes, or the warning signs, if you like, is for people to report events that are less serious. The problem we have in the system is that I think people see events that they think are not that serious and they do not report them because they do not think they are that serious.

Q25 Dr Naysmith: Give us an example of the sort of thing you are talking about. You have told us about a scalpel that was not sharp but when someone looked at it turned out to be sharp. That should not have been reported at all. Give me an example of a mid-range thing that you think ought to be reported and often is not.

Professor Sir Bruce Keogh: A mid-range thing might be some. I can give you an example of a problem I had once where an instrument broke during an operation. It did not break, something unscrewed, and that caused some delay and difficulty during the operation. It did not result in harm as a result of that, but, speaking to colleagues later in another hospital, I found that they had had a similar event. In my book, out of thousands of operations, that had happened once and I might be have thought that it is not an important incident, but, I guess, if things like that are added up, it may be that that is happening once a year in a number of places around the country and that could help people to identify that there is a problem with the screw thread on that particular bit of kit.

Q26 Dr Naysmith: Would it include something like a gas line being wrongly connected and anaesthetic set up but detected before the operation began? Should that be reported?  
Professor Sir Bruce Keogh: Yes, I think it should. That is exactly the sort of thing.

Q27 Dr Taylor: The reason we are doing this inquiry is because we have been absolutely appalled by the devastating round figure that we have been given. 10% of people going into hospital in the UK are harmed by the admission. That is utterly unacceptable. We also heard, as I think Howard said, that reported incidents are far less than those that are picked up by a systematic research/review of the notes. So this is a truly awful situation. What I want to ask specifically is have we any idea of the financial cost of the harm done?  
Professor Sir Bruce Keogh: We have some idea through the NHS litigation authority. We know that the cost in terms of litigation in the last financial year was of the order of two-thirds of a billion pounds.

Q28 Dr Taylor: Two-thirds of?  
Professor Sir Bruce Keogh: A billion.

Q29 Dr Taylor: Two-thirds of a billion.  
Professor Sir Bruce Keogh: Roughly 600 million.
Q30 Dr Taylor: Two-thirds of a billion on litigation. Any other costs we know?

Mr Fletcher: I think a couple of other perspectives on this. The issue here is that there is no doubt that unsafe care does cost the NHS money and waste scarce resources, and I think the estimates of that vary, depending on how you look at the issue. Bruce, for example, has given the example of the costs of paid litigation. The work that the Audit Office did when it did its review a few years ago and trusts were asked to estimate the cost of unsafe care in their context, we had a range of £88,000 to £400,000 a year. When we have looked from the NPSA end, for example, at specific types of problems, so when we did a very large review of 200,000 plus reports on falls. Tried to estimate the cost of that to the NHS. in England and Wales that figure came out at around £15 million per year in terms of the costs associated with those falls, and then there has been some work internationally looking at administrative data. So we look at the data that are routinely collected on admissions to hospital and look at any of those that are associated with complications. I was looking at some work, for example, from Australia where they came up with an estimate that around 18% of their hospital inpatient budget was associated with costs to do with care for people with there being some event, some problem with their care. As I say, I think different methods of looking at costing will give you different perspectives on this, and that just gives you some of the range.

Q31 Dr Taylor: What about specific conditions? For example, healthcare-associated infections. The figure we have been given for the cost of that is a billion a year.

Professor Dame Christine Beasley: Yes, it is worked out. What do we know is if you get, for example, MRSA *bacteremia* in hospital, you will probably stay for another at least five to ten days, if you get *Clostridium difficile*, probably 21 days. So you work out the number of bed days and that adds up to that sort of figure. That is how we work it out; that is a sort of proxy.

Q32 Dr Taylor: So you would accept about a billion?

Professor Dame Christine Beasley: Yes.

Q33 Dr Taylor: You are probably aware of this report that this committee did in 2005 on the prevention of venous thromboembolism in hospitalised patients, because that estimated the cost of this preventable complication at £640 million a year. Are you aware of the number of preventable deaths that occur because of venous thromboembolism at the moment?

Professor Dame Christine Beasley: No.

Dr Taylor: It is 25,000 a year, and we still have not got mandatory risk assessment. So the costs, if we add all this together, are absolutely astronomical, and here we are trying to find enough money for NICE to afford certain treatment, so it is absolutely crucial that we are doing this inquiry and that we get some answers. I think we are giving the answers rather than you at the moment, which I am not allowed to do, so I had better shut up!

Chairman: The inquiry is not over yet. This is the first session.

Q34 Stephen Hesford: Given that we are a £100 billion, or thereabouts, health economy here and Mr Fletcher mentioned Australia, are there some international comparisons that we can look at and benefit from in terms of the figures that Richard was mentioning in cost and, if there are, how would we do that?

Mr Fletcher: The US, for example, the work that the Institute of Medicine did for example, has attempted to estimate an overall cost to the system of unsafe care, but it is a huge range. You end up with these figures that have a huge range, depending on the assumptions that you make and the way that you look at the issues. So there are data around, but I think this is an area that still probably needs more work. I guess. If you look at safety globally, it is properly understanding what some of the costings are behind unsafe care but, equally, what we need to do around building the business case for investment in particular interventions as well; because I think the other side of this coin is where is the best bet in terms of spending funds to actually address these things, and I think the concept of the business case for patient safety is gaining momentum internationally but it is still a new area as well.

Q35 Sandra Gidley: I have some questions for Martin Fletcher. NPSA has been around a few years now; lots of stats, lots of data. What solutions have you actually come up with? Are you able to give us any examples?

Mr Fletcher: We can obviously provide detail of some of the examples that I will talk about now, but can I talk about the type of solutions that we have developed and then give you some examples of those? One of the areas that we have focused on is this whole area of safety culture. We know from the experience of other high risk industries that what we need to do is build a strong culture of safety at an organisational level, and so we have developed a number of tools. Probably the best known one is the *Seven Steps to Patient Safety* that was referenced before, which is really a key set of guidance in the form of seven steps that organisations can take to build a stronger safety culture, and it looks at issues like organisational leadership, team work, communication, and the like. So that is one area. A second area has been action in relation to very specific clinical risks. I talked earlier about the fact that we routinely review these data on reports that are associated with patient deaths and serious injury, and the reason we are doing that is to take an example of an individual report and look to see whether there is a generalised risk that may need action across the NHS. So we would typically, having got maybe one report, go into our bigger database and try to see whether there is a more
Mr Fletcher: In terms of local accountability?

Q39 Sandra Gidley: That a problem is known about. You issue a directive or notification, or whatever you want to call it, and you have a variable implementation rate around the country. Where does the buck stop? Who is to blame if this problem is known about and repeated somewhere because they simply have not bothered to act on your advice?

Mr Fletcher: Before I answer that, let me explain how the system works. There is a thing called a central alerting system, so all our advice goes out through that to trusts, and there is a nominated responsible person at trust level, usually in the risk-management, clinical governance area, who is responsible to ensure that action is taken at a local level and the right people are involved in that action; and we will often recommend in our guidance who we think those right people are.

Q40 Sandra Gidley: How is that audited?

Mr Fletcher: We would normally specify a date for compliance, and trusts are required then to report compliance on the central alerting system by the due date, and then there are a couple of pathways we can take there. Sometimes what we will do is initiate our own audit or evaluation of that, and we have done that with quite a few of our medication safety alerts.

The other thing that we have done is we work quite closely with the Healthcare Commission. For example, in the health check each year part of what they looked at was compliance around some of the medication safety alerts that we had issued and they were able to go in, in more detail, and review that as part of their health check and report on that. That is typically how the loop is closed.

Q41 Sandra Gidley: So the sanction would be, if somebody does not do it, a slap over the wrist by the Healthcare Commission? What sanctions do you have? It is all very well reporting that you have done it, but what happens if somebody does not?

Mr Fletcher: The Healthcare Commission obviously have powers to intervene if they have concern about lack of compliance.

Q42 Sandra Gidley: They have lots of other things to do as well though? Okay: The under reporting bothers me. I just wondered how successful you thought the NHS had been in eliminating the blame culture and replacing it with one based on fair blame, openness, reporting and learning?

Mr Fletcher: Again, I think significant progress has been made but more needs to be done. The evidence I would give is the trend in reporting is upwards, so more individuals are reporting more often. For example, we have just completed a pilot with the College of Anaesthetists where we did some work on specialty based reporting for anaesthesia. Of 148 reports in the pilot, 100 were from senior consultants. So I think our experience has been where you design the systems well, where people see a benefit in reporting and where there is feedback, people take part and see that as a value. I would not for a moment say that we still do not have issues
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around blaming in the NHS, but I think the trend is heading in the right direction. One of the things that we have really tried to promote, as I say, is that high reporting is a good thing. I think that is sometimes hard for people because of this sort of issue of, “If we have got more of these things you must be less safe”, whereas we are saying, in a way, I think you should perhaps have concerns more about an organisation that is reporting less than reporting more, because reporting more is an indication of a strong safety culture.

**Q43 Sandra Gidley:** Okay. You mentioned the business case earlier when it came to evaluating patient safety interventions. Is that done routinely?

**Mr Fletcher:** We have done that. For example, a couple of years ago we issued guidance on infusion devices and the fact that if trusts could organise infusion devices at a local level better, have better storage of those, standardise ordering so that they had less types of infusion devices at the trust, that would improve safety, and we were able to do a business case based on pilots that we had done with trusts of what we thought the return on the investment would be at a trust level. So we have done that, but I think it is an area where perhaps more could be done as well.

**Q44 Sandra Gidley:** It is done sometimes but not—

**Mr Fletcher:** We tend to do it where we have got quite significant interventions, like the example I gave of the silver hydrogen peroxide. We would not do a business case around a very specific risk, because we would just expect that that is something that actually should be taken on, but where we are talking about some of these bigger system interventions, that is something we have done in the past—not always but we have done it.

**Q45 Sandra Gidley:** Who decides whether it would be done or not?

**Mr Fletcher:** The business case?

**Q46 Sandra Gidley:** Yes. Is it arbitrary? Do you have a protocol or procedure in place to decide what is evaluated and what is not?

**Mr Fletcher:** A lot of this work we do in partnership with others. Often the discussion is: what do we think is going to be useful in terms of building the case for action on a particular issue? So it will be done in consultation with stakeholders. We do not have a strict protocol that says must have a business case here or we must have a business case there.

**Q47 Chairman:** Bruce, can I ask you a question. We have heard the cost of litigation is one of the costs of the £600 million, I think it was, and the under reporting as well. Do you think there is any link between these two things? I do not mean in terms of cost. I mean in terms of potential litigation and under reporting?

**Professor Sir Bruce Keogh:** Are you getting at whether people are under reporting for fear of litigation?

**Q48 Chairman:** Yes.

**Professor Sir Bruce Keogh:** No. I do not think so. I think there will always be a small element of that, particularly at the interface between, I think, very serious incidents and incidents which might be considered by the person that might report them as being less serious. So it may be an issue there, but for the broad spectrum of under reporting which is in the mid-range of seriousness I do not believe that there is a significant relationship.

**Q49 Chairman:** Christine, would you agree with that?

**Professor Dame Christine Beasley:** Yes, I do. I do not think many people worry. There would be very few. I think it is much more about are the systems in place, do I think I need to do it? I think it is Bruce’s point about the middle range. Most people doing really serious stuff do not think about the middle range stuff as just dealing with it rather than putting it into a reporting system.

**Q50 Charlotte Atkins:** I would like to ask Mr Fletcher what patient safety criteria do PCTs need to apply to achieve world-class commissioning?

**Mr Fletcher:** I think there are a couple of areas that we are focusing on in terms of integrating patient safety into commissioning by PCTs. The first thing is that we have already seen experience around the country of commissioners taking things like the Seven Steps to Patient Safety that we talked about earlier and looking at that being integrated into their commissioning arrangements and requiring organisations to show evidence of having those processes in place at an organisational level. That is one. The second one is that I think we are increasingly seeing PCTs expecting trusts to report serious and untoward incidents and providing assurance on the action that is being taken at a local level around those incidents, including the appropriate reporting to us as a national body. Thirdly, we are currently working on a concept called Never Events. This was something that was recommended by Lord Darzi in his Next Stage Review. We are just completing feedback from the NHS, but the concept there is that we will identify a set of events that within current knowledge and standards practice are highly preventable and potentially highly catastrophic. For example, a serious patient injury as a result of a wrong procedure would be one example. The expectation is that an agreed national set of these Never Events would be made available to commissioners for the next financial year, and they could include those in their commissioning arrangements. Again, the expectation is that if that event occurred it would be reported, that local action would be taken, it would also be reported to us nationally, and that would be an area where there would be some focus in terms of assuring that the organisational systems that were in place were as robust as they needed to be to stop that sort of event ever happening again.
Q51 Charlotte Atkins: What sort of sanctions would PCTs have against what are very often powerful hospitals? The report Safety First said that they were accountable for ensuring that all providers used by their patients have effective patient safety reporting systems and are implementing technical solutions satisfactorily. Firstly, they have got to find out that that is not case, but if it is not the case, what can PCTs do? The imbalance of power is very great very often, is it not?

Professor Sir Bruce Keogh: May I take that one?

Q52 Charlotte Atkins: Certainly.

Professor Sir Bruce Keogh: I think there are two things PCTs can do. The first is they need to, I think, beef up some of the clinical involvement in their commissioning process; they need to engage secondary care clinicians in that. The second is that as part of Ara Darzi’s review there is a proposed system called Commissioning for Quality and Innovation (CQUIN), and the aim of CQUIN is to encourage a local discourse between commissioners, i.e. PCTs and providers, in the specific categories of patient safety, patient outcomes, patient reported outcomes, patient experience, and to identify areas where that provider could improve by a process of agreement. CQUIN brings with it a financial lever, which is that a proportion of the uplift of a tariff can be withheld. To give you some idea of what that means, for the first year, it could be perhaps 0.5% of the contract costs to ensure that the providers meet that target. So we are trying to put mechanisms in place to facilitate some more hard-nosed commissioning.

Q53 Charlotte Atkins: As a local MP, if you have a constituent who comes to you with some awful happening, what you end up getting is some sort of whitewash report from the trust which, basically, says, “Yes, we have taken note of what has happened and we are very sorry, but actually it really was not that serious”, and the PCT is often powerless to do much about it.

Professor Dame Christine Beasley: Would you like me to add to that?

Q54 Charlotte Atkins: Absolutely.

Professor Dame Christine Beasley: I think you are absolutely right. I think increasingly we are trying to strengthen PCTs to have bigger powers, and Bruce has talked about some of them, some of the economic work we have done, particularly around healthcare-associated infections, where you can actually demonstrate and expect your providers to do things that both produce better patient outcomes, safer care and to release money on that. We have got figures about if you do clean your hands, and all the rest of it. I think when it comes down to individual cases around individual patients the onus of that has got to be with that provider organisation, who should be held to account in the hospital, for example, for how they have managed all of that. I think a PCT will always struggle to get involved in that sort of individual issue, and I think the way we want people to be held to account is by requiring trust boards to be able to have systems in place, not only around patient safety but complaints and all the things that go with it, making sure they publish that in an open way. For the PCT, I think, it is much more about picking that up and saying, “Was that an individual case that was dealt with properly or is it a trend in this organisation?” What we know about organisations is that often organisations that are in financial trouble are in trouble around quality, around a whole range of issues, and that is when I think PCTs can start to use some of these quite big levers that they have got, and I think they are not going to have tiny levers to do that, we have got to make sure we are regulating the providers to make sure that they deliver safe care for individual patients.

Q55 Charlotte Atkins: Would not a bigger lever be if PCTs refused pay providers when Never Events occur? The costs of that should not be paid for. You were telling us earlier that if a patient has an infection, the number of extra days, weeks very often, that they have to spend in hospital costs the PCT thousands upon thousands of pounds and it is all down to ineffective procedures within the hospital. Why should the PCT pay for that? They do not in the States very often, but it appears that there is no intention to include that within the proposals that we are looking at in the UK. Why is not that the case? Why should PCTs have to pay for these costs when things go badly wrong in hospitals?

Professor Sir Bruce Keogh: The eight Never Events which have been articulated, PCTs will not be expected to pay for that. For the first year the Never Events they will be expected to report on and, thereafter, it is anticipated that they will not pay. That is the key lever in the Never Events.

Q56 Charlotte Atkins: So what will they not pay for exactly?

Mr Fletcher: I think that is why we have said in the first year we need to do more work around understanding how that would be paid for. There is interest, as you have said, in the experience of the US around this as well, because the US have just started—it is in the early stages—a similar approach through their Centres for Medicaid, and so I think we are very interested in what the experience is there. We do not want to get this wrong, because we do not want to penalise trusts in a way that is unfair in terms of the care they provide, but I think the point that you make that there should be some sort of financial consequence for unsafe care is absolutely what we are trying to build into this approach to Never Events, but not in this first year, where I think we want to focus much more on getting the infrastructure in place to make sure that it is as well targeted as possible.

Q57 Charlotte Atkins: Are you suggesting then that after the first year any Never Events which occur in a hospital, all the costs associated with that, will not be met by the PCT?

Mr Fletcher: I think that is what we have got to work through; how we could cost the consequence of a Never Event.
Q58 Charlotte Atkins: I think it is fairly easy really. It is in terms of the extra bed days spent in hospital as a result of infection, or some sort of medical mishap, or some sort of technical failure. If they are in hospital for, say, six months or, indeed, if they are in hospital for many months and then the patient dies, then there clearly should be a very severe financial penalty for the trust. It seems to be that trusts only respond when they are hit heavily in the pocket.

Mr Fletcher: As I say, I think that is the work we need to do, to look at what is the right payment consequence for these Never Events. For example, one of the proposed Never Events on the list of eight is about patients absconding from care. Obviously, a one of the proposed Never Events on the list of eight consequence for these Never Events. For example, a bed-day calculation there is not going to work. There would have to be a different way of doing that. I think it is the detail of how we make sure that the payment system around this and the consequence is appropriate for the event that is the work that we still need to do in this first year. The other point I would make too is that I think the early experience in the US is that where this is working well it is not just the funder who says, “We are not going to pay you for these things”, it is also the provider saying, “We do not think you should pay us for these things because this thing happens. We think it is fair enough that we take the cop for this.” So I think part of what we want to try and deal with is that this is actually about a shared commitment from providers and commissioners to make sure that this focus on Never Events and the payment systems is something that people buy into as an important part of making care safer.

Q59 Charlotte Atkins: On the basis of your analysis of the American experience, when would you be in a position to bring into place real financial penalties on trusts that can increasingly get it wrong?

Mr Fletcher: We have said that in the first year we do not think they should be linked to payment systems.

Professor Sir Bruce Keogh: Yes, 2010–11.

Q60 Charlotte Atkins: After that it will be part of the process?

Professor Sir Bruce Keogh: Yes.

Q61 Dr Stoate: Very briefly, that is just to flag up the scale of the problem. I am a GP and I can quote two patients who have been into hospital with urinary tract infections and have actually surfaced two months later with a bill of £35,000 per patient from the trust, which we have absolutely no control over whatsoever. I cannot believe that my practice is the only one in the country that faces that. Yet there is no way that the GP has any call back on the hospital for having effectively made a huge dent in their referral budget. It is a much bigger issue than has so far become apparent, surely.

Professor Dame Christine Beasley: I think you are absolutely right. What we are trying to do, following on from Lord Darzi’s report about putting quality right at the centre of all this, is to say how can we in quite a complex system around financial flows get a much better financial flow that is related to patient care. We do know, and we have got that experience from the tariff and all sorts of issues, that we have got to be very careful as we try and move some of this money around that we do not have unintended consequences around that. You can see that we are trying to do that with the Never Events. Some PCTs are also beginning to start to say actually if we look at what your infection rates are and other things we can commission services from other places. That is not always possible but in some areas it is, so people are beginning to flex muscles around some of those areas, and that is the work that we have to do both around tariff and around some of the Never Events, that is the work that we are starting on in trying to make that bite but doing it in such a way that does not entirely destabilise the system that will have some other unintended consequences, and we have just got to be careful about that.

Q62 Dr Naysmith: Mr Fletcher, can I switch to the National Patient Safety Forum and ask what actually do you think this body has achieved that has had a real, measurable impact on patient safety? What has it done that you are really proud of and think would not have happened if it did not exist?

Mr Fletcher: One of the major focuses for the National Patient Safety Forum over the past 12 months has been to help us get the Patient Safety Campaign in England up and running. This is the concept of taking a campaign-based approach where we put a big emphasis on front-line staff being involved in implementing these safer practices that we have been talking about today, and the Forum has played a very active role in shaping that. The other thing that has been important in that campaign is to be able to say that all of the partners around the table of the Forum support this campaign so this is not just something in isolation but it has the weight of all these important national players in terms of being something the trusts should get on board with.

Q63 Dr Naysmith: So you think it has actually achieved something so far?

Mr Fletcher: Yes, from that point of view. You asked me what I thought the big achievement was and I think getting the campaign up and running has been very important.

Q64 Dr Naysmith: One of your members has submitted evidence to this Committee, the Health Foundation, and they are part of the Forum, are they not?

Mr Fletcher: They are and they are also a partner in the campaign.

Q65 Dr Naysmith: And they say: “The failure of the National Patient Safety Forum to make significant progress in driving forward the patient safety agenda has been disappointing.” Why do you think they would say that?

Mr Fletcher: I think you are probably going to have to ask them that because from my point of view the Forum has been very important for us because one of the strengths of patient safety in this country has
been that it is not just the National Patient Safety Agency that is saying that patient safety is important, it is a lot of these national organisations are also saying that patient safety is a very important issue, so from our point of view we welcome the fact that the Forum has created an opportunity for making sure there is good understanding of what each of the national agencies are doing, good co-ordination of our effort and, as I said in the case of the campaign, we have been able to say that we can throw the weight of all these bodies behind this as an important thing for the NHS to get on board with.

Q66 Dr Naysmith: So what is the campaign setting out to do?

Mr Fletcher: The campaign is setting out to really address this issue of supporting Trusts to implement safer practices at a local level. It has two major areas of focus. One is around the role of Boards and senior leaders and, as Chris said in her comments earlier, we think that if we do not have strong leadership from Boards and senior leaders in organisations, we are not going to get the results that are required.

Q67 Dr Naysmith: Do you see any changes in any trusts and boards as a result of the start of your campaign?

Mr Fletcher: It is early days for the campaign but we certainly see trust boards which are seriously trying to provide a leadership role in relation to patient safety, absolutely, yes. There is more we need to do but there would be boards that you could go to around the country which would put patient safety as the top agenda item in their board discussions. There would be boards that you could go to which would routinely have a patient come and talk about an experience they had at that trust and what went wrong and what should be learned from it. All trusts would be routinely looking at performance matrices in relation to things like healthcare-associated infections. I think there is a lot more happening but there is a lot more to do. For example, we are working quite closely with the Appointments Commission on the induction of non-executive directors so that when they are coming in at the front end of this they have got a good understanding of patient safety. I think the campaign will help to build that impetus and momentum among the boards.

Q68 Dr Stoate: I would like to ask Professor Keogh about how information technology is being used in a way to improve patient safety. Are you confident that IT is being sufficiently used?

Professor Sir Bruce Keogh: I think it is but it has got a long way to go. I think IT in general practice is ahead in many ways of where it is in the acute sector and you will be as aware of that as anybody. I think Connecting for Health has started to address this issue in particular. I think they have recognised the growing importance of the human computer interface where there is the potential for transcription and other types of errors and they have developed a standard of safety for clinical systems which is currently out to international consultation and is likely to become an ISO standard. I think that is a major contribution from the UK. Certain areas have developed some pretty innovative hardware solutions. The first is they have developed a computer keyboard which switches itself off if it is not cleaned with alcohol every 20 minutes. The idea is somebody on the ward is working with it and then they leave the computer and the next person that comes cannot get on unless they clean the keyboard. The other thing is that we are keen on bringing computing to the bedside, if you like, and that has a number of utilities. That has to be conducted through the use of a computer tablet. The problem with computer tablets is like other bits of hardware or clothing they move around with the person. However, the tablets that they have developed are now fully immersible in alcohol so they can be completely sterilised. I think we are making some progress in the information stakes but, you are right, there is a long way to go.

Q69 Dr Stoate: I was thinking more in terms of expert systems. Are we making as much use of expert systems as we could to reduce, for example, prescribing errors?

Professor Sir Bruce Keogh: Yes we are and in fact I am very keen to see expert prescribing systems in place widely through the NHS. They fulfill in my book three major criteria: they make life easier for the person writing the prescriptions; they make life safer for the patients on the receiving end of the prescriptions; and at a trust level there is evidence that they are cost-neutral. That is based simply on the prescribing costs. If you were to extend that to the NHS as a whole and look at the errors that are eliminated, it would actually save money for the NHS. To give you an example of that in University Hospital Birmingham, where I used to work, they have introduced a prescribing system which is intelligent. They have reduced their drug errors by about 60% and that translates to about 450 drug errors a day, which is quite significant, but on the intelligence side to which you are alluding, and I will come back to thromboprophylaxis if I may. One of the problems in patient safety is that it is very easy to identify and deal with errors of commission—things that people do—because they are obvious, it is the things that people do not do where some of the safety issues lie.

Q70 Dr Stoate: That is what I want to come on to.

Professor Sir Bruce Keogh: So in this system because it is an intelligent system that switches on when people come into the hospital, they can reliably say that every single patient coming in through the portal has an assessment for the requirement for thromboprophylaxis. Furthermore, these kinds of systems give you much better documentation and an audit trail.

Q71 Dr Stoate: For example, GPs all use expert prescribing systems that significantly reduce drugs interactions because they are all flagged up. However, none of them—and I have asked everybody this—have NICE guidelines built in automatically, so for example there is nothing that
will prompt a GP to follow best practice or follow NICE guidelines on the treatment of asthma or diabetes, or whatever it might be. They will all flag up interactions and dangers but none of them will flag up “you should be doing this”. The only ones that do are the ones that are directly linked to the QOF, in other words GPs use software that directly links to QOF points for obvious reasons, but not one of them links to NICE. I have asked NICE about this and I have had assurances that it will happen, but it never has. I have had asked everybody I have had a chance to meet the same question and for some reason nobody has ever taken up this suggestion. Why is the NHS not automatically programming NICE guidelines into GP systems to ensure better patient care?

Professor Sir Bruce Keogh: Thank you, that is a good point, and I would be very keen to take that up and I would be very keen also to see in a reasonable timeframe that GP prescribing systems are also linked into hospital prescribing systems. That would be a good aim and we would then be the first country in the world to have a joined-up electronic prescribing system.

Q72 Dr Stoate: It would be so simple to do and that is what makes me so frustrated that not been done yet. A very final point on the goals set out in Coding for Success in 2007, have we made much progress in terms of patient barcoding and radio frequency tags?

Professor Dame Christine Beasley: Yes, we are making progress on that across the hospital. I do not know whether you want to add to that because we are making progress and I think Martin will have the detail.

Mr Fletcher: As you know, mismatching patients to care is one of the common contributing factors to patient safety problems. Just to give you an example, on our own data, between February 2006 and January 2007 we received over 24,000 reports where there was some element of the wrong patient being identified or the wrong treatment being identified and there being a mismatching.

Q73 Dr Stoate: That is an appalling statistic so what are we doing about it? Why are we not introducing better barcodes and identification?

Mr Fletcher: We have certainly been looking at the issue of radio frequency identification, RFID technologies, and there have been a number of pilot sites around that. We have also looked at barcoding and we have also done a number of pieces of work and guidance on the service alerts to the service. We found for example that we had to standardise wrist bands. Before we could introduce some of these technologies we had to have a standardised approach across the NHS for wrist band compliance, so we issued a safety notice on that last year. We have done quite a bit of work in the context of blood transfusion, which is obviously a very high risk area for errors around identification, and then just recently we have issued a safety notice to the NHS around the use of the NHS number because I think if we can get that used much more consistently that will then complement the work that Connecting for Health are doing and again lay the groundwork for some of the application of these technologies that have the potential to improve safety. I think the point we also need to make, as I am sure you will be aware, is that of course there is no silver bullet here and whenever we introduce new technologies we also introduce new risks as well. One of the things we have been keen to do is make sure that people do not just say “If we have the technology we have solved the problem” because there is some research, for example, where technology is being used where you dilute the checking mechanisms and you do not want to do that because you want to make sure, as I say, that you have got a number of mechanisms in place that are going to be fail-safe. I think trying to see technology in that broader human factor context has been important as well as some of this infrastructure work around standardisation that lays the groundwork for it.

Q74 Chairman: Have you done any international studies? I was given information last year that New Zealand have implemented a barcoding system for patients in hospitals to stop medication errors. Have you looked at what they are doing? I am led to believe that the New Zealand system, whilst it is smaller than the UK, is very much like the National Health Service as such. Have you looked at international areas where barcoding has been used?

Mr Fletcher: I would probably need to come back to you on that. I have not looked at the New Zealand system myself but that may well be something that has been looked at, so if I could come back to you on what we have done around that.

Q75 Dr Stoate: We visited Baltimore and in fact they showed us that by barcoding the patient and barcoding each drug dose they had seen a very significant reduction in dispensing errors to extremely low levels so there was good evidence that was working.

Professor Dame Christine Beasley: In February last year the Department did issue Coding for Success which was guidance on best practice to help people to look at what they could do in their local organisations so we picked up the best practice that was available last year.

Chairman: I would appreciate it if you could give us a note on that.

Q76 Dr Taylor: Going on with technology really to Sir Bruce, we have been told that some years ago Lord Darzi was looking at “black boxes” in theatres rather like they have on airlines. What happened to that? Was it useful and should it be extended?

Professor Sir Bruce Keogh: I have not seen the final report from Ara’s review of that black box. I think he had some difficulties introducing it but it subsequently went through a phase where it has been accepted. I do not know the final results but I can get a note to you on that.
Q77 Dr Taylor: So it is possible that it could come in?  
Professor Sir Bruce Keogh: Yes.

Q78 Dr Taylor: Just to broaden out from that, whilst we are on the airlines are there any other things about safety that we can learn from the airlines?  
Mr Fletcher: I think there is a lot we can learn from aviation as an industry that has really got a track record over 40 or 50 years on safety. Of course, I think we have to adapt it for healthcare because aviation and healthcare are obviously very different undertakings, but they both involve risks. The sorts of things that we have been really interested included the approach in aviation to teamwork. I think one of the things that aviation has done is it has had to address the issue of the hierarchy in the flight deck and the hierarchy between pilots and cabin crews. There were investigations of accidents where people knew of a concern but felt unable to raise it with the captain because they did not want to trouble him or her. I think the very structured approaches to teamwork and communication are areas where we can learn a lot in healthcare, and I think on the whole teamwork is something we probably need to put more focus on in terms of the patient safety effort in healthcare. A second area would be standard operation procedures. I think aviation has gone much further in the use of standard operation procedures. I gave the example before on standardising and simplifying processes, in a trust if you can reduce the number of infusion devices you are using then there is less chance of error because you know each of them has different buttons and different ways of calibrating things. I think aviation has got a lot to teach us around standardisation. There has been a lot of interest in things like the use of checklists for example as another tool for standardisation and that is why we have been so interested in moving forward on this work here in England around the Safe Surgery Checklist that has been developed by the World Health Organisation, because I think those sorts of tools have played a big role in the safety effort in aviation. The third area I would highlight is aviation has a very well-established history of reporting systems and they have got confidential systems, anonymous systems, blogs between pilots, and I think we have been very interested in how aviation uses those data in a sense to build a picture of where the risks to safety are, and so we have had a particular interest from our point of view in how we can learn from some of their methods for analysing the data. One of the big challenges for us with a national recording system is that a lot of the value in data is in the narrative, it is in the story that you get about what happened. I think aviation has done a lot that we can learn from in terms of taking snippets of information and building pictures of risk and areas for safety improvement.

Q79 Dr Taylor: I am very grateful for that because we have had a very good submission from a couple of airline pilots who have been involved in training. I am interested that you say standard procedures are adopted. If in the NHS we have got evidence-based best treatments for various conditions, which we have for lots of things, does that do away with the sacred cow of clinical freedom? I am looking to Sir Bruce really.

Professor Sir Bruce Keogh: I do not think it does do away with the sacred cow of clinical freedom. You could argue the other way actually, that in many senses it increases it because it enables you to treat people the way they should be treated, to recognise those patients who may be at slight variance from the recommendations or the protocols and spend time focusing on them and getting things right. I think there is another side to that argument and I would prefer the latter side.

Q80 Dr Stoate: I would like to focus on the events at Maidstone and Tunbridge Wells and the hospital-acquired infection outbreak that happened there. According to the Healthcare Commission patient safety was crowded out by other priorities such as hitting targets and balancing the books. Is this a widespread problem?

Professor Dame Christine Beasley: First of all, I would say one of the reasons that Maidstone and Tunbridge Wells came to the fore was because we had some of these systems in place that were beginning to bite, the Healthcare Commission doing inspections and all those sorts of things, so that whilst it was a very sad event for Maidstone and Tunbridge Wells it was showing that our systems were beginning to work. No, I do not think it is widespread. I think there are many, many examples across the Country where people do it all. They hit the targets, which after all are not targets just plucked out of the air but are what patients want around waiting because nobody wants to do that, and they balance their books and they deliver really good care. We have already discussed the amount of resource you can save if you really really concentrate on HCAIs. A really good example of that is Wolverhampton which was a really struggling district general hospital. They had some really intractable financial problems and the chief executive really concentrated on getting, in this case, his healthcare infections under control. He made enormous strides on both MRSA and C.diff and balanced the books and if you free up your bed days you hit the targets. I am not suggesting you can just do it by the flick of a pen, there are a lot of things to make that happen, but actually it is almost the reverse, you need to concentrate on things like quality in order to hit some of the other targets.

Q81 Dr Stoate: If Maidstone was not deflected from its course by these issues of targets and so on, was it down simply to failure of local management?

Professor Dame Christine Beasley: I suspect it was like a lot of things that Maidstone and Tunbridge Wells had some particular challenges. They had particular challenges around very old buildings in one of their hospitals. They had a whole history of things going wrong but inevitably you have to say that if those things are happening and if you are the key managers responsible for that, whether clinical
or indeed the chief executive, then you have to be held accountable, as indeed they were, for the failure of that quality of care.

Q82 Dr Stoate: If that is the case how was that allowed to happen? Why was it not picked up sooner? What are you doing to prevent such things happening in the future?

Professor Dame Christine Beasley: I think that is a fair challenge. As I said, the good thing was it was picked up and without some of the systems that we have now in place I would argue that it would have taken longer to pick up. What the Maidstone and Tunbridge Wells issue has meant is that we have looked at all the systems to say can we do better. One of the things we could do better was the Healthcare Commission now goes into all acute trusts and does a look every year at their healthcare-associated infections rather than just as part of their annual check, so we have learnt lessons from them and said, “What can we do better so that we can pick things up more quickly?”

Q83 Stephen Hesford: Some people listening to what you have just said, if I may say so, might say that it was slightly complacent. Was Tunbridge Wells not just completely awful, unacceptable, a complete embarrassment to the system and it should not have happened?

Professor Dame Christine Beasley: Absolutely. I am not complacent about it at all. In fact, when I came into post four years ago I was given responsibility for healthcare-associated infections and my friends said, “Don’t touch it with a bargepole, you can’t make any difference,” and perhaps those people who were not my friends just let me get on with it. I was absolutely clear that infection was something that we were not taking seriously and we needed to do something about and so absolutely I am not complacent about it because I have devoted the last four years of my life to try and move it on. In Maidstone and Tunbridge Wells it was not just about infection, it was a failure of care, and it was absolutely unacceptable for those patients and their relatives who got caught up in that. There is absolutely no excuse for that. What I am saying is that some of our systems helped deal with it but that does not excuse it. We should always strive to get much more involved in it. What I am absolutely clear about now is there is not a chief executive in the land who does not believe that quality of care and infection matter as much as money and other things. I am absolutely sure of that.

Q84 Dr Naysmith: Professor Beasley, we know that poor practice in prescribing antibiotics, things like the use of polyparmacy and broad-spectrum therapy, are major factors in the outbreaks of Clostridium difficile, so what is the Department doing now to ensure that these practices are detected early and prevented?

Professor Dame Christine Beasley: We have done an awful lot, as you say and in C.diff not the only issue but one of the big issues relates to antibiotic prescribing, particularly broad spectrum. The Health Act that came in in 2006 included a code of practice for the prevention of hospital-acquired infection and required all NHS bodies to have in place policies around their prescribing, so there is absolutely a requirement to do that. We have published a range of guidance to help that including for primary care because it is very important that general practice also prescribes sensibly. We have put about £12 million into the service to help pump-prime particularly pharmacists because most acute hospitals in order to make this happen need to have a pharmacist that both encourages good practice and polices poor practice. We have done an awful lot to do that and at the same time earlier in the year we started another campaign with the public to get them to remember again that actually wanting antibiotics for infection is not necessarily the best treatment for you, so we have done a whole range of things to do that. Clearly in the latest reduction in C.diff that was announced last week—an overall reduction of 35% for all age groups and 38% for over 65s—a very significant amount of that improvement has been down to very prudent antibiotic prescribing. I do a lot of visits in the NHS and often in practice what that means is that pharmacists and others go round the wards and take out of cupboards antibiotics that have been there and they police the prescribing so that clinicians are only able to prescribe some of these antibiotics (clearly sometimes they are very necessary) against very strict protocols.

Q85 Dr Naysmith: Antibiotic prescribing really happens just as much if not more in primary care than it does in hospitals and then the infections are taken into hospital.

Professor Dame Christine Beasley: It does and, as I said, there is a lot of guidance out for general practice. Primary care trusts often have pharmacists too in the community that will work with general practice, look at their prescribing patterns if they look as though they are out of kilter, and talk with general practitioners about why that may be. There may be a reason for that so it is just as important to work with primary care as it is to work with the acute trusts.

Q86 Dr Naysmith: Have you found something you can do about doctors who think it is beneath them to wash their hands regularly?

Professor Dame Christine Beasley: We are absolutely getting there. Doctors take a little longer sometimes in this area—and I am sure my honourable friend is an exception here. It is very rare now that you go into an acute hospital where people are not following these areas and, in my experience, hospitals have been very tough with all clinicians including doctors about washing their hands.

Q87 Dr Naysmith: We have already talked about the Maidstone and Tunbridge Wells situation. I am a Bristol MP and I was around in Bristol when there were the problems at the Bristol Royal Infirmary, as it was then called. In both of those cases there were
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rumours and things being said in the local health community for years, certainly in Bristol and probably in Maidstone as well, long before it was actually brought into the public arena. What are we doing now to make sure that these things do not fester around until they blow up?

Professor Dame Christine Beasley: I think you are absolutely right. One of the things that we are trying to do, and it is happening with foundation trusts for example where we have got much bigger patient councils, is to get the involvement of local people in terms of their views on their services and what that looks like. I think that is very powerful. We have got to give local people the ability to talk about the things that nobody wants to talk about. I think that involvement is also now a part of World Class Commissioning and how can you properly engage people, not just a few people but more and more people in some of that. I think that is the only way you really get it pushed if you somehow empower and support it. Obviously things like the overview and scrutiny committees have some roles around picking up issues if they think there is a particular issue, focusing not just on a service but perhaps a health issue. I think all of those are helping but we just need to keep on pushing it.

Q88 Dr Naysmith: You think local authority scrutiny committees are being useful in this area?

Professor Dame Christine Beasley: Yes, I think they are beginning to move away from services and “are we shutting that hospital?”, although that may well be a very big issue, to beginning to focus on some particular health issues, and certainly we are trying to encourage them to do that so it is not just a service area.

Q89 Dr Naysmith: Do you think that will apply to Local Involvement Networks as well?

Professor Dame Christine Beasley: Absolutely, that is the aim. We are trying to get people to focus on some of those issues rather than perhaps some of the structure and format issues which are important but often miss some of the important issues for local communities.

Q90 Dr Naysmith: Do you think they will be able to do a bit better than some of their predecessors?

Professor Dame Christine Beasley: We hope so.

Q91 Dr Naysmith: Do you want to say anything?

Professor Sir Bruce Keogh: I do actually because for some time I have shared your view. There was the word on the street about the Bristol Royal Inquiry and there was also quite a lot of data floating about in an uncoordinated way that might have enabled that problem to have been tackled earlier. It was not being turned into information and it was in the wrong place. Some of the data that was around was anonymous with codes that were difficult to break and there was no really good benchmarking. Since that report, which I think was July 2001, clinical governance has come into place and consultant appraisals have come into place and been tightened up. We have done quite a bit of work on what makes good clinical teams. Indeed Liam Donaldson led some work on this that showed that good clinical teams have good clinical leadership, their management goals are expressed as clinical benefit, they are keen to use data to measure their performance, they are keen to compare themselves with colleagues, and there is a culture of continuous improvement. The question is how we try and get that culture right throughout the whole of the NHS. One of the things that we have been told in consultation with the NHS as part of Ara Darzi’s review is that people are very keen for us to help develop a matrix which can be used to help clinicians assess their performance and we are out to consultation on a series of matrices at the moment and we are looking to encourage clinicians to develop meaningful matrices. This goes back to a point that Martin has raised that in a sense having this information is only useful if you use it, so we are going to be looking at ways of benchmarking data so that it gives people the opportunity to see where they stand in relation to their peers. I think that will go some way to narrowing the gap between the word on the street and the problem occurring and hopefully it will eliminate the problem occurring.

Q92 Charlotte Atkins: I would like to ask Mr Fletcher about strategic health authorities. What is their role in respect of patient safety?

Mr Fletcher: It is an important role and growing and so, for example, we worked very closely with each of the ten strategic health authorities in England to create local patient safety action teams. In fact, we transferred into those teams patient safety managers who previously worked for the NPSA so they now work as part of those local action teams. A large part of the focus of those teams is to really make sure that patient safety is embedded in the local management of the NHS. We have already talked about commissioning, for example, and obviously SHAs have a role in overseeing commissioning at a local level and we are expecting these action teams will provide part of the support for making sure patient safety is part of commissioning. The action teams are doing a lot of work around improving the quality and timeliness of local investigations of incidents as well because I think one of the issues for us from the point of view of national learning is that we really need to have a good understanding of the local factors that have contributed to the incident. That is obviously important for the trust at a local level but it is also important for us in terms of issues that need wider NHS action. So these teams working with SHAs are putting a very good emphasis on supporting trusts to undertake very credible and thorough investigations where there are serious incidents. Then of course I think patient safety sits as part of the broader focus on quality improvements. Through the next stage review from Lord Darzi what we will also see is safety forming part of the wider responsibilities of SHAs in terms of the wider quality agenda that they are taking forward as part of the Darzi review.
Q93 Charlotte Atkins: Are some SHAs better than others?

Mr Fletcher: In what sense?

Q94 Charlotte Atkins: Being more effective in terms of holding the trusts to account?

Mr Fletcher: What I think we have seen is different SHAs are developing different ways of working locally and I guess to an extent that reflects differing local circumstances, so for example there are some SHAs that have created, in South Central for example, what is called a federation, and what they have done is brought all of the trusts together with the SHA and that is setting priorities for action on patient safety across the whole of the SHA. In other SHAs I think they have put more of a focus on Serious Untoward Incidents and really making sure that action is being taken in relation to those. It is varied but I think it is probably a bit early to say whether one is better or one is worse. I think it is more of a question of different things. I would not have thought there is only one model for the whole country and obviously the whole point of SHAs is to be able to adapt and respond to different local circumstances.

Q95 Charlotte Atkins: At the moment many providers are becoming foundation trusts. What impact will that have given that they are not going to be accountable to SHAs?

Mr Fletcher: I have two comments and Bruce or Chris may want to add to this. This goes back to the conversation we were having about the role of PCTs as commissioners. One of the things that is important is that increasingly foundation trusts are reporting their Serious Untoward Incidents to their commissioner rather than to the SHA, and so it is important that what commissioners do in response to that is appropriate to those events. Secondly, I think we have really tried to work very hard with the SHAs and foundation trusts around these action teams so that they are not just about the trusts that are not foundation trusts but they are developing this model of collaboration across the whole health economy around patient safety because clearly some of the issues, like for example how people move through the system, do not distinguish between a foundation trust or a non-foundation trust. So I think those collaborative models are also emerging as another way of engaging everybody.

Professor Dame Christine Beasley: Absolutely. First of all, foundation trusts are required to meet the standards of healthcare. They are assessed by the Healthcare Commission so absolutely that is the case in terms of quality and safety. In fact the SHAs and the Department have done good work with Monitor and for example aspirant foundation trusts who are not meeting the level of reduction in healthcare-associated infections have been put back before they have gone on to become foundation trusts. The rigour is not just about their financial performance, it is also about some of those other areas, and I am sure that is going to develop over time.

Q96 Charlotte Atkins: The boards of many of these trusts are choosing to meet in secret whereas at present they meet in public. Is that going to inspire openness and confidence by patients?

Professor Dame Christine Beasley: I do not think so, no.

Q97 Charlotte Atkins: Is this normal across the trust boards? My local hospital, one of these aspirant foundation trusts, is going to meet in secret, the University Hospital of North Staffordshire. Do you support that approach?

Professor Dame Christine Beasley: Bruce might want to make a comment being in a foundation trust. In my experience many, many foundation trusts have boards in the open, only taking confidential issues in a secret way. Clearly what foundation trusts do is give people some freedom and powers that others do not have. Increasingly they also need to respond to their patient councils and other people around how they behave.

Q98 Charlotte Atkins: It is a bit difficult if they are meeting in secret, is it not?

Professor Dame Christine Beasley: Yes, but they still have a patient council that can exercise a whole range of issues. In my experience and, I cannot give it as research, most foundation trusts do not meet in secret, they meet openly.

Professor Sir Bruce Keogh: Certainly that is my experience as well of meeting openly in the two foundation trusts in which I have worked. I would share your concern.

Q99 Charlotte Atkins: So the foundation trusts you know about their board meetings are out in the open and they are not in secret?

Professor Dame Christine Beasley: Yes.

Q100 Charlotte Atkins: And you would consider that to be good practice?

Professor Sir Bruce Keogh: Yes, undoubtedly.

Chairman: Could I thank all three of you once again for coming along and helping us on this the first day of our inquiry. I think at least one of you will be returning to us at some stage in the future! Thank you.
Thursday 20 November 2008

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins
Jim Dowd
Sandra Gidley
Dr Doug Naysmith
Dr Richard Taylor

Witnesses: Professor Richard Thomson, Professor of Epidemiology and Public Health, University of Newcastle, and Professor Alastair Gray, Professor of Health Economics and Director of the Health Economics Research Centre, University of Oxford, gave evidence.

Q101 Chairman: Good morning. Could I welcome you to what is our second evidence session of our inquiry into patient safety. I wonder if, for the record, I could ask you to give your name and the current position you hold.

Professor Gray: I am Alastair Gray. I am Professor of Health Economics and Director of the Health Economics Research Centre at the University of Oxford.

Professor Thomson: My name is Richard Thomson. I am Professor of Epidemiology and Public Health at the Institute of Health and Society in Newcastle upon Tyne.

Q102 Chairman: Good morning and welcome. There is a general question from me to start this session. What evidence is there about how much harm is done to patients by the NHS as a whole, NHS primary care, and independent sector providers of NHS care?

Professor Thomson: In terms of the NHS as a whole, the most reliable data, albeit still on limited numbers of patients, comes from the hospital case note review studies, the studies that have looked at medical records of patients. These are hospital-based. There have been a couple published in the UK—Charles Vincent’s being one of those—that demonstrate that around 10% of admissions to hospital suffer some form of harm but more associated with medical management than with the underlying disease processes. That figure is seen internationally in other developed healthcare systems. A recent systematic review of a whole series of similar studies internationally came to a very similar overarching figure—I think it was 9.2% in that systematic review—of patient admissions that suffer some form of harm. I suppose it is worth saying that two-thirds of that harm is minor, minimal impairment or has an impact on the patient lasting for less than a month. At the upper end of the spectrum, in terms of severe harm or death, those studies have relatively small numbers within them, so there are issues about extrapolating a small number of figures to get a sort of system-wide figure that is reliable. It is clearly an important issue. That range of studies demonstrates internationally in terms of patient safety and harm caused by health care that we need to put effort and energy into prevention. It seems to me that one of the challenges for us is to ensure that we have good, reliable data on which to make the sorts of judgments about where to focus our efforts effectively. You asked about primary care. In primary care, it is much more difficult. The data are much less robust. There have been no similar case note review type studies in a primary care setting. A review a few years ago suggested that there might be errors occurring in anywhere between five and 80 in every 100,000 consultations. That is a relatively small proportion, but those data are quite limited. On the other hand, there are a number of other measures that indicate that there is an issue in primary care. For example, about one in 25 patients admitted to hospital in some studies are shown to have been admitted because of a medication problem. That implies that there are clearly issues around medication safety in primary care that could be addressed. Surveys of patients by the Commonwealth Fund have suggested that maybe as many as six in 100 report that they have experienced some sort of error in medication over the last two years. So there are indicators there.

Q103 Chairman: Is there anything in the independent sector that has provided NHS care?

Professor Thomson: That is an area really where there is very little reliable data at all at the moment. I do not think we have anything that could give us an overarching figure for that at all.

Professor Gray: In addition to the case note reviews, there have been, as Richard said, one or two studies which have looked at surveys of patients or, indeed, population surveys. I was involved in one of them about seven years ago as part of compiling evidence for the Chief Medical Officer’s inquiry into compensation mechanisms. That involved undertaking a population survey which we commissioned MORI to do, in order to ask a representative sample of the general population whether they had experienced any adverse event as a result of medical care that they had received. That produced a figure of about 4.8% of the general population over the previous three years. We asked, if they had experienced an event, where it had occurred, if it was in a hospital, in general practice, in dental care, and et cetera. About 55% of people who reported an adverse event said that it was in an NHS hospital and 3% said that it was in an independent hospital. Translating these figures into the proportion who would have been in hospital over that three-year period came out with a figure rather consistent with the case note...
reviews, that about 8% of hospitalisations had resulted in an adverse event. It suggested that about 6% of these hospital adverse events were occurring in independent hospitals, but it is very difficult to say whether that is proportionately more or less than one might expect, given that the case mix in independent hospitals is so different, and primarily elective surgery and non emergency care.

**Q104 Chairman:** Do you think it is fair to say that there is no definitive data regarding how much harm is done to patients in the NHS? You talk about the hospital side and you know something about it, but beyond that there is really not a lot of data are available.

**Professor Thomson:** In truth, from an epidemiological perspective, the data on the total size of the problem remains limited, and that has some limitations on how we can assess progress over time. For example, there is, nonetheless, considerable potential to bring data together from a variety of sources.

**Chairman:** We may go into some of that detail in the next few minutes. We will move on.

**Q105 Sandra Gidley:** Over to some of that detail, really. Professor Thomson, you have highlighted the case note reporting system, but there are obviously other event reporting systems, such as the National Reporting and Learning System. Could you clarify from your perspective what the relative strengths and weaknesses of those are?

**Professor Thomson:** Starting off with the case note review method, the strengths of a case note review are, first of all, that it gives you a defined population within which to assess the number of incidents or the degree of harm. You can look at a population of patients admitted to hospital, and that gives you the capacity to look at a rate, the proportion of admissions that have suffered harm. I think there are other advantages. Clearly another advantage of that method is that it gives you access to the clinical detail that is in the medical record and access to all the other information that is available within the medical record that is not necessarily provided in an incident reporting system, for example. Perhaps an understated strength of the case note review method is that it tends to engage the clinical community in the process—which is not to be undervalued. On the weakness side of case note review, there are variations in some of the judgments that are made, in terms of judging, for example, preventability or causation. It is not an absolute science and there will be disagreement between observers looking at the same case as to how preventable or what degree of causation could be applied to any incident that occurred. Case note review studies cannot really give you very much about, for instance, no harm incidents. They tend not to be recorded, and often there are things that one can learn from incidents that nonetheless did not lead to harm. I suppose they are relatively costly in terms of the resources that need to go into them, but newer computerised systems of collecting data and so forth may improve that. Sometimes the causal factors may be difficult to assess from a medical record in terms of the underlying causes of an incident or an event. As far as incident reporting systems go, of course they tend to be the mainstay of safety data in many other industries. They can be more “routine-ised”, if you like, and, as we see now, embedded across the system, whereas case note review clearly at the moment is not embedded across the system. At national level, for example, they can identify rare events that probably would not be picked up by the case note review method. A recent example was quoted in the first set of evidence here, of silver hydrogen peroxide in the water system in a hospital that led to problems subsequently with dialysis.

Those sorts of rare events are probably more likely to be identified through a reporting system than through case note review methods, but reporting systems are not reliable for assessing the size of the problem because you do not have an underlying population clearly defined as you do in case note review. There are undoubtedly a number of reporting biases in terms of the sorts of incidents that get reported, the types of staff that report incidents, et cetera. I think they both have their strengths and weaknesses, therefore, and they both have their value within a system, as, indeed, do a number of other sources of data.

**Q106 Sandra Gidley:** As politicians we love to compare and contrast. How reliable are those two types of systems in showing variations, so over time or through different healthcare providers?

**Professor Thomson:** If you had a system that enabled you to routinely collect data in a case note review method—which we do not at the moment—then that would be preferable in many respects for looking at change over time or comparisons. That is because, as I said earlier, it gives you the capacity to look at absolute rates with a denominator in the equation. Monitoring trends or assessing and comparing using incident reporting systems is fraught with difficulty. That is not to say that it does not raise valuable and interesting questions that could be pursued through other mechanisms, but, to give you an example, we did some work looking at incident reporting rates in hospitals and comparing those rates with other measures of the safety culture within a hospital. That study showed that hospitals which report more incidents score better on other measures of safety culture. It is unlikely that they are hospitals with more incidents, but they have a culture that supports incident reporting and therefore they are more likely to report incidents. Clearly judgments of that type could be completely misconstrued if it was felt that a high reporting hospital was actually a hospital with a higher number of incidents.

**Q107 Sandra Gidley:** Yes, the tabloid press would probably love that one. You hinted in your response to the Chairman that primary care under-reported. I think you also said that they do not
have a case note review system. Should there be some sort of case note review system in primary care?

Professor Thomson: Starting off with the reporting, I think that it is partly a historical and cultural issue with primary care. One of the reasons hospital reporting rates are relatively high is that there is a long-standing process of having risk management systems within hospital trusts and similar things do not really exist at the unit of interest in general practice. On the other hand, general practice has a good history and culture of doing things like significant event audit. One of the challenges there is that they tend not to share the results and findings of those audits as widely as might be helpful for others to learn from. There is a good history in primary care of looking at incidents and events but not such a good history, arguably, of spreading the benefits and understanding from that. In terms of case note review in primary care, it is more complicated, in so far as the level of detail and information that is available within a primary care record is quite different from that which is available in a secondary care record. I know there is ongoing work in the UK, for example, at our National Institute for Innovation and Improvement, to assess whether a case note review method, a trigger-based method, might be of value in primary care, but I think the answer to your question is that we do not know at the moment and there is a need for more research into better ways of capturing data from primary care. There are other sources of data that can be used to get a feel for that.

Q108 Sandra Gidley: Do you think the under-reporting in primary care has the potential to mask patient safety problems or avoidable patient safety problems?

Professor Thomson: I think there would be some benefit in enhanced reporting in primary care, because clearly if there is limited reporting then the implication is that we might be missing some learning that could be disseminated. On the other hand, there are a number of other data sources that we can use that give us a feel for these issues. Looking at litigation data, for example—which again has the problem that it is in a way selective: the sorts of incidents and adverse events that come to litigation are a selective subpopulation of incidents that might happen—one gets a clearer picture that there are some key critical areas in primary care around, for example, delays and failures in diagnosis, that clearly are worthy of further exploration. In short, I think there is more that we could do to enhance primary-care reporting or to look at methods of identifying incidents within primary care.

Q109 Sandra Gidley: I just want to come back to why it is possibly under-reported. I do not know if any work has been done into this. Is it because in primary care people are working more in isolation, whereas in hospital there is more of a team culture, so that people are going to get found out anyway? Could that be a factor, or am I widely off the mark here?

Professor Thomson: I do not think there is much definitive data around here but it is likely to be due to a number of factors. One is, as I say, that there just has not been that continuing culture of reporting or the presence of risk management systems to support reporting as exist within hospitals. That is partly because of the nature of small group practices. I think there are issues over concerns in primary care as to where is the right place to report to. There are issues around the relationship between general practitioners and primary care trusts, contractual relationships and reporting relationships, that may influence willingness to report. So I think there are a number of factors there, but opportunity for improvement. One of the things that could usefully be undertaken is to find mechanisms to support primary care in sharing the learning from the significant event audits, for example, that are undertaken, and often limited to within an individual practice or only held and understood and discussed at a local level.

Q110 Dr Naysmith: You were talking about primary care and people not being quite sure of who it is they should report to. Is there clear guidance for GPs and for primary care practices, or does it need tightening up?

Professor Thomson: I must admit that I am not fully up-to-date with the guidance that is available to primary care.

Q111 Sandra Gidley: Primary care is not just GPs, of course.

Professor Thomson: No.

Dr Naysmith: No, of course not. That is why I said primary care.

Q112 Chairman: Would mandatory reporting of patient safety incidents give us better data?

Professor Thomson: I have mixed views on that, I must admit. I think mandatory reporting then raises all sorts of questions about what it is you do in order to make something mandatory. Just saying it is mandatory does not necessarily solve the problem. Even in other mandatory systems of reporting we know there is still under-reporting. For example, the reporting of notifiable infectious diseases is mandatory but they are under-reported still. One might argue—and I think this is a debatable point—for a greater emphasis on the requirement to report incidents where severe harm or death occurs. I think there is a debate either side of that.

Q113 Chairman: You describe individual organisations having a culture of reporting or not. Patient choice is a big issue now in the National Health Service, but the real issue is about informed choice. Do you think that if we were to look around at incidents in different institutions, that informed
choice would be not informed at all because of the culture or the nature of collecting or not evidence in terms of incidents?

Professor Thomson: I think it would be problematic. I think the issue there would be interpretation of the data. As I was saying earlier, one of the things we found was that organisations with a better safety culture, if you like, were more likely to report incidents and a false interpretation of that might be, “This is a more risky organisation” and that clearly would not lead to informed choice. My sense is that at this stage it would be inappropriate to start reporting those sorts of data too widely into the public domain because of the risk of them being absolutely misinterpreted and the risk of turning off the tap of reporting.

Q114 Sandra Gidley: Perhaps I could pick up on something you said. You said that you felt it would be more important to report the serious incidents. My background is community pharmacy. In the large chains, going back quite a few years now, they encouraged the reporting of near misses. By amalgamating all that data some practices were changed, which I think probably avoided a serious adverse incident later. Is there a case for surgeries perhaps working in clusters so that they can share information about near misses?

Professor Thomson: First, I am totally with you that there is much that can be learned from near misses, particularly near misses that had the potential to have a severe impact. In the context of being mandatory, however, it would be very difficult to define that, I suspect. Certainly the reporting of those sorts of incidents should be encouraged. In some respects there is less of a threat to the individual in reporting a near miss than there is in an incident that has caused harm. In terms of clusters, there are so many different ways in which one can approach this issue of incident reporting and so many different levels at which one can look at it—at the hospital level, at a regional level, and at a national level—and each of those levels needs addressing in a slightly different way, I think.

Q115 Dr Taylor: I absolutely agree: near misses are absolutely crucial to report. It was those misses using potassium chloride to flush out drips rather than saline that raised the huge problem, so no longer can you possibly do that.

Professor Thomson: Yes.

Q116 Dr Taylor: I would like to come back to case note review. I am going to expose my ignorance: What triggers case note review in secondary care? When is it done?

Professor Thomson: The case note review studies I was talking about earlier are the examples where a systematic approach has been taken across an organisation to take a random sample of cases and review those.

Q117 Dr Taylor: These are entirely separate research projects.
and to recognise the strengths and weaknesses of each of them, but, at the very least, some of them can act as alerts to the system, where you can then go back to that system and say, “Is this something that we are picking up in incident reporting? What does the literature tell us about it? How can we bring together that information in a coherent way?”

Professor Thomson: I suppose I should say at this point, as I said in my submission, that I was on secondment to the NPSA for three and a half years and I am probably responsible for the Patient Safety Observatory and the terminology, so you can blame me on that one. I think this issue of bringing together this range of sources and data and intelligence in an overall surveillance and monitoring system is critical, not only to understand the size of the problem and to identify key issues but to support priority setting, to support feedback, to support the development of interventions, and, indeed, to identify where there is further research needed. I suppose when we introduced the concept of the Patient Safety Observatory initially it had three components to it. Part of it was conceptual—you know, this is a public health approach and a way of thinking about data and information in a sensible way—part of it was about collaboration—it was bringing together people across organisations that had information, so getting people from the MRHA and other organisations around the table to discuss common issues—and part of it was about a structure to deliver that. I think those three components are important. From a public health perspective, that is the way we should be taking it.

Q121 Dr Taylor: You have given us one of our key recommendations at the end of this.

Professor Thomson: A lot of that work is still ongoing at the NPSA—and to their credit, I think.

Q122 Charlotte Atkins: Is there any technological fix to all this? Could information technology be used to capture automatically comprehensive patient safety data?

Professor Thomson: I should start off, perhaps, by saying that I am not an information technology expert. Having said that, technology has much to offer in terms of safety improvement. We know, for instance, that technological interventions in terms of computerised prescribing and automated alerts and reminders within GP systems have an important role to play in safety. In terms of there being some sort of overarching technological fix, I suspect there is no single overarching technological fix because that is counter to what we have just been talking about, that you need to draw information, intelligence, and so forth from a variety of sources. There are some things that could be done. For example, as Connecting for Health develops front-end systems for healthcare IT, having gateways, if you like, into reporting on that front-end system could potentially enhance reporting and also allow some management, I suspect, of the issue about reporting going to different organisations and different bodies.

I think there is some potential there, therefore, as there is in terms of electronic patient records. Clearly one sees potential, for example in primary care now, in terms of data on prescribing. That is one good example where it is now possible to extract information from GP systems that might identify potential safety issues, and potentially identify them in advance of them becoming an issue. Being able to generate information on patients who are on a particular medication and should be monitored, and identifying that they have not been monitored within the time scale they should have, is a way of building IT into prevention and safety. But I do not think there is a panacea answer to that.

Professor Gray: I think it is a very good question. As a health economist, I am very keen to convey the idea that we should be thinking about what can be done about these adverse events as well as simply trying to quantify the size of the problem. To me that means thinking about what interventions are available, how effective are they likely to be, and how cost-effective are they likely to be. We can try to divide up these adverse events into things that are preventable and things that are not but they are preventable at a cost, which for some of them might be quite a high cost. Therefore the way in which I would look at this would be in the same way that one would look at preventing heart disease: some of it is preventable using current methods but there is a cost involved in doing that and therefore we need to evaluate these interventions in the same way that NICE, for example, has to evaluate other interventions in health care to see whether they are a good use of healthcare resources.

Q123 Charlotte Atkins: Presumably we are going to be having the electronic patient record pretty much more generally within our hospitals, and hopefully linking up also with GPs. Would that improve matters?

Professor Gray: It might but then information in itself, as we have found out from the NHS information programme, is not necessarily a cheap thing to generate. But certainly I think it could have potential in this area to draw attention to particular areas.

Professor Thomson: On the other hand, as Alastair was saying, critical to all of this is using these data in a way that helps to improve safety, and that means getting back and doing in depth studies to understand the underlying causal factors and to be able to address those. That in itself does not readily fall out of any automated information system.
Q124 Jim Dowd: A number of the questions I was going to ask have been covered but could we look at the figures for the acute sector. They are largely extrapolated from a very limited data set originally. I wonder if you would say a few words about the health warning with which we should regard those figures. Do they overstate the case? Do they understate it? Do they provide any useful information?

Professor Thomson: At a global level, the figure of about 10% of patients suffering some sort of harm seems to be pretty robust—again with the qualification that a lot of that is pretty minor. The difficulties arise in particular when we extrapolate the smaller numbers at the more severe end of the spectrum. A number of the extrapolations that have been widely quoted, when you go back to try to delve into their source it disappears into the mist, to be honest. The figure of 40,000, if you delve back into it, ultimately goes all the way back to a *Sunday Times* headline, and that is about as far as you can take it back. I think a number of the figures, as you have implied, have been extrapolated by whomever—and I do not think by the original authors of the reports—from very small numbers of deaths. If you look at the study that Charles Vincent undertook, there were nine deaths within that study, in three of which the care was felt to have contributed to but not caused the death of the patient. Very small numbers of that type, extrapolating it at whole system level, gives you a very high likelihood of it being inaccurate. I think we need to look at those figures with some degree of care. That does say to me that there are still needs for us to better understand the absolute size of the problem at the more severe end of the problem, and extrapolating them simply from those studies is inadequate.

Professor Gray: I think it would be fair to say that some of these studies which have been quoted very widely have been pilot studies which have stated the need for much larger studies to get more robust estimates, and they have hedged their estimates around with qualifications which obviously tend not to be included when people quote these figures elsewhere. When one looks at the figures on the cost to the NHS of adverse events, the numbers are subject to all of the points which Richard has made about the uncertainty in the epidemiology, added to which is further uncertainty about the cost of these adverse events, and so you see some really quite big variations in these numbers which I think have to be treated with a certain amount of caution.

Q125 Jim Dowd: Does that render them valueless?

Professor Gray: No, I do not think it renders them valueless. I think we just have to treat them with due caution. The surprising thing—and this again is something that has come out of the points that Professor Thomson has made—is that, despite the small size of many of these studies and the fact that they have been done in different settings and using different methods, there is a surprising degree of agreement between them in terms of the general size of the problem. I think it is nevertheless difficult to extrapolate from a very small study, which often is only in one or two hospitals over a short period of time, maybe only in a small number of specialities, to every hospital in the country and every patient, many of whom were being admitted for completely different reasons, where the risk of adverse event may be completely different.

Q126 Jim Dowd: Across the acute sector are there variations in reporting in individual institutions? Professor Thomson, you mentioned earlier that where people think this is genuinely seeking information, they will be more open and more likely to provide it than in an institution where they are going to be blamed for it. Are there wide variations between institutions?

Professor Thomson: The data from the NRLS show that there is variation between institutions in reporting rates—for a variety of reasons—so there clearly is variation and some of that is related to the underlying safety of the organisation and some of it is related to the willingness to report and the culture within the organisation. Probably, at this stage, more of the variation is related to those cultural issues. Having said that, one of the challenges in any form of incident reporting system is for those reporting to be able to see that there is some benefit in their reporting incidents and to receive feedback and to see that improvements are being made as a result of that process. I think that remains one of the challenges in incident reporting still, and not just in health care but generally.

Professor Gray: I think one would find the same looking at the litigation figures, that there would be quite significant variations from one hospital to another and we know that there are differences in the standards of risk management that hospitals are achieving within the NHS Litigation Authority’s framework, but, again, it is quite hard to separate out the issues of risk management and safety culture from other issues to do with the complexity of the case mix of the hospital and the fact that some hospitals may be of a similar size but dealing with quite different types of patients.

Q127 Chairman: You have talked about one or two hospitals and one or two specialists inside hospitals, why has the NHS not done a review on a large scale of adverse events?

Professor Gray: It is a good question. Maybe a recommendation which will come out of this is that there really needs to be some larger scale studies, perhaps on the scale of some of the American studies, which include a more robust sample size and a more randomly drawn sample of case notes, for example, in order to get a better estimate of what these true rates actually are.

Professor Thomson: Clearly there is a resource issue, is there not? It is not without cost to set up a system to make case note review more widely applied. As with any intervention, we need to be sure that the cost is worth the benefit.
Q128 Chairman: We are currently in times of surplus as far as the NHS is concerned, probably for one of the first times in its history, in 60 years. If it was costs, why are people not saying now, “This is the time to do it”? Have you any inkling that they are?

Professor Gray: There is a new funding stream which the National Institute of Health Research is starting from January of next year which specifically includes patient safety as one of the key criteria. I think that is intending to spend about £5 million a year on research, so it would then be up to individual researchers to put proposals into that funding scheme. But I would certainly hope that one of the areas that people would be looking to get funded would be for the research on quantifying the size of this problem.

Q129 Chairman: Would it have to be something that was brought from outside the NHS or from specialist areas of NHS expenditure? It would not come out of an SHA’s budget, would it? Or should it?

Professor Thomson: I think part of this comes down to what are we talking about in terms of case note review. A number of hospitals do have their own systems in place for undertaking case note review as part of their safety management systems. For instance, the hospitals involved in the safer patient initiative headed up by the Health Foundation use methods of case note review. But if we are talking about a model that would allow monitoring over time at a national level, I think that is a different exercise. My sense would be that there are two or three things that we ought to be doing. First, I think there still is a need for a more definitive study on the size and extent of the problem at the more severe end of the spectrum for the reasons that we have spoken about. To be honest, we have been seeking funding on doing some of that work. I think there is an argument to be made for developing a system of implementing a monitoring approach to case note review across the country, perhaps randomly surveying hospitals and patient records to provide that monitoring function. The other thing I would say is that there is more that could be done at each level of the service in terms of the surveillance and monitoring approach we were talking about earlier, so at a hospital level, bringing together data sources from the various opportunities that exist, in terms of incident reporting, case note review, hospital-acquired infections, audits, routine safety indicators, et cetera, et cetera.

Q130 Dr Naysmith: Professor Gray, we were saying until the very end some tough financial questions for you, and of course you have become a bit bored sitting there waiting for them to arrive. Some of them have been answered already, but let us look if we can, as rigorously as we can, at what the financial cost is of the harm that happens in the NHS that the NHS does. What evidence is there? Is there any really good evidence? You have mentioned there are a few little pilots studies and things. Is the evidence not very good?

Professor Gray: There are some figures that are incontrovertible; for example, the amount that the Litigation Authority spends each year. It is a pay-as-you go system, so what it spends it has to get from the contributing members in the NHS and we know that currently that is about £580 million in the current year.

Q131 Dr Naysmith: Does that include costs of lawyers’ fees?

Professor Gray: That would include the legal costs as well as any compensation payments for pain and suffering and provision for future care.

Dr Naysmith: I think the published figures do not include the lawyers’ costs.

Q132 Chairman: We have a table that has been submitted as the costs of litigation but that does not have the lawyers’ costs on it. They are published as well, are they? Are they published on a hospital-by-hospital basis?

Professor Gray: They are, yes. They are all available on the Litigation Authority’s website. So that is at the hard end, that is what we know about.

Q133 Dr Naysmith: That is reliable, is it?

Professor Gray: Yes, but clearly they are likely to be, first of all, a small proportion of all the adverse events occurring, although they probably contain a high proportion of the most serious adverse events. Events involving brain injury, long-term disability, and damage would be in there, but it is a small proportion of the total. When we look at the other figures that are widely quoted, the £1 billion or £2 billion for excess hospital days, I think they are largely traceable back to Charles Vincent’s two hospital study which, on the basis of case note review, identified a proportion of inpatient cases where an adverse event could have been interpreted as occurring, then looked at what additional bed days occurred as a result of that adverse event, and then finally tried to divide these adverse events into those that were preventable and those that were not. The figure of £1 billion (basically the figure quoted in the original publication of just over £900 million a year) was an extrapolation to the entire NHS, based on the preventable adverse events and the additional bed days that would be occurring as a result of that.

Q134 Dr Naysmith: There are quite a lot of assumptions being made.

Professor Gray: Certainly, in terms of going from a small number to the national picture, it is a large extrapolation. Then the National Audit Office quoted a figure of £2 billion and that has been quite widely circulated as well. It is traceable back to the same source, but they were talking about all adverse events, instead of just the preventable ones, which were approximately half of the total.

Q135 Dr Naysmith: I was going to look at that in the next question, but, just to stick with the costs, we have a table here that gives the payments made by NHS bodies in England in settlement of clinical...
negligence claims in a year, and the latest figure, for 2007–08, is £633 million. But that is in settlement, it does not include lawyers’ fees, and, also, the figure does not include payments made centrally by the DoH in settlement for clinical negligence claims, so it is a lot more than that.

**Professor Gray:** What was the figure in that table for 2006–07?

**Q136 Dr Naysmith:** £579 million.

**Professor Gray:** That is the figure I was quoting, the £580 million. My understanding was that it did include legal costs as well.

**Q137 Dr Naysmith:** Okay, we will have to sort that out. But it does not include centrally from the DoH in settlement of clinical negligence claims, so that must be quite a figure.

**Professor Gray:** That is the clinical negligence scheme for trusts. There are some other amounts, including the existing liabilities scheme: cases that have been inherited from a long time in the past.

**Q138 Chairman:** Do you have a figure for that as a percentage of the in-year? Do you have a figure for payments made centrally by the Department of Health as opposed to these figures here?

**Professor Gray:** I do not have that figure on me.

**Q139 Chairman:** If it is possible for you to get it, could you share it with us?

**Professor Gray:** I could provide that for you, yes.

**Chairman:** Thank you.

**Q140 Dr Naysmith:** Do you know anything about the cost of the NHS of treating patients who have transferred from the independent sector as a consequence of an adverse event?

**Professor Gray:** No. That was a very interesting question. I was sent that question in advance and tried to see if I could find any information on that. Certainly, in the public domain I was not aware of anything that would allow us to quantify that.

**Q141 Dr Naysmith:** Why do you think that was difficult to get? Do you think it is not kept centrally?

**Professor Gray:** It may not be.

**Q142 Dr Naysmith:** So we might have to approach individual institutions where there is a possibility that such a thing happened. Do you want to come back on that, Professor Thomson?

**Professor Thomson:** I did some work with the independent sector a few years ago around quality indicators. At one stage we sought to look at data on transfers from the independent sector into the NHS. This is a while ago now but I certainly was not able to find anything robust that was published on that.

**Q143 Dr Naysmith:** If you were seeking that information, where would you go?

**Professor Gray:** I think it would involve a certain amount of digging. The hospital episode statistics, the main routine source of information on people being admitted to inpatient care, would contain information on where the patient had been admitted from and the reason for the admission. It is all based on diagnosis codes and it may not be easy to answer precisely the question that you are interested in from there, but I think it might give you a rough order of magnitude.

**Q144 Dr Naysmith:** Thank you. Professor Gray, you mentioned two sources of costs. You talked about £1 billion per year for the cost of healthcare-associated infections. Was that the £1 billion you were talking about?

**Professor Gray:** The previous £1 billion was a general estimate of the cost of adverse events based on a sample of inpatients. The healthcare-associated infection estimate has come from a different source which was a study commissioned by the Department of Health. It was a team from the London School of Hygiene who did this study in one hospital in the mid-1990s.

**Q145 Dr Naysmith:** That is where it came from.

**Professor Gray:** They estimated, on the basis of the patients in one hospital over a period of time, how many hospital-acquired infections occurred, what the cost of treating them was in relation to the costs of patients who had not acquired an infection, and, again, extrapolated it to a national figure.

**Q146 Dr Naysmith:** That must be a pretty unreliable figure, must it not? It could be a lot less or a lot more.

**Professor Gray:** It could be, yes. Certainly, I would think there would be wide confidence intervals around it.

**Q147 Dr Naysmith:** Another figure came from a publication of the Chief Medical Officer’s Expert Group, *An organisation with a memory.* It cited a figure of £2 billion per year for the estimated cost for additional hospital bed days due to adverse events. That is not the same as your £1 billion either.

**Professor Gray:** That is Professor Vincent’s study. That £2 billion is all adverse events. Not just preventable adverse events, but all adverse events based on the extrapolation from the Vincent et al study.

**Q148 Dr Naysmith:** The National Patient Safety Agency has estimated the annual cost of medication errors—that is just medication errors—as three-quarters of a billion pounds.

**Professor Gray:** Yes. I went back and had a look at the figures in that one as well. That is an estimate which came from two main sources. One is trying to get some handle on how many medication errors occur amongst people already in hospital and the other on what proportion of people are admitted to hospital as a result of medication errors. Based on systematic reviews of literature to get estimates of these rates plus studies of individual hospitals, the figures were attached to these. Also, a small amount
are based on litigation costs—I think it was a very small part of that total—and that is how we got the £750 million for medication errors.

Q149 Dr Naysmith: £774 million.
Professor Gray: Yes.

Q150 Dr Naysmith: Finally, the National Health Service Litigation Authority states that at 31 March 2008 it had net liabilities of £11.95 billion, mainly relating to clinical negligence claims.
Professor Gray: Yes.

Q151 Dr Naysmith: All of those things taken together, if you could get a proper figure out of that which included everything, would be a huge figure.
Professor Gray: The final figure you quote there, the NHS Litigation Authority’s net liabilities, is an attempt to try to estimate the value of all future liabilities, not an annual cost. It is saying that there is a stock of outstanding claims and there are also some claims which have not even been brought yet but which they anticipate would be brought. Then they have had to make estimates of what the likelihood is of them proceeding to settlement, what would be the value of settlement, and what is the strength of evidence in these cases. There are a large number of assumptions that that estimate is based on. I would say it is a slightly hypothetical figure, which had to be done, but it certainly should not be interpreted as the annual cost. It is not in any way the annual cost, which is much more to do with the £580 million in 2006–07 or the £630 million figure you mentioned for the most recent period.

Q152 Dr Naysmith: These four areas which I highlighted just now, a couple of which you had already mentioned, are these the main areas of cost or is there anywhere else that we have not taken account of yet?
Professor Gray: These are also figures which overlap to some extent. Quite a few of the figures one would obtain if you did a case note review would be the type of medication errors that have been reported in studies looking specifically at that. I do not think one could simply add together all of these things, but probably we are coming to a figure of perhaps 2%–3%. If I were forced to give a percentage of NHS expenditure, it might be something in the order of £2 billion to £3 billion a year, about 3% of the NHS budget, that you could potentially attribute to these adverse events. We are missing here, of course, that there are patients, for example, who would not be detected in case note reviews because it may not be obvious that anything has gone wrong in hospital but, subsequently, after discharge something goes wrong. If it is serious enough, they may be readmitted, in which case they would be picked up, but they may not be readmitted or they may see a domiciliary nurse or a general practitioner about a problem and it is not necessarily going to be picked up using the same information. There are other costs, therefore, which are being incurred by patients, including the pain and suffering of this and loss of earnings. In the population study which I mentioned previously we had performed, about 25% of the people who said they had experienced an adverse event considered it to be serious enough that they had had to take either up to a year off work or retire as a result of the disability or injury that had occurred. There are quite serious costs being incurred by members of the population which are not accounted for in the NHS budget. I think it is important that we do not lose sight of that.

Dr Naysmith: Thank you very much. You have been very helpful.

Q153 Dr Taylor: We have accepted that approximately 10% of patients have experienced harm, we have accepted that we need a lot more data, that we need a lot more research into the causes, but we cannot just sit on our backsides and do nothing for the moment, so from both of you what should we be doing now? Professor Gray, you have mentioned financial incentives in your paper. Could you expand that a little bit. Is that something we should be encouraging people to do now?
Professor Gray: We have seen, for example, with the general practitioners’ contract that if we have a clear idea of the direction in which we want to go, if we feel that care of people with diabetes or people with hypertension is not as good as it should be then giving financial incentives may encourage people to do a lot more than was being done in the past. That seems to have been quite a powerful mechanism to induce change in the way in which people have approached these problems. There are clearly dangers as well in introducing some of these financial incentives, that people may focus on them to the exclusion or detriment of other things, so I think we have to be careful about doing that, but I do think there is scope to provide more financial incentive for hospitals to embrace a safety culture and to pursue risk management policies where appropriate.

Q154 Dr Taylor: This was what you meant in your third point in your summary?
Professor Gray: That is right. That is only one of the things I had in mind. I think we have seen some attempt to do that with the Litigation Authority in discounts which it makes available to trusts if they meet certain risk management standards, so it does give the hospital a financial incentive of up to a 20% or 30% reduction on its contributions if it reaches high levels of risk management.

Q155 Dr Taylor: Professor Thomson, you said in point 34: “At each level within the system there should be approaches to prioritising investment in safety improvement based upon an understanding . . .” Would that cover, for example, if one ward is raising a number of complaints about the standard of care, that you would look very carefully at the staffing levels there and improve those if you could? Is that the sort of thing you were thinking of?
Professor Thomson: I was saying there that it is important that each organisation has its co-ordinated approach to safety management and
Q156 Dr Taylor: So it should be doing that now. 
Professor Thomson: Yes.

Q157 Chairman: Is it true to say that none of the figures that we have include the costs of unreported primary care incidents? 
Professor Gray: Do you mean where an adverse event has occurred as a result of a general practice consultation but has not been reported?

Q158 Chairman: Yes. 
Professor Gray: If it was sufficiently severe, of course it may result in a hospital admission or another consultation at a later date, in which case it would be counted by some of these procedures.

Q159 Dr Naysmith: It could also arise as an estimate from a survey which picked up— 
Professor Gray: Yes.

Q160 Dr Naysmith: Somebody could say, on the basis that a certain proportion of events are not reported, and then make an estimate. 
Professor Gray: Yes, absolutely. That would fall into the same category I was thinking of. For example, if somebody has a knee operation which to all intents and purposes goes well on the day but when they get home it starts to swell or to bleed or there is some evidence of an infection, that may not mean they go back into hospital but it certainly imposes costs, both financial and otherwise, on the patient involved but they are not going to be included in these figures.

Q161 Jim Dowd: How do you differentiate then between a failure of a course of treatment, whatever it might be, and treatment that just does not go as well as the clinician originally intended? 
Professor Gray: I submitted a small Venn diagram as part of my written evidence which tried to distinguish between errors and adverse events. There are some errors which would not result in an adverse event—and I am primarily thinking of near misses here—and there are adverse events which are not necessarily the result of error. There are side-effects, for example, which we know about associated with certain drugs or procedures, so we know that a proportion of patients will experience these side-effects not through any error but simply as a consequence of the treatment itself.

Q162 Jim Dowd: Would it include things like a negative reaction to a pharmaceutical, where you have prescribed medication in good faith, imagining it would work, but the patient reacted adversely? 
Professor Gray: If it came to light that there was a serious adverse side-effect that had not been known about previously, then one would want to take steps to flag that up and perhaps modify the prescribing rules. But all of these studies which have tried to divide adverse events into preventable adverse events and others are really addressing that question: What is the result of some error or something which has gone wrong which was avoidable and something which was an inevitable if unfortunate consequence of the treatment? 
Chairman: Could I thank you both very much indeed for coming along and helping us with this inquiry. Thank you.


Q163 Chairman: Good morning. Could I thank you for coming along to our second evidence session. I wonder if I could ask you, first of all, to give us your name and your current position or the reason that you are here. 
Mrs Bowen: My name is Mrs Clare Bowen. My daughter died on the operating table in the John Radcliffe Hospital. 
Mr Bromiley: My name is Martin Bromiley. My late wife died in March 2005 during an attempted operation.

Q164 Chairman: And you hold the position of? 
Mr Bromiley: I am a current airline pilot, and in my spare time in a voluntary capacity I am Chairman of the group called the Clinical Human Factors Group. 
Ms Ocloo: My name is Josephine Ocloo. My daughter died in 1996 through what I believe was medical negligence. I am a Patients for Patient Safety Champion for England, which is part of the World Health Organisation World Alliance for Patient Safety.

Q165 Chairman: Thank you for that. Thank you also for starting a few minutes early. Potentially we could finish a few minutes early as well but I would not be as brave to say that, having chaired this Committee for a few years. Could I ask a question to all of you. Could you each tell us about your personal experience of losing a family member as the result of an adverse event during medical treatment. 
Mrs Bowen: All of my children have a condition called spherocytosis. They are all quite severe cases and it required the removal of their spleen. My son had the operation in January 2006 at the John Radcliffe and it changed his life quite considerably so we decided that it would benefit my daughter Bethany, who was older than my son, to go in and have the operation. We consented to laparoscopy surgery, mainly on the fact that we were not given any other alternative. They thought this was the best thing possible and this is what they were going to do. We discussed the situation with the surgeons and they agreed they were going to take the spleen, drop it into the pelvis, make a bikini line cut and take out
the spleen. Beth was admitted to hospital. Everything was going, so far as we knew, well. She went down to surgery and the next thing we knew the doctors came back up and told us that they had cut a major blood vessel and Bethany had bled to death on the operating table. Subsequently, a lot of information came to light because we fought for it. The hospital were very reluctant to give us any information; we had to ask for everything we were given. Their story changed considerably over time. We found out that the blood vessel they were talking about was her aorta. That they could not have cut through her aorta, that it must have been a problem with her heart—even though she had two cuts in her aorta and cuts to her stomach and her bowel. We found out that a trainee was using a brand new piece of equipment called a morcellator on Beth. This bit of equipment had never been used in paediatrics in the UK before. It is used widely in gynaecology. They had not received any new training on this. Actually, they decided to use this equipment after the consent form was signed. The additional risks just were not told to us. After Beth collapsed, they could not regain her blood pressure for 21 minutes. There were various reasons behind that. I believe that they did not initially realise that they had made a mistake. The doctors were, I think, in denial of the fact that they had made a mistake during the surgery and they thought that it was just something that had happened to the patient that had not been to do with them. It was 21 minutes before they regained her blood pressure and she had suffered too much brain damage, damage to her heart, and just could not regain consciousness after that initial collapse.

**Mr Bromiley:** My late wife suffered from sinus problems, although apart from that was very healthy, and as a result a consultant had recommended that she should have routine surgery to clear the sinuses out. For reasons of timing and convenience, we had opted to have that done at a private clinic. The clinic and the NHS hospital are co-located and the consultants of course were one and the same. On 29 March 2005 Elaine was admitted for that surgery. Problems occurred during the anaesthetic process. She was transferred in an unconscious state to the intensive care unit next door and she died 13 days after the original attempted operation. During the time in intensive care, the ENT surgeon who had been involved had come to see me on a couple of occasions. He had explained that this was something that could not have been predicted and that when the emergency occurred they made all the right decisions but it did not work out. I accepted that. That is, regrettably, life sometimes. I remember a conversation I had with one of the team in intensive care about it. I said, “You know, I accept it is just one of those things, that maybe when this is investigated something can be learned” and he said to me, “But we won’t investigate, not unless you sue or complain.” For me as an airline pilot, that is where everything changed, because to me it is perfectly normal to investigate when something does not happen so you can learn from it, and here we had a situation where somebody was healthy, was going to be made more healthy, and was actually dead. I could not understand why you would not want to learn from it. It is a long story, but in the end I was granted an independent review of the care. That was conducted by Professor Michael Harmer, the then President of the Association of Anaesthetists of Great Britain and Ireland, currently the Department Chief Medical Officer of Wales. His report, combined with the inquest that followed his report, enabled us to build up a fairly clear picture of what happened during that procedure. In essence, there were no advance warnings of any problem. When Elaine was anaesthetised the oxygen levels in her body fell to very low levels. Initially, the anaesthetist, who was experienced—for 16 years he had been working, and he was regarded as diligent by his colleagues—along with the very experienced, senior ODP with him, carried out all the sorts of things that you would expect in this case, particularly with attempts to intubate (to put a tube down her airway). Over the next few minutes a team gathered around them. This included one more ODP, two recovery nurses who were highly experienced, the ENT surgeon who had 30 years’ experience—in fact he set up the ENT Department in the NHS hospital next-door—as well as another consultant anaesthetist. The operating theatre was equipped to the best standards that you would hope to find, and, indeed, there was no piece of equipment missing which they could have hoped to have had. Arguably, it technically was a dream team to deal with this sort of emergency, but what we know happened, if you will excuse the phraseology, was that the situational awareness, the shared mental model of the three consultants, was different. They lost awareness of time; they lost awareness, perhaps more importantly, of the seriousness of the situation; they became fixated—which is not unusual under stress—on intubation to the exclusion of any other options, such as some form of surgical access. Meanwhile, the recovery nurses and the ODPs were fairly aware of what was happening and what needed to happen. They had prepared the tracheotomy tray, one of them went out and phoned the intensive care unit, but, unfortunately, despite their awareness—to quote from the inquest—were unable to broach the subject of what should actually happen. Elaine was on very low oxygen for 21 minutes or so, and it was a situation ultimately at that stage that was unrecoverable. There are protocols for dealing with this sort if situation. It is referred to as “Can’t intubate, can’t ventilate”. It is a recognised emergency in anaesthesia. From my background in aviation, I could see very quickly that these were in fact failings in what you refer to as “non-technical skills”: situation awareness, leadership, teamwork, prioritisation, communication, and assertiveness. These same human factors of failings in non-technical skills are the direct cause of 75% of aviation accidents.

**Ms Ocloo:** My daughter was diagnosed with a dangerous heart condition shortly after her second birthday and she went on to have major heart surgery called Fallot’s tetralogy. It was a successful correction. She had this under the care of a leading specialist heart hospital and the family were very
happy and very relieved. My daughter was one of identical twins and despite this heart surgery she went on to lead a normal life, just going back to this hospital every year or every two years for check-ups. We were never given any reason to believe that after that surgery, which they said was a successful correction, she would not lead a normal life. It was when she was about 15 and a half that she began to complain of chest pains. Obviously we were distraught because we had never had any problems and never any warnings she might experience further problems after the surgery. We took her back to the hospital. We knew the hospital, we were familiar with the hospital, and we were familiar with the consultant, and we obviously raised our concerns. Krista was then brought in in January 1996 for a catheterisation which was exploratory surgery to look at what was going on with the heart. She stayed in overnight. The family was reassured that they did not find anything, she was absolutely fine, and we actually went off and celebrated because my daughter was a teenager and that was quite traumatic, she was doing her A levels and the thought that she might ever require any more surgery for her heart would be very difficult for a teenager. We were basically told that that was fine and we would get another appointment in due course as usual. Six months after that catheterisation we did actually call up the hospital and we said that we had not heard anything and why had we not been given any further appointments and they told us to come back in two years’ time. We again took that as further reassurance that everything was fine because Krista had always been seen under this hospital every year or every two years. And then 11 months after that catheterisation on what was a normal evening for me, I had come back from my work as a lecturer, my daughters were in their bedrooms, one studying for A levels, and Krista had a cold and had gone to bed. Then my other daughter Kelly shouted up to me that something appeared to be wrong with Krista. I ran up into the bedroom and found Krista dead in bed. That was in effect when my life collapsed. No warning, no indication that anything was wrong, and if that was not bad enough the horror has continued for every year since my daughter died, and I have been fighting now for 12 years to find out why my daughter died in those circumstances. Very soon after she died, as you would be in those circumstances, I was off work, I was ill, I was grieving, and I went to my GP. My GP handed me the catheterisation report which said that Krista had a number of problems with her heart which were serious and that she actually should have been followed up in six months’ time and they needed to keep her under serious supervision. That was the first shock. I then attempted to get an inquest and was turned down for an inquest. The coroner basically wrote me quite a terse, dismissive letter saying that he was not inclined to get into any of the issues that I was raising about Krista’s care, and eventually the finding was that Krista had died of natural causes. I then felt forced to go into the complaints system. It is hard to put into words how awful it is to have to battle through systems when dealing with the unexpected and sudden death of a loved child but I had to go through the complaints system because I then knew that something had gone wrong, there were serious questions about her treatment, and I had not been given any information. I then went through the first stage of the complaints system which I can only say was a brush-off. I spent four months writing letters. Each of those letters was agonising and back came pat responses which in the beginning, because I did not understand that this happened to other people, it left you feeling as if there was something wrong with you. It was just a constant brush-off. You do not really have the strength to deal with this, so the first stage was hopeless. I then went to an independent panel review. I gather at the time in my area I was one of the few that had been able to get one so I gather it was quite difficult to get an independent panel review and after again I think probably a year, a whole year of agony, back came another report which again I felt completely ignored the major questions that I was raising. It was some two and a half years after my daughter died that I heard on the radio that there were problems at this hospital. A whistle-blower had gone to the press and I then went public for the first time. Families and harmed patients are often blamed for going to the media and seeking publicity. I certainly did not want my personal life in the media but after two and a half years I realised that I was going to have to do something. I then campaigned; I went public; I was contacted by 50 other families; and we then demanded that there should be an inquiry. The outcome of that inquiry was that there were failings but there was no negligence. They wrote specifically to tell me in my case that there was no negligence. I then decided to go into court, funding it myself. I went into court without any insurance because I could not afford the £40,000 I would have to pay to insure myself if I lost. I got a ruling of negligence but I lost on causation. I could not prove the negligence was directly causative of my daughter’s death. Really, after that, it has only been in the last two years that new evidence has emerged which showed at that inquiry that most of those families were complaining against the one doctor. There appeared to be issues amongst those families about discrimination and the fact that the doctor may well have withheld information from us. I also have evidence from a cardiologist saying that there was serious negligence in my case and also that records from Krista’s notes were removed from the hospital before I went into court, and she worked at the hospital. I have provided all of that in evidence to the GMC and they have still refused to investigate.

Q166 Chairman: Perhaps I ought to declare an interest in that I am a lay member of the General Medical Council, although I have no dealings with the screening or fitness to practise side. My term will end in a few weeks’ time but I thought I would say that in view of that last comment. My next question was to ask all three of you whether you would say that the staff and organisations involved with you were open and honest with you? I think Clare, probably the answer to that from your perspective is
that they were not, and perhaps the same with you Josephine as well. If you have nothing to add to what to what you have said in relation to that, I wonder if Martin would answer.

Mr Bromiley: I think my situation was slightly different because it happened essentially in a private clinic, and because of my professional background, which was a topic of conversation during the period of time that I was waiting on the intensive care unit, when it came to persuading the clinic that there ought to be an independent investigation there really was not a problem. They did not have any rules for how to deal with this sort of thing so when I said to the director, “I would like an investigation,” she just said yes because she did not know what else to say. I think what my case demonstrates very clearly is that when you have an independent investigation by somebody who is regarded as an expert in the field, there is a tremendous amount of learning that can take place. There has never been any reluctance of people to contribute to the investigation, with one exception, I have to say, from the ENT surgeon who was rather difficult, I think it is fair to say, but, nonetheless, we were able to establish fairly clearly what had happened. Without an independent expert to review a case I cannot see how you can possibly reach anywhere close to the truth. Even in Elaine’s case notes were missing.

Mrs Bowen: Can I just add that we did have an allegedly independent witness that came in to help with the coroner’s inquest.

Q167 Chairman: We may be asking Clare one or two questions about that in a few minutes. Could I just find my opening question at the beginning? What lessons can be learned from your individual experiences and do you think they have been learned?

Mrs Bowen: Not at all. For example, I have been in contact with the hospital with my brother-in-law over the last few weeks. We still have not received a copy of the Serious Untoward Incident Report into Beth’s case, and the comment from the Director of Nursing was that, “I need to run it past the chairperson because there might be things in there he wants to take out.” If that is not withholding evidence I do not know what is. I think one of the problems when you have no medical knowledge at all is that you do not know what questions to ask and it was only when we got into meetings with the hospital and we said to them, “Do you have this?” they would go, “Well yes, here it is,” and it was not until we asked for things that they were given. Even when I said to the hospital, “Is there anything else you haven’t shown us that could help us? Is there anything we haven’t had?,” they would say, “No, you have everything,” and then at the inquest they still brought out more slides and things that we had never seen. So unless you know the questions to ask, and you need someone with you, and you need an independent person to ask these questions for you because as a grieving parent or widow you cannot deal with it. You need the help because in my case the hospital would not give us any information at all. I do not think that they are any different now because I think they were very much in denial of the fact that anything that they had done had caused Beth’s death, and I still believe they are in that situation. I am in contact with them at the moment because I have a two-year-old that needs to go through the same operation, and I have gone to Birmingham Hospital rather than John Radcliffe now to talk to them. John Radcliffe actually put in his notes that there is a risk of sudden death from heart failure because of the family history. My husband died of a heart attack in February this year and the hospital saw that almost as a get-out clause “Oh, he died of a heart attack, therefore it must have been linked into Beth,” and that is not the case and they have not learned anything at all.

Q168 Chairman: Martin, have you seen any lessons learned or not?

Mr Bromiley: I think there are lessons that can be learned which I would like to share with you if that is okay. Obviously that is influenced by the fact that since Elaine’s death, certainly for the last two and a half years I have spent a tremendous amount of time working with clinicians, human factors experts, and policymakers, from the Chief Medical Officer right down. I think the first lesson is clearly one of independent investigation. We know that in aviation and in the rail industry that has brought about a culture whereby we can learn from what happens. If you take the latest official figures from the Department of Health that were in your submission for the number of deaths in England, it is in the region of 3,200, which is more than the current number of road deaths in the UK. Independent investigation offers us the chance to learn. In Elaine’s case, if you go to almost any anaesthetic department in the UK you will find anaesthetists who are aware of the case, who have debated it, very hotly in many cases, and have been able to take lessons away from it. That is all for the cost of probably £5,000 for the investigation and a few articles that have been written in clinicians’ journals. The second lesson I firmly believe is one that in the Health Service there is a focus—and again we have seen it in the submissions that you have received from the Department of Health, the NPSA and the various Royal Colleges—on the problem of systemic error, system error, system failure. There is, I believe, an over-focus on system failure and correcting systems. It is almost like a mantra now in the NHS that if you correct the systems then mistakes will not be made by people. Experience in aviation is very much the case that, yes, you need the systems, and we have some fantastic systems on board our aircraft to help us, and you also need soft systems such as the use of check-lists and briefings, et cetera, but just as importantly you need to train and develop the people. In the NHS at the moment there are very few examples of training and development for people around human factors and non-technical skills. For example, in my case, 50% of assessments that are done on me as a pilot are non-technical skills because it is that crucial to safety. That is a really important point to bear in mind. At the moment there is lots of talk about human error in the Department of Health, lots of talk about it at the top.
of the NHS, but at the clinical level where people are the final line of defence, who operate the systems, then they just do not get the education and training in those areas. I think that is another important lesson as well. None of the clinicians involved in Elaine’s case has ever faced any disciplinary action, and that is exactly how it should be. They made inadvertent human error. They did not try and hide it, as far as we know. They behaved properly and they did their best. They have been, if you like, protected if this case by good fortune perhaps, but I believe it is essential that the NHS has a clear policy of not disciplining people who make a genuine human error. I believe they should have the right to discipline in the event of gross negligence or deliberate acts, but while we have a policy which means that people can be disciplined, there will be the cases where evidence is hidden and we will not get that open culture.

Q169 Chairman: Josephine, lessons that could be learned and have they been?

Ms Ocloo: No, I certainly do not think the lessons have been learned in my case. I have battled for a very long time to make sure that the full facts in my case come out and I have not been able to make sure that happens, although I have been able to bring quite a lot of them out in the open myself. One of the things I have been able to demonstrate through my own case is that in each subsequent inquiry that I went through more evidence came out but I was only able to do that through sheer determination to try and expose what I believe is quite serious wrongdoing. I actually feel that the system systematically attempted to stop me from exposing what went on and I think that there is a culture of denial within the NHS which is comprehensive, which happens at every level, and which if we do not address we will never be able to deal with creating a proper, safe patient safety culture in which everyone is protected. I think that tackling that culture of denial is absolutely fundamental, and important to that of course are proper systems for investigation and for being able to hold people to account. I would say that in some of the debates around developing a patient safety culture, the issues about developing systems around independent investigation and accountability have been ones which have been downplayed in those debates. I go to lots of conferences and you will rarely see harmed patients in those conferences and you will certainly not see harmed patients who have a grievance. If we look at some of the figures, and I put this in my submission, there is some evidence that 25% of patient safety incidents could be negligence and yet only tiny numbers of legal claims (5,500–6,000 legal claims roughly over the last couple of years) have been brought, so it is not a huge number and it indicates that lots of people are still not able to take any action when something serious goes wrong. I also highlighted that the complaints system has been reviewed consistently over the last 13 years and recent evidence shows that we are still not getting it right. Of course we have had all the serious criticism post-Shipman about professional regulation and there are still problems there as well. What I would say is that when something goes wrong we have to find out what happened because how can we possibly learn and make sure that it does not happen again if we do not know what happened. I think that one of the things preventing us from finding out what happened in many cases is this culture of denial which is so serious, I think, within NHS organisations, which is then subsequently reinforced by a whole range of organisations. Attempts by harmed patients to try and raise these issues about the failings of the system to allow learning, because there has been no proper investigation, are then blocked, often because they cannot participate in any of the mainstream patient safety debates.

Chairman: I think Doug has a supplementary question.

Q170 Dr Naysmith: A quick question to ask Mr Bromiley and it arises out of Beth’s case, Clare. We understand that the procedure that was used was a training exercise at the time and that the doctor operating the morcellator, which was a new clinical tool that was being used, had never used the tool before, in fact he had never heard of it before that morning. The surgeon who was directly supervising him had never seen or operated the tool before. There was someone senior in the room, another surgeon, who had used it before some years previously but not in this country. Can you conceive, Mr Bromiley, of a junior airline pilot being allowed to take off an aeroplane without proper supervision? Does it ever happen in your industry?

Mr Bromiley: No. There may have been instances such as that 40 or 50 years ago when there was perhaps a spirit of adventure amongst pilots, it was a very macho culture, but today not a chance.

Mrs Bowen: I think with Beth they made the decision on the morning to do it. We were talking about human factors and about denial, and at no point did they think anything could go wrong, to the extent that they did not even have the adrenaline drawn up in the operating theatre. When they walked into that operating theatre they had this almost gung-ho attitude, we can do this, this is fantastic, it is going to be the best thing. If it had gone right and Beth had not died on the operating table, they would have been celebrated and patted on the back for introducing a new fantastic technique into the country. The risk assessments just were not done. Again, they have all this documentation with risk assessments, they must do this, they must do that, but if it is not done at the ground level and they do not learn these lessons then this is going to happen again. With Beth it was just no-one stopped to think about what they were doing and no-one made them and there was a hierarchy in the operating theatre. The same in Martin’s case, none of the nurses or anyone said, “Hold on a minute, do you not think we should step back here?”

Chairman: Could I thank all three of you for that. It took a bit of time to open this session up and I do appreciate that. We are now going to ask some specific questions around your experiences.
Obviously if you have given the answer before you do not have to repeat it. I am going to start with Sandra.

Q171 Sandra Gidley: I want to pick up on this denial issue. I was interested in what Josephine said because that is the impression I was getting as you all spoke. A very quick and simple question really: do you think that it was almost an institutional and deliberate denial and obstruction? Why do you think that was? It is very hard for you to say but you have all had to struggle to get information out of the system.

Mrs Bowen: It is a bit of both. It is institutional denial because the hospitals do not want to see that things have gone wrong. Even with this thing about Beth’s heart, they wanted to say that it was a problem with Beth’s heart and they looked for months for something else to be the case. Instead of investigating what had actually happened, they wanted to fit pieces around the puzzle so that it was not their fault. I also think it was a denial on the doctors’ part because they did not believe they could do anything wrong. If a surgeon goes into an operation not believing anything can go wrong they do not know how to react when something does go wrong. I believe in Beth’s case when Beth collapsed it took them 21 minutes to regain her blood pressure, and they denied all the way through that they did anything wrong in those 21 minutes. I believe they did but they did not realise quickly enough that something had gone wrong. It is almost like an inbuilt subconscious denial. They do not think they can do anything wrong. They do not think they can make mistakes and it is an arrogance born out of a detachment, I suppose, which all doctors have to have to some extent. A surgeon would not put a knife to a child if they could not detach from the patient slightly. It is when that detachment becomes arrogance that they then deny the fact that they can make mistakes. When they deny the fact that they can make mistakes then the human factor comes in, then “I can’t do anything wrong” comes in, and that is where the doctors have it. The institutions do have it as well because they hide things from you and they do not want to be seen to be making mistakes.

Q172 Sandra Gidley: Would you agree with that, Mr Bromiley?

Mr Bromiley: Yes, certainly in my own culture in aviation we have a firm belief that error is absolutely normal. That is knocked into us when we go into a simulator and we are given a situation to deal with. We all make mistakes. Intriguingly, a few weeks ago I was shown a video from a clinical simulator. A team of clinicians had been briefed on my late wife’s case and they had all said, “Yes, that’s fine but I wouldn’t have done that.” A week later they were given a situation to deal with in the simulator which started off very differently, it was a knife attack victim but ended up in the same scenario, and they managed it almost identically to the way it was managed in my late wife’s case. What I am saying is that we have tools in aviation, and we have the Civil Aviation Authority, our regulator, actually stating in its documentation that error is normal and what we need to do is to work on systems that catch it. We have simulator sessions that help us to keep real, I suppose, and we do have a system of speaking up, so that if I do something that is wrong I might sit there thinking, “I hope nobody notices,” but I know my colleague will say something. That helps to perhaps make you a little more humble and a little more thoughtful. Again the accident investigations, we can all sit there and read them and think, “Maybe I’ve been close to that before.” We do not have that in health care and there is, regrettably, a culture at some levels of arrogance which we need to tackle.

Q173 Sandra Gidley: So there is denial and arrogance?

Ms Ocloo: Can I say something?

Q174 Sandra Gidley: Sorry, I thought you had said quite a lot but if there is anything more you want to say that is fine.

Ms Ocloo: I want to make one point which is first of all when something goes wrong it can be a mistake or sometimes it can be active wrong-doing, so I think it is both. I think that we obviously need to know what the issue is and then respond appropriately. Sometimes that may be through disciplinary measures but of course in a large number of cases it will not need that because they will be genuine mistakes. I think that because of widespread systems within the NHS which cover up when things go wrong, we cannot actually understand what has happened. It is not that the NHS is so different from lots of other professions. In social work in the 1980s there were lots of issues from lots of different groups that we worked with as social workers, disabled groups, black and minority ethnic groups, who raised issues about services that were harming them and were failing them and systems that were not accountable. We have seen that in the Police. Those public organisations have been forced to some extent to look at their systems for dealing with those issues. I think that in the NHS what has been deeply disturbing for me is that the dominant discourse or debate has centred around this idea of a no-blame culture and that seems to have drowned out a lot of discussion about systems of accountability which also need to go hand-in-hand with a non-punitive culture. I think this is a particular issue that we actually need to look at, what are appropriate systems of accountability which do not just target people in a random and generally punitive way but also do provide those proper checks and balances.

Q175 Sandra Gidley: You are using the term “no-blame” as though it is almost synonymous with no responsibility.

Ms Ocloo: I think that it can be seen like that at some point. I think that people often do see it like that and that is very problematic. An understanding when I have been in patient safety debate is the debate is around this idea that we should be creating a no-blame culture. I talk about an “open reporting culture” rather than a no-blame culture and I try to say that we have also got to look at issues of
accountability, but that seems to be treated as if that is somehow negating the idea of creating an open reporting culture.

Q176 Sandra Gidley: I can see there is a tension. Would it have helped each of you if in your case there had been a more rapid response and somebody had actually been attributed with perhaps not the cause but it was dealt with quickly, it was clear what had gone wrong, and there may have been some responsibility, and maybe if somebody had said sorry, or is that too much to ask?

Mrs Bowen: Not at all because I think in my case if someone had come out, if the doctors had come out and said the entire truth, “This is what happened,” on the day in the room when they told me Beth had died they told me the truth, I know they did, they were very emotional and they told me the truth. They told me they had cut a blood vessel and she had bled to death. It changed within two days. They came back and they said, “We cut the aorta in two places, probably the morcellator, but the resulting blood loss not significant. We do not know what killed her.” About six months later: “The aorta was certainly not damaged by the morcellator, the cuts did not have any explanation and the blood loss was insignificant. We do not know how she died.” Within six months it changed from “we did this”. I think there is a massive difference between a doctor coming up to you and saying, “We did this and this is what we did,” to someone else saying, “You did this.” If the doctor can themselves acknowledge that they made a mistake, it shows you that they are not in denial, that they can make mistakes, that they understand they can make mistakes and they understand that they can learn from them. In Beth’s case the hospital admitted negligence yet in the inquest the doctors refuted it completely. I have no confidence at all that those doctors will not do this again. If they had come to me and said, “We are sorry, this is what we did,” you can then understand that they are sorry and that they will learn from their mistakes.

Q177 Sandra Gidley: Does anybody else wish to comment on that?

Ms Ocloo: I think it is absolutely important that we deal with these issues quickly. All I want to say on behalf of other harmed patients that I know on the circuit is that spending years and years going round in circles trying to get answers is simply not untypical and we do have the evidence that it happens. Most of those people will never get any explanations. I think often the harmed patient gets treated as if they were somehow malicious and they are trying to apportion blame. This, again, is because they are not able to get some type of explanation very, very quickly. I do not think it is always about an apology. I think that what you need to know to come to terms with it is what happened. How can you possibly lose a loved one in very difficult circumstances and then just be expected to get on with your life? You need to know quickly for yourself and the organisation needs to know.

Q178 Sandra Gidley: I think I can guess the answer to this question but I will read it as it is on the paper: from your experiences, do you think that the NHS is succeeding in moving towards a “safety culture”—one based on “fair blame”, openness, reporting and learning? I think I can take that as a No from what you have said.

Mr Bromiley: From my many conversations with people at senior levels in the NHS, that is both clinicians and policymakers, the answer is that is what they all want, but until we start to engage frontline clinicians and train them and talk to them about human error and human factors, we are really going to struggle to get there. The quality of reporting in the NHS is relatively low at the moment, although the quantity is high, and that is because the workforce is largely uneducated around a safety culture. It is almost like a big secret.

Mrs Bowen: My feelings are that there are a lot of good doctors out there who are only good doctors because nothing has happened yet because they have not made a mistake. It will continue being like that until they are trained in the fact that they can do something wrong. There are so many forms, regulations, rules, risk assessments they have to go through but if they do not do it they are irrelevant, so a safety culture can only happen when the people on the ground are made to look at themselves and the mistakes that they can make.

Ms Ocloo: I think some progress has happened in the hospital sector and we should not negate everything. Over the last ten years I do think that people have tried to move forward with putting proper systems in place and I have certainly seen evidence of that, particularly I think in the hospitals sector, but in primary care there are still major problems about incident reporting. If you look at the data you will see that very little is coming through from primary care whereas we do get a lot more from the hospital sector. I would reiterate that until we have a more even debate where we look at lots of different aspects of the patient safety culture, both to do with incident reporting but also to do with learning from complaints and learning from serious wrong-doing. Again, it is some of those serious incidents that are not coming through and being reported, so there is some evidence of progress but I think there are some particular areas that we need to address where there is no debate, and I think it is some of those tensions about the culture of denial and accountability: we have to open up that debate in a proper way and really look at that.

Q179 Jim Dowd: Mr Bromiley, just on the point there about making doctors aware of their errors, do you believe that should be done at medical school as a specific element of becoming a clinician, a doctor?

Mr Bromiley: To a small extent it is already in the syllabus although it is not monitored. I think it needs to come at two levels. Yes, it needs to come as part of a student’s training. It does not matter which professional group they belong to, the training should be similar for all, and they must be examined, as the Royal College of Surgeons of Edinburgh are looking at at the minute. My bigger concern is with
everybody else who is already in the workforce. That is where in aviation we have worked really hard. Even now if you were to look at my own company the operations director sits on the board of my company, and he flies occasionally, and he still has to attend the same recurrent mandatory training as I do because he is equally prone, if not more so because of his lack of flying, to human error. We really need to think about how we educate and develop these non-technical skills in current clinicians. I do not think that we can simply say we are going to mandate a two-day training course and everybody has got to go through it in the next two years. We need to mandate the need for that education process and we need to mandate a deadline and then to leave it to the experts, the Royal Colleges, the NHS organisations, the experts and the clinicians to then work out the process of doing that but, yes, it must happen at current clinician level as well as trainee level.

Q180 Chairman: Martin, have you heard of the word “revalidation”?

Mr Bromiley: Yes I have.

Q181 Chairman: What is your understanding of what may or may not happen with that?

Mr Bromiley: There has to be evidence pulled together over a period. I think it is going to be done every five years and that may be a great opportunity to incorporate some form of education process., whether that is done through individual personal development or by some wider scheme, I do not know, that is not my place to say, but I am well aware of the opportunity that that may bring.

Q182 Jim Dowd: The main point of my questions was actually to do with the coroners’ system. Mrs Bowen and Ms Ocloo have already mentioned that they had some engagement with it which did not sound particularly helpful, to put it mildly. The Government is conducting a review of the coroners’ system at the moment. What changes do you think ought to be incorporated to ensure that it does become an effective way of finding out the truth around a death, whether through medical accident, or anything else for that matter?

Mrs Bowen: In my case the coroner’s inquest wanted to find an answer; that is all they wanted. They had all these pieces of evidence and the coroner put them together and if he could find a pathway through to an answer, however unrealistic it was, he was happy to take that. He was happy to disregard any evidence that did not fit his line of enquiry. For example, with Beth’s aorta the pathologist said that it was pulled and twisted like it would be in a car accident, which would fit with the morcellator because you pull up the spleen into the morcellator, therefore he must have pulled the aorta into the morcellator with it, and it twisted it because there is a rotating blade inside. That fitted perfectly. However, when it came to other evidence we could not quite fit it. Because the hospital had thrown away the bag, the blade, they destroyed the evidence, we had no evidence to fit along that path. The only other things he could find came towards, “It might be this thing therefore we will say it is this.” We did not have the opportunity to investigate further the evidence that did not fit the big picture. It needs an investigation outside of the coroner. It was my solicitor, who we were forced to appoint because we had no idea how to go through a coroner’s inquest and the hospital’s solicitor, and things that we could find, and as parents of a child who has just died you do not want to be trawling through pieces of paper and internet reports and contacting experts; you want an independent body to do that for you. We had an independent witness at Beth’s inquest. He was a medical person, he was a doctor who had done lots of operations, but he had not seen a morcellator and he had never used one before, and yet he was allowed to stand up at an inquest and say, “It couldn’t have been the morcellator.” He had never even seen one before so why was his independent statement allowed to be put to the coroner? The whole coroner process is very, very difficult. It is difficult to find answers. It is almost like you as a parent do not find answers through it. You just get a result at the end and whatever result the coroner comes up with, that is what happened. I do not believe that enough investigation is done behind coroners’ inquests to be able to find the truth.

Ms Ocloo: I was not granted an inquest and that happens and I gather the coroner can use their discretion in granting an inquest. First of all, we have got to make sure that that is not happening routinely. That has been one of the major criticisms in the past and people have not been able to fight back against that. We have got to make sure first of all that cases are not being screened out and just put down as “death due to natural causes”. I think that when the inquest then takes place, in my mind, there are a lot of similarities with a court case. First of all, most families cannot get to court in the first place and then when they do get into court they are having to deal with a legal test, the Bolam test, which is enormously difficult to deal with, and that requires you to have your evidence and to be able to get your evidence together. We know that because of this culture of denial lots of families complain about missing medical records and so on and so forth. It is very difficult for you to properly prepare your case and of course it is doubly difficult to do that if you are not able to properly access an organisation that can assist you or to have trained lawyers. My real feeling is that there are distinct things about inquests, legal systems, complaints systems but if you look at them altogether these are all massive hurdles that families have to jump in some shape or form to try and get their cases investigated. Some of the issues are very similar. Families are not able to get their evidence together; they are not able to get support to put their evidence across. It is very, very difficult for them to properly make their case in those arenas. I think those are still issues in the Coroners’ Court but that they are features in other areas as well.

Mrs Bowen: One thing I would add is that evidence did come up in Beth’s case which said that the doctors were doing things against the
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manufacturer’s guidelines and without training. Even though it came up in court and they admitted things in court, nothing was done. We walked out of that court having listened to the doctors saying they used an Endocatch bag with the morcellator, after hearing the manufacturer of the bag saying, “We do not allow this, we tell them not to do it,” and the doctors sit there and say, “We have not got anything else so we are allowed to use it.” The coroner does nothing and can do nothing about those things. That must be addressed.

Q183 Jim Dowd: One of the proposals that the Government is clear about is amending what is known as Rule 43. I do not know if you are aware of what that is but effectively to give that statutory force. If the coroner comes across an event which has led to a death then it can notify and it will go to the Lord Chancellor and be published. That is certainly one of the amendments which we look forward to seeing. I think I have the grasp of what you are saying so my next question is almost superfluous but I will ask it anyway; how would you react to the setting up of an independent investigative process for patients or families particularly where there has been a death or serious injury to look into serious incidents and deaths in the NHS with a combined role of patient advocate?

Ms Ocloo: I would dearly love to see something like that. It is much needed and I know that harmed patients out there on the circuit are desperate to see something like that. We have just got to be careful to make sure that we set it up in the right way and I hope that there will be lots of thought that goes into that. As far as I am concerned—and I have not seen the redress scheme emerge that was proposed, although there were lots of arguments about having one—but people were desperately disappointed when advocating for the Scheme, because it turned out that there would not be independent investigation and that the investigation would be at the local level which was seen as problematic. Independent investigation is what people want and it would be much welcomed.

Q184 Jim Dowd: Mr Bromiley, you made the allusion earlier to the Air Accident Investigation Branch for example, something along those lines? 

Mr Bromiley: I think the system needs to be reviewed thoroughly by an industry expert from outside of healthcare, first of all, and I cannot believe that they would not recommend independent investigation. Health care is technically very complex and it requires proper investigation, for the sake of the clinicians let alone the patients. A clinician needs to know and have peace of mind that whatever they did there is no political influence from their bosses, somebody independent who is an expert will review their work and will look on it in a proper light and lessons can be learned and an independent investigative process is the best way forward.

Mrs Bowen: Independent investigation needs to be able to look into whatever they need to look at and all the information they need. One of things that I have found as well is that the doctors’ evidence in the Coroner’s Court has a massive influence. If a doctor is in denial that they could have done anything wrong then the coroner is swayed by that. If you have no physical evidence, as we did not have in Beth’s case, all we had was the doctors’ evidence, and the junior doctor sat on the stand and believed that he was adequately trained in the use of the morcellator. He was allowed to judge that he was adequately trained. He had ten or 15 minutes’ worth of verbal training. In no other situation in life are you allowed to say, with an airline for example, “I have had 15 minutes training, yes, I can fly this aeroplane.” There has to be some redress on the doctors’ testimony and they have to be able to step back from the doctors’ testimony—and I am not saying it is not the truth but I am saying it is not necessarily right— independent of the situation, so they need to be able to look at it from a medical point of view without believing that everything that the doctors say is correct.

Ms Ocloo: Just adding to that, I think that many times families are not able to get answers and explanations because the evidence has mysteriously disappeared. This is not new, we all know about it. In court I just could not understand why it was okay that it was said that these records were missing and yet no-one was held to account for it. I could not understand why it was not a criminal offence. Why were those records missing? Those were strategic records the loss of which would mean I would probably lose my case and you could just take them and no-one would be held to account on that. The balance is tipped in favour of the health profession when something goes wrong and we have to have more of a level playing field. One of the things around that is to do something about this issue of medical records going missing and what penalties there should be if that happens.

Q185 Dr Taylor: I want to explore the complaints system. Just by introduction, even though I am an MP and a retired doctor I have had just as little success as you have with following up complaints from some constituents about actual deaths, so I am absolutely right on your side. I want to go through the complaints system. Josephine, you used it before the so-called changes came in in 1996 which were supposed to come in to improve it, so the system that you should have tried to use was the one with stage one which is local resolution, stage two which is independent review and then on to the Ombudsman. Firstly, starting really with Clare, I think you have implied that you did not get any help. Were you aware of PALS or ICAS?

Mrs Bowen: I was not aware of ICAS. We were made aware of PALS about three months after Beth had died only because a friend who worked in the hospital, an anaesthetist, had said, “Have you not been contacted by the patient liaison person?” and we did not even know anything about it. We were eventually given a booklet, so I asked to meet someone at the hospital and, to be quite frank, she was worse at hiding things than the doctors. She would sit there and I asked her if we could see Beth’s medical records and she would say, “I don’t know about that.
I will have to check whether you are allowed to.” It got to the stage that six months after we originally met this lady the hospital banned her from speaking to us again because she would send me emails with the title “Serious untoward investigation 366” and I would email back saying, “You are not talking about a number, you are talking about my daughter.” So my experience of PALS was limited; they were defensive and unhelpful.

Q186 Dr Taylor: Yes, the basic fault is that they are paid by the trust that is investigating?
Mrs Bowen: Yes, they are not independent. It was almost like they put up a wall that they were expecting me to take out litigation, they were expecting the litigation route so they wanted to prevent it and defend that point right from the very start.

Ms Ocloo: Adopting the culture of denial.

Q187 Dr Taylor: Nobody told you about ICAS, the Independent Complaints Advocacy Service?
Mrs Bowen: No.

Q188 Dr Taylor: Were you aware of them?
Mr Bromiley: To be honest with you, I was not interested in complaining because as far as I was aware nothing untoward had happened. All I wanted was an investigation to discover what could be learned from it and until that process was complete I had no reason to complain.

Q189 Dr Taylor: You have absolutely highlighted what a number of my constituents have said to me: “We do not want to complain; we just want things made better”, but the only way the NHS is capable of doing that is going down the complaints process route.

Mr Bromiley: Can I perhaps give an example. I can imagine a scenario where a plane crashes and the airline sat there and said, “Okay, let’s just see if anybody complains.” It is preposterous. The first people to try and find out what happened is the airline because they want to know what on earth has happened. The doctors as well need to be the ones to get that investigation.

Mrs Bowen: I do not think the doctors in many cases would put their hands up because they would feel that they were leaving themselves vulnerable to litigation or to prosecution. If you have done nothing wrong in terms of negligence, if it is just a human factor and you have stepped back and you have looked before the operation or before the situation and minimised as much as possible all those human factors, if you have discussed them, if you have prepared for them, if you have accepted they could happen and prepared for that situation, if you know in that case nothing is going to happen, then they will stand up and put their hands up and say, “We are sorry.” If they feel that there is a possibility of them being held to account, being blamed for what has happened, then they are not going to do it.

Ms Ocloo: Can I make two points about the complaints system. Although I used it in 1998, looking at all of the recent reports, a lot of the criticisms are quite similar, continuing to make the point particularly about this issue of a lack of independence, so there has been some cosmetic tweaking but the system has continued to operate in a similar way. A big complaint that I have and others in my situation have is that we do not want the independent panel review stage to go from the Healthcare Commission. It is so disappointing. I was at a Department of Health conference in June on professional regulation and the conference was very good because it was one of those few times where patients and the public were invited and consulted, so there were quite a few patients there and patients who had made a complaint. In actual fact, it was quite unusual, the workshop got quite rowdy because there were so many patients who had made complaints who were absolutely insistent. It was the usual workshop where they will tell you what is happening and they said, “We are telling you this is what is happening,” and the patients were saying, “And we are telling you we do not want that to happen.” Some of us have been fighting for years. We got the IRP to the Healthcare Commission stage and we do not want it to go anywhere else. We feel that that has been closest to giving us an opportunity to get an independent investigation and so switching that to the Ombudsman is very problematic.

Q190 Dr Taylor: Yes, at least in that system there was an automatic independent review. In the system that we are moving on to, to some of our horror, it is local resolution and then the Ombudsman and nothing in between.

Ms Ocloo: Exactly and it is scary because it feels as if again after 13 years of review we have gone backwards. What I would also like to say is that recently when some new evidence came to light in my case and I went to the GMC and then I went public, the hospital after 12 years wrote to me suggesting that I had gone full circle. They did not offer me an independent investigation, they offered to conduct the very investigation where I was also making allegations about them removing medical records before I went to court. They were not going to do it independently and then they said, “We presume that you would like to be kept informed.” I just thought I am going round and round in circles. Again, at a local level the systems are not in place to allow people to get that investigation.

Q191 Dr Taylor: So you all feel extremely strongly that there has got to be automatic independent investigation?

Ms Ocloo: Yes.

Mr Bromiley: Yes.
Q192 Dr Taylor: Another thing you have mentioned is records going missing and no action being taken. What could one do about that?

Mrs Bowen: In Beth’s case they cleared the operating theatre. As soon as Beth was brought into the anaesthetic room we were told they had completely cleared the theatre of swabs, blood, bag, spleen, everything just went, the morcellator blade. They did not even know at that point that the blade in the morcellator had not malfunctioned. They could have had an entire box of defective equipment in the hospital and they would not have known about it. The operating theatre, the situation has to be completely sealed. When we explained this in Beth’s case they said, “Oh, but we use the operating theatres all the time.” It would not take more than a couple of days to get someone in there to look at the situation, to look at everything and then re-open the theatre. I would rather close an operating theatre down for a few days than have defective equipment in another operating theatre and for someone else to die the next day. It has to be completely sealed and every single piece of equipment and evidence there is investigated by someone who comes in from outside the hospital. In Beth’s case they even went to look for the equipment a couple of hours later and because it had been taken to the bag and bagged up they thought it had gone now. You cannot get a clear answer as to what has happened without all the evidence. An independent person would be as hampered as anyone else if all the evidence was not there.

Ms Ocloo: There needs to be severe penalties if evidence goes missing, both for the hospital and for the Chief Executive.

Q193 Dr Taylor: The other issue you raised was the selection of the so-called independent doctor. How can we make that better?

Mrs Bowen: The independent doctor in Beth’s case was known to the chairperson of the trust. It has to be selected by the independent body. They have to have people who they know will look at the case as an independent investigation which, to be perfectly honest, I am a bit involved in trying to fight for it. I am a bit shocked that I have not seen anything. I was a bit involved in trying to get independent medical experts. I think that is a real problem. I think that from the hospital side there is quite a lot of evidence that they choose people who will present the evidence in the way that they want. To get genuine independence is difficult. There is a stigma attached to doctors who might like to stand up and just tell the truth. It is not a case of being against the medical profession or in favour of the patient; it is a genuine independent opinion. I think there is still quite a lot of stigma attached to doctors who speak up or so-called whistle-blow. Doctors should have an obligation to speak up and tell the truth. I think we should do something more about trying to get rid of that stigma. Those doctors get quite badly labelled and stigmatised. If we get rid of some of that, then we might get more of a flow of doctors who could come through who would not feel that their reputation might be tarnished.

Mrs Bowen: Doctors do not want to criticise each other. That is the case, that is what it is. You need a medical person to give you advice that they are in the same situation as a doctor in the hospital. You almost want someone who is medically trained without being in the medical profession. It is a very difficult question and it is something that needs to be looked into very, very carefully. It needs to be completely detached from the hospitals.

Dr Taylor: Thank you, you have given us a lot to think about.

Q194 Sandra Gidley: We have now got something called the NHS Redress Act which I do not think has been implemented anywhere yet, but the idea is that harmed patients and families will be able to have problems resolved and investigated and hopefully not resort to litigation. Do you think that this is likely to happen or is it just another well-meaning bit of government legislation? Josephine, I know you were involved.

Ms Ocloo: I was a bit involved in trying to get independent investigation. To be perfectly honest, we have got to stop going round in circles with some of these things. We need to look at this in more detail, what is the point of setting up a redress scheme if we do not properly deal with this issue of independent investigation and how do the two come together? I think there has got to be some specialist inquiry that looks into all of these areas and the systems that are in place for dealing with these issues around accountability and investigation. There has got to be a proper big inquiry and then of course we might want to have a scheme like a redress scheme but I think it needs to be broader than the current one that we have got.

Q195 Sandra Gidley: Quite, me too.

Ms Ocloo: I think that various reports like Making Amends said that we should have a no-fault compensation scheme of some type. On the circuit I think that patients feel broadly that that is probably quite a good idea. The redress scheme was quite narrow, only covering cases under a certain amount, and of course the major failing for me was that you were not going to get that independent investigation. To be perfectly honest, we have got to stop going round in circles with some of these things. We need to look at this in more detail, what is the point of setting up a redress scheme if we do not properly deal with this issue of independent investigation and how do the two come together? I think there has got to be some specialist inquiry that looks into all of these areas and the systems that are in place for dealing with these issues around accountability and investigation. There has got to be a proper big inquiry and then of course we might want to have a scheme like a redress scheme but I think it needs to be broader than the current one that we have got.

Q196 Sandra Gidley: But there will have to be a report produced in each case which will have to be publicised, which was not in the original draft of the Bill. Are you saying that because that does not have to be independently produced it is not as of great value as it might have been?

Ms Ocloo: Yes, I am very suspicious. I think that with a redress scheme unless there is proper independent investigation we are going to get a repeat of the same problems, the battling, we are back to square one again. I would rather not see a new scheme emerge unless it deals with that issue of independent investigation which, to be perfectly honest, I think is a thread that runs through all of the other complaints about all of the other systems and
their failings. We have got to address that issue head-on and decide how we are going to deal with it and then make the reforms to a number of bodies.

Mrs Bowen: Back to a point I was talking about earlier, if the doctors admit their mistake it is a world away from someone telling them that they have made a mistake. You can have a redress system. As happened in my case, if you look at Martin’s SUI report, it has got errors and complete downright mistakes and falsifications in there because the hospital produced it. It says what they want it to say. Until you get an independent report that is going to tell you the truth and the hospital is open to that report and the doctors are open to take what it says, then it is going to be pointless and worthless, another piece of paper that doctors are just going to ignore.

Q197 Sandra Gidley: So there are cultural changes needed; the scheme in itself is not enough?

Ms Ocloo: I do not know anything about Clare’s story but I know it is far more recent than mine and it is so sad to hear her talking about all of the same things about independence that I have been raising for years. It is really sad.

Q198 Sandra Gidley: The Redress Scheme’s criteria are going to be based on the legal definition of negligence, which includes the requirement to show that care ran counter to “responsible”, “reasonable” or “respectable” clinical opinion. Do you think that is about right or should some other standard be used or do you not feel qualified to say?

Mrs Bowen: I think it needs to take into account more of the human factor. A person’s care can be, as in Martin’s case, perfectly adequate but if the doctor or surgeon does something wrong personally then you have to look at that and you have to look at the training that needs to go on. There is a difference between the care that someone receives. Beth’s care was very good. However, the decisions that were made around that care were dreadful and the decisions that were made on the day and in the operating theatre are what caused her death. It was not necessarily the care that she received. Does that make sense?

Ms Ocloo: Lots of people cannot prove causation. In other words, you have got very sick people and they say they would have died anyway and if you cannot prove breach of duty and breach of standards of care together with causation then you cannot win your case. I have only found out years later that missing medical records went missing in my case and I probably could have proved causation, but the fact is I still got a legal ruling of negligence and the hospital said that counted for nothing. In other words, an awful lot of people—older people, very sick people—if they cannot prove causation and yet they get quite appalling standards of care, but it does not meet that kind of legal test, then it is almost as if it does not count. I am not quite sure why we have not looked at other models. I do think there is a debate to be had around this. It would seem a shame to rush straight towards the very onerous Bolam legal test without looking at how it could work on other levels.

Q199 Dr Naysmith: This is the last little group of questions and some of them have been answered already so you do not need to go over old ground too much, although it has all been fascinating. Do you think there are adequate means to allow patients, their families and the public to influence safety standards in the NHS? I suspect that your answer to that question would be no and if that is the case then what more could be done to ensure that the voices of patients and the public are heard properly when patient safety is being discussed?

Ms Ocloo: I do know with the document Safety First that recommendation eight states quite specifically that families, patients and carers need to be involved in the patient safety agenda. It is not happening.

Q200 Dr Naysmith: That has not been your experience at all?

Ms Ocloo: My personal experience is that I am walking around with a label on my forehead which says that she is a harmed patient who has made a complaint so therefore do not allow her to participate in these debates. She is complaining, she is a patient that has had a poor experience of health care rather than a good experience so she has an axe to grind, she is not independent, and all the rest. There are a lot of very negative labels so there is a difficulty about involving patients who have had poor experiences. They can often be very negatively labelled. The evidence shows that they are not being involved in the patient safety agenda because they are being kept out. There are quite a lot of fears about the complainer or the harmed patient and there is quite a lot of evidence that recommendation eight is not being implemented in patient safety. If you go around patient safety conferences you do not see patients or the public.

Q201 Dr Naysmith: What are the one or two things that you think would really make a difference?

Ms Ocloo: I think that there has got to be some quite tough enforcement of recommendation eight. In Safety First it says it needs to be happening. We have patient and public involvement in lots of other sectors—education, social work and so on and so forth—there is no reason why it should not happen. Some clear guidance has got to be produced about different ways of involving patients and the public in the patient safety agenda. It is a bit difficult to think of very concrete things.

Q202 Dr Naysmith: Have either of you two got anything to add?

Mr Bromiley: The only thing I would say is that I have a bit of a quandary over this one because on the one hand patients do need to be involved in certain aspects of changing the way the NHS operates, certainly in the way that we are treated. I do not mean treated in the clinical sense; I mean treated in a personal sense. I am also deeply aware, though, as a professional from a different industry that there should not really be a need for patients to be involved because the drive for change should be
coming from the clinicians themselves. They should be the ones wanting to improve the care of patients. They should be the ones wanting to improve the safety. I do not know that I can comment any further beyond that.

**Mrs Bowen:** I would like to talk following on from that about how a patient is involved in the whole process of the operation. The doctors felt that it was not necessary to get our consent to use a new piece of equipment. It is almost saying that we are of inferior intelligence and we cannot make those decisions ourselves.

**Q203 Sandra Gidley:** That must be an ethics issue, I am sorry.

**Mrs Bowen:** I know. You have to involve the patient in every single step of the operation or the procedure. You have to be able to talk to them. If you are going to do training in the operation the patient or their parents should be spoken to about that. I know that they will say, “You cannot tell a patient we are doing training because they will not want to do it,” but if they felt that all the safety procedures and human factor procedures were taken into account, then I do not believe that people would not want that to happen in the operation. Another thing that I really would like to see is cameras in operating theatres. If there is a camera videoing the operation in an operating theatre then if there were any problems afterwards you would be able to come back to that video. One of the things I am really concerned about is timing. Doctors lose track of time in operations. One of the things they said to me was, “We couldn’t keep looking at our watches while we were trying to resuscitate Beth.” You should be looking at the clock. Twenty minutes can go before you even realise it and you can think it is two minutes. If that camera had been in the operating theatre, my situation would have been completely different. The thing is doctors do not want cameras in the operating theatre. To me it is the patient’s choice. The patient and their rights and their needs should be put first before the fact that the doctors feel slightly uncomfortable being videoed in an operating theatre. It should be up to the patient to consent to what happens during their treatment and I think that patients are not involved enough at the very basic levels and are not treated as if they are intelligent enough to deal with those situations.

**Q204 Dr Naysmith:** One of the things that has come in fairly recently is foundation trusts. I wonder if you think that members of foundation trusts ought to be able to have some discussion at least with the hospitals that they are representing and they are representatives of about this sort of thing?

**Ms Ocloo:** Foundation trusts are supposed to be exceptional as hospital trusts because of their unique governance arrangements and the fact that they are supposed to be able to—

**Q205 Dr Naysmith:** Shortly they will become the majority of trusts.

**Ms Ocloo:** Exactly and they are supposed to be able to promote their greater community engagement. First of all, there are some questions about the links between governing bodies and their membership. You can have huge numbers of members—

**Q206 Dr Naysmith:** You talked about lots of other cases that appeared when you got publicity for yours. Probably in the area there would be rumours about this sort of thing that ought to get picked up by the membership of the trust?

**Ms Ocloo:** Yes, but the problem is with these trusts, including foundation trusts (because I am actually doing some research on patient and public involvement in a foundation trust) problems are that there has not been a debate. The debate about user involvement in patient safety is quite a long way behind other areas. Even in health there is much more user involvement in other parts of health than there is in patient safety and that is because there are some quite distinct fears and barriers that are put up to keeping the harmed patient out, and we have been speaking about that. You need to deal with some of that and it cannot just be enforcement. There is also the issue of paternalism. All of the writing says that we have got to move away from the paternalistic “doctor is the expert doing on behalf of . . . ” to more of a partnership model.

**Q207 Dr Naysmith:** Let me ask you a couple of fairly quick direct questions. Just recently the reporting of adverse reactions to drugs has been extended to patients. It used to be the card system that doctors did but now that has been extended so that patients can report directly adverse reactions to the centre. Do you think that should apply to patient safety issues such as the ones that we have been talking about?

**Ms Ocloo:** There is a national reporting scheme but patients do not report to it because they are not told about it at a local level by trusts.

**Q208 Dr Naysmith:** Clare or Martin, what do you think about reporting adverse events?

**Mrs Bowen:** In Beth’s case, Beth was overdosed on Diazepam before she went down to theatre because they calculated her weight wrong. It was just “And?” If patients do not feel that they are being listened to then they are not going to report them. I do think that a way of reporting things that you see in hospitals, even if it is something as simple as the doctor did not wash their hands before they came up and spoke to me, you need to be able to have a way of making sure that voice is heard.

**Mr Bromiley:** I think we need to tackle the problem of doctors reporting before we worry about patients reporting. There are two issues. In terms of doctors reporting it is incredibly complex. If an incident occurs and a nurse has to fill out a form about an incident, he or she has to fill out a number of forms, was it a medical device, was it medication, and one for the trust. Why are there so many forms? Again in the aviation industry we just have one. You tick boxes and if they need detail more than two sides of A4 then it can be asked for. In the case of patients
Mr Martin Bromiley, Ms Josephine Ocloo and Mrs Clare Bowen

20 November 2008

what we need is perhaps not reports but a little card that you are handed when you walk into the hospital that says: “We are trying to be really safe here. If you see anything that you think is unsafe and you do not feel able to mention it write it on this card and stick it in the postbox on your way out.” We do not need a massive complex reporting system for patients that generates lots of statistics. What we need is something that generates action at local level fairly quickly.

Q209 Dr Naysmith: You will know that the NPSA and Action Against Medical Accidents have recently recruited 22 members of the public to act as Patient Safety Champions giving the patient perspective on safety issues. Do you think that is a good idea or is it just a gimmick?

Ms Ocloo: I am a champion but I am not one of the 22. I started off as one of the original champions so I have not got involved as part of the 22 who are involved in Patient Safety Action Teams.

Q210 Dr Naysmith: Do you think it is a worthwhile thing to do?

Ms Ocloo: Actually my view is this: fair enough to have some champions but the real issue is the exclusion of patients and the public generally from the patient safety agenda. First of all, great with the champions, but of course lots of them are not harmed patients for example; they are professionals. I think that we have got to do something to get harmed patients involved. People like Martin and Clare are champions anyway, they do not have to have a label. Awful things have happened and they have got involved and they have tried to change things. We need to involve people like that and we have really got to try to get recommendation eight implemented on the ground. That is not just about a few champions, it is about involving a much broader mass of people at a local level.

Q211 Dr Naysmith: I think we have got that message quite loudly and clearly. Do either of you want to comment on the 22 champions?

Mr Bromiley: I do not know. I am meeting them next week to do a bit of training for them. I will let you know.

Mrs Bowen: Unless you have people who have some knowledge of going through the systems then they are not going to know what it is that needs changing. I have learned so much that I really would never have wanted to learn in the last two years about hospitals and the way they work and the awful things that can happen and the awful risks they can take. If you had said to me before Beth died, “Can a trainee use a piece of equipment they have never had any training on?” I would have said, “No, that would not happen in the NHS,” but it does and no one knows about it and people off the street would not know that those things need changing.

Dr Naysmith: Thank you all, you have been brilliant witnesses in your different ways.

Q212 Jim Dowd: Just one brief question to Ms Ocloo. You are obviously considerably experienced professionally in this field. We have been talking about systems to be put in place to compel compliance but is there no institution or trust or acute unit of which you are aware that already has in place a system resembling something you would like to see. Is nobody doing it willingly?

Ms Ocloo: A good practice example?

Q213 Jim Dowd: Yes.

Ms Ocloo: When you say about compelling compliance, are you talking about the reference to complaints and dealing with investigations?

Q214 Jim Dowd: Any trust of which you are aware for example which has somebody dedicated to dealing specifically with patient safety from the patients’ point of view?

Ms Ocloo: They do have a range of systems in place and some work better than others. You have got individuals, for example, they may be PALS or they may be complaints officers, but all the reports say that it is variable in terms of how they are working. The problem is that rather than having a few individuals looking at this there are some big areas that are not working. That whole tranche on the accountability side, those organisations need to be reviewed together, and then I think within trusts this issue about being open, which is linked to dealing with the culture of denial, there are problems about how that is operating on the ground. This is an area that is really complex and I think that is the part of the patient safety agenda that people are reluctant to talk about and that is why we are not really getting at the answers. I think there needs to be a specialist review and a debate over a range of issues so that we can open up that side of things and look at getting the right thing, not rushing into something and getting it wrong again.

Chairman: Could I on behalf of the Committee thank all three of you for coming along this morning and giving evidence. Hopefully this evidence session is going to form a large part of what we will find in relation to patient safety. Once again your personal experiences have been invaluable to this Committee in this inquiry. Thank you very much indeed.
Thursday 15 January 2009

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins
Mr Peter Bone
Jim Dowd
Sandra Gidley
Dr Doug Naysmith
Mr Lee Scott
Dr Howard Stoate
Dr Richard Taylor

Witnesses: Professor Andy Adam, President, Royal College of Radiologists, Dr David Whitaker, Immediate Past President, Association of Anaesthetists of Great Britain and Ireland, and Professor Brian Toft, Professor of Patient Safety, Coventry University, gave evidence.

Q215 Chairman: Good morning, gentlemen. Could I welcome you to our third evidence session on our inquiry into patient safety? I wonder if we could ask you, for the sake of the record, to give us your name and the position you currently hold.

Professor Toft: I am Brian Toft; I am Professor of Patient Safety at Coventry University.

Professor Adam: I am Andy Adam; I am Professor of Interventional Radiology and President of the Royal College of Radiologists.

Dr Whitaker: I am David Whitaker; I am a consultant anaesthetist at the Manchester Royal Infirmary; I am the Immediate Past President of the Association of Anaesthetists; I am Chairman of the European Board of Anaesthesiology Safety Committee and a member of the Safety Committee of the World Federation of Societies of Anaesthesiologists.

Q216 Chairman: Thank you for that. A general question to all three of you, although some of the questions today will be specific to individuals and we can try and tie that down. We have got one or two pressing statements being made in the Chamber a bit later on, so we are hoping to run through this morning pretty quickly. Do you think that technology is a problem for patient safety or a solution—or both?

Professor Toft: Of course, as the committee will know only too well, it is a two-edged sword: it can be for the good, it can be for ill. For example, Professor Mike Murphy is going to speak later on this morning about the excellent work he has done at Oxford Radcliffe on bar-coding and blood transfusions. The stuff there has reduced errors phenomenally. On the other hand, we can see that people have a moral hazard when it comes to technology; that is to say, they rely on the technology in such a way as they actually make mistakes—they believe it to be safe. A good example of that would be in the United States of America in 2006 when six neonates were given 1,000 times too much heparin because the drug was pulled from an automatic computerised drawer. They swiped the drawer believing that they were taking out a weaker solution and, in fact, the person that stocked the drawer just stocked it with far too high a concentration of heparin and that was given to the children and they did not check it; they assumed that the technology was okay. Recently, at St Mary’s Hospital, at the back end of last year, there was a case where a lady had a gall bladder taken out that she should not have had done. It is quite interesting that that particular hospital was using the WHO Safe Surgery Checklist. That is new technology to the medical profession. So it failed on that occasion. That does not mean to say it is a bad thing; it just says that it failed on that occasion.

Q217 Chairman: Is this the one that was announced on the radio this morning?

Professor Toft: I could not say. I was travelling at half past five this morning, so I do not really know. St Mary’s is the one where Lord Darzi is the Honorary Consultant. They were using that technology and it failed. The bar-coding technology used by Professor Mike Murphy may well have saved the day there. Besides getting things like that, you have also got things like work arounds. Nurses and doctors will engage in new technology and if it does not work in the way in which they expect it to work, then they will do work arounds. They will do things like take bar-codes and stick them to their jumpers and then put them onto people, which can then lead to people being wrongly identified, and there are papers for this; there have been studies to do with this. By the way, I should perhaps inform the committee that I only study failure. I am not interested in success; it is just the bad things in life I look at because they are far more interesting! In terms of technology more generally and trying to move technology forward, we then have improvements. A good example of failure occurring in an improvement in technology is at Papworth Hospital. Originally they had a system where they used a thing called a check digit in the symbiology, which is like the bar-code, which is intended to make a check of the number so it is accurate, so that the machine can actually say this is an accurate number, and they implemented a new system quite recently, in May last year, and this new system does not have the check digit in. The check digit is actually being mandated by the Department of Health saying that the GS1 technology which contains this should be used under these circumstances. Now we have a system being put into a hospital which neither complies with the Department of Health’s own requirements on this thing and it has made it more unsafe. So you can see, from that perspective, technology in one sense is
very good because it can improve matters and in another sense it can also create lots of problems. At that point I will stop, Chairman.

Professor Adam: Yes, I agree with Professor Toft that it can bring challenges in terms of training and patterns of practice that must be met if it is not going to increase risk, but I think in the Health Service in particular the balance between the advantages and disadvantages of new technology in terms of patient safety are overwhelmingly in favour of increasing patient safety. I think new technology in terms of treatment brings in minimally invasive methods of treatment that are much safer than traditional surgical techniques; new methods of diagnosis, which again tend to be less invasive and more informative, so in that sense they improve patient safety. If there is anything to be said in general terms about technology and patient safety, it is that unfortunately the National Health Service is slower than the health systems of most developed countries in adopting new technology, and this is why I am very pleased that the NHS Next Stage Review has made innovation one of the aims of the new review of the new system that is about to be introduced, and that is why I am also pleased that the Health Innovation Council has been set up by Lord Darzi, which is looking at the speed of adoption of new technology and how to encourage that in the National Health Service. I applaud that and I believe that should make a major contribution to improving patient safety.

Dr Whitaker: I agree with both my colleagues. I think it has a bigger part to play in solutions rather than hazards but, I think, to put the whole thing into context, in all high-risk industries about 75% of accidents are caused by human factors and I think you have to bear that in mind. We do not know what the percentage is within medical accidents at the moment, but the NPSA Critical Incident Reporting System has now got a new question added which may give us the handle on that in the future. What we need to do is the right thing to all patients. We do the right thing to most patients most of the time, but what we really need to do is do all the right things to all of the patients all of the time, and technology can help in this. A safety culture is very important to get that 100% compliance, but technology can help in this way. A simple thing is the pin index system on oxygen cylinders which means you can only connect an oxygen cylinder to an oxygen yoke, and that has been established for many years. The Association first discussed that at its AGM in 1932, and all the technology that anaesthetists use now for monitoring oxygen saturation, ECG, blood pressure makes a significant contribution to patient safety and medical indemnity insurance subscriptions for anaesthetists have gone down in this country and have started to go down in other countries as well. Also oximetry technology, which I spoke of at the Associate Parliamentary Health Group last year on healthcare in Africa, has now been “highly recommended” by the World Health Organisation (and that is the highest level of recommendation that they give) and it should now be used in every one of the 230 million operations that take place every year in the world. It is already in use in this country but it will obviously help in the poor resource countries. Also, the laryngeal mask, which is a world-beating British invention, which is a novel airway device invented by Professor Brain 20 years ago, has now been used on over 300 million patients worldwide, it has made a major contribution to safety in anaesthesia and in difficult airway situations and also when resuscitating patients. Patients never see this, because they are unconscious when it is being used, and this remarkable technology deserves very widespread recognition. Technology can become part of the problem when it fails or it is over relied upon, as my colleagues have mentioned.

Q218 Chairman: A specific question now to you, Brian. You did the investigation into the death of Wayne Jowett?

Professor Toft: I did.

Q219 Chairman: What conclusions did you draw from the case and has the National Health Service acted on those conclusions?

Professor Toft: My conclusions regarding Wayne were that there had been procedure failures. There was inadvertent human error (that was certainly the case) but there was also systems failure. There were systems simply not in place that would have protected him, but people did not know that. It is unknown, if you will. One of the things was the failure of the technology. You can connect any Luer syringe to a spinal needle, which meant that Vincristine could be put into his back. Once they got to that stage, that was it, finished. One of my recommendations was they should change the technology and design a spinal needle to which a Luer syringe could not be connected. That seemed to me to be a reasonable way to progress. Since that point in 2001, and we are now in 2009, we still have not got that connector. There has been a lot of reasons for this. In the first instance, although I have had no close supervision of it, there is the commercial interest—who will be the manufacturer who would be prepared to put money into creating such a syringe—and then, will the medical profession buy it? The next thing, of course, would be the designing of the syringe—how would we design it—and then a whole range of other issues surrounding whether professionals will be prepared to use it when they are used to using their own methodologies. Would the needle work in the way it is supposed to do? What about the law of unintended consequences? In systemic terms, will the creation of this create another problem in another area and lead to a patient death for another reason? And so forth. It has been those kinds of things. I did ring the Department of Health yesterday and ask them how we were doing, as the saying goes, and they said they had some prototypes that they were working on now and they hoped, within the not too distant future, they would have a suitable solution to that problem. Of course, I cannot say how long the future is.
Q220 Chairman: Were there other conclusions that have been acted on?

Professor Toft: Absolutely; yes, I would say that there was reticence. I tend to be, as you can tell, a bit voluble, and my recommendations tend to be a bit the same way, but I do not like people dying particularly, so I am very thorough in what I do, at least I believe I am, and there was certainly some resistance by professionals in the field to my recommendations. In fact, when they asked for my recommendations, I put them forward. They were all accepted by government by the way, Kevin. I then found that when they actually did the guidance for my recommendations they only incorporated half of them, or approximately half of them, into the guidance to be implemented in hospitals. I then had a very robust conversation with Professor Mike Richards, who is the Cancer Czar for the country, who saw my point and took on absolutely my point and, eventually, all the recommendations were implemented apart from the one with the technology. It was a hard-fought battle, if you will, but they are now all there and I am very happy to report that when I contacted the NPSA yesterday, as far as we are aware, there have been certainly no deaths in this country as a direct result of inadvertent administration of vincristine and there have been no near misses either, so I would like to think that the recommendations actually work.

Q221 Chairman: Why is it? Manufacturing? Does it have too close a relationship with some or all clinicians?

Professor Toft: It may well be. There are certainly sensitivities around people from outside telling professionals in another sphere precisely what they ought to be doing and certainly in terms of the technology, commercial manufacturers of medical devices do not necessarily want to change their production lines because, thank you very much, they have been making some money. A good example of that would be a category of medicines called look-alike sound-alike medicines. I had the great honour to do an investigation at United Bristol Healthcare Trust into why four children were given 500 times too much heparin consecutively, one after the other after the other. It turns out that it is because of a National Health specification on the way in which the labelling on ampoules is produced—it is all, I think, Pantone yellow and black. I asked why this had not been changed and why did they not do something about it, and they said manufacturers do not want to change their branding and their labelling as it costs money and they will lose their branding position in the market, and so forth. I did, in fact, speak to a gentleman called Lee McGill, at the European Commission, about this, and he very kindly sent me an email back saying that he would try and bring this to the EU’s attention. However, he did say that the different directorates in the EU have different opinions, and very often there are silos in between them and, therefore, it becomes extremely difficult for people to do these things. So I thought I would bring this to Parliament’s attention, because perhaps Parliament could do something if I cannot.

Q222 Dr Taylor: Again to Brian. Root cause analysis. The first sentence in paragraph 4.4 of your submission is, “There is evidence, however, from the root cause analysis of four patient safety incidents I carried out that the current national reporting and learning system is not as effective as it needs to be.” Can you tell us something about root cause analysis? Is it being used enough and, if not, why not?

Professor Toft: It is certainly being used—that is a fact—but there is evidence from a study done by Wallace et al in this country that the depth and level of understanding of the people undertaking it is not sufficient for the job that it entails.

Q223 Dr Taylor: What sort of people are undertaking it other than you at the moment?

Professor Toft: It is not just me. The NPSA, very wisely in my view, did a three-day course where people were trained from hospitals how to engage in root cause analysis. This was at a very superficial level but, nonetheless, given from a standing start, they did extremely well; it was well done. The idea was that these people would then be the trainers of the trainers, but if you have only been on three-day course yourself and you suddenly find yourself engaged with lots and lots of other jobs to do, it then becomes very difficult, if not impossible, to actually fulfil that promise. You will do some but perhaps not as well as you would want to do it; perhaps you do not even get an opportunity to do it. The problem there was that, although they were well trained from that level, they had great difficulty inserting that training into the hospitals concerned, and the study certainly showed that, and the study done in Australia by Braithwaite also came up with very similar things. So we have got people doing it, but not trained to a sufficient level that you could pull things out of it. They work at a more operational level; so they can tell you what went on but they cannot tell you why it went on. I have been doing what I have been doing for 30 years now and I think I might just be getting competent at it; so it is not an easy thing.

Q224 Dr Taylor: What sort of people are being trained, are going on this three-day course?

Professor Toft: Generally speaking, there have been doctors and there have been nurses. I would have said mainly nurses were the larger part of the people that have actually gone on the training courses.

Q225 Dr Taylor: Who are the people that should take it on?

Professor Toft: I think everybody should be trained in it. That is my view, of course, and I have been known to be called radical and extreme. I think that everybody should be trained in root cause analysis, because if you understand the way in which errors occur, then you can usually see them unfolding before they do. It is a case of seeing the symptoms. If everybody was trained at least in part in doing them, then they would not have the problem of some poor soul who has got 10,000 jobs to do being given a job.
and they then do the root cause analysis in their part-time, in their spare time, pretty much like you do select committees in your part-time, other than your real job of being MP.

Q226 Dr Taylor: Should it be in medical student training, in nurse student training?  
Professor Toft: Absolutely. It should be in medical student training. Right from the very beginning that they start their training there should be a gradual build up of notions of error, how human error is created, how the whole system works together, how it leads to the creation of errors but, most importantly, everybody should be told directly that nobody is perfect—nobody. We all make errors, me included. I have studied it for 30 years and I make the same ones, much to my embarrassment, more than once. Nonetheless, nobody is perfect, and therefore the doctors need to know that so that they feel more able to come forward and say, “I have had a near miss today”, and so forth, because very often the opprobrium that comes with having made an error stops them from doing so.

Q227 Dr Taylor: Ought the people doing the root cause analysis to be from outside the particular institution being investigated?  
Professor Toft: Without doubt. There is undoubtedly pressure put on people from within their own institution and from within their own profession to, if you will, massage or bowdlerise their own results, and certainly I have had an experience of that quite recently.

Q228 Dr Taylor: So the training for everybody would be to prevent untoward incidents happening but, if they happen, the investigation should be done by somebody outside.  
Professor Toft: I absolutely believe so. I am running an investigation at the moment, a review, and it took me nearly ten months to get two retired surgeon (and I say the word “retired”) to come and sit on my panel. The active surgeons, the ones that were operating, were too frightened to sit on it in case the results that were produced were against what had already been produced by the British Orthopaedic Association. So I am doing a review of a review, and one surgeon actually said to me, “I have to think very deeply about this, Brian, but I am probably not going to sit on your panel because I am quite frightened for my livelihood.”

Q229 Dr Taylor: How can you get across the profession’s almost natural intention of protecting themselves?  
Professor Toft: That is a huge question, and I am afraid I have no easy answer for that. One of the ways I would say is by influencing the culture of all organisations and having them recognise that people will make mistakes and that they should then support the people and their mistakes. They should support them heavily when they have made a mistake because, apart from the Shipmans and Beverly Allitts of this world, over which I have no trouble, of the remainder, I have never yet found a physician or a nurse that has been involved in any of the incidents I have looked at, which have been quite serious, that has not been profoundly disturbed by what took place. If you spend all your life looking after people, keeping them free of pain, and you suddenly find out that your inadvertent action has resulted in exactly the opposite, your raison d’être for living has gone. In some cases I would say that the healthcare professionals involved actually needed more care, help, advice and support than the families did.

Q230 Dr Stoate: Your memorandum refers to involuntary automaticity. Could you explain to the committee what that is, reasonably succinctly?  
Professor Toft: I will do my best. I am going to start by talking about automaticity. You may remember that when you started to drive, on your first day behind the wheel, you would put the ignition key in, twist it on, sit there with white knuckles and set off and everything that you did you thought about consciously, you paid attention to: “I must change gear, depress the clutch”, and so forth. By the way, I do not drive, it is far too dangerous. I let my wife do that. You have to concentrate very heavily on what you are doing, so you process the rules one by one cognitively. Eventually, a year later, you step in, click, yes, you have got it, and away you go, and that is automaticity. You become so well practised that the cognitive system says, “I am in driving mode; I will now just tell you what the rules are”, and then you slip in, you just do them automatically. Generally speaking, people talk about automaticity and its benefit because it is very helpful. When you start driving you cannot speak to your next-door passenger because you are too busy concentrating: when you have been driving for 12 months, you can talk to everybody, you can look at the sat-nav, you can look at your map and all that kind of stuff, so you can do more than two things at once, so it is a very useful thing. However, it has a cost. One of the first people to recognise this cost was a guy called Barshi who works for NASA. What he found was that pilots, when they are doing landing routines and cockpit routines, sometimes get into a litany a bit like in church. The priest calls to the congregation and the congregation call back. In church you do not have to do anything. If you are in an aeroplane and you do not do things, it is likely to become complicated. The example he gave was of an aircraft coming into Casper, Wyoming, and he said that the co-pilot said, “Landing wheels down”, and the pilot repeated, “Landing wheels down.” He said, “Three greens”, the pilot said, “Three greens.” He said, “Landing wheels down and locked”, and the pilot replied, “Landing wheels down and locked”, and then the plane landed with the wheels up. Just remember that when you go on your holidays! Clearly, that kind of behaviour is not conscious and it certainly is not wanted. You have done something without being effective; they should be able to do the check without being effective. That is what involuntary automaticity is. In a medical sense I did an investigation where a patient received two and a half times too much radiotherapy. To get this amount of
radiotherapy the patient had had 14 separate treatments and she had been attended to by 12 different radiotherapists working in assorted pairs, using a verbal double-checking protocol—so a standard operating procedure. They would call the patient’s name out, they would call out the amount of radiation which was to be given, they would call out whether or not a thing called a wedge was in the beam of the radiation. Because it is a constant source of radiation, the wedge acts as piece of lead, so it absorbs radiation. So if it is supposed to be in and it is not in, what do you think happens? Clearly, the patient gets over radiated, and this is what happened. On the console, the controls of the linear accelerator, there was a thing that said, “Wedge”, and it would say either “in” or it would say “out”. The word that should have been there was “in” and the word that was actually there was “out”, and on 14 consecutive occasions two dedicated, conscientious radiotherapists, using a verbal double-checking safety protocol, read the word “out” as “in”. I could not understand how people who were so dedicated to their patients could do that, so I did the research and I came up with this notion of involuntary automaticity, which Parliament very kindly, through Steve Webb, asked questions about, and that is how it came about. But that is what it is; it is about people seeing what they expect to see and it not being so.

Q231 Dr Stoate: That was the short answer. Professor Toft: The very short answer!

Q232 Dr Stoate: The slightly longer answer, but hopefully not too much longer: what do we do about preventing it? Are there technological solutions which are failsafe? Professor Toft: In terms of radiotherapy there are. What happened was that the data was entered manually. The data could have been entered in technologically; it could have gone from one source to another source, into the Linear Accelerator database, and if that had taken place, then I would not have found that and the incident would not have taken place.

Q233 Dr Stoate: So there are ways of preventing it? Professor Toft: There are ways, but the one thing I would just point out is involuntary automaticity is forced upon the healthcare professional by the system in which they are operating; they have no control over it whatsoever. If you are captured by this, you are captured by it and it is completely unconscious. Therefore, if a person is put into that situation, what I have argued in my latest paper, which is coming out in February in the Quality and Safety in Healthcare Journal, is that since managers are responsible for the environment in which clinical people work, the actual work environment, if a clinician should say that these working conditions are so onerous that I could easily fall into involuntary automaticity and the manager does nothing, then I have recommended that in law (because I have written it with a lawyer) in fact the manager should be held accountable for the incident and not the clinician.

Q234 Dr Stoate: It is fair to say, it is not only a good thing, it is an essential thing to have? Professor Toft: It is an essential thing.

Q235 Charlotte Atkins: Professor Adam, one of the conclusions in the report Towards Safer Radiotherapy is that over reliance on automated procedures is a factor in some patient safety incidents in radiotherapy. Can you tell us a bit more about that? Professor Adam: To some extent, to a large extent, it really overlaps with what you have just heard from Brian, that one can used an established method of doing something without second checks and making sure that what is supposed happen has actually happened, and this is partly why one must not rely on just this kind of process and why there are recommendations, for example, in the document Towards Safer Radiotherapy for using additional checks such as in-vivo dosimetry. In-vivo dosimetry, essentially, uses a machine that checks that the dose that is going to be delivered to the patient is the correct dose. It is not in itself sufficient, and all the things that we have just heard from Brian are also very important, but there are additional things that you can do to make sure that you do not just rely on certain processes that are subject to human error.

Q236 Charlotte Atkins: So it is a mix of better training and better technology, is it? Professor Adam: Exactly, you need both, and the further training also has to have processes such as back-checking, checking that what you are supposed to do has actually had the intended effect—the kind of thing that you have just heard from Brian.

Q237 Charlotte Atkins: The fairly horrifying concern, I think, for any patient is that you have these experts who are following procedures but somehow just overlook the fact that what their eyes are showing them their brain does not recognise. Professor Adam: Yes.

Q238 Charlotte Atkins: When people are confronted with results of investigations into these accidents, into this misjudgements, in your experience, do they learn from those experiences or do they just internalise, move on and carry on as they did in the past? Professor Adam: Of course, it does depend on the individual, but the system does try to encourage methods of learning, and the Royal College of Radiologists is putting a lot of effort into that. For example, we really favour a no-blame system where you report near misses, so that we have much more widespread publicity of where things nearly went wrong, because there are many more of those than serious injury, so that people can refer to those and learn from them. Also, the few cases where there is serious injury. By the way—one has to put things into perspective—real, serious clinical injury in
radiotherapy is very rare, something like three in 100,000, but those also ought to be publicly available so that people can refer to them and learn from them, and having them inadequately accessible is a problem. Of course, there is a difference between individuals, but that is just part of the problem. Accessibility of the information is also an issue, and that is something that is being looked at.

Q239 Charlotte Atkins: Do you think the culture is changing? Do you think that with new people coming into the profession the culture is changing and it is improving, or do you find there is a real mix between the younger new recruits and the more established radiotherapists who have been in the business a long time?

Professor Adam: I believe that there is much more openness now and much more widespread recognition that information is good. For example, as I am sure you have heard, the National Patient Safety Agency will say more reporting to them is an indication of a good organisation, so that organisations that report more near misses should be considered better than ones that do not, rather than the reverse. I think that is something that is becoming generally accepted and people are recognising that, and that is a very good thing.

Q240 Charlotte Atkins: With hospitals worrying about their ratings in terms of patient image and everything else, is there not any pressure from managements, chief executives of hospitals not to report near misses on the basis that it might affect their rating in the public mind?

Professor Adam: I have not found that, and I think that is partly because people are realising that there is real benefit from doing that, but it has to be done in the proper way. There has to be this no-blame culture—

Q241 Charlotte Atkins: Is there not a different objective? A chief executive might have a very different agenda than perhaps a radiotherapist?

Professor Adam: I think where problems arise is where lawyers get involved. If there is serious injury and it is a legal issue, then, of course, there are pressures from lawyers about what can be disclosed and what cannot be disclosed, and even the doctors involved do not have complete control over that because you would be going against legal advice. I think there, there are there real issues, but lower down the scale, where you are talking about near misses or accidents that are not particularly serious, although there is an issue there as to whether there are concerns about disclosure, people feel that it is a good thing and I do believe that there is a real change in culture. As I say, when the courts get involved it is more complicated.

Q242 Mr Scott: Professor Adam, can you outline the risks and benefits of technology as regards patient safety in two specialty areas of clinical oncology and clinical radiology?

Professor Adam: Yes, I think technology has benefits and risks in both, but, as I said in the general answer I gave at the beginning, I believe, in both of these disciplines the contribution towards increasing patient safety is vastly greater than the risks introduced by new technology. Perhaps I could give examples in both. In a study of clinical oncology there is new technology, such as image-guided radiotherapy, that is much safer than past techniques, and I will explain that. You have tumours in organs that move. The most obvious example, perhaps, is a tumour in the lung. Obviously, as the patient breathes in and out the tumour will move up and down. Having the x-ray beam which is treating the patient tracking that tumour and shining the treating beam to exactly the right area obviously is a lot safer than having the tumour being missed because the tumour has changed its position. That is image-guided radiotherapy. Intensity modulated radiotherapy (that is controlling the intensity, the strength, of the beam, using a computer, so you get a beam that is the three-dimensional shape of the tumour, avoiding structures that are vulnerable and should not be radiated and giving the dose where it should go) again, is an example of technology increasing safety. Proton beam therapy, which does not exist in this country, sadly, and we are sending patients abroad to be treated with that—protons are positively charged particles that have a very, very short range and so, using protons to treat patients in critical areas, for example, next to the spinal cord, you can really give the dose near dangerous areas, destroy the tumour and not harm adjacent structures. The cyber knife—again there is only one, I believe, in the country, in the private sector and none in the NHS—uses a system of robotic control of a pencil beam and introduces an even greater level of safety, where the pencil beam has sub-millimetre accuracy and destroys tumours with great safety without damaging adjacent structures. Those are just four examples. In clinical radiology, both diagnostic and interventional. Let us start with interventional, because I believe that with regard to patient safety there is perhaps no other discipline in the Health Service where the gap between the potential of discipline to increase patient safety and reality is greater, and this really relates to the lack of availability of interventional radiology, both in and out of hours. Of course the problem is even more serious out of hours. Only 10% of trusts in this country offer a formal interventional radiology on call service out of hours. Interventional radiology is pinhole surgery controlled by imaging. You are really using tiny instruments that advance to the right part of the body, under x-ray control, to do what you need to do, and there are many examples of procedures that increase patient safety but perhaps an obvious one is stopping haemorrhage. If you have someone who is bleeding from the large bowel that comes into hospital and they are losing a lot of blood and their blood pressure is low, opening them up and performing open surgery in that setting has great risks. You can introduce a tiny catheter under local anaesthetic and block the artery that is
bleeding. That is called embolisation. That can be done at a tiny fraction of the risk that surgery carries, and it is almost always successful. That should be available in every acute hospital. Every patient should have access to it. There have been lots of recommendations regarding this. For example, when there were ten maternal deaths at Northwick Park between 2002 and 2005, the Healthcare Commission made two national recommendations. One of those two national recommendations was that interventional radiology should be available to all patients that need it. We are nowhere near achieving that goal, and this is sad because—

Q243 Mr Scott: Is that purely financial?
Professor Adam: It is not purely financial. It is partly financial, but not financial in the sense that the money is not there to fund it. Because interventional radiology is extremely cost-effective, you would actually save a lot of money if it were used more widely, so in that sense it is not financial, but it is financial in another way, that the funding structure of interventional radiology is a huge problem. There is a paradox there. We have to look at how it developed, and it developed through diagnostic radiology, it developed through the invasive techniques that diagnostic radiologists were using to reach a diagnosis, for example in angiography, where you put a catheter in, squirt some dye that shows up on x-ray and that shows you what is going on. Those techniques were developed and adapted to do the kind of thing that I have been describing. Therefore, interventional radiology is the only discipline that directly treats patients—it is essentially pinhole surgery, as I said before—that sits within a service department that does not have the infrastructure for clinical practice. That precludes the setting up of contracts with PCTs and that is where money comes in and funds what you do. Interventional radiology is funded out of budgets of radiology departments; the same budgets that fund CT scans and MRI scans. There are huge pressures on those, as we know, and when interventional radiology techniques are introduced in a hospital, new techniques, actually that is usually a drain on the resources of the x-ray department, so there are huge disincentives to introduce new interventional radiology. So funding is an issue, but only in that way because, as I said before, it is extremely cost-effective. For example, if you treat the fibroids of a woman that is bleeding from the uterus with hysterectomy, which is the usual way or one of the common surgical ways of doing it, it costs twice as much as blocking the arteries to that uterus and treating the fibroid and destroying the fibroid using interventional radiological techniques and, on top of that, the woman can still have children, whereas, of course, if the uterus is out she cannot have any more children. So it is safer, it is effective, it is cheaper and we are not using it because of structural problems. What we really need to do is designated roles in radiology so that the career structure develops, so that young people go into it. They are very enthusiastic. Lots and lots of radiologists really want to do this. So the people are there, they are full of enthusiasm, they want to do it, but we do not have the structure to offer them, for the reasons that I have explained.

Q244 Sandra Gidley: I want to move on to your memo, which mentions teleradiology and says that there were a number of problems associated with it. I wondered whether you thought it was more of a threat to patient safety than a benefit.
Professor Adam: Again, it is both, but it depends on how it is used. There are huge benefits in some situations. For example, the British Army in the field uses teleradiology. Images are beamed sometimes thousands of miles away so that one can get a specialist opinion quickly when it is needed, and that is wonderful. In the context of the NHS, one can get a super specialist opinion, again, quickly and improve on an opinion that you would have given without the benefit of that expert opinion. So there are great benefits from teleradiology. Where the risks come in is when one uses this wonderful new tool in a way in which it should not be used. If you are using it simply to save money rather than improve the standard of patient care and increase patient safety, then problems can arise, and there are two areas that affect that. One is the actual pattern of practice. Modern diagnostic radiology is a clinical discipline that relies enormously on the interaction between the referring physician and the radiologist. When you are reporting films, very often you would get additional information about the clinical state of the patient, you will have access to pathology results, biochemistry results and, most importantly, you will have access to the previous images of that patient. There is a saying in radiology that the world’s greatest consultant is the old films, because very often comparison with the old films will give you invaluable information. If you are trying to do that from thousand of miles away, especially if you are doing it from abroad in a completely different system, then problems can arise and your report may end up describing what is there but it may not tell the referring physician what it really is, and that can result in an uninformative report and can lead to the wrong treatment. That is one issue. The other one is the issue of regulation. I think we often take for granted in this country and we underestimate how well off we are in the way that the medical profession is regulated and what the benefits are which accrue from that in terms of patient safety. A radiologist in this country is regulated and is accountable at various levels. First of all, you are accountable to the patient, who, if something goes wrong, can complain about you, and quite rightly so. You are accountable to the referring physician or surgeon, who may operate on the basis of what you have said. You are accountable to the clinical governance arrangements within your own department, and there are many now in the x-ray department. There are many methods of increasing patient safety, including regular discrepancy meetings, for example—that is, error meetings where you look at errors that are made to learn lessons. You are accountable to the clinical
governance arrangements within your own hospital, you are accountable to the General Medical Council, you are accountable to the courts ultimately and, as from this year, doctors in this country are going to be licensed; they are going to have a license to practise that will last for five years. So there are seven levels of accountability. These things, especially if teleradiology is used to get reports from abroad, certainly do not apply in that same way, and you may have a situation where the people that are providing these reports are essentially, in practical terms, accountable to the company that employs them, who then gives assurance to those that commission that service. I think that is an important consideration that really needs to be addressed, because there are real issues for patient safety there. At the very least, patients ought to know when their images are being sent abroad, because they may not realise that this is happening and they do not have the same structure as they take for granted here.

Q245 Sandra Gidley: Have there been problems in this direction, or is it just a concern that there could be problems?

Professor Adam: There have been problems. It is not the kind of thing where a large case study has been done (and it would be extremely difficult to do a comparative randomised study), but the problems that arise is that reports will come in and you will see that they are of the type that I have described—descriptive reports, reports that tell you that something is there but where there is a non-committal conclusion and where it is less useful than a report that you would expect to get from a local radiology department.

Q246 Sandra Gidley: I may have misread this, but one of the concerns seemed to be that there was no guarantee of the picture of the patient that you thought you were looking at matching the existing clinical records so that you have the whole picture there. Why is that a problem when we have got an NHS IT system?

Professor Adam: That you are looking at the wrong image, you mean?

Q247 Sandra Gidley: Yes.

Professor Adam: That can happen both in radiology and in teleradiology. It would be very rare, but, nevertheless, that is the kind of issue that sometimes is down to technology, is sometimes down to human error. It is not specific to teleradiology. Where there is a problem is that you may not know who the person is that is reporting that film—there are no ways of checking it. We often take the databases that we have in this country and the systems that we have for granted. For example, we have a specialist register, so every radiologist is on the specialist register. There are many European countries where there is no specialist register accessible to the public. So one assumes that something that we have exists elsewhere, but sometimes it does not.

Q248 Sandra Gidley: What is the best way to get some evidence on this? Has there been much research done? What research needs to be done to establish what are the safest processes or where the dangers are?

Professor Adam: Most of the research that has been carried out into teleradiology has not been on regulatory issues, it has been on image quality and technical aspects of this. I think that it is high time that research was carried out on precisely these issues and actually finding out what the regulatory processes are that are used and what is acceptable and what is not acceptable when contracts are being drawn up.

Q249 Dr Naysmith: Dr Whitaker, you have been sitting rather quietly all morning listening to what has been a fascinating morning so far.

Dr Whitaker: I agree.

Q250 Dr Naysmith: Now is your chance to contribute on anaesthesia, your speciality. Obviously, the safety of the apparatus and the bits of equipment being used in your speciality are of paramount importance in this aspect, but you say in your memorandum that the regulatory aspect of this, which is overseen by the MHRA, is done well but, as regards buying the safest equipment, “the National Health Service rarely uses its purchasing power as it could and”, in your opinion, “should”. Could you expand on that a little?

Dr Whitaker: Yes. Perhaps I can say a little bit about standards. We were talking about standards just now. The EU regulations are more balanced to the mobility of labour than patient safety, but there you go. The standards that the MHRA use are drawn up by a standards committee, British Standards ISO, which can take three to five years to draw up, and on the committees there are representatives from the manufacturers and also clinicians. We are very lucky in anaesthesia to have a number of clinicians who are interested in this work. They have to go through painstakingly and look through all iterations of the documents and make sure that it is all going to be safe, and they often do this in their own time and often now the meetings are in Europe and they are having trouble getting expenses to do this. This is a historical thing, because prior to 1990 all this money was top-sliced and paid centrally by the scientific and technical branch of the Department of Health for all specialties. At that time I believe it was about a quarter of a million pounds for the whole NHS, but, unfortunately, this was devolved down to trusts at that time and, effectively, has been lost and, frequently, when these consultants go to their own trusts and ask for the expenses they have trouble getting them because the local trust does not see the purpose of them going to an international standards meeting. Recently there have been several European initiatives that have wanted to encourage clinicians to be involved in these committees rather than dominated by the
manufacturers. I think BERR (the Department for Business, Enterprise and Regulatory Reform) has made a statement on this as well, and we think it is now time for this money to be top-sliced again and come back maybe to be administered by the MHRA itself so that there can be adequate standards made. Because these standards take three or four years to develop, often because lessons learned from critical incident reporting and other developments can take place, some pieces of equipment that will already meet the minimum standards will actually have new safety features that are more advanced, and that is where a PASA purchasing for safety policy can come in, because they can more immediately take account of those new developments. Brian was talking about the Luer connectors. In fact, to get a new standard in this process for a Luer connector will take five, seven years, but the MPSA, I think, has recently, before Christmas, issued a statement saying that PASA will only purchase this new type of connector after 2010; it will only be on their purchasing list. This is a way of responding more quickly to these changes, and it is also a way, I think, of influencing manufacturers to develop safety features.

Q251 Dr Naysmith: Can I just be clear what you are saying? You are saying that the MHRA is administering safety standards adequately but these standards are out of date, that there should be more up-to-date standards?

Dr Whitaker: The process takes a long time to develop, three or four years, to get a new standard for something and other developments can take place in the meantime. Also, they are minimum standards. So there could be new ideas come in, new radiology things that come in, that will not yet be in the international standards, but, I think, for the patients' sake we should be getting that technology if it is thought to be valuable and safe.

Q252 Dr Naysmith: How should this purchasing power be being used then? How should the purchasing power of the NHS change from what you have just outlined?

Dr Whitaker: I think it is changing. I think they are starting to take account. This Luer lock thing, I think, is very interesting, and they are developing product councils, with which clinicians are getting involved, that can give them direct information to try and influence this. The value of PASA is, of course, that the NHS is a massive purchasing body and a manufacturer would like to be doing business with the NHS, and so I think that is how they can influence things. One reason why they are not investing in new Luer lock connectors is probably they all wait for the standard, because they do not want to start new tooling equipment until the standard comes, but if the NHS says, “We are not going to buy the connectors unless they meet these new rules”, that will be a good thing. Another example is the NPSA have said that all drugs should be in a pre-filled syringe that has maybe some tagging system on it to identify it; and for a common anaesthetic agent, propofol, one company makes a syringe like that, but not all hospitals purchase it, and that is an example where purchasing for safety would help support manufacturers who are making safety innovations and bring the others up to standard.

Q253 Dr Naysmith: Could I quote you something that the Royal College of Anaesthetists said in evidence to us? They said, “Patients may be placed at risk where equipment is old or poorly maintained and where new equipment is introduced without appropriate training for the user.” Would you agree with these statements?

Dr Whitaker: Yes, traditionally equipment has not been replaced as quickly as it might have been. Often the NHS finance manager will probably have had three or four new cars in the time that he has replaced one anaesthetic machine. Each hospital needs to have a rolling programme of either renewal or a rolling programme of finance so that it does not have to always become a crisis at the end of ten years when the equipment is starting to fail. Things are improving but there is still a culture there that responds to the crisis as it occurs. I would say, though, that manufacturers are very responsible in the UK. We have good relations with BAREMA (the British Anaesthetic and Respiratory Equipment Manufacturers Association). They exchange ideas of good practice with us.

Q254 Dr Naysmith: Do they participate in training? Do they fulfil their training—

Dr Whitaker: The manufacturers, yes, they are very keen on that. The manufacturers appreciate that it is necessary, if they are going to bring in a new product, that the new product goes well in hospital, because it is bad commercially if it does not. We have just got 12 new ventilators, 12 theatres re-equipped, and the manufacturer trained three of my consultant colleagues to be trainers and then they trained the rest of the other 50 consultants in, I think, a one and a half hour programme. We went through a training manual to make sure we knew what all the knobs and buttons did. That sort of thing happens. Patient controlled analgesia pumps—when we got new ones of those the manufacturer sent a nurse that worked for them that was trained to come and train the staff, including the night staff as well, because often when you have these training programmes the staff that work at night never get to find out about it, it all happens during the day—so they are starting to understand that.

Q255 Chairman: Is the issue of training part of the procurement process? Is there a figure on it to your knowledge?

Dr Whitaker: When equipment bids come in, the hospital can ask for training to be included. Certainly the PCA one that I am familiar with, the companies that were tendering said they would provide some different levels of training in with the price. So it was part of that.
Q256 Chairman: So it was priced, even if it was not absolutely transparent?
Dr Whitaker: Yes.

Q257 Jim Dowd: Dr Whitaker, I want to look at bar-coding being used for double-checking prior to drug administration in anaesthesia. They do this in New Zealand, I am led to believe. Could you briefly describe how the system works and whether you think it would be beneficial in the UK?
Dr Whitaker: Yes. This is really all about medication safety and getting the right medication for the patient, and anaesthetists are expert in this. Someone at my stage in my career has probably given over 500,000 intravenous medications to patients, and some of them will have been incorrect and some of those I will know about. I remember in the 1980s I gave 30 mg of morphine to a patient when I intended to give ten. The reason for that was the only difference on the ampoule was a three and a ten. Then in the 1990s, using a hand-labelled syringe, I gave a cardiac patient a drug labelled PRA when I meant to give acepromazine. The reason for that was that the manufacturer made these two drugs and they had given steroids to a patient and they noticed they had the e label on so there is no misunderstanding. The two situations both occurred because I had mistaken the labelling. The other suggestion that has been made by the Chief Medical Officer’s group.

Q258 Jim Dowd: Do we not always get audio visual aids!
Dr Whitaker: I have not brought a bar-code machine! It is a pre-filled syringe, and this one comes from the manufacturer with the drug in, with the label with the right colour, and it is clear for everyone to see. That is slightly more expensive, but it cuts out the ampoule, it cuts out the transport, it cuts out the storage and it produces a much safer product. The idea with the bar-coding is to go a stage further. This would then have a bar-code put on by the manufacturer and you would put this against the bar-code reader and the thing says to you: “Ephedrine hydrochloride 30 mgs”, so you know what it is—it is a double-check with a computer. This has been piloted in New Zealand and now the NPSA, in partnership with the College and the Association, has been piloting it at Papworth Hospital and Wrexham. The pilot project has just finished and I understand it has gone well and we are going to hear about this in the coming months. Just to be a control situation, nine other hospitals have been piloting double-checking with individuals. So the ODA in the operating theatre, the anaesthetist, said, “Can you tell me what this is?” and the ODA read it out for you so you know that you have checked the drug and everything, but bar-coding takes out that even further human element, because people have shown—the sorts of things that Brian was talking about—that even situations like that can fool a human being.

Q259 Jim Dowd: Do you think there is any reason why it could not be extended to the UK and why we could not utilise it here?
Dr Whitaker: There are two things. In New Zealand I believe one of the inhibitions has been getting pre-filled syringes bar-coded and centrally provided. I understand in Wrexham these have been provided by the local pharmacy, and that has worked very well. That is a bit of a cultural change that needs to take place. Also, the equipment, obviously, compared to some of the new x-ray equipment, is not in the same ball park figure, but there will be a cost there as well and there will some training issues, of course.

Q260 Jim Dowd: What about going to the manufacturers to put the codes on if they are pre-filled?
Dr Whitaker: Yes, again, that could be done. Again, it may be the ‘purchasing for safety’ (PASA) would have to say, “From 2010 we are only going to buy ephedrine looking like this.” There are some pharmacy issues, mainly with stability of drugs in these situations, but maybe certain high-risk drugs, such as heparin that Brian has done a report on and potassium, should automatically come in pre-filled syringes so that it cuts out error of drawing drugs up into the wrong ampoule. Sometimes pharmacists will, usually for costs reasons, change their suppliers of, say, heparin maybe three times in three months and you end up in the drug cupboard with three different boxes looking different with the same drug. This is because they have not had sufficient buffer stock of these important drugs, so that if the manufacturer does have a manufacturing problem you have still got six months’ supply of an important drug so you do not have to change the packaging and confuse the operator. The doctor, patient, the three or four metres round the patient where the end-user is working is the most dangerous area and everything should be focused on making sure that that is as safe as possible and the end-user does not inherit the errors of the system further back.

Q261 Jim Dowd: As a lay person, the danger, the weakness in this system is the accuracy of the labelling, because everything is staked on that, is it not?
Dr Whitaker: Correct. A number of years ago there was a muscle relaxant put into a steroid ampoule. I think the company made these two drugs and they carried on making one a bit longer than they thought, and, fortunately, an anaesthetist spotted it. They had given steroids to a patient and they noticed that they had the effect of muscle relaxation and were able to pick it up. Errors will occur; the thing with patient safety is to try and reduce harm as much as possible. To say it will be none, I think, is possibly unrealistic.

Q262 Sandra Gidley: Can you clarify: is the patient bar-coded and is the drug checked against a bar-coded patient as well?
Dr Whitaker: No. Barcodes have been used for blood transfusion, but in this particular situation the patient is checked to make sure Dr David Whitaker
is the patient and then all the drugs that are given are checked so that the anaesthetist is giving the correct drugs.

Q263 Sandra Gidley: I am just wondering. To quote your example earlier, that you gave the wrong morphine, if we juxtapose that with the example we heard earlier of the involuntary automaticity, you might say, “Oh, morphine 30 mgs, yes, that is fine”, forgetting momentarily—that is the human error bit—that actually 10 had been intended, but if it had been written up before hand and the patient was bar-coded that error would have also been discovered at that stage, so is there a stage further that we could go?

Dr Whitaker: Yes, there are lots of further stages we can go to tighten these things up, and bar coding. If you watched the children’s Christmas lectures, there was the IT chap who was talking about very small chips that have got infinite numbers on, so you could use those. Bar-codes is tested technology.

Q264 Jim Dowd: They do that for pets, do they not?
Dr Whitaker: In the newsagents where you buy your copy of the Times they are bar-coded.

Q265 Dr Stoate: It could be a condition of registration of birth: you have to have a chip put under your skin!
Chairman: Can I disassociate from that. Richard, I think you have probably got a final question in this session.

Q266 Dr Taylor: Thank you very much. As we are unbelievably ahead of schedule, could I ask a very general question. Have each of you got any ideas of accidents actually waiting to happen. In the old days we had things like chlorpropamide and chlorpromazine, which was one of the classical errors that were made. Have you any views of things that we should be getting onto now that are accidents waiting to happen?

Professor Toft: Very definitely. Look-alike drugs are a killer. The National Patient Safety Agency, between January 2005 and July 2006, had 800 incidents of the wrong drug being administered to patients per month. Twenty-five patients died and there were 28 serious injuries. Look-alike drugs are real killers. People think they have got the right drug in their hand when they have not, and it is not because they are stupid or because they do not know what to do, it is because they are captured by the situation and they think they see what they see, but they do not, and that is a real killer. If I could recommend anything that you do, you would do something to the manufactures to stop that from happening.

Q267 Sandra Gidley: But they are doing that. Some of the generics manufacturers are producing packs.
Professor Toft: Wockhardt is doing it because I asked them to.

Q268 Sandra Gidley: I still think there are potential dangers though.

Professor Toft: Wockhardt were involved in the incident I was involved in investigating at UBHT, and so I contacted them, and when I told them what had happened they were literally aghast, and their head of safety, reliability and quality took it on his own back to inform the company, a minute generally, and as of November last year they changed all their heparin packaging and labelling so that it did not resemble the Pantone yellow and black that had been previously the case, which I think is well worth mentioning because they are clearly proactive—reactive in one sense but proactive in the general sense—but they took it on board and acted on it.

Q269 Jim Dowd: Can we ask you to contact all the others then?
Professor Toft: Jim, I would be delighted to do it. If I can have the power of this committee, I would be delighted to do it.

Jim Dowd: Tell them we said so.

Q270 Dr Stoate: You have got it.
Professor Adam: I have not got an example of a process error, but what I will say to you is that somewhere in the country today someone is going to either have a serious injury or die because interventional technology is not available to them, and they will either get surgery or no treatment at all, and that is an accident waiting to happen.

Dr Whitaker: Following on from Brian, the National Blood Transfusion Service blood bag, I think, needs to be redesigned. Blood transfusion is very safe in this country, but the commonest form of error is the administration at the bedside or it is an administrative error. It is covered with all sorts of information, you only need to check about six things to make sure you have got the right blood for patient: it has got the address of the manufacturer made the bag, a number of different bar-codes that are all used in the process way back and the end-user is confused by it, and the whole label is actually upside down. Again, the thing was designed for the donor session where the bag hangs up the other way round as it comes out of the patient and, when you give it back to a patient, the label is upside down. This is a thing that has grown up out of evolution that I think could do with a serious look at. I have been to a number of countries around the world. I always ask, “Can I see a bag of your blood?”, and they have all got the labels upside down.

Chairman: Can I thank all three of you very much indeed for coming and helping us in this inquiry.
Witnesses: Professor Mike Murphy, Consultant Haematologist, John Radcliffe Hospital, Professor Bryony Dean Franklin, Centre for Medication Safety and Service Quality, Imperial College Healthcare NHS Trust, and Mr Roger Lamb, Healthcare Manager, GS1 UK, gave evidence.

Q271 Chairman: Good morning. Could I welcome you to the second session of our third day’s evidence taking in relation to our Patient Safety Inquiry. I wonder if I could ask you, for the sake of the record, to give us your name and the current position that you hold.

Professor Franklin: I am Professor Bryony Dean Franklin; I am Executive Lead Pharmacist for Research at Imperial College Healthcare NHS Trust and Director of the Centre for Medication Safety and Service Quality.

Professor Murphy: I am Professor Mike Murphy; I am Professor of Blood Transfusion Medicine at the University of Oxford; I am a consultant haematologist for NHS blood and transplants at the Oxford, Radcliffe Hospitals and I am the Secretary of the National Blood Transfusion Committee.

Q272 Dr Naysmith: You are going to get asked why blood bags are upside down!

Professor Murphy: I was thinking that.

Mr Lamb: My name is Roger Lamb; I work for GS1 UK, which is an international standards organisation. Some of you might know us better by our former name, which The European Article Coding System, if you will remember. We are the Healthcare Manager for GS1 UK.

Q273 Chairman: Thank you. I have got a question to all of you and then the other questions will be specifically to individuals. Automatic identification and data capture has been seen as a revolutionary technology with the potential to transform the efficiency of healthcare. Do you think that is true or is there an element of commercial hype in relation to this?

Professor Franklin: I think it is somewhere in between. AIDC is a tool and it is a necessary tool for many of the systems that can be used to improve patient safety, but it is only that. It is a tool, it is a means to an end, and actually it is the bigger system that uses it that has the potential, or otherwise, to help patient safety. I ought to say for the committee, the experience and the examples that I am familiar with are in relation to medication safety in particular, and certainly for medication it is an important tool for automated dispensing robots, verification of patients or drugs at the point administration, but, as I say, it is a tool; it is not in itself the answer.

Professor Murphy: I would agree with that. To improve patient safety, I think, requires a combination of both technology and training, and it is very important that the user has a good understanding of the technology, how to use it and its limitations in terms of improving practice.

Mr Lamb: Clearly, the technology alone does not solve the problem, but the technology does help in improving patient safety. Because it ensures replicability of processes and repeatability of processes, so it gives you that reduction in error that helps make the whole process of dealing with patients more efficient and more effective. It is a tried and trusted technology; it has been around for 35 years. We do not think about it, even when we go into a supermarket nowadays and we get to the checkout, that we are not being charged for the colour of our television when we buy a can of beans, and that is the technology being able to automatically identify the fact that the items are different through the bar-code.

Q274 Mr Syms: Can I start, Mr Lamb, by asking you to explain what your organisation’s role is and how it relates to patient safety in the National Health Service.

Mr Lamb: Yes, certainly. GS1 UK is part of over 100 member organisations around the world who are part of the GS1 family. We are an international standards organisation. We are a not-for-profit company. Our standards are used in AIDC, which is automatic identification and data technology. You could think of us really as an issuing authority for numbers that go into barcodes. We ensure that those numbers are globally unique. Those numbers are at the heart of everything we do. We have a set of standards around numbers for different things, so you can identify not just items but you can identify assets, you can identify documents, you can identify people through our numbers. Our numbers have been taken up across a number of different industries, so our standards are cross-sectoral, our standards are open, and our standards are ratified by ISO. Our standards have been accepted within the Department of Health in a publication called Coding for Success that was launched a couple of years ago, and we are working very closely with a number of agencies to implement our numbering standards across a number of different applications.

Q275 Mr Syms: Is there a danger of thinking that the answer to patient safety is always a technological fix, when actually it is much more complicated than that?

Mr Lamb: I think it is a combination of things. Clearly, good technology can be implemented badly. Systems, if they are not in place, people will potentially work around if they do not understand why they are being asked to do things. I think awareness, training, and education are very important, but, also, it is a question of understanding why people do need to use technology in helping them change. That is probably a change in management issue as well. It is about people and processes and understanding why the new solution is better than the old solution and the impact of why they have to follow the new processes.

Q276 Dr Stoate: Are there any countries that are particularly good at this from that we could learn from?

Mr Lamb: I think we can learn from a number of other countries. Through the GS1 Group we have a healthcare user group. We are capturing information that is going on in a number of other countries around the world. There is work going on in the USA with the FDA around ePedigree, which used to...
authenticate drugs at the point of distribution; there is work going on around unique device identification for medical devices; there is work going on in Japan, where different technologies are being used—and we mentioned about chips a bit earlier on—using radio frequency identification; there is work around business messaging using our standards going on in Australia; and there are lots of activities in other countries, including New Zealand, who are very, very keen on the technology and are implementing it in terms of bedside verification at the point of care.

Q277 Dr Stoate: Is there any of that which could be easily and quickly transferred here or would we need to start again in the NHS?  
Mr Lamb: Because the work that is going on is going on to create global standards that will allow interoperability and compatibility, then, healthcare being a global industry, it means that it does not really matter where the manufacturer of the medicine or the device is, they can put something on that device to uniquely identify it that can be read in any other country in the world. I think it is a global solution.

Q278 Dr Stoate: Could you think of a particular thing, for example, that it would be very simple to bring over from another country that we simply should just get on with?  
Mr Lamb: We have started to implement our barcodes in a number of different ways on medicines that are manufactured in hospitals. That is something that is being done today and more of that can be done. There is also the use of different types of barcode to carry additional information, like batch numbers, for instance, on vaccines. Some work has been done in Canada which suggests that the problem in Canada is that they do not know which batch number necessarily has been given to which person or whether or not they were even given the vaccine—and some people are having to be revaccinated—because the system is quite hard to manage. You could scan a barcode, pick up the batch number and record that against the individual, and then you would know exactly what vaccine was given to which person at that time.

Q279 Dr Stoate: Is there any reason why the NHS is not doing more of this?  
Mr Lamb: I think it is a question of focus. There are a lot of initiatives going on. We have a programme at the moment in a number of areas and vaccines is an area in which we would like to do something more in the future, but at the end of the day it is probably about resource and focus and getting the message out to the hospitals so that they can pick it up. Hospitals need to have champions in them to make these things happen. I think the best champion in a hospital would probably be the CEO—so having the CEO aware of it and maybe it being part of his key performance indicators would help to drive that programme forward.

Dr Stoate: Thank you, Chairman.
this patient”—because his condition had changed or whatever it was. In the case of Dennis Quaid, the Hollywood actor, his children in America were given the adult dose of a drug which was to flush out toxins when they should have been given the infant dose. The adult dose was 1,000 times stronger. Because that medicine did not have a barcode on it, the nurse administered the adult dose, it effectively turned their blood to water and they nearly died. These mistakes are not discriminatory. The real tragedy in that is that the same mistake was made by a different nurse in a different hospital a year earlier, when the adult dose was given to six babies and three of them died. We can eliminate those kinds of errors through this humble barcode.

Q285 Dr Taylor: What are the obstacles? Why are we not adopting it straight away?

Mr Lamb: Potentially it is about resource priority. Other initiatives going, and helping hospitals hear the message. A bit more money and resource might help but some hospitals have perhaps taken this up a bit more enthusiastically and others have been a bit slower.

Q286 Dr Taylor: You have used a buzz word in your recommended actions. You said: “leveraging Coding for Success.” What should we be recommending to get Coding for Success leveraged?

Mr Lamb: I did not realise that leveraging was a buzz word. As I said earlier, it is getting this message out to people. Coding for Success was published two years ago and a copy of it went to every CEO, every chief financial officer, and every CIO of every trust. I do not know if they read it or passed it down to somebody else, but adoption is what we would like to see. Anything to publicise that would help. We have just had our standards for the wristbands signed off and endorsed by Martin Fletcher, the CEO of the NPSA. We hope that with the help of local Patient Safety Agency teams we can drive that adoption down through the individual trusts. I think it is about publicity and endorsement at the highest level. I have met Ann Keen and she is very supportive of our standards, and at the Patient Safety Conference in London last year she mentioned our standards in her opening speech. It is not for the want of trying; it is about just getting that message through.

Dr Taylor: Thank you.

Q287 Chairman: Roger, are you familiar with the Papworth and Wrexham pilots that have been taking place on bar coding?

Mr Lamb: I am not familiar with those particular ones, no.

Chairman: Right, we will move on.

Q288 Jim Dowd: It occurs to me that if there is to be bar coding of pharmaceuticals, would there need to be an international standard for that? Would it need to be the same the whole world over?

Mr Lamb: I think it would be and it is—and we have one. We have a way of identifying the drug uniquely. Proprietary coding systems and proprietary systems to try to identify things do not tend to work. It is a bit like having lockers in a changing room, where it is all well and good if you go into a changing room and you know which locker you put your clothes in because they are all numbered uniquely, but as soon as those lockers come out of those changing rooms and are sort of swimming around together you potentially could have numbers which are duplicated. You do need to have an international system, therefore, which ensures that everybody does it the same way, that everybody records the date the same way and the batch number the same way, so that everyone knows that when they are reading the number they know how to interpret it properly.

Q289 Jim Dowd: I do not know if you were here when I was at the questions of Dr Whitaker about the New Zealand experience. Was your organisation involved in that at all?

Mr Lamb: GS1 New Zealand has very close link with the New Zealand government. They have done some work with Bruce Anderson over there and they have recently published a report which showed that through using this technology in this area over the next 12 years over 1,000 lives could be saved as a result of misidentification. But it is not just about saving lives; it is about potential harm, both permanent and temporary, and the numbers there are getting into the tens of thousands. Clearly, if those numbers were extrapolated to the UK you could see that maybe as many as half a million people could be saved from some sort of harm over the next 12 years if implementation took place.

Q290 Jim Dowd: Professor Murphy, blood transfusions and the dangers inherent there is where you have done most of your work. Could you briefly outline to the Committee the dangers that are inherent in blood transfusion and, also, how you have managed both to identify and deal with these by the use of technology?

Professor Murphy: There are a number of risks associated with blood transfusion. We are fortunate in the UK that we have a national incident reporting scheme called SHOT, the Serious Hazards of Transfusion scheme. They produce an annual report outlining the serious events that have occurred in relation to blood transfusion over a year and they make recommendations in terms of improving patient safety. Over the ten or 11 years that they have been producing reports there have been over 4,000 serious adverse events and 70% of them have been incorrect blood component transfused, so the patient getting blood that is the wrong blood for them, often intended for another patient. The most serious type of wrong blood transfusion is an ABO-incompatible red cell transfusion. There have been 213 of those in the 11 years which have caused 24 deaths and 107 cases of major morbidity—that is admission to ITU or renal failure. Those ABO-incompatible red cell transfusions are due to errors. They are entirely avoidable. There are other risks of blood transfusions, as I am sure you are aware: the transmission of infection, for example, and immune consequences of blood transfusion.
Q291 Jim Dowd: You are talking about contamination of the blood there?
Professor Murphy: Yes, that is right. In relation to transmission of infection there have been 60 events in the last 11 years. Those have mostly been bacterial contamination associated with platelet transfusions. Platelets are stored at room temperature, so the risk of bacterial contamination is higher. There has really only been a handful of cases of viral transmission: hepatitis, HIV. There have been four cases of transmission of variant Creutzfeldt-Jakob disease (variant CJD). We are mainly concerned today about the errors resulting in serious adverse events to transfusion and, as I have said, there have been over 200 of those in the last 11 years and 24 deaths. There are about 20 of these occurring every year, two deaths every year. These are the sorts of cases that end up on the front pages of local press, as some of you may have come across in your own parts of the country.

Q292 Jim Dowd: As, indeed, they deserve to.
Professor Murphy: Absolutely—because they are avoidable. The transfusion process is complicated. It starts with the collection of blood from a patient for blood grouping and cross-matching. A sample goes to the laboratory that carries out blood grouping/matching. The blood is put in a storage refrigerator for collection by one of the nursing or portering staff and then there is a checking process at the bedside to make sure that the blood is being given to the right patient. Errors can occur in all those steps and result in the wrong blood being transfused. SHOT documents those and has clearly shown that errors throughout all those steps can cause problems. There have been a number of initiatives to try to reduce these wrong transfusions. A number of bodies in the UK—such as SHOT itself, the National Patient Safety Agency, the National Blood Transfusion Committee, and the UK CMOs have run a Better Blood Transfusion initiative over the last ten or 11 years—have all made recommendations about improving transfusion safety, largely about improving training for the many staff who are involved in the transfusion process and also exploring the use of technology to make it easier for the staff to get the process right—not to rely on the technology alone, but to make it easier for the staff to get it right to do whatever part of the process they are doing absolutely correctly. Shall I go on now and describe what we have done in Oxford?

Q293 Jim Dowd: I suspect so. You have already answered four of my questions and hopefully you will have answered them all by the time you carry on.
Professor Murphy: Are there any questions about what I have described so far?

Q294 Jim Dowd: As we have established from previous witnesses, you cannot eradicate the possibility of error. You have reduced it, obviously, by the way you have adapted your system. Have you identified the area where the greatest risk now lies? How do you ensure that the right patient gets the right wristband, because everything else springs from that?
Professor Murphy: Maybe I should just describe the system that we have developed. This is not something that has happened overnight. We have been working on it for six and seven years and we carried out lots of pilots before we launched into implementing it throughout all the Oxford hospitals. We started off in a day case haematology ward. The first thing we had to do was to get a barcode on a patient’s wristband, so we had to interact with the hospital IT department to ensure that we could have printed wristbands rather than written wristbands—the sort of printed wristband that Roger has here—with the patient’s ID details on and a barcode. Rather than a linear barcode which will just encode one number, we used one of these dotted—
Mr Lamb: Two-dimensional.
Professor Murphy: —two-dimensional barcodes which can encode a patient’s surname, first name, date of birth, gender, and hospital number or, indeed, NHS number—and we might come on to talk about the NHS number later. Basically, the nurse or the doctor taking the sample for blood transfusion has a handheld at the bedside and they first verbally identify the patient. The normal identification steps will happen but the patient will be first asked to state their surname, first name, date of birth, and that will be checked against the written details on the wristband. Then the sample is taken, put into the tube, the barcode is scanned on the wristband, the patient’s details come up on the wristband. The handheld is just reading what is on the barcode. The nurse or doctor will again check that those details match the written details on the wristband and what the patient is telling them in terms of first name, surname, date of birth, and they will check the hospital number too. The sample goes to the laboratory. The laboratories have automated processes, so they scan the barcode on the tube and that enters the patient’s information into the laboratory system. The testing is carried out and then the blood bag gets a sticky label on it, produced by the laboratory, the patient’s name—

Q295 Jim Dowd: Which way up is this label?
Professor Murphy: It is the same way up as described earlier, so it is great for the laboratory. Anaesthetists clearly have difficulty reading things upside down.

Q296 Jim Dowd: Perhaps they should just print them all sideways.
Professor Murphy: It is a fair point that we need to make it easier for users to do things right. If we are making it difficult by having it the wrong way round, then we should look at addressing that. We have an automated system for collecting blood from the blood fridge. The laboratory puts the blood in the blood fridge. What happens in terms of collection is that, when a patient needs a transfusion, the nurse will scan the patient’s
wristband, produce what we call a pick-up slip with the patient’s ID, and that will be either taken by the nurse or collected by a porter to go to a PC by the fridge. There is a process of scanning the barcode into the PC, the patient’s details come up, the fridge opens, the blood is pulled out, scanned again to make sure that it matches, taken to the bedside, and then there is a checking process at the bedside both involving verbal ID and scanning the barcode on the wristband and the blood to make sure that everything matches. The handheld is prompting the nurse through each stage of the process. That is key. When we carried out our work, the first thing we did was to carry out some observations of the current practice and watched what nurses were doing in terms of identifying patients and bedside checking. We worked out that the old process involved 27 critical steps. It involved two nurses, two wristbands in Oxford (we had an additional identification with a number for the sample which followed the process around called a Red Label System—so they had two wristbands) and we found that they only did this process correctly in 10% of cases. After we had implemented the system, we got it right. They were doing it right every time.

Q297 Jim Dowd: That is a significant improvement. Was it particularly expensive, the system you have now compared to what it was, and did you have any difficulty in persuading the trust to find the money?

Professor Murphy: Good question. We started off in a small way, carrying out pilots with research monies and we built up our experience and demonstrated that this system did work. We got feedback from the staff, tried to customise it so that it was good for the staff to use, and got feedback from the patients as well, and we gradually rolled it out from a day case haematology unit, with non-urgent transfusions, to more complex clinical scenarios like cardiac surgery and intensive care. We built up our experience, mostly with research monies, and we highlighted what we did by going further refinements of this process.

Q298 Jim Dowd: If it increased the accuracy rate from 10% to virtually 100%, the failure rate under the old process must have had a cost somewhere. Other than specifically to patients, it must have had a material cost to the hospital.

Professor Murphy: We estimated, with very rough estimates in terms of saving staff time, that we could save £0.5 million a year in terms of nursing time. That is working out how much time it would save and then costing that up. Nurses can be very busy on wards and I do not believe that the trust has employed less nurses because of the work that we have done.

Q299 Jim Dowd: They are off doing other things.

Professor Murphy: They are doing other things. It does save them time and they are absolutely confident that they are doing it right.

Q300 Jim Dowd: Could I just say that I think I have cracked this label business. With the sophistication of modern labelling machines, you could print on a single label one each way up. That would suit everybody.

Professor Murphy: Yes. I think we would be reluctant to put it on both sides of the bag because one of the checks involves making—

Jim Dowd: Make two labels then, and stick one on each side.

Sandra Gidley: That was my idea.

Jim Dowd: Put one upside down and one the other way round, because clearly they are put that way up to suit the people who store the blood rather than what they are going to be used for.

Q301 Sandra Gidley: Obviously you have a very close, ongoing relationship with the trust, so it was relatively easy to persuade them of the benefits of your system, but is anything being done to ensure that the system is adopted more widely in the NHS?

Professor Murphy: We did write a national specification. We were given some money from Connecting for Health to write a national specification for blood transfusion using the electronic system. That is being trialled now at Mayday Hospital in a study funded by Connecting for Health.

Q302 Sandra Gidley: Why does it have to be trialled if you have been doing this for years? Is this yet another way of delaying things?

Professor Murphy: It certainly has held things back. For my sins, I am chairing the steering committee of this pilot at Mayday and I think we have all been incredibly frustrated about how slow it has been. The trust has wanted to add in further refinements of this process.
Q303 Sandra Gidley: Can you expand on that? Do they know what they are doing or are they justifying their jobs? You may like to be a little more diplomatic in your reply.

Professor Murphy: Do I think they are doing it—

Q304 Sandra Gidley: My understanding of a trial is that you do not just adapt these things willy-nilly. You have been doing it for some time, you have considerable expertise. Why do some people think they know better?

Professor Murphy: I share your frustration. Even as chair of the steering group I keep asking the same question. The pilot is overdue and there is no doubt that that is holding back some trusts from adopting the very basic systems.

Q305 Sandra Gidley: The other trusts are being stopped from adopting a system you have developed over a period of five years—you have written the spec. They are being stopped from potentially buying something they want to buy or investing in something in which they want to invest because on this pilot there are people who think they know better and want to change it.

Professor Murphy: They are not being actively stopped. All the trusts in the country are very aware of this pilot and it is being promoted as something that needs to be done before a national roll-out can be considered and so it may be putting off a lot of trusts from moving forward on implementing the system that we have developed.

Q306 Sandra Gidley: Who makes these decisions in the trusts?

Professor Murphy: The decision-making is individual. It is trust by trust. That is obviously a problem, in that the implementation of this system that is going on now is piecemeal, it depends on individual decision-making in each trust.

Q307 Sandra Gidley: Do you have people working in the blood service who want to adopt this but are being stopped at management level for whatever reason, or is there just a caution at the level of implementation and are there any other reasons for that apart from the delay of the pilot?

Professor Murphy: It is the latter. They are not being actively discouraged, but waiting for the results of this further pilot may be being used as a bit of an excuse for holding back.

Q308 Sandra Gidley: There are not any financial barriers.

Professor Murphy: Yes, there are huge financial barriers. As I was saying earlier, I described the cost to the Oxford hospitals. Finance for the equipment is one; finance for the training is another. There are IT connectivity problems within hospitals, between patient administration systems and laboratory systems and other systems within hospitals. We would like to use the NHS number, but we have problems with that, in that we cannot—

Q309 Sandra Gidley: You said you wanted to talk about the NHS number.

Professor Murphy: I do not know whether this is—

Q310 Sandra Gidley: If you are having problems with it and it is safety issue, that probably is something. I would like to think that I am a name not a number, but . . . . I gather we all have two NHS numbers now and it is all very confusing.

Professor Murphy: That is right. That is part of the problem. Sometimes we cannot get hold of an NHS number quickly enough, so that we would like to use an NHS number but we cannot get hold of it at the time we want to use it in 17% of patients. An NHS number has lots of advantages in terms of patients travelling between different hospitals and sharing information between different hospitals. We could very easily use it for our system instead of the hospital number but we cannot get it in 17% of patients. It would be very difficult to run two systems side by side, so for the moment we are not pushing on with the use of the NHS number, with putting it into the bar code for patient identification in Oxford.

Q311 Dr Naysmith: Before we leave the subject of blood transfusion, Professor Murphy, it is sometimes said that the use of a fresh and stored blood can be replaced by artificial substitutes in some areas, and that in many respects could be safer. Is there any milestone in that sort of area of research in saving the bar coding of individuals?

Professor Murphy: It is a great idea. There has been a huge amount of money spent on it, particularly in the United States, but it is one of those things in my career that always seems to be five years for the future, and five years on it is still five years away. At the moment it seems ten years away, because there are a lot of concerns of morbidity and mortality associated with the products which have been trialled in the recent past. So it is a long way away.

Q312 Dr Naysmith: It is still a long way off.

Professor Murphy: But you make a very important point about trying to ensure that patients only receive blood when they really need it, and that is a really important patient safety measure. There has been a huge amount of work through the UK CMOs Better Blood Transfusion Initiative, the National Blood Transfusion Committee and so on, to reduce the inappropriate use of blood. The use of red cells in England has reduced by about 20% in the last five or six years. As well as being great for patient safety, that has also resulted in a huge cost saving.

Dr Naysmith: Thank you very much.

Chairman: Bryony, you will be pleased to know we are going to move on to you.

Q313 Dr Stoate: We have heard a lot this morning about the uses of technology and we have heard great stories about how technology can benefit patients and reduce safety issues. Your memorandum, however, says that the research base
and the evidence of technology is rather limited. Whereabouts are the limitations and what do we need to do about them?

Professor Franklin: I think there are several areas. Many of the technologies that are used within the medication field have been developed and tested in other countries. Particularly in the United States, where the systems for prescribing, dispensing, and administering are very different from those in the UK for many reasons, we cannot automatically assume that something that has benefits in the United States has benefits in the UK. One of the issues, therefore, is that we have often very little UK data and where systems have been tested and designed in a very different health system it is really important that we know if it works in the NHS, which is a very different health system. That is part of the issue. In particular, we have very little UK data on things like smart infusion pumps, which is a technology that is being widely advocated. We have little data on the bar code verification of medication at the point of administration—there is a very small amount but not very much data. We have slightly more data on the impact of electronic prescribing systems, but it is still very much in its infancy. There are even fewer studies promoting technologies used in primary care. I think we do need an evidence base for these products. They are expensive, they are very time-consuming. We would expect to have an evidence base for a medication that we were going to use in a patient and, in a similar way, I think we need an evidence base for a technology which is going to significantly change the way we use things. Some of those technologies have a huge benefits, others are neutral and cost a lot of money, and others might even cause patient harm if they are not used correctly. It is not a magic bullet; it is a very complex intervention and it depends how it is used. As well as the robust research evidence, we also need perhaps a toolkit of methods that trusts can use to evaluate things as they introduce them, that is perhaps not quite as robust in terms of the research but allows trusts to assess things that they can compare with other trusts. They can check that it is having benefits in their own organisation. We also have an absence of economic evaluation. Some of these systems, particularly trust-wide electronic prescribing systems, cost an enormous amount in terms of the capital, the training burden. We have already heard about the difficulties of training staff who might work one shift a week, only nights, locums, et cetera.

The training burden is a huge as well as the ongoing maintenance and upgrade, so we need an economic evaluation of the benefits versus the costs. We also need a better understanding of the relationship between error and harm. We know that a many, many errors occur. Fortunately, the vast majority do not cause patient harm, however, they can affect the patient’s confidence in the health system. I am sure we all hear relatives saying, “The pharmacist gave me 29 tablets instead of 28, so how do I know he has given me the right drug?” That is not going to cause the patient harm, but it does affect their confidence. On the other hand, you could say, “We should put the most resource where the harm is.” That relationship between error and harm is not yet totally understood. Which are the errors that have the most potential for harm? In some cases we know specific drugs—vincristine administered incorrectly, methotrexate administered daily—but once you take those away from the others we do not really yet know what are the characteristics of an error that make it most likely to cause patient harm. Really we need an understanding of what the problem is, so that the problem drives the solution rather than the technology driving the solution, if that makes sense.

Professor Franklin: You are absolutely right: 80% of drug use is within primary care and yet we have much less data. I think that will change soon. Certainly I am involved with several research consortia who have been studying errors in primary care. We have just completed a multi-centre study in the UK of errors in care homes. It was a Department of Health funded study and reports from that will be published shortly. We are also involved in a very large study evaluating the impact of the electronic transmission of prescriptions in primary care and the impact that has on safety, doctors’ time, pharmacists’ time, what do patients think of it, so the evidence base is growing but it is a long way behind secondary care. In the same way, we need evidence for the benefits or otherwise of technologies. Do they work? Do they create new problems? How can we introduce them to best benefit?

Professor Franklin: Most GPs have electronic prescribing systems. It is not my area of expertise but I think they vary in terms of the amount of decision support they have, so there is clinical decision support there. In fact that is one area where primary care is vastly ahead of secondary care, because most GPs do prescribe using computerised prescribing systems with decision support.
Q316 Dr Stoate: It does not give you decision support, but it gives you drug interaction support.

Professor Franklin: It does, yes.

Q317 Dr Stoate: The one thing GP computers do is come up automatically with drug interactions, but they do not otherwise say, “That drug is not indicated for hypertension” for example.

Professor Franklin: I do not believe so. I think some systems might have the opportunity to do that but you would then have to have the codes for that patient’s diagnosis.

Q318 Dr Stoate: Where do we need to go in terms of sorting some of this stuff out?

Professor Franklin: Diagnosis is not my area, so I would not feel I could comment on that. Certainly the prescribing systems in primary care do have more advanced decision support in terms of drug interactions, dosage checking, et cetera, than those that we currently use in secondary care.

Q319 Dr Stoate: That is true, but, given the thinness of the evidence base which you have mentioned now and in your evidence, do you think that the department might be rushing things a bit in its automatic identification and data capture system recommended in Coding for Success? Do you think we have gone ahead of ourselves, given the lack of knowledge we have on what is currently happening?

Professor Franklin: No, I do not actually. I think a uniform system for identifying products is an essential prerequisite for many of the systems that will come later. Many of those systems that can come later have enormous potential, and we are not going to get anywhere with those unless we have a uniform coding system. I think that is essential. Indeed, the Coding for Success report includes data from several systems that we have introduced and tested at Charing Cross and other hospitals, at Imperial, which do show benefit, so obviously we are in favour of that. We think these systems do have huge potential, but they have to be introduced properly.

Mike has given a great example of a system that was piloted, evaluated. You cannot just put these things in and expect to see a magic result overnight.

Dr Stoate: Thank you very much.

Q320 Charlotte Atkins: You state that technology that improves patient safety in other countries might not work in the NHS. Why is that?

Professor Franklin: It is mainly due to the different systems that are used in different countries. One example might be that in the United States in hospitals it would be custom and practice that many of the prescribers are not based within the hospital, they are based within their own offices, and they prescribe for their patients that are in the hospital. They would therefore give verbal orders over the telephone for a prescription to be written that would be written down by a nurse on a piece of paper, it would be faxed to the pharmacy and the pharmacist would enter it into a computer system, so it is perhaps not surprising that a computerised physician order entry system, allowing the doctor to enter that prescription directly into a computer from his or her office, would have enormous benefits in terms of efficiency and safety. In the UK, on the other hand, verbal orders are generally banned, doctors are prescribing from the hospital directly on to a specially formatted drug chart at the end of the patient’s bed, and the benefits are less clear. There are also, in some situations, practices that we have in the UK that we do not have elsewhere. In the UK it is common practice that when a patient is discharged from hospital we supply several weeks of medication to keep them going until they get to see their GP. That is not the case in many hospitals in the United States or in many European countries, so systems that are designed elsewhere will not have the facility for putting in discharge prescriptions, which is one of the main benefits that we might be able to use in the UK setting. It is to do with differences in culture and differences in practice. In the United States, instead of sending whole boxes of medication to the ward, they have individually dispensed doses, mainly due to the requirement for individualised patient billing and a greater risk of theft, because it is a private healthcare system. That is very low in the UK. There are all sorts of different driving forces that mean their systems are very different, so something that benefits their system will not necessarily benefit our system and vice versa.

Q321 Charlotte Atkins: It is not so much that there is a fault within the NHS.

Professor Franklin: No.

Q322 Charlotte Atkins: It is the fact that we have different cultures and different systems. Presumably the principles are still the same of ensuring that there is verification, that verbal instructions are not written down incorrectly, that the person you are treating is the person you are treating, and that you are not giving them the wrong drug. Certainly, where we have seen electronic patient records work and where the clinicians are willing to accept the system and use it, it does seem to cut down on error and cut down on bureaucracy as well.

Professor Franklin: That is right. The principles are the same, we are all trying to achieve the same endpoint, but something that works in one context will not necessarily have the same benefits in another. You might see a system that has reduced the error rate from 20% to 5% but if the error rate in the UK was currently 4% we might not have anywhere to improve. There are lots of different factors to take into account.

Q323 Charlotte Atkins: Which countries do you think we can learn the most from in terms of the problems we are facing being similar to what other countries are facing? Which systems are closest to the UK?

Professor Franklin: In terms of the systems for prescribing, dispensing, and administration in hospital, which is my main area of experience, New Zealand and Australia are the nearest to the UK system. Their systems are very similar to ours. The system used within mainland Europe is very different...
and the system used in America is very different again, so you cannot really have much to learn between those three.

Q324 Charlotte Atkins: Is it for historical reasons that Australia and New Zealand are similar? Why has that developed in a similar way?

Professor Franklin: It is partly historical. The differences in the US have often been driven by the fact that it is a private healthcare system. It is much more similar in terms of a national health system in Australia and New Zealand. It is to do with the different driving forces. In the UK we do not need to know how much every single patient costs us in terms of their medication at the moment, whereas that is something that has been needed for a long time in the US—you know, every single paracetamol tablet has to be accounted for and charged.

Charlotte Atkins: Thank you very much.

Q325 Dr Naysmith: Professor, Franklin, in your memorandum you listed various ways in which technology can compromise patient safety. Could you elaborate on this, please.

Professor Franklin: There are several things that I listed in my submission. To elaborate on some of those a bit more, one is over-reliance on technology. For example, if we are all used to reading the barcode on a drug you might then not check with your eyes the strength and details of that drug, and there is always the possibility that the barcode might have been put on incorrectly, particularly if it was done at a later stage of overlabelling, so you remove then that basic check of: “Have I got the right drug and the right dose?” That leads to deskillling. We hear about doctors in primary care who are now very unwilling to prescribe in a patient’s home or at a care home because they do not have the computer system in front of them with the interactions. As a pharmacist, when I first qualified, I knew all of the additional instructions—which medicines had to be with food, after food, before food—off the top of my head. Now I know that the computer system puts all those in, so on the rare occasion that a computer goes down and we have to typewrite labels, we all have to look up every single label. In some ways that is inevitable but it is something that we just need to recognise and be aware of. Another example is where one of the systems we have tried, an electronic prescribing system, actually had very little clinical decision support, so it did not include allergy checking, and although we had made that clear to the prescribers, we still found doctors who would make errors due to not checking a patient’s allergy status and prescribing something they were allergic to because they kind of assumed, almost subconsciously, that the computer would do it: “The computer must be right. The computer must know this.” Actually the computer only does certain things. It cannot replace the human brain and the human cognition. We also see development of workarounds—and I think several people have referred to workarounds this morning. An example we have seen is relating to barcodes, where we have had a system where patients are identified by a barcode, but sometimes a barcode around a wrist will not scan, perhaps because it is curved or it has got damaged in the shower, or whatever else, so we find nurses printing out duplicate barcodes and sticking them to the patient’s table because they scan beautifully on a hard, wooden, flat surface, but then, if the patient moves beds, you are identifying the table and not the patient. You then have an enormous potential for risk. Even though overall the system, we believe, did improve patient safety, you have the potential for these issues if staff perceive that the system does not work or it is frustrating because they cannot get the barcode to scan, and you then get these workarounds. We also have new types of errors, because sometimes an electronic system or a technology system will require selection from pull-down menus, and I think we all know how easy it is to select the wrong email from your Blackberry or the wrong file name when opening a Word document. In the same way, when presented with an enormous list of drugs it is quite easy to select the wrong one, particularly if a prescriber is presented with a much longer list of drugs than he or she is otherwise familiar with. For example, if you type “beclomet” in a drug list, you get a long list of drugs because there are lots of drugs that start with that prefix. You also get additional steps put into processes. Again using the example of electronic prescribing, when a doctor prescribes on paper he or she really just has to prescribe the name of the drug, the dose and the route: Aspirin, 150 mg, by mouth, once daily. With many electronic systems, you then have to pick the specific tablet. Aspirin does not come as 150 mg, so you have to pick either two 75 mg or half of a 300 mg, and suddenly the prescriber has to make the choice between those. That is a very straightforward example but you can imagine much more complex situations where the prescriber is having to make a choice they did not previously have to make and that is because the system needs to know the exact tablet because it is perhaps linked to a barcode verification at the point of administration. No longer can you leave the nurse, therefore, to make that decision; you have to specify it, so there are additional steps and any additional step can introduce new errors. Finally, you can remove some steps. An electronically prescribing system that allows you to prescribe without seeing the patient means that you might miss vital information (for example, that the patient has a feeding tube in and cannot swallow a tablet, or that they are bright yellow with jaundice). You miss what is really important clinical information about the patient because you can now do it without seeing the patient. Those are just some examples.

Q326 Dr Naysmith: That is quite a broad range of different types of examples. Is there any broad conclusion you can come to in trying to say how we are going to deal with this new thing that is being introduced into treatment.

Professor Franklin: I think the main thing is awareness of these things. Certainly with the systems that we have studied, both evaluating their impact and also studying their implementation and how
they use them, a lot of it is about being aware of these things, so perhaps if a hospital is putting in a system that has been used elsewhere, go along and see what lessons they have learned. Do not assume that you can just put it in and it will work, because it will not. It requires an enormous change in work patterns. There is a growing area called the socio-technical aspects, which is to do with how humans and work systems work together, and how the technology will change people’s work patterns and the social interactions, and it is important to study those things. I really believe that, overall, these systems have enormous potential benefit but realising these benefits means paying close attention to all these issues and monitoring it, introducing it slowly, evaluating it, rolling out, as we have heard with Mike’s example.

Dr Naysmith: Thank you very much.

Q327 Chairman: Roger, is the barcoding of medicines a potential protection against fake medicines, or is barcoding easy to fake or replicate?

Mr Lamb: You can copy a barcode, certainly. It is quite easy to do but there are other ways that you can protect against that. For instance, you could put a randomised serial number in there, which you can store in a two dimensional barcode more easily than a mini barcode, and then you could check against that randomised serial number with a manufacturer’s database to ensure that this was a number that should be available to be used at that time. If it did not match a number that had not already been used or a number that did not exist, then you would know that it was potentially a fake. You can use encryption and those kinds of things in the number to protect against that, so there are ways of staying ahead of the counterfeiters, yes.

Q328 Chairman: Is that used in other walks of barcoding, not just medicines. Is it used elsewhere in the world?

Mr Lamb: It is something that is also being looked at in the aerospace industry. Clearly counterfeiting is not limited to medicines. Bus crashes and plane crashes can have counterfeit parts in them.

Q329 Chairman: When you say it has been looked at, has it been implemented?

Mr Lamb: It has not been implemented yet, no. There is some work that is going on in that area but it does involve putting together an infrastructure. Every manufacturer has to join the club, effectively, and agree to put all of their medicines up on a database, and the links from there to the manufacturer’s own database to check serial numbers have to be there and the technology has to be in place, for instance, at the pharmacy or wherever you are having the check being done. We are doing some work around global traceability standards. Our standards are not cast in stone. Our standards have been developing for 35 years. Our standards are designed for our members and the NHS is a member. The standards are designed by members. We get together with manufacturers and distributors, wholesalers and industry associations, the hospitals, the pharmacies, and regulators. We all agree what is best for the supply chain within healthcare, how can we all work together to ensure that these things will work, and that the interoperability and compatibility is there and everybody gets out of it what they want.

Chairman: Could I thank you all very much for coming along and assisting us with this area this morning. Thank you.
Thursday 22 January 2009

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins
Mr Peter Bone
Sandra Gidley
Dr Doug Naysmith
Dr Howard Stoate
Mr Robert Symes
Dr Richard Taylor

Witnesses: Mr John Black, President, Royal College of Surgeons of England, Rev Dr Pauline Pearson, Deputy Director, CETL4HealthNE; Centre for Excellence in Healthcare Professional Education, Newcastle University, and Professor David Webb, Professor of Therapeutics and Clinical Pharmacology, gave evidence.

Q330 Chairman: Good morning. Could I welcome you to what is our fourth evidence session on our inquiry into patient safety? If I could ask you, for the record, to give us your name and the current position that you hold?
Rev Dr Pearson: Pauline Pearson. I am Deputy Director of CETL4HealthNE and senior lecturer at Newcastle University.
Mr Black: I am John Black, President of the Royal College of Surgeons.
Professor Webb: David Webb, Professor of Therapeutics in the University of Edinburgh.

Q331 Chairman: Once again, welcome. I have got a general question and then we will be asking some specifics to you as individuals. Mine is really just to open this session. Do you agree that patient safety is not sufficiently taken into account in clinical education and training?
Mr Black: No, I do not agree. I think there is an enormous emphasis on this element, certainly in the surgical specialities. Safety is what we are all about, and you cannot have any safe system unless training and education are done at the highest level. Do not forget, you must have clinical and technical skills, and the higher they are the safer the system will be.
Professor Webb: I would support what has been said. I think undergraduate medical training is all about patient safety and trying to educate doctors to be effective in their work. There have been some fairly radical changes in the way undergraduates are prepared to work as doctors, and I think mostly those have been very positive, but I think there are some areas where there is still room for improvement, and that is, perhaps, what we are going to talk about.
Rev Dr Pearson: I think I would say that it is taken seriously by people providing courses for all the health professions that we have looked at, but it is often implicit rather than explicit, so it is there in the curriculum but it is not always made clear or clearly assessed.

Q332 Chairman: David, John seemed pretty firm that it is sufficiently taken into account, but you said it could be improved. Would you like to enlarge on that?
Professor Webb: I think that comes back to my own specific area and perhaps other areas, where as you evolve an undergraduate curriculum some things improve, other things perhaps can get lost, and I think there are some areas where, for the benefit of safety, we could beef things up a little. I am going to talk about prescribing. I think that is an important area.
Mr Black: If I may come back, I cannot imply that it could not be made better and more emphasis could be put on it, but I do think there is emphasis on safety at the moment.
Chairman: Presumably a lot of this is about practice, and we are going to ask you individually about those areas, starting with Robert.

Q333 Mr Symes: The first question is to Dr Pearson. Your centre has been involved in the study on “Patient safety in health care professional educational curricula”. Can you tell us more about the research and what has it shown?
Rev Dr Pearson: It has been a study that has been ongoing for 30 months that finished in the autumn last year. It was a two-stage study looking at four different health care profession’s pre-registration education. We looked at doctors, nurses, physiotherapists and pharmacists and their pre-registration education. We looked initially at the curricula of 13 courses across England and Scotland and interviewed the course directors, course leaders, module leaders. We then looked at eight courses in more detail, so two for each of the professions involved. In those we looked at students’ experience early in the curriculum and later in the curriculum through focus groups with students; we observed the delivery of the curriculum in areas that we imported from the curriculum documents; we also talked to newly qualified practitioners about how they felt they had been prepared. We then also talked to people responsible for patient safety in trusts and asked for documents about patient safety guidelines in those trusts, so we were understanding the organisational context. Finally, we undertook observation in those clinical settings, looking at particularly settings that were used as placements for students and observing the experience that students had, and also undertook focus groups with clinicians who were involved in supporting, teaching or guiding students in those practice settings. Out of that whole lot of obviously quite a big study and quite a lot of different findings, I think that one of the key things was the relationship for the student with the clinical educator. It is called different things in...
Q334 Mr Syms: Who should take the lead in making changes? Do the curriculum-setting bodies need to take steps to ensure that patient safety is fully integrated into all the clinical curricula?

Rev Dr Pearson: I think we feel that one of the major groups that really need to act on this are the regulators; that it is important for regulators to and professional bodies to make sure that they are setting standards that are clear for patient safety curricula, that are actually clear about what needs to be assessed and checked—for example, suitability of placements, the experience of those charged with education of students. Also, I think, we need commissioners to look at where patient safety fits into the courses that they are commissioning. We think that the educators need to have much clearer evidence about where patient safety is in the curricula—not to have it as a separate entity but to have it clear to all students and those who deliver courses—and we have suggested that it might be helped by patient safety champions within both trusts and in higher education who would promote curriculum change.

Q335 Dr Taylor: Dr Pearson, I am really following up on that, because you certainly separate the formal curriculum training from the training when they are out on the job getting work experience, and you do say patient safety in the curriculum is largely implicit rather than explicit. So your first suggestion for improving that is patient safety champions?

Rev Dr Pearson: Yes.

Q336 Dr Taylor: Can you go on and give us any other recommendations for improving the formal curriculum to help?

Rev Dr Pearson: Yes, I think one of the other key things is actually formally enabling students to question and challenge practice, to actually be critical of practice. It is something that we do, but, again, it is often implicit, and we are not setting students up to actually think through: how do I deal with it if this practitioner does something in a particular way and I think it is wrong or I have been taught in university that it is wrong?

Q337 Dr Taylor: Do you think, these days, students have the courage to do that? In my day, which is quite a long time ago, if you were one of these questioning sort of students you got an awful reputation. Are students much more with it and able to do this now?

Rev Dr Pearson: No, I think that is why we need to actually do some work within courses to actually help students to do that more. We also have to educate the educators so that they promote that sort of behaviour. In the data that we gathered there were some examples where students had felt that they were put down when they had asked questions, but we had other examples where students were encouraged to ask questions, were encouraged to look at a range of options and to think through what the possibilities were. We also heard (another idea that I think would be worth pursuing) in physiotherapy, I think it was, but it may have relevance across different disciplines, about people keeping a reflective diary. Most courses, certainly in medicine, seem to have reflective portfolios now, but reflective diaries of incidents where safety was challenged or where they did or did not question practice and how they could have gone about it so that it is actually enabling them to go through the thought process as students before they get into practice as qualified practitioners.

Q338 Dr Taylor: How do we teach the consultants and the others doing the training to accept this questioning?

Rev Dr Pearson: I think we felt that that is partly about them being clear about the importance of not going with the status quo and the fact that because health care is continuously changing, and several of our people that we spoke to talked about the amount of change and the difficulty in the volume of knowledge that people might be expected to have, you are actually looking at trying to give people skills and principles to work from rather than necessarily a lot of factual knowledge. I think it is convincing those people of that really that is important.

Q339 Dr Taylor: Did you get the impression that the placement educators, the people out in the field, were instructed that patient safety was a prominent part of what they were trying to teach?

Rev Dr Pearson: Some of them were aware of it and others were not. It was not explicit. Again, very often they would flag. The practice environments had a lot of material, posters and guidance, so it was there in the environment, but it was not necessarily flagged, it was by some at some points. So it was not absolutely a black picture, but not for everybody.

Dr Taylor: You have given as a huge number of recommendations, for which thank you very much.

Q340 Sandra Gidley: I have got a formal question, but there is something that has been bugging me that I have to get of my system before we go on to it. We heard from John Black in his opening comments that it was knowledge that was important, but we have heard from previous witnesses that it is systems,
attitudes and behaviours that are important. What would you say was the balance of the two? I can see how knowledge is included in the curriculum, but I am struggling to see how all of the things that we have heard over the last week or so are or can be included in the curriculum?

**Rev Dr Pearson:** I think there are people who argue that there is almost too much emphasis in modern curricula on behaviours and attitudes. It is something that we actually do pay a huge amount of attention to in medicine, in nursing, in pharmacy and physio (in each of those professions) very differently. I think, clearly, you need a secure knowledge base about core things, and I guess some of the debate is about what are the core things, but attitudes and behaviours and systems are about the structure that will enable people to adapt as knowledge changes and, certainly through CETL (Centre of Excellence for Teaching and Learning), we are very much trying to look, not just at producing practitioners for five years beyond when they qualify, but trying to look at how will things change in the next ten or 15 years and what different things should we be setting the ground work in place for? I think it is about a balance between different sorts of foundation. You need the foundations of behaviours and attitudes which can be built on and you also need core bits of knowledge from which people can build, and you cannot take those two apart: you need probably both to be significant.

**Q341 Sandra Gidley:** So attitudes and behaviours are looked at in the individual courses, but do the health professionals actually do enough training together, both during their pre-registration training and post registration training?

**Rev Dr Pearson:** In our study we found that there were moves, and it has been a sort of slow move towards more inter-professional learning, which is not necessarily the same as sitting in the same place hearing about anatomy or something, it is actually learning together. There were examples. There is an example, for example, of a role play initiative in one area where students from medicine, from nursing and from pharmacy were in a simulated environment of a busy shift in A&E, with a variety of demands on them, and seeking to work together to make decisions to give each other information and then to reflect on how they had done or not done, and that was an example in which students from at least two of the disciplines involved mentioned how valuable that was to them in realising how far they fell short of what was needed. These were interview focus groups with final year students in all of the disciplines, and it was among those final year students who participated in that that we heard how they valued that opportunity. The other examples that I can draw from, other than our specific study, would be examples where medical students and pharmacy students are working together looking at problems of discharge prescriptions, and then practising writing prescriptions and dealing with errors in prescriptions and understanding some of the processes together that are involved there. So those are the sort of examples, but at the moment I think there is not as much as there probably should be.

**Q342 Sandra Gidley:** Is it not logistically difficult in some places though? Southampton has a very good school of medicine and school of nursing, but the nearest school of pharmacy is in Portsmouth! I was a pharmacy student in Bath. The nearest school of medicine was in Bristol. It would mean a lot of extra expense to do some of this stuff, however worthy.

**Rev Dr Pearson:** Some of it could be done using either long-distance video conferencing opportunities or email—not email, but messaging, or that sort of technology, and, again, that is being explored so that students actually are in maybe peer and cross-professional groups on some sort of electronic network. You can do some things, but other things are difficult, like the simulation.

**Q343 Sandra Gidley:** We have heard a lot about teams. Is actually the answer concentrating on training the teams together and promoting the non-technical skills in that sort of environment? If that is not the answer, what is?

**Rev Dr Pearson:** I am very committed to inter-professional learning, but I do not think it is the absolute answer to everything. There are things that each profession has individually that they need to distinguish and develop skills in. Moving and handling is quite an important area where there is a lot of risks for physios, for nurses, it is not very significant for pharmacists, and maybe a bit for medics. You have to look at what individual professions are expected to do, but certainly emphasis on working together effectively. I think it can actually be done and it is important to emphasise.

**Q344 Charlotte Atkins:** Mr Black, let us follow up that discussion in respect of surgeons. We have already heard in this inquiry about the harm that can be caused by a lack of non-technical skills in surgical teams where deaths have actually occurred. Do you think there is a problem in the way that surgeons work in clinical teams, and, if so, what can be done about it?

**Mr Black:** Surgeons work in clinical teams all the time: obviously they have done it through their career from when they qualify. You work in a team in theatre, you work in a team on the ward and, particularly if you deal with cancer patients, you deal with a multi-disciplinary team. So, team working is implicit and you are used to it; you are doing it all the time. That does not mean to say that problems cannot arise within the team, which is where the human factors come in, and the College has been aware of this for a long time. I quote from a document of ten years ago: "The appreciation of the importance of factors other than purely clinical ones that can affect clinical judgment". We actually published a document in 2000, *Consultant Surgeons, Team Working and Surgical Practice*, so we are very well aware of the importance of teams, and we can only do everything we can to make it better.
Q345 Charlotte Atkins: Do you think over the ten years since you published that document that things have improved?
Mr Black: I think they probably have improved, but, of course, there is always room for improvement, whatever you do.

Q346 Charlotte Atkins: Sometimes a comparison is made between health care and aviation in terms of the use of human factors. Do you think it is a fair comparison, and do you think that health care lags behind aviation in terms of the way that they look at the issues that lead to near misses and actually appear to have much more of a reporting culture, so that, if there is a problem, then it is an absolute must that the professionals involved report it and own up to it?
Mr Black: Yes, we have learnt a lot from the aviation industry. The analogy can be taken a little far, but particularly with check lists. You have to remember that every aeroplane behaves more or less the same, every patient is completely different, but we have learnt a lot from check lists and the near miss reporting. The college, in association with one of the special associations, runs a thing called CORESS, which is exactly that, anonymous near miss reporting. This is very well publicised, very well read, and I think people are very well aware of it. The best analogy where the aircraft industry can actually help patient safety is when it comes to hospital care infections, where the most important factor is overcrowding. The Department of Health figures are that, if you go above 82%, the incidence of infections goes up. When the pilot on your aeroplane takes off, the aeroplane is never overcrowded and it never takes on 20 more passengers without staff coming with them to look after them. So that is an analogy that could be made, but check lists, team working is different. Pilots learn mnemonics—what to do in an emergency—and there are an awful lot of those around in surgery as well, the classic one being ABC, which is the basic resuscitation: airway, breathing, circulation.

Q347 Charlotte Atkins: Surgeons are obviously working in different teams every day of their lives where they are not in established teams. Do you think that surgeons have the human skills which enable them to ensure that the whole of the team feels comfortable with raising any concerns, perhaps during an operation?
Mr Black: I hope they do. They should do. Again, our document from ten years ago said there are ways in which people concerned about patient safety can make their concerns known, and I hope the ethos is that everybody in the operating team should say so, and not just on the operating team. On the wards, or when assessing a patient, if something does not seem to be right, people should speak up, and I hope that we do encourage people to speak up. It is certainly part of our education and training that this should be encouraged.

Q348 Charlotte Atkins: I believe that non-technical skills are not yet mandatory in terms of being included in the curriculum for medical students in general.
Mr Black: Undergraduate students?

Q349 Charlotte Atkins: Yes.
Mr Black: I cannot comment on that, but it is certainly there in the curricula for surgical training. Our curricula for the nine surgical specialities are detailed online, and the syllabus element is available to everybody and it is there both in the generic sections and in the specific sections.

Q350 Charlotte Atkins: I know that the Royal College itself runs a two-day course on safety and leadership for interventional procedures and surgery. Presumably that was developed because you felt that there was a gap in surgeons’ training.
Mr Black: Yes, indeed, it was.

Q351 Charlotte Atkins: When was that set up?
Mr Black: The education department was set up in 1991 or 1992, after there were problems with the introduction of laparoscopic surgery. It got more momentum after the Bristol Inquiry, where this all came up, and the SLIPS course was started. We are about to open the latest phase of our education department in London, which has a mock operating theatre with screens on two sides, where team working can be studied with people looking in to see what is going on, and the people in the mock operating theatre are being watched from outside, rather like an aircraft simulator, to go back to your original question.
Charlotte Atkins: I think my colleague is going to follow up on that.

Q352 Dr Naysmith: You have answered the question, but should all members of surgical teams and other clinical teams do more training in a team setting? Do you think it should somehow or other be mandatory that teams train together?
Mr Black: I know what you mean, but you spend your life in the team, and the greatest menace to the team actually is the continuing change in team members due to working hours legislation, a subject no doubt we will be coming on to later. It is very nice if you can have a set team and stay with them all the time—it is much, much easier—and the check list, of course, aims to overcome that. That is something that we have learnt from the aircraft industry where the captain has never met the second pilot, so you overcome these problems with a check-list. In hospitals that is not quite so much of a problem, but it would be nice to have continuity of the team members. One of the things we have lost, not so much in operating theatres but on ward care of patients, is what used to be called “a firm”, where there were two consultants, usually one trainee and one pre-registration person. That was a very good structure where team bonding was very, very strong indeed and there would be absolutely no worries about reporting safety fears in that environment.
Q353 Dr Naysmith: I think it probably depended on who was in charge of the team, because when I did my PhD with a very famous surgeon in Edinburgh he did not hold with any criticism at all.

Mr Black: I recognise the stereotype. The world has changed; we are not like that any more.

Q354 Sandra Gidley: We have heard mention of the check list a couple of times. Last week the NPSA issued a patient safety alert and mandated the use of the Safe Surgery Saves Lives check list. My big surprise here is that it was not being done anyway. If it is not being done, are you confident that all surgeons will now adopt this way of working?

Mr Black: It was being done. Lots and lots of hospitals have had safety check lists for a long, long time and when the original WHO 15-point one came up with the College council, most people said, “But we have got far more rigorous ones in use in our hospital at the moment.” For example, in my own hospital in Worcester you would not have got through the theatre door on that check list; it is far more rigorous. Clearly, remember, this is designed for international use, but it is a good thing because you cannot be too careful on the real basics. Of course it will be accepted by surgeons, and it does not take much time to do, and we have given it our full support.

Q355 Sandra Gidley: That is good, but I was not aware that the NPSA were in the business of issuing patient safety alerts if there was not a good reason for it. So there must have been something that prompted them to do this?

Mr Black: I think they look at surgical safety in general. There was a publication in the New England Journal of Medicine following this WHO trial, so they know about it. They chose the opportunity of the production of this evidence that this did appear to reduce morbidity and mortality to launch this initiative, but, of course, the NPSA has no power to mandate its use, although it was implied in the media that they did, but it is a good thing because it has drawn everyone’s attention to it and we fully support it.

Q356 Sandra Gidley: So this will not be a burden?

Mr Black: It is not a burden at all. The Royal College of Surgeons has given its full backing to the list.

Q357 Sandra Gidley: If we still have some old dinosaurs, I am told the world has changed, but if we still have some who refuse to go down this route, there will be a disciplinary procedure?

Mr Black: You do not need to go that far, because surgery is a team undertaking and the only sanction you need is, if you do not do it, the operation does not go ahead.

Q358 Sandra Gidley: But do not a lot of consultants think they are above that sort of thing?

Mr Black: No, of course they do not. You would not expect me to say yes to that.

Q359 Sandra Gidley: I am glad you did not. So you are telling me it would not happen.

Mr Black: I am absolutely certain it would not happen.

Sandra Gidley: Thank you.

Q360 Chairman: John, could the use of these lists be something that appraisal and revalidation would look at in terms of an individual?

Mr Black: They are the use of a check list. We are setting the standards for re-accreditation of specialists and the use of a check list will be part of this. It is also in all our web curricula.

Q361 Chairman: So a responsible officer might be somebody who would look at the individuals and make sure that they are taking these on board in their work?

Mr Black: That is right. It was very interesting. In this New England Journal of Medicine study something like 20% of all theatre professionals—not just the surgeons, the anaesthetists, the theatre nurses, everybody—were not sure of its value, but when they were asked if they were having an operation would they want to have it used, 95% said yes.

Q362 Sandra Gidley: It is the 5% I am worried about.

Mr Black: Yes, indeed.

Q363 Dr Taylor: In your written evidence you have given us a lot of examples of things that your college is doing. Do you think the medical royal colleges could play more of a role in the respect specifically of patient safety?

Mr Black: We hope we are, Richard. We hope it is absolutely something which we do. In the safety issues, we have talked about human factors, operating factors. That is a relatively small part of the whole patient journey. You have to have proper systems, proper training, proper knowledge. That is what we are all about. The surgical college actually was founded because of concerns about patient safety and surgery done by others, so it should, and I hope it does, pervade everything we do.

Q364 Dr Taylor: What did you think of Dr Pearson’s suggestion of patient safety champions in each trust?

Mr Black: I think you are seeing this. There is always a slight danger that if you have a champion for safety people think it is not their problem, that this person will do it and part of us should each be our own individual patient safety champion; it should be absolutely second to none in what we do. Of course, everybody wants to be safe surgeons. It seems obvious that nobody actually ever wants anything to go wrong.

Q365 Dr Taylor: You tell us you have embarked on a major project: patient reported outcomes from ISTCs in a sample of NHS hospitals?

Mr Black: Yes.
Q366 Dr Taylor: This is of great interest to us following our ISTC inquiry. You said early results will be published at the end of 2008?

Mr Black: I have not seen them yet.

Q367 Dr Taylor: But we can expect something soon?

Mr Black: You can expect something, and it will be published.

Q368 Dr Taylor: You and I both remember the relative dread with which we expected the college to come and inspect us and go through accreditation of training?

Mr Black: We did.

Q369 Dr Taylor: And go through random selection of notes. Do you think we should think of bringing that back? Would that help with safety?

Mr Black: I think the highest standard of training is very implicit for the whole safety scene, and there is considerable concern in the royal colleges. Since the advent of PMETB we have not been able to visit hospitals. The data is collected in various ways—tick boxes. You cannot beat an experienced assessor talking to a trainee to find out what is actually going on.

Q370 Dr Taylor: In previous sessions when we have mentioned this, the arguments against it have been there are so many royal colleges we could not possibly do it, but that does not really hold water, does it, because it only needs the physicians and the surgeons, basically, to do it at houseman level?

Mr Black: Yes, it does. It is a five-yearly inspection. Trainees are assessed every year anyway, what is called an ARCP, used to be called a RITA, so concerns are picked up there, and that triggers the visit from the college. I think the argument against it was it did interfere with the service, but I think there are ways around that and, if properly organised, it does not. As I say, we have been very concerned about this. The other thing is, if we make a recommendation I think the medical professionals do have a lot of ownership of that. We are not seen as threatening in the way that a Department of Health agency doing the same thing would be. Not that we are not rigorous, I must emphasise.

Q371 Dr Naysmith: A few moments ago you answered a question about patient safety champions, which you very neatly deflected with a skill that most politicians around this table would appreciate. I am not sure whether you thought patient champions was or was not a good idea?

Mr Black: I think it is a very good idea for somebody to have overall responsibility for safety, to make sure the checks are done, to make sure the teams are together. Of course I am not against that. I am sorry, but I do retain the genuine concern that people might think it is someone else’s problem. It is not someone else’s problem. If you are a health professional, it is your problem.

Q372 Dr Naysmith: So both things are needed. The trusts need to instil that discipline and have someone to keep an eye on it?

Mr Black: Both are needed.

Q373 Mr Bone: Mr Black, last Sunday in one of our quality newspapers under the heading, “New EU working laws will be a disaster for NHS”, you made some startling comments. You said the new European Union Working Time Directive rules are an impending disaster that will devastate medical training and lead to dangerous lapses in patient care. Given that the European Union is trying to look after doctors and clinicians, are you not being unfair to the European Union and is this not rather alarmist?

Mr Black: I am afraid I am not, and I wish I was being alarmist. This is, in our view, the biggest threat to patient safety and, not only that, to delivery of service for a long, long time. It has been coming for ten years. There has been a reduction in hours gradually, but the actual final cut to 48 hours with a legal thing that you cannot work more than that has reduced the level of cover. The level of cover in hospitals at the moment is groaning, it is under strain, but the number of people needed to supply 24-hour care, the number of handovers and just finding the sheer number of doctors to keep units open, is looking like it is going to be impossible with 48 hours. The people just are not there to do it, and those that are there will be spread so thin, unless something can be done about it, we anticipate significant service failures. I know it has been coming for a long time, but there have already been implications. Richard Taylor and I worked at adjacent hospital trusts. The problems with his actually first-rate small DGH started with a reduction in junior doctors’ hours. That is what destabilised it originally. Next summer, if this is implemented, there are many hospitals and units that will not be able to provide a service and will be closing, and we would foresee many more Kiddermisters.

Q374 Mr Bone: Did you say, on that last point, hospitals will be closing?

Mr Black: I think units will be—

Q375 Mr Bone: Units or hospitals?

Mr Black: Units or hospitals will say, “We have not got the doctors to be on call to night”, and what our patient groups are concerned about is this will lead to service reconfiguration that has not been planned.

Q376 Mr Bone: Would not the European Union say to you, “Look, you have known this has been coming for ten years. If you had a privately run health service you would be the first people jumping up and down and saying, ‘Why have you not got all these extra doctors you need’”? Mr Black: Yes.

Q377 Mr Bone: You have got a state run health service, that for ten years has known these rules are going to come in, that suddenly says, “Oh, by the
Mr Black: Consultants in the NHS—it all depends on the contract, and it is not so much done in hours, it is done in PAs.

Q382 Sandra Gidley: How would that equate to hours of work?

Mr Black: It would equate to hours. It depends. Contracts are very variable. The basic ten PA contract is something like ten four hour sessions. Interestingly enough, the European Working Time Directive exempts people with executive responsibility who make individual decisions.

Q383 Sandra Gidley: Does that mean consultants are exempt from the Working Time Directive?

Mr Black: I do not think it has been tested at all, but it seems strange that this health and safety is designed to protect the health of the workers, not the patients. So it says if you have got executive responsibility and you are allowed to make a decision, it does not matter how tired you are, which is crazy.

Q384 Sandra Gidley: Who is going to be adding up the NHS hours and the private practice hours?

Mr Black: I cannot answer that question, but the EWTD from next summer will apply to everybody. I do not think it applies to MPs. It does not apply to me because I am the head of an organisation, so the whole thing is bizarre. We talk a lot to our colleagues in Germany and particularly in Ireland. It was apparently not designed to apply to professional people with a very irregular work load, particularly out of hours. It was really intended to stop people who do repetitive jobs, hard work, being exploited. We are not being exploited.

Q385 Sandra Gidley: Surely is hard work though.

Mr Black: It is. Of course it is hard work. You do not go into surgery or medicine thinking it is going to be very easy, but our trainees are telling us that their lives would be better, they would be less tired and the patient care they provided would be safer if they apparently worked more hours.

Q386 Chairman: There was a vote in the European Parliament a while ago that said what they should do in relation to doctors is to look at when they are actually working at work as opposed to potentially resting at work. What did you think about that?

Mr Black: I thought it was very sensible, because of the variability of the things. I used to be on call for 400,000 patients in a large DGH in Worcester and about one night in four nothing would happen very much. The cases would be admitted; the consultant would be freed up to do the emergencies with the trainees. At seven, eight in the evening everything finished, nothing much, a couple of patients admitted. One night in four, we worked virtually all night, but all the hours, you see, the people who were sleeping in a bed, that counts as working hours, whereas when you are up all night you call other people in, and some of the time it was intermediate. So it is the inflexibility of the system. I am sure it is very worthy legislation, but it is not designed for professional
people providing a surgical service, and the anomaly is, if it is implemented, we predict, and I am certainly not being alarmist, I am absolutely convinced that it will be disastrous. We have had enormous support by saying this, and there is still time. We have done everything we can as well. We did a report with the College of Anaesthetists to see if there was a way round working 48 hours. We did produce some solutions which probably would work, but the NHS cannot deliver them because they are so radical. If we had twice the number of consultants and closed half the hospitals, we could possibly do it, but we think the present set-up of hospitals is pretty good and provides a local service and we do not want any more small DGHs closing.

Q387 Mr Bone: Finally, why is it that we cannot do it and our European Union colleagues can?
Mr Black: In Germany they have got a specialty opt-out which they have managed to achieve, and we are talking to them. Interestingly enough, the Irish have the usual Irish system of optimism, half truths and fudges and they have decided that they cannot go on like this, and they have been very interested in our initiative and the 65-hour ideal on-call week as defined by the Association of Surgeons in Training and the British Orthopaedic Trainees Associations. Our training organisations are pan-British Isles groups and we are talking to the Irish about it shortly.

Q388 Mr Bone: I am getting the view from what you are saying there that we are going to abide by the laws very strictly in this country, which is our concern, whereas I think you are indicating that some our European colleagues might be more flexible with the interpretation.
Mr Black: I think they are. Of course there is a legal way out; it is actually political will. I am told that lots of the measures that have been done with the economy recently break all sorts of European laws.

Q389 Mr Bone: They do.
Mr Black: We would like to see some of the European laws dealt with to, in our view, make the NHS safer.

Q390 Chairman: Is not taking resting time as not work time just a way round it?
Mr Black: Maybe, maybe not, but it is complicated and it is how it is interpreted in local trusts and whether you are resident or whether you are not resident. The simple way, the neat way, is to fix it for good, and that is to produce a reasonable working hours maximum for which you may be on call. Once that is done, we are confident that it would fix the situation in terms of providing safe cover for hospitals and also the training side, in that fewer people would be needed, they would have more time available to attend the wards, the out-patient clinics, the ward rounds and the training sessions.

Q391 Chairman: Would that include people resting as well, if there was no—

Mr Black: Yes, I think so. The 65 hours is the optimum. As I say, that was not produced by the senior members of the profession like myself, this was produced by those actively training at this moment who are concerned about the lowered intensity of their training and, of course, that means they would have to stay in training longer, which they do not want, and if people stay in training longer there could be a shortage of consultants. We really do think that this derogation—it is not a derogation, it is an opt-out—is vitally important.

Chairman: We are going to move on to clinical education safety now, you will be pleased to know, David.

Q392 Dr Stoate: I do not know what the world is coming to. When I was a junior doctor we had units of medical time and they were four hours each, and I had to do 30 of them a week in many of my jobs—120 hours a week—and look where it got me! Anyway, we shall move on. We have moved from surgery on to therapeutics. Again, when I was a young doctor we took therapeutics as an extremely important part of the curriculum and we spent a long, long time looking at therapeutics and pharmakinetics and clinical pharmacology. That is, I gather, considered such an important part of the curriculum. Professor Webb, you are quoted as saying that many patients are being made ill and even killed by prescribing errors as a result of inadequate pharmacology education. What is going on?
Professor Webb: If I can start by going backwards slightly, prescribing is an important, complex, high-level skill. It involves making a diagnosis through taking a history, doing an examination and arranging investigations and then creating a therapeutic plan. All doctors prescribe—surgeons and physicians. It is one of the things you do the first day you get qualified and you do it mostly for the rest of your working life, and you do it largely unsupervised. I think all the evidence suggests that junior doctors are on their own from day one in hospital. Clearly, medicines have fantastic benefits for patients, but they come with a risk as well, and the key thing is making sure that patients get the benefits and, wherever possible, not the risks. We have an ageing population who often have more than one illness, and so need more tablets than perhaps they would in the past, and we have more tablets anyway—we have lots more medicines available to us—and some of them are rather more powerful than the ones that existed 30 years ago. When I qualified we had two drugs we would use for people who had had heart attacks; now we might use 22—or it is a lot more complicated. You would think that probably students would get more therapeutics teaching on that basis, but actually they got a lot less, and the reason they got a lot less is a document called Tomorrow’s Doctors that was produced by the GMC in 1993, which was a very important, a very positive step for medicine. It radically reorganised their education with integration, which we have heard about already, and around organ bases. The problem with it being organ based—our hearts,
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Professor Webb: A number of us have raised concerns about this. I think the first was Ken Woods, Chief Executive of the MHRA, who raised this in 2001. A number of us from the British Pharmacological Society raised this again in 2005 and there are two really important pieces of research that have been published since that time. The first was a study from Simon Maxwell in Edinburgh that showed that among 2,500 medical students across the UK, the vast majority, thought they were either poorly or very poorly prepared for prescribing at qualification, and the majority thought they would not meet the then GMC competencies in prescribing. So that is a concern.

Q394 Dr Stoate: But even more alarming, if this is all well-known and well documented and all out in the open, why has not PMETB, the colleges, the GMC jumped on it?

Professor Webb: To quote the GMC, this is Peter Rubin in 2007, “There is no evidence that supports recent claims that trainee doctors are insufficiently prepared for prescribing.” He said that in 2007. The GMC now publish their own findings from a report on three medical schools about how prepared medical graduates are to begin practice, and it is very clear from this document that of all the things they do there is one that stands out head and shoulders above the others as one that they are not prepared for.

Q395 Dr Stoate: You have not answered my question. It answers my question as to what is happening; it does not answer my question as to how it happened and why it has not been sorted.

Professor Webb: I have not idea why it has not been sorted, but I think it will be sorted. There are ways forward. I am an outsider, a clinical pharmacologist concerned that doctors are not getting trained in the right way. I cannot implement that change; it is up to the GMC to implement that change. We have made it very clear to the GMC that we think there is a problem; they have now identified it themselves. The good news is that the document in 1993, which was renewed in 2003, was much the same as the original document whereas the 2009 version now enshrines a series of competences in prescribing that were generated by a Medical Schools Council Safe Prescribing Working Group, chaired by Professor Robert Lechler, and was multi-professional—it involved medical students, it involved doctors in hospitals and in general practice, it involved pharmacists and it involved clinical pharmacologists—and those prescribing competences will be there, I hope. They are there in the draft; I hope they will be there very fully in the final document. The key thing then is that you know in every discipline that if you do not assess competences, students do not think they are a high priority. The other thing that has been lost is therapeutics exams, or competences in prescribing, and what we need is some very clear assessment that doctors are actually competent to prescribe.

Q396 Dr Stoate: I certainly agree with you there. One of the things we have learnt on this inquiry is that there is a massive lack of evidence for most of this stuff. The National Patient Safety Agency admitted that only a very small number of adverse incidents ever actually get reported compared to the number that there are, and certainly in primary care there is almost no evidence whatsoever. Obviously, you would say that would you not. The question I put to you is, how do you know things are as bad as they are given the lack of evidence for real harm caused by prescribing errors?

Professor Webb: It is not easy, so I will start with what we do know. We do know from our report in Edinburgh and the report from the GMC that there is evidence of unpreparation, a perception of that from the point of view of the medical students, but this was a triangulated report and it was very clear that those colleagues, doctors with whom they were working and the pharmacists with whom they were working, shared not only the perception but the pharmacists were very concerned about the error rates that were occurring. So we have evidence that there are errors occurring, we have evidence that goes back to a report from a London hospital in 2002 which showed that about 0.4% of prescriptions have potentially serious errors; so errors are occurring.

Q397 Dr Stoate: Do we have any evidence that they are really harming patients? If there is a real lack of evidence for patient harm, we have not been able to get this evidence. Do you have any evidence that these medication errors are directly causing patient harm?

Professor Webb: I think that is really difficult. How would you do that? You would have to divide medical schools, train students differently and look at the mortality and morbidity rates from the people they treated. It is an extremely hard piece of work to do, to show that the teaching makes a difference. I think if we know, and we do know, that teaching can make a difference to error rates—it reduces error rates—and we know there are error rates, it stands to reason to me that teaching would be of value in preventing potential harm to patients.
Q398 Dr Stoate: Can you, in that case, outline very simply for the committee exactly what changes you would propose to put things right to ensure that the next generation of medical students are up to speed and, hopefully, the current generation of young doctors are quickly brought up to the speed they should have been at some years ago?

Professor Webb: First of all, Tomorrow’s Doctors in 2009 is a crucial document. It needs to be very explicit about the prescribing competences required, and these are not particularly high level, they are what you would expect, and that they ought to be assessed in an effective way by the medical schools. The second thing is (and I think this came out of the Safe Prescribing Working Group at the Medical Schools Council) the Department of Health is putting money into an e-learning for healthcare initiative in prescribing which will produce a range of materials online that students and doctors can use to support their prescribing skills. I think that is going to be a tremendous help; so I think that is important. My own personal concern is that because this is a high-level and complex task (and I know the GMC focuses on the fact that it is the prescribing skills, the writing of the prescription, that they need to learn), I actually think medical students still need to understand how drugs work, how they might not work well together in certain cases and know a basic maybe 50 or 100 drugs that they might use on a regular basis, and I think a little bit of knowledge is absolutely crucial around pharmacology and clinical pharmacology as well as prescribing.

Q399 Dr Stoate: Personally, I am horrified that is not happening, because it certainly happened in my day and I still remember most of it now. I could probably even write the Creb Cycle up if I had to. Can you give examples of any good practice in UK medical schools, either here or elsewhere, that we could perhaps flag up?

Professor Webb: I am going to start with my university, because Edinburgh has produced, in fact, Dr Simon Maxwell has produced a website called e-Drug, which is designed to help students to create their own formularies, which will be part of the Department of Health project on which he is helping, so I think that e-Drug programme is useful. Safety in practice in prescribing comes right at the end of the training period for medical students. That is something that Edinburgh has led on. Both of those initiatives were commended by the GMC in a recent visit. St George’s Hospital in London has a very good booklet about clinical pharmacology and therapeutics; it also gives a limited formulary list of 100 drugs that students need to know about. That, I think, is impressive. UCL, again, has a very in-depth programme of training from pharmacology through to therapeutics which I think is very impressive. All of those are led by clinical pharmacologists, and, if I can have my plug, it is worth remembering that if we lost our clinical pharmacologists (and we certainly are losing them at the moment), then people like Sir Alasdair Breckenridge, who runs the MHRA, Sir Michael Rawlins who runs NICE—they are all clinical pharmacologists—we will not have that cadre of people if we lose that specialty.

Q400 Dr Stoate: Let us hope things do improve. Just a last point: do you think there will be any benefits in medical students and pharmacy students being taught the same curriculum at the same time, or is that not likely to work?

Professor Webb: Sandra raised some practical issues. We bussed students down from Aberdeen from pharmacy school to learn with our students in an inter-professional way, and it is really interesting. I think there are two areas where it is good. Certainly in terms of the pharmacology there are obviously some overlaps, but pharmacy students tend to learn their pharmacology in much more depth than medical students do, and then, at the point of prescribing, learning how drug interactions happen. I think there is fantastic benefit from putting the two together because pharmacists are the guardians of safe prescribing and I think they could help medical students learn what an important professional responsibility it is and a little more about how to do it properly. Those are the key areas. In the middle, doctors are about diagnosis and treatment. It is a slightly different process.

Q401 Dr Stoate: A final supplementary, and that is the use of expert systems to help prescribing physicians. Do you think they are a help or hindrance, particularly on GP’s desks?

Professor Webb: You will know that you can bypass all those safety flags that come up. You do not want too many flags, otherwise people do not use the system, but I think they have some benefits and I think nothing would be better than being able to know, when a patient is coming to the hospital, what medicines they are actually receiving from their general practitioner at the time they arrive.

Q402 Chairman: Given what you have said about the deficiencies in medical students’ training, do you think that the non-clinical prescribers—pharmacists and nurses—are likely to prescribe safer and probably better than you or your doctors?

Professor Webb: I think the situations are different, in that, in general, nurses and pharmacists do not undertake history, examination and diagnostic activity; what they do is take patients who have a diagnosis and treat to very carefully defined protocols, which many doctors do as well, so that there are conditions where it is driven by protocol, the treatment one uses. Hypertension is an important area. What we would use first, second and third line is pretty well described and, I think, could be done by a different range of professionals. Within a certain context I am sure they do it just as well, and I think pharmacists really understand the importance of safe prescribing.
Q403 Chairman: You used the phrase yourself that students should be taught how drugs work. That is pretty fundamental in terms of prescribing, is it not?

Professor Webb: I am afraid it has largely disappeared in many medical schools.

Q404 Dr Naysmith: A couple of tidying up points, Professor Webb. I think you and Howard kind of agreed that the evidence base about adverse drug events was not very good. Is that right?

Professor Webb: Yes.

Q405 Dr Naysmith: How could it be improved? How do you think you could improve the recording and the incidence of adverse drug events?

Professor Webb: I think a lot of this goes back to the ‘champions’ thing. I think we need local champions for clinical governance and patient safety who are interested in medicines; I also think we need open reporting systems that do not carry guilt. That is perhaps an analogy with the aircraft industry. What we want is reporting, lots of reporting, because a lot of problems that occur are systems problems and need systems solutions, so I think we need as much open reporting as possible. I am involved with a regional monitoring centre for the yellow card system, which is a system for reporting adverse drug effects. We have a very good centre in Edinburgh which runs for the whole of Scotland. Eight years ago we received from MHRA all the local data for Scotland so that we could tell our colleagues how well they were doing, and that really geared up their reporting. We had a region that was reporting very few adverse effects but it soon went back to their locality that they needed to work a bit harder. We do not get that local reporting now, and I think it is really important that it comes from the locality, not from the centre.

Q406 Dr Naysmith: This is self-reporting we are talking about?

Professor Webb: We are talking about doctors and patients.

Q407 Dr Naysmith: Both.

Professor Webb: I think it should come from the local region. It is much more likely to be successful if it is being driven from the local region.

Q408 Dr Naysmith: One final point, I think, related to what you said earlier. I am not quite sure I got it right. You said you bussed down pharmacy students from Aberdeen to Edinburgh. Is there not a medical school in Aberdeen?

Professor Webb: There is, but we thought the initiative was an interesting one to bring them together. It was a project.

Dr Naysmith: Thank you.

Chairman: Can I thank you very much indeed for coming along this morning and helping us with this is inquiry. Thank you.

Witnesses: Ms Kathryn Fawkes, Senior Theatre Nurse, Great Ormond Street Hospital, London,
Dr Susannah Long, Clinical Research Fellow, Clinical Safety Research Unit, Imperial College London,
Mr Simon Kreckler, Clinical Research Fellow, Nuffield Department of Surgery, and Ms Sarah Dheansa, Matron for Surgical Care, Queen Victoria Hospital, East Grinstead, gave evidence.

Dr Long: I can only talk for my training, obviously. I qualified in 2000, so I started my training in 1994, in the old-style system, I think. Although I knew safety was of crucial importance, that everything I was learning was so that I could treat my patients safely, it was never really made explicit. I never really heard the expression “patient safety”. The only thing I can vaguely remember is a talk given to us as undergraduates by one of the defence unions about prescribing safely and trying to avoid complaints. When I qualified, I was always very worried about making mistakes, but I never really stepped back and thought about why mistakes might occur or what the consequences might be or anything like that. It was not until I joined Professor Vincent’s group that I realised that there was so much science underlying patient safety of which I was just completely unaware. I have thought, ever since joining the group, that I would have loved to have known about these things earlier on.

Dr Kreckler: I can certainly echo those views. In the first session it was said that it was very much implicit rather than explicit and that has certainly been my experience. There is a lot of activity going on now, particularly in the last couple of years, trying to
bring patient safety to the undergraduate curriculum. I have been personally involved in training not only undergraduates but foundation year doctors, and when you start teaching about patient safety, they are completely unaware of safety as a concept in its own right. Perhaps to echo some of the things that were said by Mr Black earlier, surgery specifically does focus a lot on technical ability, technical safety. Everyone wants to be a good surgeon and a safe surgeon but I still do not think there is sufficient emphasis on the non-technical aspect of safe practice.

**Ms Fawkes:** From a personal perspective, my educational background is a bit different from that of some of those whom I work with. One of the things that has been brought to my attention when I work with paediatric nurses is that there is a lot more social factor in their education programme, less science factor, and there is not a lot about patient safety. Without the science factor you miss a lot of it.

**Ms Dheansa:** The one thing in relation to patient safety that is not mandatory anywhere is the leadership side, the communication that very much links with patient safety. When consultants become consultants, there is no mandatory requirement for them to do any leadership. I think a lot of things around patient safety, because of complex communication channels, links back in with leadership. I would say that I do think they need to be looking at some leadership.

**Q411 Chairman:** The issue that came up in our earlier session was the issue of clinical teams and the need to train together and presumably to get to know one another. Communication would be important there. Also, there was the concept not just of training together but retraining. What are your views about that?

**Ms Dheansa:** As nurses, when you are doing your Advanced Life Support you are trained in a multidisciplinary team with doctors. I think it is paramount to making sure that people understand each other’s roles and that you are all on a par, as an equal, and that especially nurses feel able to voice concerns that they have and do not look at the surgeon and become very, very frightened to speak up when things are going wrong.

**Dr Long:** I would agree with that. I work in a specialty where multidisciplinary team working is basically what we are doing all the time, but it was not until I worked as a junior doctor in those teams that I understood what the different people’s roles were and what my role was and how to interact with the other team members and how to make sure that things ran smoothly.

**Q412 Chairman:** Was none of that in your basic education?

**Dr Long:** Not as an undergraduate.

**Dr Kreckler:** Coming from a surgical background, I think there is a lot to be said for teams of scrub nurses, anaesthetists, surgeons training together. In a practical sense, though, it would be very difficult to achieve. There is a very high turnover. As a junior, I am with one team one minute and another team the next minute. When you are doing emergency work, the people turning up to work with you may never have met before. The training needs to be more directed at training an individual to fulfil a role so that they can then slot into a team within that specific environment.

**Q413 Chairman:** Teams differ. In most circumstances they would be led by the senior surgeon. Do they differ in terms of how they interact with one another?

**Dr Kreckler:** There are certainly different team dynamics. If you do not know the people you are working with, if you turn up to do a case and the anaesthetist you have never met before and the scrub nurse you have never met before, it is very difficult to have that interactional need, especially when things need to move more quickly perhaps.

**Q414 Chairman:** Your slot in the team would be something that you could do, and you would just fit into a team because you were trained to do that.

**Dr Kreckler:** I think that is probably where the training needs to head, yes.

**Q415 Chairman:** Are there any changes you would like to see in clinical education and training? Clearly this is with patient safety in mind, being the subject of our inquiry.

**Dr Long:** From my point of view just the general awareness. As I said before, I was not aware of safety as a concept and had not thought about it, so I think that is probably the most important thing.

**Ms Dheansa:** I think leadership training should be as mandatory as the teaching qualification. Everyone post-registration within nursing and doctors must have a teaching qualification and I think leadership needs to be made mandatory.

**Ms Fawkes:** I think you also need a basic understanding of science as a foundation and then build upon it and have it reinforced throughout the programmes; for example, anatomy and physiology. I am told by a lot of the neuro-nurses that they are not being taught that, that until they go through the surgical course they have had very little anatomy and physiology. I think you should teach that at the beginning level and incorporate it throughout your programme into your different body systems as you study them. With that you can then add patient safety, depending on what the subject is you are talking about, whether it is moving and handling, whether it is wearing protective equipment, or what is a high risk area, and also adding in risk assessment. I do not think they are taught a lot about risk assessment and how to think critically in given situations.

**Dr Kreckler:** I would add that change in the NHS is incredibly difficult at all levels and in all aspects. The hardest thing to overcome is the cultural barrier. If we integrate patient safety from day one in medical school and continue enforcing it right the way
through to consultants at revalidation level. Once that culture has dissipated through the whole system, you will find making new initiatives with regard to patient safety aspects much more easy to facilitate, I would have thought.

Chairman: Thank you.

Q416 Charlotte Atkins: It would be really helpful if you could describe any patient safety challenges you have met in your own practice and maybe outline some of the reasons why they happened.

Dr Long: I am an elderly care physician, so if you imagine an elderly patient coming into hospital with an acute medical problem, perhaps they have cognitive impairment and they are quite frail, there are so many things that I have seen go wrong from the moment they come into the hospital until the moment they leave. The first problems on admission might be, for example, that we are not always aware of what medication somebody is taking and whether they have been compliant with them at home. Often we do not know what their usual functional state is, and that can lead to unnecessary admissions and things like that. They go through the admission process, they are moved around the hospital, forms are handed over between different teams on different shifts, and I have seen several instances where messages have not gone through, things have not been followed up, or things have been missed initially. When they then get to their final ward, there are so many problems on the ward for an elderly person. There are the obvious things like wandering and falls, et cetera, or becoming acutely confused, and people not picking up when new problems are occurring. There are so many things that I do not really know when to stop. When the patients are discharged, there are then problems with communicating with primary care, making sure follow-up is adequate, making sure that the patients understand what their treatment should be. I saw a patient a while ago who had been discharged on a whole new range of medications for heart failure, but she went home and returned to what she was taking before and was readmitted three days later with the same problem and had to go through the whole process all over again from the beginning. I have heard of or been involved in serious safety issues, but I think it is meaningful to concentrate on the common things that you would see if you went on to a ward now.

Ms Dheansa: I would agree with what Susannah has just explained about complex communication channels.

Ms Fawkes: I would like to add to that the cultural issues. For example, I had a situation where in one of the operating theatres they were using laser and the person that set it up did not stand up to the control tech. They did not want to test fire. The nurse involved did not stand up and say, “You need to test fire.” He used it on the patient, it was put down into the NG tube and, as it turned out, the tube was placed by a member of staff. It was put down into the NG tube and, as it turned out, the tube was placed by a member of staff. The following morning a patient a while ago who had been discharged on a whole new range of medications for heart failure, but she went home and returned to what she was taking before and was readmitted three days later with the same problem and had to go through the whole process all over again from the beginning. I have heard of or been involved in serious safety issues, but I think it is meaningful to concentrate on the common things that you would see if you went on to a ward now.

Ms Fawkes: I would like to add to that the cultural issues. For example, I had a situation where in one of the operating theatres they were using laser and the person that set it up did not stand up to the control tech. They did not want to test fire. The nurse involved did not stand up and say, “You need to test fire.” He used it on the patient, it was put together wrong, and it gave the patient more of a burn than they should have been given. Because of cultural issues—the nurse who was involved was Filipino—she does not feel that it is her place to stand up and say, “You need to test fire.” So you have those kinds of issues.

Q417 Charlotte Atkins: Why did the surgeon not want to test fire?

Ms Fawkes: He just did not think it was necessary.

Q418 Charlotte Atkins: It was a waste of time.

Ms Fawkes: Yes—wanted to get things done.

Q419 Charlotte Atkins: What happened in that situation? Was there disciplinary action? What occurred as a result of that incident?

Ms Fawkes: There was an incident report written. There were different pictorial aids made to help with setting up the laser properly. There was also more education on the use of the laser for the people involved.

Dr Kreckler: One of the problems we all face, which again was referred to on the previous session, is that there really is very little redundancy in the system. Mention was made of overcrowding and the impact that has on infection rates, but it is not just on infection rates. You have patients being transferred to inappropriate areas. Because there is no space on the surgical ward, they end up on the medical ward, or people stay in CDU longer than is appropriate, or we cannot get the diagnostics through quickly enough and people end up in hospital longer, or they do not get their therapy in a timely fashion and they encounter complications, a protracted hospital stay, and further problems. In a situation that came up in a hospital I previously worked at, a patient was admitted and placed in a clinical decision unit where a naso-gastric tube was placed to drain their stomach—they were obstructed at the time. That tube was placed by a member of staff who was not adequately trained in placement—that is perhaps a reflection of the fact that they were on a non-surgical ward—and they were later transferred to a surgical ward where it was assumed that the correct checks had been put in place. The following morning a contrast swallow was requested. The contrast was put down into the NG tube and, as it turned out, the tube had been placed in the bronchus and the patient ended up on ITU for six weeks and very nearly died. With all of those problems it is not really that any particular individual is at fault there, it is just that the whole system is set up in such a way that if the right things all line up in the right order you are going to have an error occur, as it did in this case. That is really the tip of the iceberg. The serious untoward incidents are the ones we hear about and get very upset about but, beneath that, the number of times that patients go, for example, to an inappropriate clinical setting is so frequent that it is almost a miracle it does not happen more often. We need to deal with those very minor problems and those minor issues in the system rather than concentrating on the specific serious incidents when they occur, because by dealing with minor issues we will hopefully intervene in that error chain and prevent these serious events from occurring.
Q420 Charlotte Atkins: What happened after that particular unfortunate incident? Were there any changes introduced which would prevent that happening in the future or did it just carry on happening?

Dr Kreckler: I looked into it at the time. At the time there had been about 16 incidents reported nationwide of misplaced naso-gastric tubes. It is estimated that over so many x million are placed per year, so again it is a very, very small percentage. There are hospital protocols in place for specifics: if a tube is to be used for drainage versus feeding, then chest X-rays must be conducted. At the time, however, that had only just come in as a protocol and was only about to come in, and things like Ph testing were still being used, listening for bubbling when you blow air down the tube. These have all now been discredited but at the time it was certainly not clear in the hospital protocol—but it was addressed.

Ms Dheansa: Those examples of system failures, where the pressure of all the targets lines up—the four-hour wait, the infection control target, privacy and dignity mixed-sex targets—that is when the patient gets placed in the wrong environment. That is the root cause, where you have a medical nurse who is not used to putting down NG tubes. That is where the Swiss cheese layers all line up. It is sometimes that working with all of the targets—which in isolation are very, very good—when you are trying to pull them altogether makes it extremely hard on the coal face to deliver all of them.

Q421 Charlotte Atkins: What change would you introduce to improve patient care in that respect?

Ms Dheansa: It is making sure that first and foremost patient safety is deemed the most important and then all the other targets come into after that. Aspects of four-hour waits are: “Okay, if we don’t place this surgical patient in, say, a geriatric ward, they’re going to fail the four-hour wait.” There should be some clause for not so much pressure on the ground floor, with sometimes shoving patients through a funnel.

Dr Kreckler: There is a lot of opportunity for more integration between clinical and managerial aspects of health care. Clinicians are very good at looking after their patients and, to some extent, to hell with the targets. Vice versa, the managers are very interested in hitting their targets and often at the expense of clinical judgment. As a very quick and simple example, I remember seeing a patient with open MRSA wounds in A&E when I was an officer there. She was going to breach and I was waiting for an investigation for back. I said, “Please don’t move the patient. I am afraid we are going to have to accept this breach, but why transfer to CDU and spread MRSA around the hospital now and have to deep-clean other areas?” I came back and of course she had gone. There is a conflict. If we can get better integration between clinical and managerial aspects of the healthcare process I think we can certainly address a lot of these issues.

Q422 Charlotte Atkins: You think that is the most important change to help ensure that we have better patient safety.

Dr Kreckler: That certainly would be a large step forward. Something that I think the inquiry has established already is that there is a huge lack of evidence at the moment for what does work. I have been involved in research myself for the last two years. We find it very difficult to secure funding. What is quite interesting about safety research is that a safe system is inevitably a more efficient system which is inevitably a cheaper system. To give you an example, we found that when we looked at the improvements we had made over the six-month process, for every approximate pound that we had invested in the research programme we saved £4 in terms of missed patient events, if you like—complications. The problem is that it is very difficult to attribute that to a specific budget when it comes to liaising with hospital management.

Q423 Charlotte Atkins: Kathryn, what change would you see as being the most important to improve patient safety?

Ms Fawkes: I think you have to put that as the number one priority. An example that I have is that one day we were doing the list and we were trying to get the list done to meet the targets. We had one patient who had had two procedures and they needed a third, but it did not necessarily have to be done in the theatre—so it could be done in the induction room. It is hearing testing. They wanted to anaesthetise the next patient and get on with the next procedure. The first patient is asleep in theatre and they put the second patient asleep in the anaesthetic room and they switch them. They switch them through the doorway. Essentially, at one point in time, we had two patients in the theatre. These are not bad people who did this but they are trying to meet their targets and get the list done by the end of the day. Then they finished this hearing test, which takes about 45 minutes to do, in the anaesthetic room. But we had two patients in, and I have a problem with that. It is not safe to do that. You can mix records up and just a multitude of things.

Q424 Charlotte Atkins: Susannah, would you like to add what you think is the most important change that could be introduced which would improve patient safety from your point of view?

Dr Long: There are several, as you can imagine. There are some elderly-specific things, like making the hospital more elderly friendly from start to finish, making sure we communicate better with primary care before and after an admission, but there are some general things, as I said before, just making everybody aware through training of patient safety and of the theories behind it, and of what we can do as individuals to stop problems occurring. Also I do think the team working aspect of it needs to be encouraged more. Junior doctors have to do audits as part of their training—it is one of those things that you have to have on your CV when you go for job interviews—but I think often people get disillusioned or they do not really see that things are
improving as a result of what they are doing. I would say instilling in people the fact that they can change things and make things better—very simple things, just giving them the encouragement and role models to show that we can change things.

Charlotte Atkins: Thank you very much.

Q425 Chairman: Susannah, when you did your undergraduate training, did you look at issues about discharge policy from the acute sector? Earlier you gave us a frightening picture of somebody going back home and going back on to old pharmaceuticals, that had been provided for an issue that was not around when they were discharged. Were there fundamental things like that about pharmaceuticals, that had been provided for an issue back home and going back on to old medications?

Dr Long: No, that was the sort of thing I learned on the job, after I qualified, by experiencing things going wrong and by talking to other people. You sort of develop a way of continually thinking what can go wrong and what should I be doing to stop it, but you cannot always predict everything. But there was not any training on practical things like that.

Q426 Sandra Gidley: We hear a lot about the NHS trying to move towards a “no blame” or “fair blame” culture. Are we there yet or do we have a way to go?

Dr Long: It is very difficult, because, when something serious happens and a patient dies as a result of a safety incident, I think there is still an automatic reaction: people look around and try to work out who is to blame, but if there is blame, it tends to be interdisciplinary. That might be a reflection of us not understanding the difficulties faced by other disciplines. The nurses might say, “It’s the doctors’ fault” or the doctors might say, “It is the nurses’ fault”. I have been very lucky—the people I have worked for have been very encouraging and supportive in trying to take these things as a learning exercise and not blame and try to develop people so that it will not happen again—but within the hospital culture there is always going to be a bit of that.

Ms Dheansa: I think it is getting considerably better. With anonymous adverse incident reporting it is getting better.

Q427 Sandra Gidley: But we are not there yet.

Ms Dheansa: No.

Q428 Sandra Gidley: What needs to happen to get there?

Ms Dheansa: I do not know whether we will ever get there. We do not know whether we will ever get to a no blame culture.

Q429 Sandra Gidley: Is that human nature?

Ms Dheansa: Yes.

Ms Fawkes: I do not think we are there yet but, also, you need to look at the instances and discuss them and talk about what can be changed in a given situation or whatever and not have incident reports just put in the files. I think they need to be brought out for educational purposes.

Q430 Sandra Gidley: Is it better when it comes to a near miss? Are we there with “near miss” reporting? Do people feel happy and comfortable because patients have not suffered but they could have done?

Ms Dheansa: I feel that the cycle is not there within the incident reporting yet. Incidents will get reported and I am still not convinced that the feedback comes full circle.

Q431 Sandra Gidley: So you do not learn from the mistakes, basically.

Ms Dheansa: Not the near misses. A lot will be learned from the serious untoward incidents, but I do not think with those near misses—

Q432 Sandra Gidley: They could be used more proactively.

Ms Dheansa: Yes.

Q433 Sandra Gidley: That is interesting.

Dr Kreckler: I would add to that that near misses, on the whole, are not reported as much as the incidents themselves. It is: “We’ve got away with it this time” or “No harm came, so why bother reporting it.” Then I must also echo what my colleague just said, that really there is very limited feedback that comes back down the front line which also further reinforces to some extent the pointlessness of incident reporting.

Q434 Sandra Gidley: Would that be everybody’s experience? I would have thought that a lot could be learned potentially from near misses.

Dr Long: In my general experience of reporting, say, incidents I have reported, I have always been aware that somebody is taking it seriously somewhere but I have never been told what is being done. Unless it is something immediate that I have seen put in front of me, you never get feedback.

Dr Kreckler: Also, for people to report, they need to recognise that a near miss has occurred. One of the most commonly reported incidents is falls. The knee-jerk reaction to a fall is to fill out an incident form, but where there is something less obvious, where maybe a patient was not cross-matched for theatre, and blood was not required but the patient should have been cross-matched, who is likely to spot that, or, if so, who is going to act on it? There are some issues that are not necessarily spotted because they are near misses. It is not until harm occurs.

Q435 Sandra Gidley: It is unrealistic to expect you to go looking for things, but, obviously, if somebody is aware of it. Let us have a slightly different question: if a mistake happens, how easy is it to talk to the patient and be open and honest about what has happened? Do you feel confident? Is there any training on this? Is it something you pick up on the job? Is it something you hope somebody else will do?

Dr Long: I personally have no problem with doing that. It tends to start putting things right when something has gone wrong if you can be very clear and explain, “We didn’t mean this to happen, but it has, and this is what we are going to do about it for you.” Again I think I have been lucky, in that the
people I have learned from on the job have been very good at that generally and I have never seen anybody shy away from that. That is my experience. Ms Dheansa: I would echo that it is a lot more open. There is much fear of litigation and the reputation of the hospital, et cetera, but from a clinical point of view I would say that we are now able to be very, very open.

Q436 Sandra Gidley: Is everybody confident? Are people trained in that or do they learn by observation? It is quite a difficult thing to do. Dr Long: I think I learned by observation, not explicit training.

Ms Dheansa: Now we have the support of, say, the PALS co-ordinator, and the complaints person we would involve. Where I work we have a psychotherapy team which is there to offer a lot of support to the patient and the staff involved. In the organisation where I am at the moment, it is set up quite well.

Q437 Sandra Gidley: I take it that is not the norm. Ms Dheansa: No.

Q438 Sandra Gidley: Kathryn? Ms Fawkes: I cannot really comment on that because, being in theatres, I very infrequently have direct contact with the families.

Q439 Sandra Gidley: Okay. Fair point. Simon? Dr Kreckler: In surgery, complications of surgery are an occurrence that happen all the time, and communication with families and support is usually excellent in my experience. We should flag up here that in medical education we have been talking about moving away from some of the more specific education in pharmacokinetics and the other aspects of anatomy, and there has been a big drive towards training in communication skills. When I was a student, this was coming in, and I certainly think that the doctors coming through now are better equipped to deal with this sort of situation than they once were.

Q440 Chairman: Sarah, you mentioned litigation, and earlier on you said that you did not think this blame culture would change because it is embedded, in a sense. Litigation is obviously one, and your own professional regulatory body could be another if you made the mistake yourself. Are there others that spring to your mind? Ms Dheansa: Reputation of the hospital itself.

Q441 Chairman: That would go along with not being professional, as your regulatory body says you should be. Are there others? Ms Dheansa: Not that I can think of.

Q442 Chairman: What about the media? Ms Dheansa: Media, yes, definitely. The Daily Mail is just—

Q443 Chairman: You do not have to name individuals. I am interested in the concept that to get an open and honest way of looking at things is to be able to say that we have had near misses which could have been serious. Admitting that and changing the culture where something is not admitted because it has not been serious—it could have been serious but has not been—what stops you doing that? What stops the culture change inside our health system? You have litigation, you have your own regulatory body, your professional standards that you could be referred to that for, you have the local press. Which is number one that keeps the culture as it is now? Which is number one of those three? Which are numbers two and three? What do you fear most? Ms Dheansa: Litigation, the local press—and what was the third one again? Sorry.

Q444 Chairman: Your own professional body. If you have done something wrong you could go in front of a regulator. I am an ex member of the General Medical Council—as of this month—so I have had experience. Ms Dheansa: My professional regulatory body.

Q445 Chairman: That would be number one. Ms Dheansa: Yes.

Q446 Chairman: Because that is your livelihood, basically. Ms Dheansa: That is it.

Q447 Chairman: Where do the other two fall: litigation and the media? Ms Dheansa: The media can very much destroy morale on the ground floor. Very much.

Q448 Chairman: Is that collective morale or is that— Ms Dheansa: Collective morale, yes—when you are working extremely hard in the interests of the patient and when it is spun round. I would say that first and foremost would be professional, and then litigation and media together really.

Q449 Mr Sym: Kathryn, with the accent, presumably your experience is NHS and somewhere else. Ms Fawkes: And somewhere else.

Q450 Mr Sym: Do you feel more confident within the NHS or is your experience somewhere else better or worse? Has your experience been in the United States or Canada? Ms Fawkes: The United States. Out of 250 paediatric hospitals in the United States, the hospital I worked in is ranked eleventh. The experience there was a little different. I have always worked in theatres. In this particular institution, they used the Association of Operating Room Nurses Standards as their standards to work by. Everyone try to practise within those recommended guidelines.
Q451 Mr Syms: Because people are rather more litigious in the United States, was the system open there? Would you be more confident that your team would report things here, as opposed to your experience across the Atlantic, or not?

Ms Fawkes: Across the Atlantic, we had no problem going to a manager. If something happened, we would go to report to our manager that there was an occurrence because we felt that she needed to know. Recently where I work, there was an occurrence of something they told the senior sister but the manager was told by the physicians. The nurses did not go to the manager. I think it is not understanding that this sort of communication is important. The communication is in its box.

Q452 Dr Taylor: I am going to ask you some questions about senior colleagues. You have all had lots of senior colleagues, so I do not want you to be inhibited by people thinking that you are talking about a specific individual or somebody you are working for at the moment. How do senior colleagues react if you make a mistake or a near miss?

Dr Long: As I said before, I think in the majority of cases they have been great. They have been supportive, they have tried to help me or use it as a learning experience for the whole team. There has only been a very small number of instances where I have felt I have been unduly criticised or unduly blamed or made to feel bad about it.

Ms Dheansa: I do not know if it is specialty specific.

Q453 Dr Taylor: Are you really saying that the day of the godlike consultant is fading away?

Dr Long: I do not know if it is specialty specific.

Q454 Dr Taylor: What about in surgery?—because they used to be some of the worst.

Dr Kreckler: I think it is very, very important. You could argue that there is a real dinosaur around who will still be very unsympathetic to error, if you want to use that word, or natural mistakes, if you like—but, on the whole, I think that is changing. On the whole, there is a lot more senior support than perhaps there once was.

Q455 Dr Taylor: What about from the theatre point of view?

Ms Fawkes: I think it varies upon the manager and what their background and experience is. If they are open to change, understand evidence-based practice, then I think they are more open to discussing something that happens and trying to look for solutions.

Q456 Dr Taylor: In the States you were able to go direct to the manager.

Ms Fawkes: Yes. We always went to our manager if something occurred.

Q457 Dr Taylor: The difference here is that you would go to your senior nurse.

Ms Fawkes: A lot of people will go to the senior nurse and discuss it with them, versus going to the person above her who is the manager of the whole perioperative area.

Q458 Dr Taylor: With your experience in the States, does that mean you would go one higher?

Ms Fawkes: Yes. I would go one higher.

Q459 Dr Taylor: Would that be a recommendation, that you should go to the highest level you can?

Ms Fawkes: In your given area I think you should. I think you should because they are ultimately responsible.

Q460 Dr Taylor: You gave this awful example of the laser equipment being used incorrectly. I think you said it was a Filipino nurse who did not feel she could complain.

Ms Fawkes: She did not confront the doctor and say, “You need to do it this way. This is our approach, standard.”

Q461 Dr Taylor: I understand that she did not want to confront the doctor. Who should have been available to help her? Was there a more senior nurse there or was she very much on her own?

Ms Fawkes: She is the senior in that particular theatre.

Q462 Dr Taylor: She was a senior?

Ms Fawkes: Yes.

Q463 Dr Taylor: Going on on this, have you worked with senior colleagues who have discussed their own errors with you?

Dr Kreckler: It does happen but it happens rarely. In surgery, there is a forum for reviewing particularly surgical complications, the morbidity and mortality meeting. It has been in place for centuries. That is a forum where surgical decisions are reviewed and discussed, but it tends very much on the technical side of things.

Q464 Dr Taylor: You were in for the first bit and would have heard somebody saying that medical students should be taught to challenge everything. Is that feasible, do you think?

Ms Dheansa: I think the promotion of critical thinking should be—then it will embed within the culture of the organisation and the way they are working so that they do feel able to. I think it is very important, actually, and the same within nursing. I very much encourage nursing students to question everything.

Q465 Dr Taylor: All of you would teach people to question.

Ms Dheansa: Yes.

Q466 Dr Taylor: And you would all feel able to question those above you.

Dr Long: Yes.

Ms Dheansa: The majority of people above me I would feel happy to question. There will be some personalities where you know that it is probably not even worth it because they will just—
Q467 Dr Taylor: They will not take notice.
Ms Dheansa: Yes.
Dr Taylor: Thank you.

Q468 Dr Stoate: Do you all feel that patient safety incidents are adequately reported and learned from in the NHS?
Dr Long: I do not think so. A lot of things go unreported, as we have said. I know that a vast majority of reports are about things like falls, where something really obvious has happened. That seems to be what the management plan put forward is. Someone falls, a nurse calls a junior doctor, a form is filled in, and that is part of the management plan. I think people only ever report other things if something serious has gone wrong and they think that it is worthy of it. We are not encouraged to be generally open about things so much.

Q469 Dr Stoate: Does anyone have a different view, or do you all feel the same?
Dr Kreckler: There is a whole culture behind incident reporting. We know for a fact that nurses fill out 90% of incident reports whereas clinicians will only fill out 10%. I think that part of the problem behind incident reporting is that people do not necessarily see the benefit from it because there is that lack of feedback. If there was a regular loop set up, people might see the impact and be encouraged to report more liberally, and the whole thing would positively build on itself. At the moment, the incident report disappears into a black hole, never to be heard of again.

Q470 Dr Stoate: Are you saying that incidents are reported but they are not being adequately dealt with?
Dr Kreckler: They are being dealt with. This is as a frontline staff member rather than a patient safety researcher now: I have very rarely seen anything come back. Unless a serious incident has been investigated more from a litigation point of view, it very rarely comes back.

Q471 Dr Stoate: Until some manager is worried about being sued, not much happens.
Dr Kreckler: That is one way to put it, yes.

Q472 Dr Stoate: Is that a view shared by you or is that the culture?
Ms Dheansa: I have the responsibility within my job of having to sign off a lot of these. Before they go up the ladder, the investigation is carried out and then I end up as the handler. I do try to make sure that, where there are incidents, we try to institute feedback at ward meetings. It is engaging people right on the ground floor in it, so they are educated. But that is not everywhere. It is only because I so believe that we can learn from them.

Q473 Dr Stoate: At the very best, there are some pretty big gaps in the system.

Ms Dheansa: Yes.

Q474 Dr Stoate: Assuming that, can any of you think of examples where a patient safety incident has really led to proper learning and actual culture change? Can any of you give any examples that you see?
Dr Kreckler: At the local level, in terms of individual incidents we may have been involved in ourselves, the answer personally is no. But, for example, at a national level there is now re-standardisation of the crash call number to 2222 for every hospital in the country as a result of incidents that were collated and put together. I think the NPSA’s national reporting service can play an important role in picking up these rare occurrences, announcing where something can be sent out on a national level and be effective—something simple such as that.

Q475 Dr Stoate: You have come up with one simple answer. Have any of you seen a real culture change, within your unit or wider, resulting from an incident that you have all managed to learn from? Or has it been a bit woolly?
Dr Long: I think that sometimes you have a brief culture change and it sort of wears off as new staff come in. People move on and people forget about it and new problems occur. I have seen a lot of trust-wide policies and protocols, things like antibiotic prescribing guidelines after C.diff outbreaks and so on, and lots of things specific to the elderly, where all nursing staff particularly are asked to fill in lots of risk assessment tools for people on the ward for nutrition and falls and what-have-you. The one thing I would say about that is that it tends to be a knee-jerk reaction to these incidents. People think, “We have to fill out these forms and make risk assessments more” but I know that some of the nurses I work with feel that that takes a lot of their time and they do not act on it because they do not really understand what the underlying problems are.

Q476 Dr Stoate: Are you saying that you get a flurry of activity after an incident.
Dr Long: Yes.

Q477 Dr Stoate: But that very quickly disappears again.
Dr Long: In my experience.

Q478 Dr Stoate: That is pretty alarming, is it not? Do you not feel fairly alarmed by all that? It is pretty frightening stuff, is it not? You get the incident, it gets reported, you do see some change, and then a few weeks later things have gone back to business as usual.
Ms Dheansa: We had an incident where all the junior doctors were not prescribing properly and there were big prescribing errors. The trust realised this was an issue and sorted out competency training which all the junior doctors have to undertake and have to pass. That improved things. It has not eradicated the prescribing errors, but it has highlighted the staff
who really have a low knowledge, junior doctors who are not up to it, and they are not allowed to prescribe.

Q479 Dr Stoate: Do you think that is a permanent change or do you think that when the next round of junior doctors comes in it will just go back to the old style again?

Ms Dheansa: No, it is permanent. They have recently ended somebody’s contract who failed that prescribing error three times.

Q480 Dr Stoate: That is encouraging. Does anyone else have any good news for us? I am feeling fairly depressed at the moment.

Dr Long: The thing that sticks are the trust-wide things, the things everybody knows they have to do for every patient. They stick. Certainly since I have qualified there have been lots of things that have changed that have stuck.

Q481 Dr Stoate: If nurses are making these nutrition assessments but they think it is all a bit of a bore and not doing it, then not much has moved on, has it?

Dr Long: No.

Dr Stoate: Thank you.

Q482 Dr Naysmith: Could we move to another aspect of all this, to do with the aftermath of some incidents taking place—and we are probably talking about serious incidents, where harm results to a patient or maybe even more serious than that. What kind of support is given to patients and their relatives and carers when there has been an incident and it is recognised, either because it has been reported or because something goes wrong afterwards? We have heard stories here already of people having to fight to prove that something did go wrong before anybody admitted that it had gone wrong. Is that your experience?

Dr Long: As I said earlier, I have been lucky to work with seniors who have always been very open and clear with patients and their families as soon as something has gone wrong. I am not sure what formal support there is. I know that the patient liaison services have developed a lot in the years since I have qualified, but I do not think I have ever come across a case where I have felt we have not done everything we can to support people after an incident.

Q483 Dr Naysmith: What about the staff who are involved, particularly if they are relatively junior staff.

Dr Long: I think that is an area where more work should be done. We tend to support ourselves informally. We talk to each other. Again, it is very much within your own discipline usually, unless you have worked in a place for a long time and you know the other people very well. There has only been one occasion, where something really bad happened, that we all had a meeting. We were debriefed and offered counselling for something really horrible that happened. That is my experience.

Q484 Dr Naysmith: What about you, Sarah?

Ms Dheansa: I would say that patient advocacy in the PAL service is a great improvement. On any issues that we have, they are always brought in. As I have said before, we have a very good psychotherapy team that the trust, I know, has fought to keep and they are involved with the patients. We are a small specialist trust and we are quite lucky in that respect, having worked in a larger organisation where the psychotherapy team is not given the resources that are needed.

Q485 Dr Naysmith: Have you come across any incidents of trying to cover something up rather than be open with patients?

Ms Dheansa: Most of the time I have found that they are very happy to be open. Years ago I can think of an incident where a surgeon operated on the wrong eye. It turned out that the patient needed to be operated on both eyes anyway—

Q486 Dr Naysmith: That must have been a relief for everybody.

Ms Dheansa: —but still wrong-side surgery took place. Most of the time, I would say in the last five years, things are getting a lot more transparent.

Q487 Dr Naysmith: Does that apply to staff as well?

Ms Dheansa: I think so. With junior doctors, if they ask for help they will get more support. It sometimes happens with the culture, if you have a consultant who will say things to them like “Please do not hesitate not to call me because I am on the golf course” or wherever, and they have a very old, fiery attitude, that the SHO, the more junior doctor, will not ask for help when needed. That is when you start running into problems. Doctors are a lot more junior now, and at the consultant level they need to be prepared that they are going to be disturbed when they are on call and have to come in.

Q488 Dr Naysmith: Do you think that is part of the new contract?

Ms Dheansa: Yes, but it is whether . . . .

Q489 Dr Naysmith: Kathryn?

Ms Fawkes: I cannot be sure about directly with families.

Q490 Dr Naysmith: You have said you do not see patients.

Ms Fawkes: Yes.

Q491 Dr Naysmith: Do you have the support of the general staff? Probably in theatre is where most of the serious incidents take place anyway, apart from giving the wrong drug, I suppose.

Ms Fawkes: I think there is still some of a culture where some things may be . . . .

Q492 Dr Naysmith: From some of the earlier answers it sounds as if people may be reluctant to report things in theatre.
**Ms Fawkes:** I think they report things, but I think sometimes it takes a while to get change in. For example, the laser incident: it has taken two years for us to have everyone to have laser training. I think it takes a while. Part of it is financial, but it is part of patient safety.

Q493 **Dr Naysmith:** Simon, you are the sweeper-up on this one.

**Dr Kreckler:** I have personally not had a huge amount of experience of this but, anecdotally, I understand that there is a lot of support initially for patients, up until the point that litigation is mentioned. If there is any litigation whatsoever then there seem to be big brick walls that go up, and the patients then get a pretty rough ride of things. In terms of staff, again I know of colleagues who have been in coroners’ inquests and the support they have received has been almost non-existent.

Q494 **Dr Naysmith:** Non-existent?

**Dr Kreckler:** From their trusts that they work for.

Q495 **Dr Naysmith:** Do you think that is something which should be improved?

**Dr Kreckler:** Absolutely. Of course.

**Dr Naysmith:** Thank you.

Q496 **Chairman:** Sarah and Susannah, litigation was mentioned there. What is your experience if litigation is mentioned? Does it affect the way that PALS works, or not?

**Ms Dheansa:** How PALS works, did you say?

Q497 **Chairman:** Patient liaison is good at talking to patients’ families about incidents, et cetera. Simon has just said—and correct me if I am wrong on this—that everything is going fine until litigation is mentioned and then the drawbridges are pulled up a little bit. There is an issue here, if we are talking about changing culture. I just wonder if, in your experience, this word “litigation” does affect the interaction, if a patient has been involved in an incident, with their family.

**Ms Dheansa:** I can think of a recent incident where dirty instruments were used on a patient. It came to light and the trust was very open. As soon as it came to light, they brought the family in and went through it all. Obviously the family and the patient were extremely distressed by it. Our PALS team got involved and remained extremely independent.

Q498 **Chairman:** Would they have been conscious or did they change in any way if litigation—

**Ms Dheansa:** Yes, definitely. There was this feeling of the first thing that senior management were worried about was the press and litigation. But I would say in that case that it was more the press that they were worried about. It is very much reputation.

Q499 **Chairman:** But they stuck to their guns in that particular incident.

**Ms Dheansa:** Who?

Q500 **Chairman:** PALS.

**Ms Dheansa:** Yes. PALS remained completely independent.

Q501 **Chairman:** Susannah, do you have any experience of this, where PALS have reacted to litigation or threat of litigation?

**Dr Long:** I have only had experience of one case where litigation was threatened. I do not know that it made much difference. I think they were very anxious to try to resolve things, regardless of litigation or not.

**Chairman:** That is fine.

Q502 **Sandra Gidley:** I asked Mr Black earlier about the NPSA and the patient safety alerts with regards to the Safe Surgery Saves Life check list. He seemed to think that this was already something that was widely done. Will this be complied with by all surgical teams?

**Dr Kreckler:** I do not think there is any question that everyone involved in any healthcare delivery wants to do anything but the best for their patients. Check lists seem on the face of it to make complete sense. Certainly to myself—and I have been involved a lot in patient safety research—they make absolute sense.

Q503 **Sandra Gidley:** In your experience are they always used?

**Dr Kreckler:** That is what I am coming on to. The short answer to that is no. The reason for that really depends on the way in which this initiative is implemented locally. It depends on those who require to use it to understand the purpose of it, if they are adequately trained and educated and the fact that we have evidence behind this—and the recent *New England Journal* article will help a great deal with this latest initiative. Where they do not necessarily understand the purpose of it, they just see it as another box-ticking exercise to interfere with their attempt to deliver care to their patient. We have been using Saves Lives surgery checklists for the last couple of years. They were required by the NPSA towards the end of 2005. This requires that you sign a box when the patient is first consented, when they leave the ward, when they arrive in the anaesthetic room, and just before the operation starts, to confirm that you have the right patient, the right operation, and that it is the right side. I certainly know of situations where I have seen the scrub nurse bring a form down to the coffee room, to be signed by a surgeon in the coffee room rather than the surgeon going to check the patient in the room. These are not bad surgeons, these are not people who are flippantly ignoring safety protocols, they simply do not appreciate the purpose of the form because they have not been adequately trained.

Q504 **Sandra Gidley:** Surely they are not stupid. This is not rocket science. All the thousands of pounds of training we spend on a surgeon and they do not
understand the purpose behind something simple. Does it not come down to not being told what to do rather than not understanding?

**Dr Kreckler:** I think possibly the problem is that all that happens is they are simply told what to do without being given the necessary information to go with it.

**Q505 Sandra Gidley:** But I am saying that this is not rocket science. I should have thought it was blindingly obvious.

**Dr Kreckler:** Yes. I could not agree more, but, unfortunately, it is the way these things are implemented. Perhaps a simple analogy is to think back to the 1980s when the seatbelt law was brought in. At the time people were up in arms about wearing seatbelts: “I’ve never worn a seatbelt, I am a safe driver.” “I never crash my car.” You would not dream of getting into a car now without putting a seatbelt on because a culture change has come about. That culture change has to happen. It is not going to happen with a big stick and a diktat because you automatically get resistance to that. Certainly, the way the Saves Lives surgery was implemented in my experience, was that it was done one day: “This is what you’re going to do from tomorrow” and everyone was, “Oh, another box-ticking exercise.” There was no explanation, nothing to back it up. If it is done properly, I think everyone will do it and will embrace it. I think that, with time, it will become part of the culture and will be done anyway.

**Q506 Sandra Gidley:** Kathryn?

**Ms Fawkes:** We started implementing that at Great Ormond Street in the cardiac theatres about a year ago. Most everybody is on board with doing it. It has to be a team effort. It is not just the surgeon who can be non compliant. You can also have an anaesthetist who chooses not to be compliant within the process. The nurses have found it very beneficial because they are all introduced, everyone is acknowledged, they are made part of a team, the patient is discussed. They are empowered to ask questions and to say, “We don’t have this particular item today but we have this.” They are empowered to communicate. It is a very good thing.

**Q507 Sandra Gidley:** So there have been other benefits as well from that perspective.

**Ms Fawkes:** Yes. They did not say we had to do it, they worked on it through education and then they are starting to work through the process in the different theatres.

**Q508 Sandra Gidley:** What shall we do with those who do not comply with this? Should it be a matter for regulation or the employers?

**Ms Fawkes:** One hospital I worked with in the States had a computerised programme. Their surgery record and all the patient care, the nursing care plan, etcetera, was all computerised. The only way you can get to complete and close your patient after they leave the theatres is that you have to tick the box one way or another whether this checklist was done, so they have an audit trail of who is doing it and who is not.

**Q509 Sandra Gidley:** That is good. Simon.

**Dr Kreckler:** I have to say I feel slightly uncomfortable with that question. Earlier on in the inquiry we asked: Is there now a no blame culture in the NHS? and here we are trying to work out who to blame when something has not been done.

**Sandra Gidley:** I am just asking. I asked what should be done about those and the answer may be nothing.

**Q510 Chairman:** We are not coming to conclusions here.

**Dr Kreckler:** To build on what I said earlier, I think that if it is not being complied with we need to look at how it has been implemented and we need to address at the core level some way that initiatives are being started in trusts and the way that people are educated and trained. If it is not being followed, then clearly that has failed and it needs to be reviewed, with further training and education as necessary.

**Q511 Sandra Gidley:** What if you have educated somebody to death and they say, “I don’t care, I’m still not doing it. I’ve always done it like this and it has never done me or anybody any harm”?

**Dr Kreckler:** Everyone wears their seatbelts now.

**Q512 Sandra Gidley:** But what do you do to that person?

**Dr Kreckler:** It will change in time with culture.

**Ms Dheansa:** You have to take a transformational approach to it, I think.

**Dr Naysmith:** Simon, there is a significant proportion of people in this country who do not wear seatbelts. It is going on for 10%. There may be 10% of surgeons.

**Q513 Sandra Gidley:** We are talking about the 5% to which Mr Black was alluding earlier—in a slightly different context, I will admit.

**Dr Kreckler:** I think they will end up retiring soon.

**Ms Dheansa:** But there are lots of other people in that operating theatre who should be empowered to if the surgeon is not doing it.

**Q514 Sandra Gidley:** That is a very interesting point. I do not know when this incident with the Filipino sister occurred, but it might have been that if the right checklist was in place—and I am not saying the NHS is the right one—she would have been able to say something because the culture would have been different.

**Ms Fawkes:** I will say that we have not started the actual checklist but we have done what we call the time out, where we identify the patient, decide where we are operating, the correct side surgery, allergies and a couple of other pertinent things. We do not have co-operation, with everyone doing it, but the nurses have decided that they are going to do this as our minimal before we are incorporated into the
whole checklist programme. We have decided we are doing this anyway, and we do make them stop so we can identify we are doing the right patient.

Q515 Stephen Hesford: Can I apologise for not being here at the beginning of this session. You interest me, Simon, by what you have just been saying to Sandra. If you have your checklist and if you have your recalciitant surgeon who still will not use the checklist, even though they have had the training and all the rest of it, and then they have made one of these mistakes that would have been prevented by the checklist—wrong side, or something like that—given your analogy with the seatbelt thing, that the reason the culture change comes about is that people realise it prevents them getting hurt or that they will lose their licence or they get endorsements or some things will get whacked, what should happen to the surgeon who does not do the checklist and then makes the mistake that would have been prevented by the checklist in the no blame culture?

Dr Kreckler: What you have just described there is evidence-based medicine. In patient safety in general, we are just building up our evidence base at the moment. A lot of the checklists that have initially been instigated, whilst they seem to make perfect sense, do not have that evidence to back them up. We do now have that evidence coming from a recent study. I think that what we probably need to do is to collect data on how many surgeons there are who are blatantly refusing to do this in three years time. I suspect it will not be as high as 5% or as has been quoted. We do now have that evidence to back them up. We need to wait until we have evidence before we start concerning ourselves with that question.

Q516 Stephen Hesford: You are an extremely polite young man. In the situation I have just described, would that not be quite serious professional misconduct? Should we not look at it like that?

Dr Kreckler: What you have just described there is evidence-based medicine. In patient safety in general, we are just building up our evidence base at the moment. A lot of the checklists that have initially been instigated, whilst they seem to make perfect sense, do not have that evidence to back them up. We do now have that evidence coming from a recent study. I think that what we probably need to do is to collect data on how many surgeons there are who are blatantly refusing to do this in three years time. I suspect it will not be as high as 5% or as has been suggested. I think we need to wait until we have evidence before we start concerning ourselves with that question.

Q517 Stephen Hesford: But you will not adopt my suggestion that it is professional misconduct?

Dr Kreckler: It is the same thing.

Q518 Stephen Hesford: Or prima facie negligence.

Dr Kreckler: A breach of standard protocol could be construed as such anyway.

Q519 Chairman: I think that would be a matter for the regulator of the profession whether it was serious professional misconduct of not. In the earlier session I asked John Black about revalidation. I asked a very specific question about whether, if these guidelines on safer surgery were not adhered to, that should affect revalidation or appraisal. He seemed to be very firm in saying that, yes, it should. When revalidation is brought into your profession particularly, or into Susannah’s, there may be an issue about going to a regulatory body for a failure if it is the case that you do not stick to the guidelines as outlined just recently. Or do you think the culture will take a lot further getting there? Is that too simplistic an analysis? What do you think?

Dr Kreckler: Ultimately there will be a role for a big stick, but I think initially we need to approach this with a big carrot. There is an awful lot that can be done in a positive way before we have to go down a negative route.

Q520 Chairman: The concept of revalidation of course is that anybody who becomes a doctor or a surgeon will not necessarily remain in that mould of professionalism for the next 30 years and, providing they do nothing wrong, nobody is going to question them. It is actually to say that you will skill or reskill and get used to the different methods of working. Sandra was alluding to what do you do if they do not. Revalidation would immediately catch people who did not keep up-to-date with their skills and with changes in clinical practice.

Dr Kreckler: It is certainly another opportunity to build redundancy into the training and education system to ensure that the new policies are implemented.

Chairman: Thank you.

Q521 Dr Taylor: Susannah and Simon, I want to try to clarify what happens to emergency admissions at night and at weekends and to see how safe the procedure is. Obviously going back a few years, with medical admissions there was always in my day an RMO who knew what was coming in and they delegated to the most junior to do the admission procedure but knew what was coming in and so would be available for help if necessary. Is that still the case, or is it left entirely to the most junior to cope at night and at weekends?

Dr Long: It is still the case. I think that is the role of the medical registrar. I do think it is slightly personality dependent: some people are more hands-on than others. I try to know exactly what is going on with the take, who is expected, who is in, who the juniors are worried about and who I need to be worried about, where people are and what jobs need to be done. I think that is very much the role of the medical registrar.

Q522 Dr Taylor: So there is still a middle grade on.

Dr Long: Yes.

Q523 Dr Taylor: Does that go for surgery as well?

Dr Kreckler: All admissions will come through SHO/registrar level, yes.

Q524 Dr Taylor: How does the shift system affect continuity of care and the post-take ward round? Does that take place regularly? Does it take place with the same juniors to have admitted, or will they have changed by then?

Dr Long: I think it has changed with the introduction of the shift systems. I think the continuity has decreased a bit. It seems to be up to the individuals to ensure that there is a really good handover. In some hospitals I have worked in, the hospitals themselves have taken the decision to
Dr Kreckler: Because of the European Working Time Directive.

Dr Kreckler: Because of the working time rules, yes. I think the way we currently get around it is that theoretically they are on-call off site. The senior can go home when things quieten down at midnight or whatever.

Q531 Dr Taylor: You probably heard a previous witness—I forget who—say that a 65-hour week was something that should be possibly aimed at, to allow for time on-call and to allow for training. Would you agree with that or is that too much?

Dr Long: I think that is roughly what I worked as a house officer. I am not sure exactly what I worked, but I worked a system where I would come in on a Friday morning and not leave until Monday afternoon. I was supposed to have protected sleep at night, but I would never really get the protected sleep. I would always be still trying to do all the jobs on the ward. I worry that a lot of the F1s that I see now do not do nights at all. That does worry me because I know that is when I learned a lot of important skills—the skills we were talking about before: the team working, the handover, and how things work in the hospital, that I did not know until I started working.

Q532 Dr Taylor: You would agree that 48 hours is going too low?

Dr Long: I am not quite sure of the exact figures but I am concerned that people do not work in those antisocial hours, at nights and weekends, when they really get to see how the hospital works.

Q533 Dr Taylor: Is that general that a lot of F1s do not do any nights?

Dr Long: I can only speak for where I have worked recently, but in recent years I have come across quite a few cases where that is true. Dr Kreckler: It varies. We have some that do and some that do not. I could not tell you the proportion that do and the proportion that do not.

Q534 Dr Taylor: Would you go as far as Mr Black went, to say that it is an “impending disaster” when we go down to 48 hours.

Dr Long: I am not sure. I think it depends if we are aware of the dangers and if we put other systems in place to combat them, if we make sure our handovers are good between shifts. Another problem with the shift system is that people tend to defer decisions. They think, “There’s only a few hours left. I’ll leave it to the person who comes on at eight” or whatever “to make that decision.” I think we need to be very wary of that and make sure that people are encouraged to make sure the job is done before they leave. When I was a house officer, we would not leave at five o’clock if our jobs were not done: we would stay until seven or eight o’clock or whenever to make sure that everything was done. I am not sure the same attitudes are always present now.

Dr Taylor: Thank you. So communication, as you have all said many times, is absolutely vital.

Chairman: Could I thank all four of you very much indeed for coming along and sharing your individual experience with us. It is enormously useful to hear from people at the coal face, as it were. Thank you very much indeed for helping us with this inquiry today.
Thursday 5 February 2009

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins                  Dr Doug Naysmith
Sandra Gidley                    Dr Howard Stoate
Stephen Hesford                  Dr Richard Taylor

Witnesses: Dr Alison Holmes, Director of Infection Prevention and Control and Consultant in Infectious Diseases, Imperial College Healthcare NHS Trust; Professor Matt Griffiths, Visiting Professor of Prescribing and Medicines Management, Northampton University; and Professor Aneez Esmail, Professor of General Practice, The University of Manchester, gave evidence.

Q535 Chairman: Good morning. Could I welcome you to our fifth evidence session on our inquiry into patient safety? As you are aware, one of our witnesses is on a train somewhere in the South Midlands at the moment, so not too far away, but we are hoping he may get here in this session. We have an area of questioning for him specifically, and we will not ask those questions of yourselves because it is not your area of work, as it were, and expertise. Could I, for the record, ask you to introduce yourself and the current position that you hold?

Dr Holmes: I am Dr Alison Holmes; I am a Director of Infection Prevention and Control at Imperial College Healthcare NHS Trust; I am also an expert member of the Government advisory panel on antibiotic resistance and hospital acquired infection (ARHAI) and I am also a Programme Director at the National Centre for Patient Safety and Service Quality Research at Imperial.

Professor Esmail: My name is Aneez Esmail and I am a Professor of General Practice at the University of Manchester.

Q536 Chairman: Welcome once again. What do the patient safety problems in your areas of expertise say about the safety culture inside the National Health Service? Is the in-culture easy to change?

Professor Esmail: I think the point about primary care, which is where my expertise is mainly, is it is something that has really been left off the agenda in terms of patient safety. I think that we have the least understanding about some of the problems in primary care, but I do think that there is a willingness, and for a long time, in general practice particularly, there has been some sort of understanding of some of the issues and some of the problems. My work shows that there is a willingness to do things about it, but our knowledge base is very limited and very restricted, so I cannot really comment very much on the culture because certainly the work has not been done like it has in the secondary care sector.

Dr Holmes: From my perspective within the world of infection prevention and control, I have a good news message here because I think actually the model we have developed and worked on has had a significant impact and I think the organisational model that we used and developed is something that would lend itself to many other aspects of patient safety. I think that is a good news story—a local organisational model embedding infection prevention and control within the fabric of an organisation. It has had an impact. I think it is a lesson for us. There are three other points I would not mind highlighting. I think it is incredibly important and, also, what we have learned locally is, that we must have a framework for surveillance, for gathering data and for continually feeding it back and, of course, that is something that we pointed out in a paper in the BMJ in November about the importance of data, and monitoring, and feedback to get that level of clinical engagement—so the framework for surveillance and feedback is key. The last two points are that it just cannot be a service that is a separate add-on one for some experts, it really must be fully embedded within the organisation for it to work, and clinical engagement is vital.

Q537 Chairman: I do not know if you are familiar with the publication; it was ten years ago now An Organisation with a Memory was published. Do you think that progress has been made? Clearly, I think, Alison, from what you have said, you think progress has been made in the last ten years. Has it been made, to your knowledge, in other areas as well?

Dr Holmes: I think progress has been made. I am not sure how much from my coal face view is due to that publication. I think maybe the stage was set for us to make these changes and develop an organisation model, but I would like to highlight that it was actually a pragmatic choice to change the way we work and change how an organisation runs, because the historical model for infection prevention and control, with a small service covering multiple sites and everything, was just not practical and we really had to come up with a new way. I think within the context of An Organisation with a Memory people were very happy to use clinical incident reporting as a way of addressing complacency around hospital acquired infection, for instance. But actually it was a pragmatic solution to what has not worked historically with more complicated organisations. We really had to think about new ways of doing things and embedding it within our culture and our management and clinical systems.

**Professor Esmail:** I think a lot has happened since 
 *An Organisation with a Memory.* I think it did, rightly, set the agenda for us, and those of us who work in primary care. I spent a lot of time trying to persuade organisations about primary care being just as important as the secondary and acute care sector, and we began to try and find out about how big a problem it was. So we did research on trying to find out what others had done around the world, we did small studies to see whether GPs would actually report errors. There was a concern that general practitioners would never admit to doing things wrong, and so we did small studies, for example, to show that they would be very willing to do that. We tried to understand what we could learn from litigation databases. The NHS and the defence organisations do have to deal with litigation arising from things going wrong in primary care, so we looked at that and we discovered a lot about what goes wrong in primary care from that and we began to ask ourselves questions about: how could we engage primary care better? What would be the priorities for doing it? Without a doubt, we are certainly not as developed as in the secondary sector, but I remember at the time having a discussion with the Chief Medical Officer and saying that part of the problem was in primary care. We do not have the same sort of organisational structure that you can have in secondary care. We have a Chief Executive who just says, “This will happen” or “That will happen”, or a very powerful medical director. In primary care you have a situation of independent practitioners who are very nervous about any sort of organisational change coming in, people telling them what do, and we have to work with that. There are good points about it, but in trying to implement areas like patient safety culture, when you have to insist, for example, that we want to create reporting systems, all the issues around anonymity and confidentiality, and so on, still have not to this day been worked out really; so to tell people that “you must” and “you have to” is just not going to work in the setting of primary care. I do not think that reflects a desire not to do something about it, but we just have to realise it is going to be very different to how we implement things in the secondary care sector.

**Chairman:** We have got some individual specific questions for you now, starting with Doug.

**Q538 Dr Naysmith:** Good morning, Dr Holmes. I have a couple of questions for you to start with, some of which you have already made reference to, but let me start with this one. Are healthcare associated infections as big a problem as they are perceived to be, certainly by the media, who seem to focus in on them? Is it a really big important problem in terms of what the National Health Service is doing?

**Dr Holmes:** I think we have to acknowledge there is a massive media interest. In terms of the data, in the latest prevalence study of healthcare acquired infections, which is published in the *Journal of Hospital Infection* 2000, I think, the prevalence was 8% of all hospital in-patients, but, in terms of public perception, the BBC had a national poll last year where hospital acquired infection remains the number one concern above and beyond quality of care, variety of mistakes, et cetera.

**Q539 Dr Naysmith:** What I am asking you is if that perception is the right one?

**Dr Holmes:** That is why I said the number of the prevalence. It is almost one in ten infections, so it is something that we do have to be concerned about. Two things I would like to draw our attention to. One thing that does not feature quite so much, which is a very important aspect of this, is actually antibiotic resistant infections.

**Q540 Dr Naysmith:** We are coming on to that.

**Dr Holmes:** That does not feature highly enough, and that is not just for us now, that is for the future, and that is slightly more difficult to report. It has not got such snappy headlines, and conceptually it is little bit more tricky. However, that is something I would just like to flag.

**Q541 Dr Naysmith:** We will be dealing with that more in a minute or two; you are ahead of the game. What I did want to ask you, and you have already talked about it a little bit, is the framework for surveillance. How can we get better information about the scale of the problem and how much it costs the National Health Service? You have already made reference to the need for a framework for surveillance, but what does that actually mean in practice? Could we tease that out a little bit? What do we have to do to get this better information?

**Dr Holmes:** Could I deal with the question about cost and then a little bit more about getting good data? I think we are struggling here. We really do need some very good economic evaluations that are not just about bed days but also the impact in primary care, and I think we really do have to move towards thinking: this is ‘healthcare’ acquired infection, it is across a whole patient journey, and we should be working very closely across primary and acute care. So economic evaluation needs to consider not just what is happening in the hospital but the impact on people’s lives and in primary care. We also have to use data that is useful, that actually comes from the UK and, particularly, that is relevant to whether you are a large teaching hospital or a smaller DGH. It would be useful to make economic models based on English or UK data.

**Q542 Dr Naysmith:** You doubt the validity of some of the information then?

**Dr Holmes:** I think a lot more work could be done on getting economic evaluations. The other thing we need to factor in—it is not just the impact on the whole healthcare economy and within primary care as well—is this issue about impact ‘in the future’. We are using antibiotics and we are treating infections

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that might be causing us using more antibiotics in the future. The economic evaluation in the present is not really picking up some of the collateral damage in terms of impact on antibiotic resistance around us and in the future.

Q543 Dr Taylor: Good morning. You are part of (do we call it) ARHAi?
Dr Holmes: Yes.

Q544 Dr Taylor: I am most impressed with the evidence you have given us, and I am hoping that our experts have read all the references because you have given us an enormous pile of references. However, right at the beginning you said that there was some good news. Does that mean you have identified some solutions?

Dr Holmes: I think we have identified models of working that are new and have been effective. I am being very parochial here, but I think we have established ways of working with a lot of clinical engagement, embedding it into the fabric of how we run our organisations, and also a system that has demonstrated some resilience. One thing I wanted to mention earlier is actually we should maybe use infection as a marker of good management and managing multiple complex systems. The way we manage our HR, the way we manage change, the way we manage service reconfiguration—all these things are a threat and they can reflect on infection outcomes; so you could look at it as a marker of how well we can manage complex organisations. Often when organisations go through massive change that is when they have problems with c.diff. The Healthcare Commission report in High Wycombe and the Healthcare Commission report in Maidstone—reported these as organisations that were going through massive change at the same time, service reconfiguration as well as other challenges, and I think if we really do embed it in our organisations and use models which are sustainable—and it is not about enforcing, it is about developing good clinical networks, shared sets of values—that actually is sustainable through change. We published something about this, the Hammersmith Organisational Model for Infection Prevention,4 which uses a whole raft of internal reinforcement measures which has seemed to work and seemed to sustain us through massive changes that we have gone through recently in West London in huge mergers.

Q545 Dr Taylor: As Director of Infection Prevention and Control at Imperial College, you have close working relationships with every clinician on every ward, do you?

Dr Holmes: Most clinicians on most wards. I am a clinician myself, and actually it was very important that the Director of Infection Prevention and Control was seen to be somebody who saw patients. There is a huge amount of clinical chauvinism out there and, actually, it is very important for the person who is engaged in controlling antibiotics to be giving recommendations and seeing patients. So that was important. I hope in the future that will not be quite so important, but it really is critically important if you are working with your clinical colleagues and wanting to address issues around antibiotic prescribing for instance.

Q546 Dr Taylor: Coming to the over use of antibiotics, you say hospitals need to have a clear policy on the prescribing of antibiotics. Do most hospitals have that now, or ought we to be doing a survey or finding out how many hospitals do have a proper policy?

Dr Holmes: There was a survey that was done many years ago which showed significant gaps. That has improved dramatically. The other thing that has improved dramatically (and I would like to highlight this) is the role of the pharmacist. The role of the pharmacist is absolutely critical. We need to develop them more and they need to be a key member of clinical teams, providing postgraduate education for them in this field. They need to be colleagues working with us. Also, their role in terms of developing, reviewing and revising policies is absolutely key. Most hospitals would have an antibiotic policy, and that is an important quality indicator as well as having a pharmacist working in them.5

Q547 Dr Taylor: The other crucial thing, you say, is if we were able to collect data on the type and number of antibiotics prescribed and tie that in with the incidence of c.diff, that would give us some really useful information?

Dr Holmes: Yes.

Q548 Dr Taylor: Can you expand on that?

Dr Holmes: Certainly. I mentioned collateral damage when I was talking about antibiotics. They can cause side-effects, but the thing that I am particularly worried about is the driving of antibiotic resistance and antibiotic resistant infections and their relationship to c.diff—how they are linked to c.diff. We absolutely need to understand our antibiotic prescribing and our patterns of antibiotic prescribing to get a handle on it and clearly establish the relationships with c.diff, and not just c.diff but particular strain types of c.diff. That level of understanding would really help us in targeting and choosing what best antibiotic to use. Clearly, antibiotics are completely valuable and we must use them immediately when we need them, but we must use them incredibly carefully. We are running out of choices here and they are driving the c.diff problem.


Q549 Dr Taylor: I do like your choice of words: “Antimicrobial agents that induce CDI are believed to perturb the normal gut bacteria.” I think that is a lovely way of putting it. You have mentioned other antibiotic resistant infections. Are we talking E.coli?

Dr Holmes: We are talking about a whole range, gram positives and gram negatives. MRSA is one, glycopeptide-resistant enterococci is another gram positive.

Q550 Dr Taylor: Is there a simple name for any of those that somebody like me might remember?

Dr Holmes: No. Multi-resistant bacterial infections. You mention E.coli, which is a gram negative enteric bacterium which lives in the gut. I think we really do need to be mindful that this is a problem also in the community with multi-resistant gram negative urinary tract infections, and for those of us working in hospitals, particularly seeing patients in intensive care units, we are facing enormous challenges trying to treat highly resistant infections and also not wanting to drive resistance any further, and the choices are narrowing because of the organisms we are seeing.

Q551 Dr Taylor: One last one in this group: bed occupancy rates. We are reassured by ministers that there has been no correlation in the past two or three years between bed occupancy rates and infection rates.

Dr Holmes: Yes.

Q552 Dr Taylor: I cannot believe that, if you have got 90% or 92% occupation and you are rushing people through, and you do not have time to change the beds and clean things properly. Are there any facts that do show that high occupancy rates do predispose to hospital acquired infection?

Dr Holmes: I think there have been some more recent papers on this. I think the data was very interesting that earlier on—2001-2003—there was a clear correlation between bed occupancy and MRSA bacteraemia, but that relationship appears to have gone. What they were looking at was only MRSA bloodstream infections, which is the tip of the iceberg in terms of MRSA infections, and it is multi-factorial. One should never use bed occupancy for any complacency in terms of best practice, and there is a huge amount of improvement that can and has been done in spite of the bed occupancy. However, I would just like to expand on a couple of points you made. Bed occupancy is also really important in terms of staff/patient ratios: there are huge amounts of data about if you get your ratios wrong infection rates climb, particularly in high risk areas such as neonatal intensive care units, or any intensive care or high dependency unit; so staff ratios are incredibly important. The other issue about bed occupancy: if you want to clean wards or decant wards so you can do deep cleaning or a planned programme of maintenance, or whatever, it is very hard if you have not got space, because where can you put people to close a ward to clean? Also, for instance, orthopaedic infection. It is critical if you come in for a hip or a knee that you are either admitted to a ring-fenced area where everybody is MRSA screened and MRSA free. So that is ring-fenced just for you coming in for your hip or knee. That will mean that you have got to run at whatever bed occupancy it is and keep beds empty sometimes to do this. The other issue about bed occupancy is that it is not just bed occupancy. We need to think about what is our bed stock in terms of single rooms and isolation rooms we can use. How often can we isolate a patient with diarrhoea instead of closing all the beds around them? How often are we working in wards that may be not the ideal type of estate to practice 21st century medicine and clinical and scientific aspiration? So it is not just the issue about bed occupancy. Much can be done even if you have got high bed occupancy. It is not the only factor, but it certainly impinges on all those other issues.

Q553 Dr Taylor: Just to be clear, MRSA bacteraemia, you said, is the tip of the iceberg; the rest of it are the wound infections.

Dr Holmes: The pneumonias, urinary tract infections—absolutely.

Q554 Sandra Gidley: The buzz thing in 2007 was big announcements that all hospitals would have to have a deep clean. Locally there was a decision to do that even before the edict came from on high. Did it actually make a difference or was it just a gimmick?

Dr Holmes: I think it is very important to have awareness about cleaning, and there was a response also to the public’s concern about cleaning, so the cleaning was a good thing. However, I think a one-off clean is not enough; we need a sustained programme of deep cleaning which needs to have enough space that we can do it and also co-ordinate it with any planned programme of maintenance so that you can do everything at the same time and decant patients. I think a deep clean is very important, but it is not a one-off, it should be a sustained part of the organisation. There should be a rolling programme of deep clean throughout all clinical areas, but you do need space to be able to do that adequately.

Q555 Sandra Gidley: Certainly I know that patient feedback was positive, because the place looked cleaner, but is there any research to show whether it actually made a difference to infection rates or not? That is what I am trying to establish.

Dr Holmes: I am unaware of any clear research that has established that. I think it drove some very important messages and I think it was useful. You pointed out how it looked cleaner. The other issue is about de-cluttering, which it helped with, but we do have a big issue with space.

Q556 Sandra Gidley: When they design hospitals do they just not put enough cupboards in for everything, because the amount of rubbish these days when you go round. They are very messy, they do not look very clinical, and the staff do not see it. 

Dr Holmes: It is tricky to see if there is a lot of kit everywhere, but I think the staff see it on the wards; I really think they do. There is an issue about the fabric of many of our hospital buildings and, whilst wanting to give patients space, sometimes it is compromising on storage space. So the design of our buildings is absolutely critical for patient experience, patient safety and for infection prevention.

Q557 Sandra Gidley: We have had a lot of evidence that a lot of improvements can be made if you change the culture; so how important are reporting and learning for infection prevention and control?

Dr Holmes: Incredibly important. I would suggest it is the continuous feedback of data, the continuous surveillance and feedback of data, that is really important rather than just the reporting of particular events. For quality improvement within infection prevention and also for monitoring trends and targeting activity, it is having good strong surveillance mechanisms and also ones that are in real-time. Hearing about something six months later is not good enough; we really need the fast turn-around of surveillance data and information that is relevant to the people that are receiving it so that they can make change.

Q558 Sandra Gidley: So data is available from the National Reporting and Learning System. What I am not sure about is how you use it. You can see whether something is getting better or worse. It may be not quite so easy to link that to a specific intervention that may have been made or an improvement; so how is this wealth of information used in practice to change things on the ground? I am not quite sure where the link comes in?

Dr Holmes: I am talking about several different surveillance schemes. There is the national mandatory reporting of different infections, there is also a raft of local ones and also a range of networks of reporting all around quality improvement and also, locally, key performance indicators that we have set around infection. In terms of the NRLS, there has not been so much in my field, so I cannot answer that.

Q559 Sandra Gidley: Why has there not been so much, and should there be more?

Dr Holmes: One thing that has been extremely useful that has come from the NHS is their Clean your Hands programme. That has been phenomenally useful as a resource in terms of positive reinforcement, in terms of providing masses of resources, in terms of awareness campaigns and everything; that has been extraordinarily useful as a campaign.

Q560 Sandra Gidley: When did people stop washing their hands in the NHS and why do we need such a big campaign on hand-washing? It is such a basic.

Dr Holmes: Absolutely, but continuous reinforcement is needed. The other thing that is important there—I mentioned before issues about staff ratios—hand hygiene and staff ratios is important, but it needs to be embedded in the culture, it needs to be taboo not doing it, in just the same as surgeons and scrubbing. It needs to be behaviour that is completely reinforced, that is engrained there, we have got to have role models and it is always reinforced.

Q561 Sandra Gidley: So the data is really tracking progress against what you are doing.

Dr Holmes: There is a huge amount of national data but also local data. In terms of what is coming from the NRLS, it is the hand hygiene programme, which I am most familiar with, which has been incredibly valuable.

Q562 Sandra Gidley: When you are looking at the data, the information that is coming back, how useful is that for a hospital to say: “Right we tried X, Y and Z to improve our infection control rates. It is obvious that Y is the one that is having the most effect”, or is it just not useful in that way?

Dr Holmes: It is incredibly useful, and the point you raise is really important because the data needs to be used to target action, and to target action you need more information round that. You either need to drill down to each case, you need to look at themes or you need to look at where are you seeing these cases—what risk groups. So, absolutely, data drives and feedback drives activity, targets action; so it has to be useful data that you can drill down and get more information and investigate. Root cause analysis is very useful around some particular cases, but even just knowing the demographics, the speciality—all of that is incredibly valuable—and feeding it back to the people who can do something in a timely manner is absolutely critical, far more than any individual finger pointing. Continuously feeding data drives quality improvement, particularly if you are measuring something that is meaningful to the people who are getting that information.

Q563 Sandra Gidley: So we gave got the datasets about right.

Dr Holmes: I think we could do a lot more. MRSA bacteraemia is one thing: I think it is fantastic that the data is there it has driven massive change; I think we could do far more. I am particularly anxious about vulnerable patient populations in our intensive care units or our neonatal units, but we are working through networks to get more information and people are welcoming data.7

Q564 Sandra Gidley: Say you had extraordinary influence on our report, is there anything specific that we should be collecting or looking at that currently we are not? Are we missing something?

Dr Holmes: I think we need to have much better data around bloodstream infections in our intensive care units, in our renal and dialysis units and in our neonatal units. These are highly vulnerable, high-risk populations. They may not be quite as vociferous, but they are highly vulnerable and I think that is an area we should be looking at.

Q565 Charlotte Atkins: Good morning. I am sorry I was not here for the earlier part of the session. Dr Holmes, how do we embed and enforce safe ways of working that will really enforce good infection prevention control?

Dr Holmes: I think there are four main ways of doing this. We must ensure that within an organisation, so from my perspective the trust I am working in or the academic health science centre at Imperial that I am working in, we must have a shared vision and a shared belief so that all of us, every one of us, no matter what our role, profession, and that this vision is a good thing to do. For me, it is infection prevention. Everybody must feel it is important and we have a role. So from the Chief Executive through all personnel—clinical, managerial, administrative—ensuring you have a shared belief. The second thing I alluded to is we must have reinforcement systems, and positive reinforcement systems as well. So everything we do must make good infection prevention practice the easy thing to do and also positively reinforced all the time, driving internal networks to get good information, having a research agenda that also supports it and also that all our measures include measures about infection so that all our key performance indicators, whenever people are looking at them, will always have something about infection, outcomes and processes. So a shared belief, ensuring we have reinforcement systems and then, thirdly, we have to provide skills for people. We need trained staff and we need people who actually understand what their role is and how to embed and deliver good practice and supporting whatever role they have. Then lastly, I mentioned before with antibiotic prescribing, but in the context of an organisation and culture there must be consistent role models from the Chief Executive, medical directors, nurse directors, heads of estates and facilities—all of them must be involved and be role models—but then there is another aspect of that. We also must make this aspirational for people who are involved in it, not the worst possible job, and also we must develop better research. I think, being on the research agenda, it is very important, and that also drives clinical engagement as well.

Q566 Charlotte Atkins: You are talking about leadership, and so on. Do you think that there is sufficient leadership from our senior clinical staff in terms of making this a top priority?

Dr Holmes: I think that is absolutely key. We were mentioning earlier about antibiotic prescribing. Antibiotic control and infection control go hand in hand: you do not care about antibiotic resistant organisms if they do not spread. How we use antibiotics to treat infection, it is all joined up—antibiotic control, infection control—and, if we do not get engagement from senior clinicians who influence prescribing and shape the behaviour of junior doctors, we will not be able to embed it and make it part of our culture, so senior clinical leadership is vital. Also, what I was saying earlier, actually it is important that senior clinicians take on senior roles within infection prevention and it is not seen as solely a nursing role but actually it is a multi-disciplinary role. It is not solely the premise of the nursing directorate: all clinicians, whatever role you are in, must be engaged.

Q567 Charlotte Atkins: Surely it is not just about prescribing, it is also a matter of washing hands and actually saying that it is totally unacceptable for anyone, including senior consultants, to come in here without washing his or her hands.

Dr Holmes: Completely. I am sorry, I take that as a complete given. Why I was highlighting the issue about antibiotics is that is particularly a prescribing issue, and also I think everybody should be in a position to challenge prescribing. Earlier I mentioned the role of pharmacists—absolutely key. We need to develop them far more, both in acute care and in the community. Pharmacists, as well as nurses, as well as doctors—we must all work together challenging each other, driving best practice, but, absolutely, all practice, from hand hygiene to how you insert a central line, how you manager a dialysis catheter, how you look after a neonate, or how you conduct yourself in your outpatient clinic—all of that must deliver infection prevention practice.

Q568 Charlotte Atkins: The committee went to St Thomas’ a couple of weeks ago and it was very clear as soon as we entered the room that we were expected to use the hand gel, and so on. I go to hospitals quite a lot, sadly, and that is not always expected. The canister is on the wall and if you feel you are going to be good you go and put it on, but it is not something where generally staff look at you and say, “You are coming in to visit a patient: use the gel”?

Dr Holmes: I think this is why it is absolutely key about the senior buy-in—medical director, chief executive, key performance indicator, where they also identify what the professional group is that is not performing in hand hygiene and why hand hygiene monitoring should be up there as a regular indicator of quality.

Q569 Charlotte Atkins: Do you think that the regulatory and the performance managing bodies are doing enough themselves to make this a top priority?

Dr Holmes: I think there has been an awful lot done. I think what might be useful is if some activity is not duplicated. We need to find a balance between working within a framework of regulation and actually letting trusts develop good quality
improvement within their own networks, so that they are not constantly duplicating activity and maybe needing to think about having extra people on their staff to deliver all that is required for external regulation rather than concentrating on local quality improvement initiatives.

Q570 Charlotte Atkins: Maybe commissioning bodies have a part to play. Commissioning for Quality and Innovation by the Department of Health suggested that PCTs might be able to make payment to providers conditional on performance indicators for things like infection prevention and control; and I have to say that, if I was heading up a PCT and some of my patients had to stay in hospital an extra two or three weeks because of catching some sort of infection, I would want to ensure that my local provider hospital had a financial penalty for that. Instead, they have a financial advantage, because they are paid more for the patients that stay there longer.

Dr Holmes: I think external reinforcement like that is valuable. However, I have a slight anxiety. I mentioned before about how critical it is, now that patient stays are getting shorter and shorter, that we really do need to look at ‘healthcare’ acquired infection and antibiotic prescribing across the whole patient journey, and we are just beginning to work across that and look at it as a problem that is not either acute or primary but is something that we should approach together. I am slightly concerned that that may drive a wedge between some of the work we are trying to do about risk across acute and primary care boundaries. However, the quality initiative completely support and the reinforcement being there is valuable, but I think we have to be mindful that actually we really do need to address this problem, not as a primary care and acute care issue but actually across the whole patient journey, if we really do want to do something about it.

Q571 Charlotte Atkins: I appreciate that, obviously, many patients will enter a hospital already with infection; I appreciate those concerns, but where you have hospitals that warning, after warning, after warning their infection rates are much higher than acceptable, and anything is unacceptable but if they are very high, surely there has to be some sort of financial penalty: because it gets to the point where hospital managements can be in denial mode: “Oh well, it is everyone else’s fault. It is the PCT’s fault; it is the population we are having to serve” , and it really has got to get to the point where if they are not performing there has to be some sort of penalty, and financial penalties seem to be the ones that actually have an impact on performance.

Dr Holmes: I do think there are some lessons that can be learnt from the mandatory reporting of the MRSA bacteremia and the actions that have been taken at trusts that have driven down numbers in the absence of financial consequences. I do not think I am in a position to comment any more about that. I completely value external reinforcement. In my job it makes it much easier to drive change when there is a level of external reinforcement, but I actually value working with my primary care colleagues to look at it as a comprehensive problem that we can work on together. That is my concern about that.

Q572 Chairman: Could I say welcome to Professor Matt Griffiths, who has joined us. We are sorry about the delays; the weather is in nobody’s control. You are the Visiting Professor of Prescribing and Medicines Management at Northampton University. I just want to put that on the record.

Professor Griffiths: Yes.

Chairman: We will come to you in a few minutes, but we are going to move on to Professor Esmail at the moment for some further questions.

Q573 Stephen Hesford: Professor Esmail, there is a cross-over from the questions that have just been asked. Probably about 20% of my constituency population is elderly, 65 plus, and a significant proportion of those are in nursing homes. My local hospital’s infection rates are low but they have a residual band that they basically cannot get rid of. They think that much of the infection is coming from the elderly coming in from nursing homes. Dealing with primary care, with that in mind, if that is at all representative of what happens elsewhere, there does not seem to be much hard evidence on patient safety in primary care. What can be done about that, either in the GP’s practice or health centre or in other primary care settings?

Professor Esmail: I think from the specific example you gave, we are only now beginning to understand that things like community acquired infections are a big problem; and we have not had systems in place to make sure that people are screened, for example, before they enter hospital sometimes, because you cannot do it when it happens as an acute emergency. I have noticed with of my own patients that people going in for very complex operations which are planned are now being routinely screened, for example. So we are beginning to understand this relationship between what happens in the community and what happens in hospital. Of course, it happens the other way round as well: people get discharged without being screened and we do not have any idea of that, and then they come in with persisting wound infections or become ill with pneumonia and the source might have come from the hospital; so we do not have that information either. I think we are beginning to understand that more and I think we have got to do a lot more work as we understand the epidemiology of these illnesses and how we have to have a whole systems approach to that. On the issue about evidence, it is not true to say that we have no evidence. We look at literature, we have done pilot studies, and we have looked at litigation databases; so we understand how big a problem it is. Of course, I think part of the problem is we have not concentrated on it enough. If you think that most people’s contact with the NHS is through their general practitioner and you then imagine what must be happening, even if you talk about 50 incidents a day but you multiply it by the number of consultations that people have, you are
talking about huge amounts of things that potentially can go wrong. So we recognise that it is a big problem, but we do not have a very good means of measuring or putting numbers to it, for example. We always talk about ranges and how big a problem it might be, but we do not have a specific number we can quote, saying, “This is how big a problem it is.” Hospital people frequently talk about one in ten admissions or 10% of all admissions have adverse events. We cannot give you that figure for primary care, and that is a problem, but it should not prevent us from doing anything about it. This idea that we can only do something if we know that figure, I think, is misplaced. There is lots happening already and lots which can be done which does not have to be dependent on that idea.

Q574 Stephen Hesford: I am slightly confused by that, because if there are no figures to know exactly what the problem is, I am not sure what the solution is to the problem that you do not really know what it is?

Professor Esmail: Take an example of something which is widely happening in communities: warfarin prescribing. I cannot tell you at the moment how many adverse events occur in primary care because of warfarin prescribing.

Q575 Stephen Hesford: Adverse events meaning?

Professor Esmail: Let us say that the patients are getting medication repeatedly without having their level checked, or are getting too high a dose of warfarin so they are at risk of bleeding or having a haemorrhage, or something like that. I cannot tell you a precise figure as to what the problem is, but I do know, based on good practice, what should happen, and I can look at my processes in practice to say: is that happening or not? I know, for example, that before a patient gets a repeat prescription for warfarin someone needs to ask the question: “When were you last assessed?” When was your last blood level taken and what was it? Is there a record of it? So that I know that I am giving you five milligrams of warfarin, that is going to be within the accepted norm, or I am giving you too much and you need to cut back on that. So I do not need to know the exact number there; I just know that in good practice that is what should happen. I think a lot of general practice is like that. We know certain things that should happen but are not happening and we can focus on that, and that means a better understanding of processes. Of course I think that having the numbers helps, because if we want to put in very expensive intervention, something different or unusual, then we do need to be able to evaluate it. Again, we can focus on different areas and see if we can improve those, but I think we should not use that as an excuse to say we cannot do anything. That is the only point I am trying to make in that respect.

Q576 Stephen Hesford: So would you agree with the statement that there is awareness at a fairly significant level that patient safety in primary care is an unaddressed problem?

Dr Holmes: Yes. I think so, and I think all the big agencies, the National Patients Agency, the Government, even at a European level, are beginning to understand that there is a whole amount of work and understanding to be done in primary care and they are beginning to focus their attention on it. I am, for example, being asked increasingly to talk about areas in primary care, research money is becoming available to work in this area, so I think there is definitely a realisation now that there is a whole lot of work that needs to be done in primary care and think more effort and attention is being directed to that. In terms of awareness, I do not think there is a problem, because I think virtually every general practitioner. We did a study, for example, when we asked general practitioners over a three-month period to record things that should not have happened, and we were amazed, just in our small practice, how many incidents came up. We had instances where there was delayed diagnosis.

Q577 Stephen Hesford: Were those anonymised?

Professor Esmail: Yes, they were anonymised.

Q578 Stephen Hesford: Otherwise you would not get anyone telling you.

Professor Esmail: We had to do it that way. I made this point earlier before you arrived. Those sorts of issues still are not resolved in primary care, for example. Yes, there is the whole argument if we make them completely anonymised, we cannot find out the detail we want sometimes, but when we did our study, and we did it across Europe—

Q579 Stephen Hesford: But it is a start?

Professor Esmail: It is a start. That was crucially important because in some ways general practitioners were able to unburden themselves of something, and we do this now in our practice every year. We have a four-week time when we say, “All right; we are all going to report things now for a four-week period”, because we know that is sustainable. Our research evidence shows, wherever we have done it, that after about three months it begins to fall completely and people do not do it, so we have a one-month campaign and we say, “Let us report.” We have reminders and everyone is doing it, and then we collect the information and we the use it as a feedback, and we plan to do it at different times of the year so we will get a range of things going wrong and be able to investigate what happened.

Q580 Stephen Hesford: So it becomes not exactly scientific but it has a representative nature?

Professor Esmail: Yes, and I think the point is it has the effect of actually getting you to improve things, and that is very important. It means that when you find out, for example, that a patient had a blood test done and it was not followed up, you invariably go and look at your systems and what are our systems of follow-up. When a patient comes for a blood test what reminders do we have, what sort of prompts do
we have to make sure that someone follows up on that result. So it tells us to do things like that, and I think we can hugely improve systems in primary care through those sorts of techniques. We also have techniques like significant event audit. We have a system whereby we ask people to make a record of something that goes badly wrong. It is a significant event, it is not something minor; something that they feel is really big. They will make a record of it and we will discuss it as a team, and, as a result of our discussion, we will say, “Gosh, this is not very good in what happens. It highlights a flaw here. It shows we do not do this very well”, and we then actually get someone, or a team of people, to go and make the changes and we hope that it does not happen again, but if the problem arises again, we have a record of what happened before, we can follow the audit trail to see what happened. Those sorts of things can be very important and should not be neglected.

**Q581 Dr Taylor:** Going on with significant event audits, do you only look at those four weeks at a time?

**Professor Esmail:** No, that is an ongoing programme. We just talked about reporting. We have a computerised base system. For those four weeks we want them to report everything that goes wrong, from their perception, and we will get everyone to do that—nurses, reception staff, the people who work in the admin office—so everyone knows that that is the four weeks we try to collect information on. That is the purpose; it gives us an idea of how big a problem it is. Significant event audit goes on throughout the year, because I may find out last week something happened. If I got a very poor discharge of someone from hospital, I did not know something that should be happening, then I should log that so that when we come to discuss it we know. How can we actually contact the hospital to make sure that this does not happen again? Can we make sure that it is followed through? Does that audit loop get closed? Can we make sure that we have something in place that we know it is not continuing to happen? That is what significant event audit achieves, and that has to happen all the time.

**Q582 Dr Taylor:** Could you give us some other examples of what are significant events?

**Professor Esmail:** I will give you an example of a patient of mine who was discharged from hospital with a diagnosis of cancer, which I was never told about, and nor was she. Eventually we were able to find out. We kept insisting: “Why have we not had a proper discharge letter?”; and we then discovered this happened. That was a terrible case really, and what happened on that is that I discussed this. We discussed it as a team. We wrote a letter to the hospital. We asked them to investigate it. We expected a response back again. We hope we have a system in place so that that should no longer be the case, and things are improving on that. That is an example of significant event audit.

**Q583 Dr Taylor:** That is really something happening in secondary care though. What about significant events in primary care?

**Professor Esmail:** A common problem is someone has a blood test done and is found to have anaemia and we do not follow it up. We look at it, we see that the haemoglobin is low and it is just put down as probably due to iron deficiency anaemia, but actually it might be something more significant. We might have to do more investigations to see is there a cancer underlying that, are those investigations followed up, who is going to carry them out, and so on. It is becoming particularly important in primary care: continuity is a real problem. You might have one doctor seeing the patient and then someone else having to follow it up three or four weeks later, and if the record keeping is not good or the audit trail is not good, that might get missed. That is a very common example, when we have a result which might signify something more serious but is not followed up.

**Q584 Dr Taylor:** Has incorporating SEAs into the QOF made any difference?

**Professor Esmail:** I do not think it has yet. The reason is because the way that people do significant event audit in general practice varies hugely from practice to practice, and we need to have a standard way of doing it, we need to have a standard way of collecting information, we need to have a standard way of making sure that information is shared, and all that the QOF does is say, “Do you do it?”, yes or no, and that is it.

**Q585 Dr Taylor:** So you can get the money if you say, “Yes”, even if you do not do it?

**Professor Esmail:** That is lying, and that should not be the case. The point is you can do it, but are we learning from it. That is the critical question. Also important is: are we sharing the information? I might have a problem in my practice. I work in a primary care trust where there are 50 other GPs, and what I have found is a problem may also be very relevant to others. Are there mechanisms whereby we can share that sort of learning? That does not happen consistently—even the mechanism of recording them, for example. The Royal College of General Practitioners has just launched a significant event audit tool kit which suggests a format for collecting information, for reporting on it and so on, and that is only recent, but that has been the problem. So the QOF merely asks you: “Do you do it?”, yes or no, but really the question is: “How do you do it, what do we learn from it and how can we make sure it does not happen again?”

**Q586 Dr Taylor:** Even though it has been going for some few years, you have only just got a tool kit of how to do it?

**Professor Esmail:** Yes. No, a tool kit for standardising it.
Q587 Dr Taylor: Which is what it has to be?
**Professor Esmail:** What it has to be, yes. Actually significant event audit pre-dated QOF. GPs were doing it in some areas of the country ten years back, because they saw it as an important way of driving improvement. So when someone dies unexpectedly many good practices were reviewing that information and saying, “Why did they die unexpectedly? What was going on here?”, and they look at the period of care. So that was very, very important. We do it with every cancer death, and we do it, not because of some terminal cancer stuff, but we actually look at the quality of care. Was there a good follow-up? Were people informed correctly what should happen when they died? All this information is very important. We do that routinely, for example, for every cancer death. We do a review of it.

Q588 Dr Taylor: Does the tool kit standardise what is significant?
**Professor Esmail:** Yes, it will have. The point about significant event, you tend to leave it to the practitioners and the reporters to determine it. You cannot say that is irrelevant, because from a patient’s point of view it might be very important, so we tend to leave that open: either the patient raises it and we say, “Gosh, that should not have happened”, or the practitioner raises it. You cannot predefine a significant event. I think it has to be determined a lot by the circumstances and the context it occurs in.

Q589 Sandra Gidley: I must admit, I am somewhat horrified that the evidence is that GPs will not report the lower level stuff if they have to do it for more than three or four weeks, because one would have hoped that there would have been sufficient interest in improving things for patients that this would become endemic, embedded good practice.

**Professor Esmail:** It is not that they will not. The National Learning and Reporting system, as you probably know, if you look at the reports from primary care it is point 5% per cent, and most of those from general practice, so it does not even include community pharmacy, it does not include district nursing and areas like that. Is it because they do not want to or is it because they have been asked the wrong question and asked to report the wrong thing? I think that if you look at a practice like ours, when probably about 500 or 600 patients are seen every day—we have 18,000 registered patients—the volume of work is immense. The reality is that you are so caught up in the day-to-day running of things that to have a system without doing a lot more work and without the culture changing, where every incident is reported. We even have to ask ourselves, “If you report everything what is going to happen to it?”, and we do not have the capacity to even analyse everything that comes in.

Q590 Sandra Gidley: I am sure there was that attitude in hospitals once, but they seem to have managed it in hospitals. I do not buy into this, that primary care so is rushed that they cannot do things that are good practice elsewhere?

**Professor Esmail:** All right. I understand what you are saying and I realise that it comes across that we do not want to or we do not care. I am just saying that this is based on a research project of ours, and that is what we found and we have had to react to it. We found this was not just the case in Britain, we found it was the case in Australia, in the Netherlands, in Canada, in America. This was a universal problem. I think we have to ask ourselves: how can we sustain that level of reporting? One of problems is this. A lot of things that happen in primary care, whilst they should not happen, have no consequence, and that is another problem, which is why things like significant event audit have got a catechism in general practice which has been very powerful: because when something terrible goes wrong it really concentrates the mind.

Q591 Sandra Gidley: That is fine, but the lower level events and the near-misses can often educate about a potential problem as much as a significant event?

**Professor Esmail:** Yes, and that is why we have said if we can do it for a month at a time and vary that over a period of years, we will build up a very, very important profile, and we can sustain that and have good quality data and we can then work on that, and that is very important as well. I think that sort of model might work better in primary care than in hospital, where you have better structures and organisations, and so on, to do that.

Q592 Sandra Gidley: I am not convinced, but I think we are going to go round and round in circles. Let us get to some specifics. Is there a problem with prescribing and medicines management in primary care?

**Professor Esmail:** The research data shows that there is a lot of interaction. This has come about from all sorts of work where patients are admitted to hospital, for examples. Many admissions are due to drug interaction, so again we understand there is a problem there. I think at one level we have quite good safeguards in primary care. We have been computerised for a long, long time and our computer systems are constantly improving. For example, we get warned now if you prescribe something and there is interaction with another drug. That is quite sophisticated and has been around for a long, long time. We know that there are problems with the system still, but they are constantly being improved and I think people are aware of that, so at that level we are moving towards electronic prescribing. Virtually no-one writes handwritten prescriptions because there are transcription errors, for example.

Q593 Sandra Gidley: They are not allowed to; that is why they do not.

**Professor Esmail:** Yes, but the point is that that is an error that rarely exists now. Sometimes when you go on home visits you have to write handwritten prescriptions, so that still happens, but that has become minimal now, so those areas have gone. We, for example, recognise the problem and we employ a pharmacist. In fact the research shows that the solutions are not necessarily in the technology but in the people, and because so much prescribing goes on
in general practice, it is so important, we have actually employed a pharmacist who works alongside the doctors and helps us towards identifying problems where things are not going right, develops systems so that things happen properly, and in our case I would say that has made the most impact. We have good computerised systems and I think that that has helped tremendously, and where the problems arise probably are when people go into hospital, because there is not good exchange of information that goes across that, and, secondly, when people are discharged from hospital. I think when general practice handles the prescribing, on the whole, it works pretty well and I think that pharmacists play an increasingly important role in helping us reduce error in that area.

Q594 Sandra Gidley: Is there a problem with variable quality of diagnosis in primary care?  
Professor Esmail: We have always known about. I would not say variable quality. The research was based really on our small studies which we did, where we got people to report things and find out what went wrong, but also by looking at the litigation databases, for example, and what had people complained about, and what was surprising, what stood out very clearly in primary care, was that 50% of the cases in the litigation databases we looked at were because of delayed diagnosis. What happens is that someone has a condition and it is picked up quite late. Let us take a simple example of a bowel cancer. The problem is, of course, that they present sometimes with very non-specific symptoms, it may take three or four months before the diagnosis becomes known and they get referred at that point. So we know that delayed diagnosis is a big problem, it stands out, it really hits you in the face, and of course the reason for this, when we do work around diagnosis in general practice, is that things that come to general practice in primary care are very undifferentiated; people do not come with a glaring symptom. If someone came to me saying, “I am bleeding rectally”, that hits me in the face, and says, “Yes, we need to examine and understand why that is happening”, particularly if you are in a particular age group, but what happens is they come in and say, “I have not been feeling right for a while and I am not quite right here and I have got a bit of pain in my stomach.” You investigate, you look at this, and it is a rolling process and when you have completed the process, you say, “Gosh, this is a cancer”, and yet you can see they presented three or four months down the line, and from the patient’s perspective they say, “I have had this for three or four months”, but, of course, if I just referred everyone to hospital with those non-specific symptoms, we would bankrupt the system; it just could not sustain itself. So there is always that balance of trying to say when is it serious, when are the problems arising and how can we investigate as much in primary care before we refer people on? There are many examples like that: headaches which people talk about. We know that headaches are a sign of brain tumours, yet if we scanned everyone with a headache we just could not sustain that; our system cannot allow that.

Q595 Sandra Gidley: Is there not some evidence that there is a huge difference in the way individual GPs would react to those sets of symptoms, which is why the referral centres were introduced?  
Professor Esmail: That is right, and they have made a huge difference, I think, in making early diagnosis available, but we have not actually done the research to see whether it has reduced that.

Q596 Sandra Gidley: Some would say that it has gone the other way and when GPs have wanted to refer, if they are seen to be referring more than the people down the road, they are asked to look again. Who is to say who is right?  
Professor Esmail: We do not have the research evidence on that—that is what I am trying to say. We have put in these innovations. It is too early for us to even understand whether it has had an impact on things like delayed diagnosis, but what you say is absolutely right: we know there is huge variability. Of course the thing that struck me when I was looking at the research in this area is sometimes you have what I call ‘barn door cases’ and you just cannot understand why it is that people miss them. You look at the case and you read the medical legal summary and you think, as an outsider, that is an obvious case of a heart attack, and yet it was missed by the doctor, and then you ask yourself: “Is it because they did not know?”, and you think that may be the case, but it is highly unlikely, it is something that you learn really early on, so what else was going on there? I think that when we begin to understand this we begin to realise the complexities around the situation. For example, the patient had had a long history of chest pain which has never amounted to much and has been diagnosed as having indigestion, but on this occasion it was because of myocardial infarction, for example, and it can be very difficult to distinguish. These sorts of things become much more complex. So we are beginning to realise that when we look at diagnosis it is as dependent on the patient as it is on the clinician as it is on the context of where you are and when you were, and so on, and it becomes very, very difficult.

Q597 Sandra Gidley: You are describing something that is more of an art than a science by the sound of it. Is there a role for automated decision support systems that would mean you have better outcomes?  
Professor Esmail: I think they can help, definitely, in some areas. The problem is that because things are so dependent upon the context, we do not have good enough systems that can tell us about it. For example, if I get a prompt with someone who comes in with rectal bleeding and the prompt simply says, “Think about cancer”, if it is a 20 year old, that is not helpful, but if it is a 50 year old, it is. Somehow you need to have a system which can not only look at it by age, for example, which is a simple example, but, more importantly, might able to look at it by things like ethnicity, might be able to look at it by other factors that they have, other co-morbid conditions, diseases and so on, and can give that information. That is the holy grail we all look for, and I think we are a long way
away from that because it is actually very, very complicated. I think the NHS is littered with examples where someone has come along and said, “This will do it” and people have invested huge amounts of money into it and it has not delivered it. I think, yes, we should try and achieve that, but it is far more important probably to try and get doctors to work together, to understand these things, to feed back relevant information, for example, to look at cancer referrals, see what is happening about that. We can do a lot around training and improvement before trying to say: let us put all the money into trying to find a technological solution which I am not entirely certain will work.

Q598 Dr Naysmith: Professor Esmail, I want to ask you a question in a minute or two about the role of commissioners and also about the role of registering of GPs and so on. First of all, I would like to ask you: why is it there is still such a large amount of over prescribing of antibiotics by GPs? Dr Holmes went on at some length about the importance of not allowing the emergence of resistant bacteria, but GPs still do it, and we know they still do it, so why?

Professor Esmail: I would question whether. I think, for example, it is very common now; it is part of the commissioning process. We get feedback on the antibiotics prescribed for conditions and we have targets, in effect, and we use those internally. If we see that we are over prescribing, for example, if we look at our diagnosis of upper respiratory infections and we say, “Why is the prescription writing very high?”, we look at that and say “Gosh, what is going on?”, and we even look at it by doctor then and, as part of our review, we take it up with each other and say, “What is happening here?” So I would question that. I think there are many improvements that have happened. It is always given as example that GPs over prescribe. Looking at it from my part, I get people home, discharged from hospital and I think, “Gosh, they have been given a whole paraphernalia of drugs which I do even go near.”

Dr Naysmith: No-one would dare over prescribe in Dr Holmes’ hospital; they would not dream of doing it.

Q599 Dr Stoate: It is our job to stop it all, is it not!
Professor Esmail: That is right, yes

Q600 Dr Naysmith: You do not think it is a problem.
Professor Esmail: I think there is a problem, but I think that things that have happened change hugely. Take a simple example of urinary tract infection, I would imagine if you did an audit of urinary tract infection prescribing in general practice you will find that the vast majority are prescribed for three days, prescribed one antibiotic, trimethoprim, which is used in 90% of cases, and will then follow it up if it is not. If you had looked at that eight years ago you would have found a totally different pattern. I think if you looked at diagnosis of upper respiratory infections you would find that there is a lot less prescribing for sore throats, and so on. I do not have it at my fingertips, but I would like to see that data.

Q601 Dr Naysmith: It still goes on, based on some of the conversations I have with GPs, some of whom I know quite well. Let us move on. Do you think that primary care trusts acting as commissioners play enough role in ensuring safe practice in primary care particularly?

Professor Esmail: I think primary care trusts are only beginning to wake up to the idea of the importance of their role and what they can do as commissioners, especially in terms of improving patient safety in primary care, and I think they are actually scratching around to try and find out what that role entails because they have only come to it very recently. So I think there is going to be a lot of feeling to see what is going to be acceptable and what is not going to be acceptable. What will not work is if they say to doctors, “You must do X, Y and Z”. because from my experience as a researcher am guilty of it, I think up simple solutions and say, “If only everyone did this we would solve the problem”, and I know it does not work that way. I think that commissioners are going to have to be careful about what they target, in terms of the way they want to change things, and then work together with people to do that.

Q602 Dr Naysmith: Can you include examples of commissioning changing practice?
Professor Esmail: Not yet. This is a very new area and I am working together with our local PCT, and I know there are examples in Wales and there are one or two PCTs that are beginning to work on this, so we really are talking about a handful of examples at the moment. They are doing things like saying, “All right, can we, for example, begin to try and understand how big a problem it is?”, and they are using things like the global trigger tool, which is doing a systematic audit of notes in certain areas to find out how big a problem that is. The significant event audit tool kit, for example, will enable PCTs to say: can we have a look at these and see what lessons can be learnt across the board? I think prescribing is going to be a constant area they will be looking at.

Q603 Dr Naysmith: It is work in progress?
Professor Esmail: Very much so.

Q604 Dr Naysmith: It is simply worth pursuing.
Professor Esmail: Definitely, and I think they are all looking around, and I know this because I am getting more requests to speak on how to work with PCTs, so I think this is work in progress. I think they can flex their muscles and play a very important role, but they have got to built up those relationships in order to do that change.

Q605 Dr Naysmith: Can I move on to question of revalidation and the need for GPs to register with the Care and Quality Commission. Do you think that will affect patient safety, do you think it will help, or do you think it will produce a burden on the system, an unnecessary burden, bringing in the practice of too much bureaucracy?

Professor Esmail: I am sure the intention of the policy-makers is that it will help. I think the outcome will be that it will probably provide a burden and,
again, we will have to work through what is going to be suggested and what it will involve. I think potentially revalidation, as an example, will become a very powerful instrument for monitoring individual care and, if it is applied effectively, I think it will be a huge tool for improvement across spectrum, so I have high hopes for revalidation, but I hope it does not become burdensome, that it becomes part of quality improvement rather than about regulation. I think will be a great problem if it does become that.

Chairman: We are with you now, Professor Griffiths. We are running late but we have a number of questions for you.

Q606 Dr Stoate: We have heard this morning that there clearly is a problem with prescribing and medicines management affecting patient safety, but do we have any idea of the scale of the problem?

Professor Griffiths: Yes, there is some evidence out there. The NPSA did a report: Safety and Doses. It is a really, really good read and should have been a good read for all practitioners. Unfortunately, it has gone to clinical governance managers and senior managers and I do not think it has hit the practitioners that it should have, because there is a lot of evidence in there and a lot of incidents that are raised. In there is a study by Pirmohamed et al of about 19,000 patients which showed that about 6.5% of all hospital admissions were down to a direct result of medication incidents or harm, about 9% were preventable, and about 63% were probably preventable. That is a smallish study, 19,000 patients, but there are studies from the US that mirror this, and although it is a different health economy, there are transferable pieces of research that do come across that mirror that we are causing harm with medicines.

Q607 Dr Stoate: Do you think there is enough evidence or do you think we need a lot more?

Professor Griffiths: I think we probably need to go back and redo similar research, so that we can see, like for like, if we are getting any better. The NPSA report showed 60,000 medication incidents over an 18-month period through the NRLS and it basically cost the NHS around £750 million, let alone the suffering that it caused to patients.

Q608 Dr Stoate: Clearly it is something we need to address. Just to pick up on something Professor Esmail has already said, what about doing more research in general practice? Is there a significant gap there?

Professor Griffiths: In the report into NRLS, about 80% of the report came from secondary care, even though there are two million prescriptions per day in the NHS and the vast majority of transactions occur in primary care. Although the vast number is in primary care, therefore, there is still vast under-reporting. There are several reasons why there is under-reporting. To some degree, with the old paper reporting forms people felt disenfranchised with the system, that if they did something nothing was going to be done about it. I put in reports about assaults when I was in practice in casualty and nothing ever seemed to change. There is this disenfranchisement that practitioners have: If they are going to put in a report, what is going to happen? I think that the newer forms, the Datex, the computer reporting, although they can take a little while to work through you can copy certain managers in, so you can make sure that it gets to the people who hopefully will make the decisions to action the incidents.

Q609 Dr Stoate: What do we do with the problems we do not know about? Okay, we can do significant events. I think most GPs are reporting significant events. It is easy to do so, and most practices now are having quarterly meetings on significant events, so it is a problem that is being dealt with. What about the problems that GPs are not aware of? For example, in many prescription areas or other areas they have no clue that they have made an error, so how do we get evidence on that?

Professor Griffiths: Particularly in primary care, a prescription may go out and it may not even be picked up that there is an incident. In secondary care it tends to be a bit tighter, in terms of there are more links in the chain that you have to go through for the process of dispensing medicine. In primary care it can go straight from the doctor to their own dispensing pharmacy, which does not have a pharmacist but a dispensing technician, and then it goes out to the patient, so there are less links in that safety chain.

Q610 Dr Stoate: If, for example, a GP has made a wrong diagnosis and given the wrong medicine, that does not necessarily do the patient any harm, so the patient does not come back and complain of side effects but nevertheless a mistake has been made. How do we even begin to address that?

Professor Griffiths: There has been opening up of reporting through the NRLS, and through yellow card reporting—which is slightly different: it is about adverse drug reactions.

Q611 Dr Stoate: That is only takes up adverse effects. I am talking about a patient who has simply been given the wrong medicine, nothing whatever to do with their diagnosis. The patient takes that medicine for two months, just as instructed, but it is completely the wrong medicine. If no harm happens to that patient, it is a fairly significant event but there is no way of knowing about it.

Professor Griffiths: I understand what you are saying, but I was trying to say that the reporting system, through yellow card reporting and NRLS, is open to patients if they know about it. The problem—

Q612 Dr Stoate: How would they know about it?

Professor Griffiths: This is it. How would the doctor know about it?

Q613 Dr Stoate: That is my question. Is there any way we could improve education and training to try to reduce this?

Professor Griffiths: At the moment there is not a system in place that will necessarily pick up all of those incidents. There are specialist pharmacists that
will look at prescribing patterns within PCTs. Like Professor Esmail said, there is PACT data, prescribing data, which can be assessed and can be peer reviewed, and so you can see certain things there, but without looking at each individual case and reviewing each individual case it is very difficult to say that was inappropriate. There are two million prescriptions a day.

Q614 Dr Stoate: Do you see a case for more automation and expert systems?
Professor Griffiths: Yes. We have PACT data in primary care. Secondary care lacks prescribing data considerably. Everything goes on the medication administration review charts. They are paper based or cardboard drug charts, which, as soon as the patient is discharged, go into the medical notes and they get archived and library services take them off and put them away. The problem with that is that it is very hard to audit individual practitioners where you have a paper system, half of which is archived away. Electronic prescribing in secondary care will make a big difference in terms of audit and in terms of a review of prescribing patterns which is not there at the moment.

Q615 Dr Stoate: I would like to see, and I do not know whether you agree with me, is effectively NICE guidelines and NICE data being built into a GP expert system. If you, for example, typed in a diagnosis of hypotension, up would come NICE guidelines which I believe would make it less easy to make a significant prescribing error. Do you think there is a place for that?
Professor Griffiths: I think there is. I think there are very good systems out there at the moment. Clinical knowledge summaries does a lot of guiding practitioners. I also agree there has to be some flexibility in the system because of co-morbidities, age, different things, but there is a lot of decision support software out there. I have been looking at e-prescribing recently within the Trust I am working in, and the problem with some decision support software is that practitioners can get turned off by it. They do not want to see pop-ups all the time. If you get a pop-up repeatedly coming up for something that is very, very routine, then you can start to ignore those warning pop-ups. There is a potential that they can be overused, in which case you get a sort of burn out for the practitioner.

Q616 Charlotte Atkins: Dr Howard Stoate raised issues around non reporting of incidents but is the National Reporting and Learning System Data being used to help in terms of management of safety?
Professor Griffiths: Yes, to some degree. Things like the National Patient Safety Agency again does use the reporting where it sees significant incidents in terms of putting out the rapid response reports which are really, really helpful. Although we get the information in, there are feedback reports, quarterly data summaries, organisation level patient safety reports and bulletins which not very many practitioners would probably access. I think patient safety is taken extremely seriously in the NHS, but because there are so many facets to it, practitioners sometimes get overkill in terms of how many emails they receive, how many memos they receive. Pressure care, skin care, child protection, vulnerable adult protection, fire, infection control, you name it, everyone is looking after their own particular area. I am just as guilty in that with anything to do with medicine safety within my trust it is a case of “he who shouts loudest”. You try to get your messages out about your particular area and I think that is probably the case. Although the NRLS can get messages out, I think that sometimes practitioners can get swamped by the amount of messages coming to them from different directorates saying, “You must do this for child protection” or “You must do this for infection control” and from me saying, “You must do this from the medicines management point of view.”

Q617 Charlotte Atkins: Is the whole process of reporting this used as a learning experience, the fact that they have to report issues around safety? Obviously there is no point in just collecting the data if it is not used to improve the experience for the patient.
Professor Griffiths: They are used. As I said, that is why it was a shame that this did not go out as widely as I would have liked it to. I think it should be a “must read”. There are lots of anecdotes in here. Okay, there is evidence as well, but some of the stories, being anecdotal, hit home. Practitioners can think, “Oh, there but for the grace of God go I.” There are ten-times dose incidents in here. They happen time and time again internationally. There are cases of medicines that are meant to be oral going down intravenous lines. We had the famous case of vincristine being given intrathecally. It has happened worldwide 20 or 30 times in the last ten years. It is still happening. Vincristine is being given intrathecally around the world, even though we brought in measures in the UK. When you read these sorts of shock horror stories, the fact is that if you are going to give someone some oral medication and you think it is going down a PEG tube, you will check it is a PEG tube and not an intravenous catheter. These things bring home incidents to practitioners because they can put it into some sort of context to do with their own practice.

Q618 Charlotte Atkins: Does it mean that those particular incidents are not repeated but other similar sorts of problems arise? Is there any real evidence that the reporting of these incidents is leading to an improvement in practice and in systems?
Professor Griffiths: Yes, I genuinely believe that there is. There are issues in here about issues for medicines. We have just brought in a new policy into our trust where if Parkinson’s disease patients or epileptic patients do not receive medicines, if they have their medicines omitted for one reason or another, because the drug is not in stock, for example, patients can
come to harm. In the case of Parkinson’s disease, for example, the average patient spends an extra five days in hospital because we do not get their medicines to them on time. Nurses generally are extremely strict on admission units and they will not give a medicine until it is prescribed. If someone has been delayed in the admission period, then they will not give a medicine because it has not been prescribed by the hospital doctor. We have brought in a policy, as a result of looking at medication omissions, to try to ensure that these patients do get their medicines in on time. If we stiffen a Parkinson’s patient up by not giving them their medication on time, it can delay the whole hospital process and they suffer as a result. We are tackling things. There is allergy information in here—one of the other recommendations. We are making sure that we are trying to adhere to all the allergy advice, ensuring that we have other things in place. Another common issue is that sometimes patients have a penicillin allergy and it has been documented but they are prescribed a penicillin-type medication. Because it is branded and not down as a penicillin, they can then sometimes get administered that penicillin medication, so we are trying to tighten those so we have workshops around the hospital, seminars, as well as posters, warnings, stickers on boxes where they contain penicillin. We are actioning it and I do think it does make a difference.

Charlotte Atkins: Thank you.

Q619 Dr Naysmith: Professor Griffiths, if clinicians continue to practise unsafely in their use of medications, at what stage does that become an issue for managers and regulators?

Professor Griffiths: Practitioners are working on safety. It is obviously a big concern. The Fitness to Practise Report of the Nursing & Midwifery Council last year showed 14,087 potential new cases. 9.87% were down to maladministration of drugs and 7.75% were down to unsafe practice. The NMC have very, very strict guidelines. Their primary purpose is to protect members of the public. We have very strict medicine standards. They were guidelines and they were made standards. We have strengthened language in there, so that and “should” has been replaced with a “must”. We also have very good standards on prescribing. They are very comprehensive. Generally, if nurses are referred to the NMC they tend to be referred by colleagues. Again, we have quite an open process where nurses will refer other colleagues to the NMC. There is an article in yesterday’s Nursing Standard which I wrote about medicine storage and security. It basically encourages people if they see poor practice to report to the Nursing & Midwifery Council. I do think it is something we do as a profession pretty well. There are about 30 people doing my role around the country, senior nurses in medicines, and we do a whole host of different things but one of the things is to audit, to look at competencies. We do calculations and assessments of skills around the administration of medicines. At the moment I have 4,500 nurses that have that every year, but we are also going on to e-learning and competencies for our prescribers as well.

Q620 Dr Naysmith: In terms of reporting, there must be a balance. We were talking about a fair blame culture and the self-reporting of adverse incidents and so forth earlier with Professor Esmail. At what point does unsafe practice become a disciplinary matter? Colleagues reporting colleagues will eventually lead to a disciplinary matter.

Professor Griffiths: I think there needs to be a balance and it tends to come down to the individual manager.

Q621 Dr Naysmith: Should it depend on the individual manager or not?

Professor Griffiths: I think it should do because there are sometimes extenuating circumstances. Fair blame should be just that; it should be fair. I do not think it should be a scapegoat system. If we go to a scapegoat system completely, I think you will see a huge drop off in the amount of reported incidents, and I think there is a fine balance to be had. In terms of the formalising of the process, at the moment Datex and other type of incident reporting does not require any names. Again they have tried to meet this balance. I am not sure if that is necessarily the right thing. If it is a fair blame, you can be open about it and put names in. I still think it needs to be documented just to see if there are patterns occurring if practitioners move from one place to another. There is a fine balance between where you would have anonymous reporting and where you have named reporting but I think that it has to be balance, as I have said, with the fact that people are not made scapegoats out of and punished unfairly.

Chairman: We are nearly running as late as your train, Professor Griffiths, in this session. If any of you have observations coming out of this session or any further observations, we would be more than happy to take them by email or on paper or whatever. Thank you very much indeed for coming along and helping us with this inquiry.
Witnesses: Dr Jo Bibby, Director of Improvement Programmes, The Health Foundation, Dr Olga Kostopoulou, Medical Decision Making Research Group, Birmingham University, and Captain Guy Hirst, retired airline pilot, human factors trainer, gave evidence.

Q622 Chairman: Good morning. Welcome to our fifth session on our inquiry into patient safety. For the record, could you please introduce yourself and the current position you hold.

Dr Bibby: I am Dr Jo Bibby. I am the Director of Improvement Programmes at The Health Foundation.

Dr Kostopoulou: I am Dr Olga Kostopoulou. I am a research fellow at the University of Birmingham.

Captain Hirst: I am Guy Hirst. I run a consultancy for research and training in medicine called Atrainability. I was for 34 years an airline pilot involved in training pilots, mainly technical training but also, for the last 15 years, human factors training. I was involved during the transition, from before we had human factors training until after I retired two years ago.

Q623 Chairman: I will ask a general question to all of you and then there will be specific questions from individual members of the Committee. Which three changes do you think would make the biggest difference in improving safety culture inside the National Health Service?

Dr Bibby: The first of the three things we would advocate in The Health Foundation is that there needs to be a greater awareness around the avoidable harm that arises from routine clinical care. We also feel that there needs to be a building of the belief that this harm can be avoided if clinical teams have the right skills to address patient safety issues. We feel there needs to be a much greater culture of openness and learning by looking at the reliability of routine clinical care, so that clinical teams can engage in that and the defects that are arising. In the organisations we have worked with in our programme Safer Patients, we feel that all those three culture changes have played a part as a result of the programme.

Dr Kostopoulou: Since most of the NHS consultations take place in primary care, I think that any improvement in safety in primary care is likely to have a large impact on patients. One thing we have been ignoring or under-researching is the importance of prompt and accurate diagnosis of serious conditions in primary care. GPs, as the first point of contact, are very well placed to catch these conditions early. Conditions like the cancers that we talked about earlier, rapidly evolving infections, ischemic heart disease can really benefit from early detection and treatment. It is a very difficult job and sometimes it is not done well. We know that it is not done well because patients complain. More than 60% of claims against GPs are about diagnostic errors. The way we can support a diagnosis in primary care is through medical education, through training of doctors and, also, through the improvement of the electronic health record to include things like diagnostic support or other types of support during the consultation.

Captain Hirst: These are all small ideas, things could be done on a day-to-day basis. First, accept that error is normal. It is ubiquitous. We all make errors. Good, successful team working can avoid, trap and mitigate the consequences of those errors. Second, a bit of discipline in procedure and practice—and most of my work is being done in secondary care, in the hospitals—so that all the team can take individual responsibility for safety. That can be done quite easily by having a decent briefing before the day starts and a debriefing afterwards to learn from it. Third, general human factors training and coaching. A study in Boston showed, for instance, where they had a major situation there, that just training the entire team on communication protocols made a huge difference to safety. They went from almost becoming a failing hospital to a superb hospital. This is Boston in America, by the way, in case any of you are from Lincolnshire.

Chairman: Thank you.

Q624 Dr Taylor: Dr Bibby, your foundation is running the Safer Patients Initiative and Safer Clinical Systems programme. Can you tell us a bit about these and what they have achieved?

Dr Bibby: A little background on The Health Foundation. We are an independent charity. We have been working on patient safety for the last five years and we have invested upwards of £10 million on these programmes and other work. Perhaps I could give you an overview of the Safer Patients Initiative, which is our longest running programme and then move on to the Safer Clinical Systems. Safer Patients started over four years ago with four hospitals, working with the Institute for Healthcare Improvement in Boston in the United States. It was the first exercise of its kind, in that it was trying to look systematically across an organisation at how you can routinely and reliably implement evidence-based practices to improve patient safety and how you can create the right leadership framework to ensure patient safety. About three-quarters of the way into our first programme we extended that to a further 20 hospitals and they have just finished their phase of working. We are now keeping these organisations going in the form of a network. The work that we have done in safer patients was very much around acute care. We are now starting to ask if we can transfer some of these approaches into mental health community-based services, and we hope other sectors later this year. One of the things we learned when we were doing Safer Patients was that individual clinicians wanted to provide reliable care, they knew what they needed to do, but often the system they worked in did not support the delivery of that care. It might be that they did not have the supply of the right equipment, not the right clinical information, there might be issues around prescribing and medication systems. From that learning, we decided to set up a further programme of work that started just last October that focuses much more on these systems of care that provide the platform. Perhaps I could talk about some of the achievements. At a broad level I think we have demonstrated some quantifiable improvements in the reliability of care and the reduction of harm. We have seen the approaches in this programme being
adopted across the four UK countries. Wales, Northern Ireland, Scotland all have national programmes going on using these approaches. In England there is the National Patient Safety campaign and we are working with some specific strategic health authorities to adopt similar approaches across their patch. In the organisations we have worked with we see a shift in the safety culture and something that can be sustained. What has been provided to clinical teams and those organisations is a set of skills. They say to us: “Now we know how we can tackle safety issues beyond that which was in the original programme.”

Q625 Dr Taylor: I think you tell us that under Phase 1 there were impressive safety improvements at the four hospitals. After just two years they had on average halved their number of medical mistakes. That is really very impressive. Then you have added another 20. What are the initial results there?

Dr Bibby: There were five work streams within the programmes, so I could give you some examples, a flavour, of some of the results that have been achieved there. One of the work streams was around safety on the general ward and we mentioned in our submission around the reduction in cardiac arrests at Luton and Dunstable Hospital that were achieved by a system of an approach that ensured that they were monitoring the condition of patients much more reliably, carrying out key clinical observations on a reliable basis, making sure they were detecting any deterioration and acting on that earlier, so that patients were not deteriorating to a point that they might—

Q626 Dr Taylor: So you really did reduce crash calls by 30%?

Dr Bibby: The reduction in crash calls was around six fewer crash calls a month at Luton and Dunstable.

Q627 Dr Taylor: We have a list of the targets you set and the target for crash calls was a 30% reduction. Did you achieve that?

Dr Bibby: I would say that the targets were not necessarily uniformly achieved but we would say that the purpose of putting targets in to this programme was to set something to aspire to rather than saying this is a success or fail. We then looked at what was achieved in the individual organisation—so we can say, yes, that there was a significant reduction, six fewer cardiac arrests a month at Luton and Dunstable. There were other sorts or reductions that we saw. For instance, we had a work stream around critical care, where we wanted to reduce infections around critical care. An example there is at the Royal Free Hospital in London. At the start of the programme they were having 18 infections per thousand bed days within their critical care unit. They reduced that to nought by August 2007, so about a year into the programme, and they have sustained that. By introducing what we call a care bundle around the management of central lines, they have been able to eliminate central line infections from their programme. Going back to some of the evidence earlier, another area that the hospitals worked on was around adverse drug events, around anticoagulation. Again one of the hospitals that we were working with was able to achieve a 40% reduction in adverse events associated with anticoagulation. The programme set out a set of targets and goals that it wanted to achieve which it believed was possible. Some hospitals achieved some of those. All hospitals made significant improvements in their patient safety.

Q628 Dr Taylor: That is pretty impressive. Did the Safer Patients Initiative go on to other safety issues like slips and patients falling out of bed and the feeding of vulnerable patients?

Dr Bibby: In Safer Patients we were interested in looking at the clinical aspects of care rather than necessarily the physical environment of care—not that that is not important but that is just what we chose to focus on for the programme. Obviously with some of the work around medications we would expect to see impact on falls, because better medication, better prescribing leads to less confused patients and less risk of falls, but we were trying to approach it from a clinical perspective rather than, as I say, the environment of care.

Q629 Dr Taylor: I think you said you were going to extend into mental health and community. What about into primary care? We have already heard that this is the great big gap.

Dr Bibby: We would like to do that and we are having discussions with Professor Esmail and others around that. The reason we started with mental health and community is that it is easy to see the transferability of some of the approaches we have used in the acute sector into those sectors. Because of some of the discussions we have heard this morning, primary care is a different beast, in a sense, and we need different approaches, so we do not want to rush into trying to transfer something without properly thinking through what we are doing.

Dr Taylor: Thank you.

Q630 Charlotte Atkins: Dr Bibby, following on from the Safer Patients Initiative, was there measurable improvement in all the targeted areas that you selected? Or were there areas where there was not measurable improvement?

Dr Bibby: One of the areas that was probably harder to track improvement was around surgical site infections. Some of the reason for that is not necessarily that there was not improvement, but it was harder to measure, because obviously we were having to look at infections post discharge and it is not necessarily easy for hospitals to track what happens to patients once they are discharged, particularly because there is much earlier discharge nowadays. That is an area where we perhaps have not been able to quantify the improvements as clearly as we would have liked, but that is not to say there have not been improvements. The approach that Safer Patients took was to say that there is
Dr Bibby: Sometimes harder to transfer that into outcomes. Components of the care bundle, but, as I say, it is sometimes harder to transfer that into outcomes.

Q631 Charlotte Atkins: But you are happy that broadly you achieved measurable improvements right across the board. Dr Bibby: Yes.

Q632 Charlotte Atkins: Did you encounter barriers of any sorts in the pilot sites? To introduce this new system you must have seen some barriers. Dr Bibby: There are probably three barriers I would identify. First, I think there was an issue around a recognition of avoidable harm. Working in a clinical setting people often normalise harm and it becomes something that it is felt is unavoidable in the context of working with very ill people. First of all, there was something about raising the awareness that harm could be avoided. People having got that awareness, it is then: “What do we do about it?” and having the skills to know how you can improve systems of care so that you can improve the safety and the outcomes. A lot of the programme support was around building those skills. Looking forward, we are hoping that we are able to use the hospitals we have worked with as mentor sites for the wider NHS. The third area is that, inevitably when you bring in new things to a clinical setting where clinicians have ways of working, there can be, appropriately, questioning and challenge to that. The approach we would take is that, rather than saying, “You are going to do this and you are going to do it across the board,” we would start with an enthusiast, somebody who was keen to test and develop, and allow experimentation in the local theatre, in the ward or wherever it started, and prove that it worked there before we tried to spread it further within the hospital, and so it would build up ownership and belief that it was worth doing.

Q633 Charlotte Atkins: I am sure there were many success stories but are there any in particular that you would like to share with us? Dr Bibby: I have talked about some of the improvements we have seen around crash calls, central line infections, medication. The other thing is around the change in culture. One of the approaches that the hospitals that we worked with used was called Leadership WalkRoundS. The idea of that would be that usually two members of the board would visit an area in the hospital on a weekly basis, different members of the board. These were not spot checks, so it was not about trying to find things that were wrong, it would be planned ahead, the team would know they were coming. The idea of that would be to start to have a conversation about issues around patient safety in this organisation, the directors might say, “What was the last safety issue that happened?” Tell us about it so we can understand how we would prevent that again. What could be the risk that it could happen next?” When you go into the organisations where they have been doing this, you get a real sense of recognition that patient safety is something that the senior leadership are paying attention to and that they are willing to act on system practice to improve patient safety.

Charlotte Atkins: Thank you.

Q634 Dr Naysmith: Dr Bibby, you have just talked about good practice with boards and whether boards took it seriously. In general, do you think NHS boards prioritise safety now? Do they take it seriously? Dr Bibby: Obviously all NHS organisations are concerned with ensuring the safety of patients. I think we would accept that. In a sense, the question is really about where the focus is.

Q635 Dr Naysmith: It is about prioritising safety, is it not? You have chief executives and boards and they have so many different responsibilities. We obviously think in this inquiry that they should place safety quite highly, but in your experience what do you think happens? Dr Bibby: We work with over 20 organisations. We have networks of other organisations to work with where we see safety being put, quite literally, at the top of the agenda. For instance, at Torbay Hospital, one of the hospitals we worked with, they will start every board meeting with an item on patient safety, so it is sending some very visible signals there that this is something that is a priority for the leadership of the organisation. There will be a whole group of organisations in the NHS that know safety is important but do not necessarily have the ideas, the approaches, to tackle that.

Q636 Dr Naysmith: What can we do about boards like that? Dr Bibby: I think there needs to be more board development. There needs to be the sharing and development of the sorts of techniques we have used in safer patients to enable boards to engage in the safety agenda more effectively.

Q637 Dr Naysmith: Does having a “no blame” or “fair” culture that we have talked a bit about this morning mean that boards and chief executives have an excuse, so they do not have to take safety seriously? Dr Bibby: No. We would not say that at all. We would say it is the board’s responsibility to ensure that clinicians can practice in a safe environment. It is essential that boards are understanding the clinical business of their organisation and they are able to look at how they can ensure the right systems are in place to support safe care.

Q638 Dr Naysmith: You say in your memorandum to us that ministers in top NHS management need to ensure “...a co-ordinated use of managerial commissioning and regulatory levers” in order to
make patient safety the top priority in the NHS. Why do think these levers are not being properly used now?

Dr Bibby: I do not think we are saying they are not being properly used, but if you look at the patient safety agenda at the moment, quite rightly it is a complex agenda: there is a number of different levers being used, with different lines of responsibility to different agencies that have a role in patient safety. The responsibility for those different areas and those agencies is spread across the Department of Health, so what is important is that there is effective co-ordination. We would want to see that that co-ordination is taking place at the NHS management board, so that we ensure we are not getting duplication of effort, that we are not having conflicting messages going out to the NHS. The NHS finds it very difficult if it is getting different messages about how it should be addressing issues.

Q639 Dr Naysmith: You have seen areas where the practice is good and the co-ordination does take place, it does happen. Have you seen examples of good practice?

Dr Bibby: Of good co-ordination?

Q640 Dr Naysmith: Yes.

Dr Bibby: Clearly there has been a concerted effort across the infection agenda, but we would want to see that same concerted effort around some of the things you have been hearing this morning about medication errors, for instance, or errors in surgery and so on. When the Department has a priority and puts full weight behind it you can see it has an impact, but patient safety is much bigger than infection and we need to make sure there is the same co-ordinated effort across all the areas of patient safety.

Q641 Stephen Hesford: In your memorandum there is a quote: “The failure of the National Patient Safety Forum to make significant progress in driving forward the patient safety agenda has been disappointing”. Why do you say that?

Dr Bibby: Hopefully it comes across that we are an organisation that is very passionate about patient safety and we were very pleased with the formation of the Forum because that clearly sends out a signal of the importance the Department attaches to that. At the time of writing our submission we felt that the Forum was being useful in bringing together some of the different interests around patient safety. In a sense, it is not a delivery mechanism and we need to make sure there are very clear delivery mechanisms around the patient safety agenda. Since submitting our evidence there has been a new Head of Patient Safety appointed at the Department of Health and that will certainly help with some of the co-ordination issues. There have also been some changes to the way in which the Forum is working which will make it more effective as an information sharing and shaping forum. As I say, there needs to be some very clear sense of what the delivery mechanism is around the patient safety agenda.

Chairman: We are now moving on to look at diagnostic errors in primary care.

Q642 Dr Stoate: Dr Kostopoulou, as the Committee well knows I am a GP who still does some general practice so I am well aware of the issues facing general practice, but I want to explore the patient safety culture within primary care and start with your memorandum which says that there is a problem with diagnostic error amongst GPs but they are often not aware of it. How would you define “diagnostic error” in primary care?

Dr Kostopoulou: How would I define it?

Q643 Dr Stoate: Yes. Dr Kostopoulou: It is difficult to define, which is why it has been so elusive and under-researched. We only get to find out about it when patients sue or when doctors become aware of a patient deteriorating or patients come back. This does not happen very often though because, as you are aware, some GPs work in large practices, patients may go to see different doctors or they may get lost in the secondary care system. Feedback is missing and the problem is that without feedback we do not learn. We cannot change the healthcare system in the way primary and secondary care are organised to give doctors more feedback, but we can construct more structured training environments where feedback is immediate and provided on a large number of cases if we want to improve learning, for example.

Q644 Dr Stoate: For example, if you have got a delayed diagnosis, if somebody comes in with symptoms of an everyday nature, as Professor Esmail was saying earlier, undifferentiated, and it does take a while for the GP to have gone through the diagnostic sieve, to await new developments, to use time as a tool in diagnosis, is that a diagnostic error or is that simply the nature of general practice?

Dr Kostopoulou: That is very true. Some things will not be diagnosable and we are not really talking about those things where no GP would really be able to diagnose that. We are talking about things that can be diagnosed and can be caught early and GPs may not consider something that is slightly less common but more serious, or they may miss some red flags if they are there. There are ways of getting them to become more aware of those situations, possibly through education and training, so we can “de-bias” the way people think. Because GPs serve a population with a lower rate of serious disease they tend to think it is the most common thing, and they are usually right, and once you consider that this is the diagnosis and it explains most of the symptoms you may just stop there and not explore other possibilities.

Q645 Dr Stoate: Does that tell you anything about the culture of safety in general practice or does it just tell you a bit about how GPs are trained?

Dr Kostopoulou: It is not necessarily the culture of safety. GPs have adapted to the population they serve and also to the healthcare system. Do not forget that we have got time limits on consultations.
If you need to finish a consultation within ten minutes you are more likely to think of the most obvious or most common diagnosis, you have got less time to explore other possibilities. Also, the healthcare system puts pressure on GPs to reduce “unnecessary” investigations or “unnecessary” referrals. Even if a GP may consider there is something more serious, they may wait, they may want to be convinced and collect more evidence before they decide to refer. This is an interaction of the system where they work, the difficulty of the population they serve and the cases that they see. They do have a difficult job to do.

Q646 Dr Taylor: Sure, but that does not tell us anything about the safety culture because that is what I am trying to get at. We all know the problems of diagnosis, and we will come on to training in a minute, but does that tell us anything about the culture in general practice? Do you think there is a real problem that GPs are not taking patient safety significantly seriously?

Dr Kostopoulou: There may be. I cannot say that there is or there is not. Because they have to work under such difficult conditions it is possible they forget patient safety in some cases. We know that they do not report diagnostic errors, but I am not sure whether other kinds of doctors report their own diagnostic errors, so it might not be a GP problem.

Q647 Dr Taylor: Do you see a solution to this?

Dr Kostopoulou: Yes, and I have already mentioned a couple of things. I am a big believer in catching things early, so medical education and training. Also, supporting GPs while they work through better designed systems, electronic systems, the electronic record and decision support. These are long-term and we need to put a lot of effort into research on how to do these things properly.

Q648 Dr Taylor: How would you change the education and training of GPs in particular to try and put this right? What changes would you make?

Dr Kostopoulou: Simple things, like what I called “de-bias” earlier. Simple things like, “Why might my diagnosis be wrong? Are there any features here that I have not managed to explain or I have ignored?” These are little things that will open up our minds to other information that we may not be paying attention to. These are things that could be taught much earlier at medical school. I do not think students are taught at medical schools how to diagnose formally, how to form differential diagnoses, how to test diagnoses. They need to know about probability, for example, about the diagnostic value of information and also that diagnosis is a psychological process and what are the common pitfalls.

Q649 Dr Stoate: Do you think that has changed over the years because I remember all that being taught when I was a medical student? Has that changed?

Dr Kostopoulou: Students learn typical features of diseases, but as a doctor you probably know you do not often see patients presenting typically. As a doctor you need to differentiate competing diagnoses, so what you need to know is not the list of features of each diagnosis but what features help you differentiate between easily confusable diseases.

Q650 Dr Stoate: You think that is not taught sufficiently well?

Dr Kostopoulou: No, there is no formal teaching on diagnosis and clinical reasoning, nothing like this.

Q651 Dr Stoate: That is obviously an issue which we need to look at. If I can just briefly pick up on your statement that you want to see more automation and more electronic support effectively. Do you see any drawbacks to that type of usage of expert systems?

Dr Kostopoulou: The most obvious drawback is the expert system suggesting the wrong diagnosis. We need to make sure they are more reliable than their users. Also, they may increase referral rates or investigation rates, but I am not sure how bad that is. Can I just go back to the training. We have not explored at all training students or doctors with simulated patients, that is computerised scenarios that will give them immediate feedback, large numbers of them carefully structured. At the end of the day we train our pilots and we train our surgeons on simulations, so why can we not train our doctors to learn diagnosis on simulations. That is completely unexplored in medical education.

Q652 Dr Stoate: That is also very interesting. If a GP is practising unsafely or making consistent errors, how much is that an issue for the GMC or other professional body to be responsible for?

Dr Kostopoulou: There may be very bad GPs; I do not think there are very many. I am talking mostly about the average GP, how most GPs practise. If we want to improve safety we need to look at how most GPs practise. The GMC has a role in setting standards for medical education, for example.

Q653 Dr Stoate: You would involve them much more in setting the curriculum and training?

Dr Kostopoulou: I think so, yes.

Q654 Dr Stoate: How does the “fair blame” culture apply to general practice?

Dr Kostopoulou: It is not really something I am involved in, there are probably other people much more knowledgeable who can talk about that. I worry sometimes. We know that there is an increase in the rate of litigation against GPs so it might be that they are becoming more reluctant to discuss their errors. That might be a problem. In terms of a “fair blame” culture, I am not sure.

Dr Stoate: Thank you very much.

Dr Taylor: Very quickly on that. I am horrified when you say there is no teaching on diagnosis because, as Howard and I both remember, the diagnostic process was history, exam, differential diagnosis and investigation.

Dr Stoate: Clinical Method.

Dr Taylor: Clinical Method, surely that is still taught.
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Q653 Dr Stoate: We remember it cover-to-cover even after all this time, do we not?
Dr Taylor: Inspection, palpation, percussion, auscultation.
Chairman: We get these reminiscences regularly.

Q654 Dr Stoate: Surely that is still taught?
Dr Kostopoulou: The problem is that when students start practising this goes out of the window.

Q655 Dr Taylor: I am shocked!
Dr Kostopoulou: You are doctors, you know that you do not go over a list of things. You employ shortcuts, you do not go over a whole list and do these things systematically. That is how people become experienced and faster at doing these things.

Q656 Dr Stoate: And they miss out some of the very important things.
Dr Kostopoulou: Inevitably.
Chairman: Can I thank the historical wing of the Health Select Committee for that intervention!
Dr Stoate: It is called experience.

Q657 Chairman: I am an ex-member of the General Medical Council as of last month and it is often said that people come out of training quite well and then go into work with an individual to get the experience that is vital for them and pick up the habits of the individual and have to drop off some of the things they have learned in school. Would you go along with that?
Dr Kostopoulou: Yes, I do. That is why I think there needs to be continuous training as a type of professional development for practising doctors.

Q658 Chairman: Do you see revalidation as a part of that doctor’s journey?
Dr Kostopoulou: Yes, why not.

Q659 Chairman: You talked about simulation of diagnostics as opposed to simulation of surgery that we have in the healthcare system. Is there anywhere in the world that actually does simulation of diagnostics in training?
Dr Kostopoulou: Yes, only for medical students as far as I know. I am not aware of doing it for doctors. There is much more work involved in developing scenarios for experienced clinicians.

Q660 Chairman: Having said that, simulated surgeries are used in general practice training much more so by the College now to test competencies and we do have some patients simulating surgeries.
Dr Kostopoulou: You are talking about actors?

Q661 Dr Stoate: Actors, yes.
Dr Kostopoulou: It is actually much easier and less costly to develop these things in computers and much more controllable because then you can also get immediate feedback, have them on the internet, do them in your own time, do all sorts of nice things with them.

Q662 Dr Stoate: We remember it cover-to-cover even after all this time, do we not?

Q663 Stephen Hesford: I have a concern that there may be a sort of class distinction in terms of diagnostic errors. If a database or looking at diagnostic errors is from litigation, given that the propensity for litigation is probably a middle class exercise, is there not going to be a missing of diagnostic errors who are not middle class, those in poorer areas?
Dr Kostopoulou: Yes.

Q664 Stephen Hesford: Is there any research evidence to suggest that doctors do not listen as much to unemployed people, black and ethnic minorities, so there is a diagnostic error in the sense they are not giving the same service to those who have not got sharper elbows? Is there any issue around that?
Dr Kostopoulou: Yes, I think there is some evidence that middle class patients are able to demand things more than lower class patients which can easily influence their management. I am not aware of any other evidence in addition to that. What I would say about a litigation database is I think there are ways of looking at diagnostic error and measuring threat beyond litigation and beyond waiting for doctors to report them if we can take advantage of the electronic record that is common between primary and secondary care, and in some areas of the country this exists, if we can use data mining techniques so we can develop some automated algorithms to screen patient records, to identify records that are at high risk of a diagnostic error. This has been done in the US, in a Veterans Affairs Hospital, where they looked at primary care clinics and the algorithms they used were primary care visits followed by another primary care visit or by an unscheduled hospitalisation or an unscheduled emergency admission within ten days, and we can use a month.

Q665 Stephen Hesford: Meaning that was suggestive that something had been missed?
Dr Kostopoulou: Yes. These were patients at risk of a diagnostic error and they did find increased risk in those records. Overall, the rate was about 0.67% and for those records they identified it had increased to about 25%. We can increase our chances of identifying patients where errors have happened and then look at those records and see whether an error had happened and then we can inform ourselves about the rate of diagnostic error that has been so elusive so far if we want to convince people that it is an important issue.

Chairman: We will move on to human factors now.

Q666 Charlotte Atkins: Captain Hirst, it is your opportunity now. Healthcare is often unhealthily compared with aviation in regards to “human factors”. Do you think the comparison is fair and, if so, why do you think healthcare lags behind aviation so much?
Captain Hirst: The answer is yes and no. It has lagged because there has not been very much of it in the past in healthcare. I was involved in aviation in
bringing human factors training in in British Airways and it came about in aviation from a serious of unexplained accidents which were always called “pilot error” in America and basically the regulators in America decided that they would close down a couple of the large airlines if they did not improve their records. They went to the University of Texas who did a lot of work on human error and why it occurred. Then, as usual, after the Americans started we took it on in this country. We went down a lot of rocky roads in getting to where we are now, which is by no means perfect, but if you go on any flight deck of any aeroplane today you will hear people speaking the human factors language, understanding about decision-making processes, situation awareness, teamwork, leadership and all those things. There are little pockets in the Health Service where particular early adopters, as Dr Gawande would say, have realised that this same sort of idea about human factors is applicable because it is about people working together. I would suggest it is individual pockets rather than it has been taken on from the top downwards. I think the reasons are that it is such a complex organisation, healthcare in every country, but in this country particularly, 1.3 million people and there are so many different bodies. Aviation is incredibly regulated, we all know where we sit and stand in the line of things, if you like. There is the Civil Aviation Authority that regulates us, the airline you work for line of things, if you like. There is the Civil Aviation Authority that regulates us, the airline you work for and it all feeds down to the individual pilot, cabin crew member, engineer, whatever it is, so we have a structure and a reporting process and reporting lines. Once it had been decided to implement an innovation like human factors 15 years ago, it could happen fairly easily, whereas the huge amorphous structure of healthcare makes it more difficult.

Q667 Charlotte Atkins: Obviously one of the things that aviation has pioneered is the “fair blame” environment.
Captain Hirst: Yes.

Q668 Charlotte Atkins: What do you think the NHS needs to do to achieve that “fair blame” reporting and learning culture, which clearly has made a difference in aviation?
Captain Hirst: It has. People bandy around all sorts of words, like “no blame”, and I would not be an advocate of no blame because you have to occasionally blame. It is getting the balance right. I think my favourite term would be “just culture”, a culture where people are happy to admit when they have made errors so that others can learn from them and not be penalised or punished or have a fear of punishment because, as somebody said earlier on today, that will just drive people underground; it happens in every industry. We have got lots of reporting systems in aviation, we have discrete reporting systems; open reporting systems, but, most importantly, the regulators demand that we do report and if we are found doing something and not reporting it, that is a sackable offence. I have to say that in my own airline they have produced a standing instruction to all employees saying that basically it is not the policy of British Airways to institute disciplinary proceedings in response to reporting of any incident affecting safety, apart from gross negligence. That was there and it said you will not be penalised. That was very favourable for the employee and made one feel comfortable to report things so that people could learn from them. It did not mean that people did not have to undergo some retraining, some embarrassment or whatever it might be, but it did mean that they were not in fear of being sacked, if you like, unless it was culpable negligence.

Q669 Charlotte Atkins: Presumably there was a whistle-blowing culture as well that if it was not reported for any reason then someone else would report it?
Captain Hirst: There is a lot of technology blowing the whistle these days. There are cockpit voice recorders, data recorders, all this sort of thing. What it did do was it rooted out the real bad apples, I guess, and people could not behave in a totally inappropriate manner, an unprofessional manner, you had to fit in. I think perhaps with 1.2 million employees in the National Health Service there must be some bad apples in there. At many conferences I have spoken at, a question that often comes up is, “What can we do about somebody who is a completely off the wall character” within an organisation, a hospital, a ward or whatever it might, “How does it get dealt with?” There does not seem to be a process at the moment to do that.

Q670 Charlotte Atkins: So what can we do about that person then, an obvious person within the NHS that everyone agrees needs to be moved on?
Captain Hirst: My opinion, without knowing the individual involved, is one has to be sensitive. You have got to first find out why people are like that, is it a lack of skill, a lack of knowledge or a lack of insight, have they just not got it. One has to develop and maybe offer them training and counselling to help them out. If they then do not do it, there needs to be some disciplinary action, they should not be holding down a job, because it does not only affect their patients, it affects the whole cohesion of the team. If people are in fear of some errant character who is senior particularly that makes life very difficult for people to speak up, particularly if their future promotion might depend on keeping in their good books.

Q671 Charlotte Atkins: So what is the secret then? Is it the regulatory bodies, do they have to be more heavy-handed and say that this will happen, as they did in aviation?
Captain Hirst: The concern is everyone is frightened of regulation and I cannot understand that, having been part of a very regulated system and I used to regulate on behalf of the Civil Aviation Authority. Regulation does not mean draconian, people have the wrong idea about it. The regulator should be your friend. If you have got a problem, they should
be part of the process in helping you. I talk to clinicians all the time, we run courses, and people put their hands up and say, “fear of litigation” and I am not sure the evidence is quite there that the litigation is so fearsome. We do a little bit of work with the Medical Protection Society and I was listening to one of their lectures in dentistry and he was explaining that if you are open and honest with patients when you have made a mistake, people do not tend to go for you, if you like, legally, people understand. Driving people underground, not admitting to errors, not being truthful and cover-ups, that is when people get really angry. Maybe I am being naïve, but that is my feeling.

Q672 Charlotte Atkins: I think that is right. I think from most MPs’ postbags often they want to know why it happened. They often want an apology, but most of all they want to understand why it happened and stop it happening to anybody else.

Captain Hirst: Having worked in the Health Service pretty much full-time for the last four or five years and having talked to lots of people, it is a much more complex thing than flying an aeroplane. With an aeroplane, we tend to get into one which is pretty fit normally, not always but fairly much so, whereas in Healthcare one is dealing with a hugely complex organisation at the sharp end of it with all the potential errors that flow down to the operating table or whatever it might be. They are the last line of defence, the surgeons I have watched and the theatre teams. The human condition is infinitely variable and there are all the pressures of being part of the Health Service. I am not unaware of the huge task ahead and I just hope that you people can sort something out of it. I do feel that the principles involved that we have learnt where every pilot understands these processes, the cognitive processes of how we make decisions, are important. I looked at the curriculum, the ISCP that is produced now and I of how we make decisions, are important. I looked at the regulator know that somebody has—

Chairman: That would be one of them? Captain Hirst: That is one. Also, medical fitness to practise. Every six months we had a fairly comprehensive medical. I remember a case many years ago when a pilot was not performing, but he had been a really good chap and had been a training pilot on a previous fleet, he came on a new aeroplane type and did not quite progress as he should. People made excuses for him because they considered he was a good operator, and that was a bit of confirmation bias where everybody thought he must be good, he was just a bit slower on this bit, but they found out a long time afterwards he was having a benign brain tumour. We have to pass exams as pilots on the human condition and we have to understand about fatigue and all these things. I was surprised when we first came in to do some work in healthcare that that was not the norm for clinicians or other healthcare workers to understand about such things, because I feel understanding is part of the way to maybe solving.

Q673 Chairman: You said that the regulator would get involved with the aviation industry if they are found not doing something. How would the regulator find them if they were not telling the regulator? I do not know if there are any comparisons with our health system, but how would the regulator know that somebody has—

Chairman: Has made a big error?

Q674 Chairman: Yes, other than the obvious. Captain Hirst: A heap of wreckage all over the countryside! Obviously there are incidents like that, but we have high fidelity simulators and on four or five days a year we are in front of effectively the regulator demonstrating our skills in abnormal situations.

Q675 Chairman: From your experience that you have had working with clinicians recently how far do you think non-technical skills have been integrated into the education and training of clinicians?

Captain Hirst: Variably. In some places very, very little and in other places quite substantially and significantly. At the moment, human factors and non-technical skill training is voluntary and unless you have got a very strong medical director or matron who make the staff go onto the courses and be partake in the coaching, some people who are not interested in it or do not think it is necessary for them just do not get involved. Jo has already mentioned Luton & Dunstable Hospital. They have a chief executive there who is passionate about patient safety on an everyday basis and they have a medical director who is passionate and, therefore, the staff are passionate. They have a pride in it there whereas maybe in other places it is not so high on the agenda, as you were saying yourself—prioritisation.

Q676 Dr Naysmith: Do you think it should be mandatory? You said it is voluntary at the moment and in some places it is a high priority, but do you think it should be mandatory?

Captain Hirst: I personally do, yes. The people who are frightened of it, this new training, this new tree-hugging stuff, are going to be the people who are not going to attend while such training is voluntary those are normally the people who fear they might struggle with it. In aviation and other safety critical industries they say over 70% of accidents are caused by human beings and eight out of ten are not a reflection on their technical skills, it is their interaction with other people that causes accidents. That has got to be a huge driver for people to understand these concepts.

Q678 Stephen Hesford: While clinicians work in teams, they do not often work in established teams in the NHS. You have already made it clear how different the airline industry is from the NHS, and that is helpful. They are working with different
people all the time and almost self-evidently it creates a problem. How do you get round this almost transferable situation?

**Captain Hirst:** Actually, that is exactly the case in civil aviation. In my company I flew the Jumbo for the last 10 years and we had 1,000 pilots on the Jumbo and 15,000 cabin crew or whatever it was and we never flew with the same people, but we had protocols, we had standard procedures, we had a full briefing before every flight where we discussed what was going to happen and it was all written down in the book. We changed procedures as a result of incidents. I can remember one where, rather embarrassingly, people almost kept running over the ground engineers when we were taxiing away because you could not see them. The ground engineers were not very happy about that. It was a simple little thing like the protocols we were using in terms of our communication between the air traffic controllers at busy airports and the chap on the ground were poor and there was potential for error. That got picked up, analysed, root cause analysis, and then we changed procedures. I do not think that working with different teams makes teamwork not possible. Sometimes there is probably a lack of understanding of the difference between teamwork and group working where actually people happen to work in the same place, but they are not really a cohesive team with the same goals. Most of our work has been in the theatre environment and ICUs and people are members of three or four different teams, in one part you are a little team in the theatre and then you are part of a bigger team in the hospital and not everybody sees their role as part of the bigger team correctly and maybe do not engage with the management at times, for instance.

**Q679 Chairman:** The example you gave about not running over the ground staff, was that a sort of soft skills communication thing or was it as much about technical understanding, about, “At this point I should be on the phone to the air traffic controller”? That is a technical thing.

**Captain Hirst:** It was actually communication breakdowns. The Captain said to the co-pilot “Can you see him?” The co-pilot assumed the ‘him’ to refer to another aeroplane which he could see so his response of “Yes” was incorrectly interpreted by the Captain who then taxied while the ground engineer was still in front of the aeroplane. It is about how to communicate effectively, asking the right questions.

**Q680 Chairman:** You mentioned “it is in the book”.

**Captain Hirst:** It is in the book.

**Q681 Chairman:** I am not sure if the NHS has a book.

**Captain Hirst:** There is not a book, but maybe there should be.

**Q682 Chairman:** There may be books or pamphlets or something. Is it possible to have a book?

**Captain Hirst:** Yes, of course it is. I have talked with them at the cardiothoracic unit at Great Ormond Street and there are certain critical events in neonatal heart surgery where they could develop protocols where the same language is used each time—at absolutely critical times use consistent language, so there can be absolutely no confusion. I do not see why that could not happen. It could be developed in each hospital.

**Q683 Chairman:** Is there a gap there?

**Captain Hirst:** I think there is, yes.

**Dr Taylor:** I was going to ask you about bad apples but you have already answered that. Really, I would just like to make a comment. I have often been called a medical dinosaur and he is coming close to me!

**Dr Stoate:** Humbug!

**Q684 Dr Taylor:** Non-technical skills were not even thought of when I trained. Look through the list now it is absolutely marvellous that they are now being actively trained. I hope people are being trained how to diagnose as well as being trained about the non-technical skills. My question has been answered.

**Captain Hirst:** For instance, there is a lot of exposure at the moment about checklists, the NPSA and the World Health Organization, and it is a wonderful idea. We have had checklists in aviation since the 1930s. Nobody knew about human factors training and understanding about communications until 20 years ago in aviation. It is no good saying “use a checklist”, people have to understand it has to be sympathetically introduced with the right sort of training to know why you are using it, how you are using it. I do not think just saying, “Use that, everything will be okay”, will work. I am concerned that in some hospitals we go to they are bringing in sensible programmes to introduce it and in others it is almost by email. “From next week you will use a checklist” and I do not think that will work. That is my concern, that a “from on high” downwards diktat is not the way to really get serious change. What you need to do is get people in the critical areas in the hospitals who adopt and really believe in these ideas and they will transfer them to their colleagues and the bad apples will be the only people who are not doing it the same way as everybody else and it will either bring them in line or—

**Q685 Dr Taylor:** Hopefully the bad apples are going to be exposed by their juniors.

**Captain Hirst:** We do not want a snitch culture but as a patient, which I have been, I would hope if there was someone who was completely out of kilter there were people who would do something about it.

**Q686 Chairman:** It is part of a doctor’s professional code of conduct, if you like. The regulator would say they have a duty and a responsibility to report a fellow doctor under those circumstances. Could I just go back a little bit with you. You mentioned the issue of the threat of litigation that may be one of the things that is not altering the culture in medical care as it does in aviation. What about the other issue about the media? You have obviously spoken to a lot
of people who do work in teams. Do they feel that
the media is an individual threat or a threat to
the institution or the wider team? What do you feel?
Captain Hirst: I think people are always concerned
about the media. Pilots are concerned about the
media. Sometimes a story that everything has gone
well is not good news, is it? I have a very close friend
who is a news editor on one of the main stations and
I keep saying this to him and he said, “Well, we can’t
tell them boring things like everything was successful
in the hospital today”. There is a perception that
healthcare professionals are concerned about the
media. Whether that is a right perception I cannot
really comment. All of these things are a concern, but
the fear of it is probably worse than the actuality,
if you know what I mean. We did some training
recently at a hospital and a certain consultant
surgeon said he had been most impressed by this idea
of briefing and debriefing. It had seemed anathema
to me when I walked into the operating theatre for
the first time and nobody got the team round and
said, “This is what is going to happen today. We can
expect that and, by the way, that list has changed the
order”. It all happened by luck rather than
judgment. The surgeon I mentioned earlier said he
could not have understood the benefits of briefing
and de-briefing without actually doing it. At a lot of
theatres we visit we are told, “We have got a really
busy list today, we haven’t got time for a briefing
beforehand because we have got to get the list
started”. Our view from practice as well and research
is that if at eight o’clock in the morning people have
five minutes together, they know each other, they are
not as in awe of the consultant perhaps and may feel
happy to speak up if they have spotted a potential
for error. It is all those things of, if you like, lowering
the power gradients and such like that we feel is part
of introducing a safety culture. They are only little
things, we are not talking about a zillion pound
robotic computer but almost not quite commonsense, the sorts of things we do in
everyday life.

Q687 Chairman: A football manager’s culture.
Captain Hirst: Yes.

Q688 Dr Naysmith: Could I ask a question about air
safety, it has nothing to do with the National Health
Service. What did you think about the guy who came
in and landed on the Hudson River?
Captain Hirst: One of my jobs these days is I am
ITN’s sort of expert on aviation and they asked me
live on the lunchtime news a couple of weeks ago and
I said I thought he did a sensational job, however it
was not only him, it was his colleague, the cabin crew
and the air traffic controller, and benign conditions,
there were no waves and no ferries in the way. A lot
helped him, but I think it was stunning because it
was the first time it ever happened that somebody
landed on water.

Q689 Dr Naysmith: What will they do about birds
then?
Captain Hirst: They do it at Heathrow. If you ever
pass Heathrow on the Bath Road you will see the
odd flash and it is not 5 November, they fire flares up
to frighten them away, but that is as far as the
technology has gone. Do not worry about it, it does
not happen very often.

Chairman: We have practically got the network back
on time now. Could I thank the three of you for
giving evidence at this second session. If you have
anything to add in view of what you have heard here
this morning, please feel free to get that to us. Thank
you very much.
Thursday 5 March 2009

Members present

Mr Kevin Barron, in the Chair
Charlotte Atkins
Jim Dowd
Sandra Gidley
Stephen Hesford
Dr Doug Naysmith

Mr Lee Scott
Dr Howard Stoate
Mr Robert Syms
Dr Richard Taylor

Witnesses: Professor Sir Ian Kennedy, Chairman of the Healthcare Commission, Baroness Young of Old Scone, a Member of the House of Lords, Chairman of the Care Quality Commission, and Dr Bill Moyes, Executive Chairman of Monitor, gave evidence.

Q690 Chairman: Good morning. We are just a few minutes early, which is quite exceptional in my experience, sitting in this chair, so I think I am going to seize the opportunity and start a few minutes early as well. I wonder if I could ask you to give us your name and the current position that you hold?

Baroness Young of Old Scone: Barbara Young; I am the Chairman of the Care Quality Commission and we start work in 26 days, I think.

Professor Sir Ian Kennedy: My name is Ian Kennedy. We cease working in 26 days.

Dr Moyes: I am Bill Moyes; I am the Executive Chairman of Monitor, which is the regulator for foundation trusts.

Q691 Chairman: Welcome to what is our sixth evidence session in relation to our inquiry into patient safety. I have got a question really for Ian and Bill to start with. How does patient safety now compare with ten years ago?

Dr Moyes: Monitor has only existed for five years and foundation trusts have only existed for five years, so my perspective, I think, is more about today and the future rather than historical, which Ian will have a very firm grasp on, I am sure. Looking today, I am very cheered by Lord Darzi’s report and by the focus on quality that he has put in his report. I am very optimistic about the ability of foundation trusts to translate that into reality with good, strong boards and a very, very strong focus on governance. So sitting in my seat and looking forward, I think I am quite optimistic about the future. Ian.

Professor Sir Ian Kennedy: Thank you for inviting me. With your indulgence, I put in a supplementary paper and two other papers which are to be published next week and I was grateful to you for allowing me to do that. Certainly safety is now up there in the agenda in the NHS and also in the independent sector. The Healthcare Commission, I think, has played some role, but so have others. If I could draw a distinction between what I would call structural responses, which have been quite significant, the creation of the NPSA, the National Patient Safety Forum and other such exercises, Darzi’s review, and so on, contrast that with cultural changes and behavioural changes and I think they lag behind in translating ideas into reality. At the same time I think it is proper to recognise that these are problems throughout the developed world in terms of the safety of patients, and this country, in my view, is leading both in thinking about it and beginning to do something about it. You heard a lot of evidence on November 20, I think, about how we lack information properly to be able to answer your question. If I were to pick two reasons for that, I would say that we still search for agreement, consensus, on what constitutes safe care, what is good care, how do you identify it, and then we have still limited data, information, about deviation from what might be described as good care. Without going on too long, I would say that limited data, in a way, is a function of concentrating perhaps too much on the acute sector and also on things which are called ‘incidents’. I am interested in how we get a grip on primary care, which, after all, is where 90% plus of care is delivered, and how we concentrate on omissions as well. Failure to diagnose, late diagnosis, are as important in the safety and quality of patients, and many of the things that end up in acute care are a function of what happened earlier along the pattern of care.

Q692 Chairman: In your supplementary, Ian, you mentioned a number of problems, in particular the issue of excessive focus on analysis of incidents, which you have just mentioned, the need to define good services and the need for a system of early alerts. How should they be addressed?

Professor Sir Ian Kennedy: Taking early alerts, the Healthcare Commission has moved from a position (and it may crop up in your questions later) where we were engaged in investigations, and we have done some very important investigations, but my memory of what I saw in Bristol and what we have recently seen in the case of Baby P, for example, tells me that we ought to be able to get in earlier, and that to me involves the creation of a system whereby, with the Strategic Health Authorities and with the executives in the trusts, you begin to identify the important data which should be sucked in—it is only data which organisations should themselves be collecting—and then working with what patients tell you, working with what complaints tell you, working from other sources—from visits, from local intelligence—you begin to
find a way whereby you can spot what might be described as the beginning of spikes. We have done this recently. We have put this system into operation in the Healthcare Commission. It has taken a while, but we recently identified outliers in mortality rates and that caused us to inquire. Data does not tell you anything, you have to go find out, and when we did, we found that almost all of them were explicable but one was not without further attention and that had led to a full-scale investigation in Mid Staffs which we shall be reporting on later. So that is as regards surveillance. How we track omissions, failures to do things, is enormously challenging. There are people, like Charlie Vincent over there, who know more than I do. Over the last three days I have been chairing a group concerned with awarding Academic Health Science Centre status, and I was a cheered by some of the innovative thinking, particularly on the sharing of records across primary and secondary care, beginning to track why people are showing up here, and it may be because of here, and sharing that with proper security. So incidents, surveillance, in my view, and primary care are areas where we need to put our energy.

Q693 Chairman: Thank you. Bill, you suggested that a new horizon, as it were, quality, is going to that a new horizon, as it were, quality, is going to be a way of improving patient safety. What is the cause and effect? How does quality improve patient safety? What are the mechanisms that you see coming out from the Darzi review that are going to do that?

Dr Moyes: The thing I welcomed, first of all, was that Lord Darzi talked quite explicitly about safety as being the driving force in the NHS, in the planning of services, in the delivery of services and in the assessment of performance. He is talking about safety there, quality in the round being safety, patient experience and clinical outcome. First of all, I welcome that. If services are planned around the best evidence of what the good outcomes are, what safe services are, things like stroke services, for example, then I think that will have a real impact. The second thing I really welcome is the real drive to develop descriptions of what a safe and high quality service looks like and the ways of measuring it. Ian made that point a few minutes ago, and I very much agree with that. So there is great drive in the department, in NICE and in CQC and the Healthcare Commission to be quite specific, which I think is very important. We have come in behind that with developing a framework for reporting quality. We set the reporting framework for foundation trusts, so we have been working with the department and the Healthcare Commission to try and describe a framework within which each foundation trust every year in its annual report can describe quite explicitly what they have achieved in relation to polity and safety and what they plan to achieve in the future. The other thing I think is quite important is the emphasis that we have placed on the role of the board, because the other thing that I think has been lacking in the past has been absolute clarity about who is accountable for the delivery of services in the round, and we are quite clear in foundation trusts that that is the board. It is not the medical director, it is the board. Therefore, saying to the board, "You are accountable and you have to give an account of yourself and, therefore, you have to know what is going on in your hospital and you have to have ways of spotting the areas of problem and intervening", I think also would be very powerful. All of that seems to me to add up to quite a useful way forward for the NHS.

Q694 Mr Symes: This is for you all. The arrangements for the regulation of NHS care providers seem unclear. How could they be made clearer and would that make them more effective?

Baroness Young of Old Scone: There is no doubt that regulation of quality and the whole quality field at the moment is very complicated and there are a lot of players on the pitch, but I think there is an opportunity for us to make sure that all of that effort is aligned because there are distinctive contributions that each of the players are making. Clearly, the bodies that particularly are important in the safety area are ourselves, the National Patient Safety Agency, NICE, the Litigation Authority, the PCTs the SHAs, Monitor, probably a good few others besides, the providers themselves, of course. Our role is as the regulator of quality in which safety is our first principle of quality. We have a six-part model of quality in our manifesto, which you may want to have a look at, and the first principle is safety. We will be looking at how we can bring a focus on safety performance through the work we do on registration of all providers, which will happen from 2010, the work we do on special reviews, the work we do on investigations, where things are ostensibly wrong, the information that we provide for the public and for providers and for commissioners and particularly on the kind of centrepiece of our regulatory work, which will be a risk profile for each provider. Safety will be a fundamental part of that and we will enrich that risk profile with information, not just from stuff that we collect ourselves through our regulatory processes, but from a whole variety of other players, including Monitor, including including the SHAs and the performance management system, including the commissioners, including the Litigation Authority and also from things like professional quality assurance processes and accreditation. So it will be a very rich and increasing profile for each provider, and safety will be a fundamental element of that. We have just been gathering up the number of bodies we have a Memorandum of Understanding with, and it is rather large, but we are now working through the list. Just to give you a couple of examples, clearly the National Patient Safety Agency, the information that they get on incidents will be used to enrich the risk profile of the providers, so we will understand what is coming in, that will inform our view about whether they are on the ball on safety or not and we will, in turn, help promote the NPSA alerts and guidance that they issue and, as we do
our periodic assessment of providers, looking at whether they are using those alerts and guidance effectively. Another example is that in working with Monitor we will obviously be working with the providers that we are regulating in terms of things that they are not getting right where we need to either enforce or work with them to improve, but if there is enforcement action required, we will want very much to talk, in the case of non-foundation trusts, to the SHA about the performance of their trusts, in the case of foundation trusts to Monitor about the performance of their trusts, and they have levers that we do not have. We have regulatory levers which are quite powerful, but they have levers in respect of governance, for example, in the case of Monitor, and we will also be talking to the commissioners and the PCTs and saying, “Hang on a minute. Why are you commissioning services from this bunch if they are actually not that good on safety?” So there is a variety of alliances that we will be forming through our Memorandum of Understanding that will help use all of the levers available to drive the safety agenda.

Q695 Mr Syms: So you see making them fit together in a more coherent way.

Baroness Young of Old Scone: You are where you are. You might not start from here, but I am not a great believer in structural change. I think, quite frankly, you can make any system work because it is about how you manage across the boundaries between organisations and keep a clear focus on what you are all trying to achieve, and that is, I think the thing that we are going to be working on over the next year or so to make sure that we genuinely are all clear what the objective is, i.e. improved safety, and what our distinctive roles are and that we do not have any friction, overlap or duplication; that we are working together.

Professor Sir Ian Kennedy: I think clarity is in two halves. First of all, there are people out there and we might try to join up, but there are many audiences watching what we do: there are the patients, the public, managers, yourselves and others, the media, and I think for them it is a pretty difficult task, but Barbara is quite right, we are where we are, and this state of affairs was created, dare I say it, in large part by yourselves through the variety of statutory provisions. Then the other clarity which Barbara has talked about is, whatever the audiences can work out what we do, how we can ourselves do it, and there I think Barbara is right, that we can try through MOUs, through other things, to align ourselves. One of the critical features, in my view, which the Healthcare Commission did not have, which you have, I think, in CQC, to a greater extent, is the capacity of one agency to, as it were, corral, co-ordinate, organise the activities of others who would otherwise presume to trawl through hospitals, request information and generally muddy the waters sometimes, and that does create the possibility of alignment. The NPSA is going to, as I understand it, at the end of this week or early next week, come out with a risk profile based upon the data it has, and that is the sort of thing that you will then seek to align your activity. It is possible to align. Indeed, just one example: in three years the Healthcare Commission cut by over 50% the number of requests for special data that was being asked for by government and by the Department of Health by saying, “Hang on, it already exists. Can it be used for other purposes?”, and so on. So you can do that, but it is a bit of a struggle and it is not your primary task.

Q696 Mr Syms: So you feel positive about the Care Quality Commission because they have more levers to do what they need to do?

Professor Sir Ian Kennedy: I feel positive because it is led by the people who are leading it. They do have those levers, and you have seen the vision already set out that they intend to do that. I think, following on from the Healthcare Commission, safety is the highest priority, continues to be the highest priority, and working with others to try to align how we can inform our audiences. This is what is the case, and come to us and find out and we will try to do something about it.

Q697 Mr Syms: Dr Moyes. Dr Moyes: I think Monitor’s role underpins the work of a lot of other bodies. Our compliance system gives Monitor an overview of all aspects of the performance of foundation trusts, drawing on material from other bodies, including the Healthcare Commission and, in future, the Care Quality Commission, and we do provide a focus for other people like commissioners, and so on, where there are problems. So a foundation trust in its authorisation has lots of obligations: an obligation to deliver targets and standards, to deliver its contracts, an obligation to monitor the quality of services that it delivers, an obligation to be economic and efficient, and so on. Our job is to intervene if a foundation trust is not being compliant with that obligation of its authorisations; so if it is not delivering targets and standards, if it is not delivering its contracts, if there is some major failure, including a clinical failure, then, ultimately, if the board of the hospital cannot put it right, our job is to intervene and put it right, and we are the only body that can actually change the board; we are the only body that can actually force change in the hospital. The other thing is what I mentioned earlier, to make sure that foundation trusts report honestly and transparently; so we set the reporting framework, the content of the annual report. Our assessment process of applicants, I think, has proved to be a transformational process from those trusts—they really do start to think about the organisation—and we are increasingly taking a role in helping foundation trusts develop, think about how they should function—non-executive directors and executive directors—but I think the key point I would make about Monitor is that we underpin the
work of others and, when failure seems possible or likely, our job is to intervene and try and make sure it does not happen.

**Baroness Young of Old Scone:** Can I comment on both of those contributions? One is on the gatekeeping role, which Ian very kindly mentioned. This was given to us in the Health and Social Care Act, which is the job of kind of corralling everybody else in the regulatory field of health and social care, trying to make sure we are all marching in step, as it were. My nose tells me that there is a little bit of reluctance to enact that part of the Act at the moment, and I personally believe that it is a fundamental role that we can bring to the party of helping all of our colleague regulators work successfully together; so we would be very grateful for your support in that role. The second point I wanted to comment on was the point that Bill made about Monitor being the only body that can force change. I think until 1 April that is the case. As of 1 April, of course, we do have enforcement powers over foundation trusts, though we would not be sensibly using them if Bill and Monitor were not absolutely with us all the way in us exploring our concerns about a foundation trust and getting to the point where we ultimately decide whether their ability to kick the board around the block or our ability to withdraw registration, or suspend registration or apply conditions was the most successful, the most profitable and useful tool to use at that particular time. So I think we can force foundation trusts to make some change, but we would want to do it very jointly with Monitor.

**Professor Sir Ian Kennedy:** I am sorry to be coming in like this, but the emphasis on the board that Bill laid earlier is critical, it is a view we share, but you already see, even in that set of responses, that if I were the Chairman of a board I would not be entirely sure who I am obliged to please, as it were, and that requirement for clarity will now depend upon the working together of these two agencies. The structures, because they have grown, they have grown a bit like Topsy, and they do need very powerful and insightful leadership, otherwise, as I say, if I was the Chairman of a local trust I would not know quite what the tune is we are playing, or I might not.

**Chairman:** We are going to sort out the overlaps. Sandra.

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**Q698 Sandra Gidley:** A question to start off with to Sir Ian and Dr Moyes. Regulation is quite expensive. How much does it cost NHS organisations to meet all the requirements that your respective organisations put upon them? Have you made an estimate of that?

**Professor Sir Ian Kennedy:** How much does it cost?

**Q699 Sandra Gidley:** Yes.

**Professor Sir Ian Kennedy:** Nought point one per cent of the total cost of public funding allocated to the sector, or, if you want to put it another way, 94p for every thousand pounds spent, but I would ask a slightly different question. Furthermore, in the Healthcare Commission, it is a relatively small organisation compared with other regulators in the public sector, regulating a huge sector of £110 billion and 1.3 million employees. We have to do it smarter. I would ask the following question. It is not how much it costs, with respect, it is how it can be made maximally efficient. That is the challenge we have set ourselves. The second question is, what is the cost to safety if you did not have regulation? I think we have just recently lived through, and we are living through, other sectors of our public and private life in which regulation has, as it were, eased back, and we know what the cost of that is because we are living with it. I think the costs, therefore, have to be set quite clearly against the benefits. Costs are easier to calculate, both in financial terms and in terms of, “I have to fill in this form, morale is low”, and so on and so forth. The benefits, and I could enumerate them but I will not unless you press me, are huge in terms of what regulation can bring for the benefit of patients, for the encouragement of staff and for the improvement of safe care.

**Q700 Sandra Gidley:** The question I did ask was about cost. I was not clear whether that was the cost for each organisation that has to provide information or that was your cost of the total budget?

**Professor Sir Ian Kennedy:** That is the cost to the public purse of what the Healthcare Commission does. As regards the cost to each individual trust, I do not have that data. It may well be that it is discoverable, but I would have thought it is quite difficult to calculate, because, of course, it depends on lots of things, namely the energy put into it. I can say, we have done objective analysis commissioned by external agencies as to evaluation of our interventions and our general monitoring, and of those who are regulated—that is the most difficult correspondent to talk to—81% of those asked said that we did effectively focus their attention on safety, and 93% of those regulated said, by our interventions and our regulation, we had a positive impact on the care of patients, and those are the regulated.

**Q701 Sandra Gidley:** Dr Moyes?

**Dr Moyes:** This year we will spend about £15,250,000, and of course that is on different aspects of regulation. Like Ian, we do not ask individual foundation trusts what they think the cost is to them, and in practice I think it might be quite hard for them to identify precisely what the cost is because quite a lot of different parts of foundation trusts are involved in being regulated and a lot depends on how intensely they are regulated. We have everything from a couple of foundation trusts that are performing so satisfactorily that we get reports from them twice a year, full year accounts and half year accounts and that is all, through to trusts that we are in touch with pretty much every week, or certainly every month, because their performance is a problem. So I think the cost itself to each foundation trust may not tell you very much, and
that is one of the reasons we do not ask it. Like Ian, we ask about how the sector views us—we get IPSOS MORI to do independent surveys and focus groups, and so on—and we have the same kind of figures as Ian: about 90% per cent of the people that we regulate say that we are operating a sensible system, looking at the right issues and tackling them in pretty much the right way. I feel, on balance, that is a reasonable outcome.

Q702 Sandra Gidley: By the same token, neither of you know how much time this all takes up and whether the trusts think it is the best use of their time to balance all of the different regulations they have to comply with?

Professor Sir Ian Kennedy: I can give you a very specific answer, because that was a question we put through our study, and even of the regulated, the public, of course, would want more regulation than we currently do and we know that, but 70% in our first year said it was (and you have this data) “a good use of their time” and, furthermore, it ought to be understood that the system that the Healthcare Commission has developed (and I am sure Barbara will pay appropriate attention to it) is one in which we only ask of trusts what they should be asking of themselves, not least as regards safety. We ask for information, we engage, through our local organisational mechanisms, with them to find out whether they are doing what they are claiming to be doing, namely looking after patients, and if they do not have that information, then we ask why they do not have it, and if they do and we look at it and we are satisfied, we get out of their hair.

Q703 Sandra Gidley: Are you saying that every piece of information collected by the trusts is necessary? I will put it different way. If you had your time again, if you could have a groundhog day and you could perhaps learn from any mistakes you may or may not have made, do you think there are better ways of spending the money to improve patient safety, or is regulation the holy grail here?

Professor Sir Ian Kennedy: Both. If I had my time again, I do not think I would do a great deal that I do not think I would do a great deal that was different, because the vision which we published in 2002, which was described at the time by a number of commentators as ambitious, which persuaded me that it was worth trying, has stood the test of time. Of course you could do more for safety, but the system of regulation that we have introduced and the fact that we are regulated has, I think, made a significant difference through our system of looking for information, persuading boards that this is the information that they need to collect, analysing it, sharing it, visiting when we need to, and the total result has been, in my view, the raising of safety on the agenda and some attention to the problems that need to be resolved. Barbara, I am sure, if you are inviting her to answer, will answer also, but there are some who have a view that regulation is a punitive policing, top-down, heavy (and the B word is usually introduced) burden and that if any regulation is called for it should be “light touch”, although Lord Mandelson has now, this morning, changed the word “light touch” to “right touch”. In my view, right touch is exactly the point. Regulation is a lever: it is neutral. It is available to government to do a job. It is neither burdensome, nor the other. It has to be efficient in so far as it has to be cost-effective, the benefits outweigh the costs—and, in my view, in the Healthcare Commission case they do—and it has to be effective in so far as delivering what you have asked us to deliver, which is to promote improvement. In my case it has done that.

Q704 Sandra Gidley: I think we need to look to the future now. Baroness Young, how are you going to achieve that aim: minimum burden but greatest improvement in safety?

Baroness Young of Old Scone: We have made a commitment to be what I call a modern regulator.

Q705 Sandra Gidley: Yes; I wish I knew what that meant. It is one of those phrases that is bandied around endlessly and means zilch.

Baroness Young of Old Scone: For me it is risk-based, it is proportionate, it is working with providers on issues that they ought to be focused on because they are important issues and also with a strong focus, and, indeed, we have introduced into our structure and our processes a strong focus on looking at the administrative burden particularly of changes in regulation that we make. So we will be doing impact assessments of all of the regulatory changes that we make to ensure that they are not putting disproportionate burdens on the folk we are regulating. But I think the point that Ian made is absolutely the case, and that is that, if the regulator is asking questions about things that the governance structure or the commissioners or the performance managers are not asking questions about, somebody is on the wrong page. So we have got to explore, if people are saying, “We do not want to look at this because we do not think it is important”, why there is a difference of view as to the importance of a particular issue. So I think the alignment point that we made previously about making sure that we are all clear about what it is we are trying to achieve in terms of safety and quality outcomes means that then you look at what the best mechanisms are for getting that delivered in a way that does not become too burdensome. There is a lot of experience from other regulatory fields on this which I hope I can bring with me from the environment, and media regulation.

Q706 Sandra Gidley: That was quite vague. It sounds as though you do not know what the effective mechanisms are.

Baroness Young of Old Scone: It will vary with the issue and it will vary with the organisation. For some organisations a ticking off behind the bike sheds is just as effective as doing any formal enforcement mechanism. In some cases there will be issues that are best resolved, for example, through a professional process rather than a regulatory process or through a managerial process
Dr Moyes: Can I comment on that from my modern regulator. About being a truly risk-based, proportionate and specific objective for the Care Quality Commission. I think there is a lot we can do by having a very slightly different approach to not constantly bothering people with requests for information, which drives them crazy. So I think there is a lot we can do by having a very specific objective for the Care Quality Commission about being a truly risk-based, proportionate and modern regulator.

Dr Moyes: Can I comment on that from my perspective? The thing I would like to persuade you of is that real value is getting the boards of foundation trusts to recognise that they are responsible for the running of all aspects of their organisation, getting them to self-certify to us, which in the main we do. There is very little direct collection of data by us. We get the boards to tell us about what they are doing. Forcing them, therefore, to look at the performance of their own organisation, I think, is also very important, and I think the third thing that is also having an impact is making clear to boards that, if they really cannot change in circumstances where failure is happening or is possible, then we will force change and it will happen. I think increasingly that as boards recognise that that is a real possibility, they do look very carefully at the performance of their organisation and we do find the self-certification process is taken very seriously by boards and boards learn a lot from it. So I think telling boards that they are actually the front line can be very important in circumstances where things are not happening properly is a very important development. It may not be the holy grail, but I think it has been a real shift in the way a board works in the organisations that I deal with, and I would like to see that as a lasting legacy.

Q707 Dr Stoate: Professor Kennedy, I would like to ask you about the Annual Health Check, which is essentially self-examination by a trust on an annual basis. How can you be certain that it is an effective way of improving patient safety?

Professor Sir Ian Kennedy: The fundamental point about self-assessment is what Bill has just said, and we share that analytical starting point, but the people who are responsible for delivering the care that patients are entitled to and clinicians who look after them are entitled to, not least safe care, is the board. They are responsible; they are accountable. The Annual Health Check is only part of what we do, as you know. It responds to Parliament’s request that we do an annual assessment of performance. What we do is say: you have got to tell us what you are doing, but we do not leave it at that, because that would be, first of all, arguably perilous and, secondly, mechanistic in the worst sense of the word. So it is not just what the boards assess themselves as doing—that is the first step—because then there is a series of other steps. We have over 2,000 sets of data, and this is in response to the previous question. We do not go out and collect, as Bill says, lots of the other stuff. We find out where it already exists and pull it together, and we test, on the basis of an understanding of what might constitute a risk to the care of patients, and that is where agreement on what constitutes risky behaviour is required, and we have our own definitions. We test and, if we do not think that the self-assessment coincides with our understanding of risk, we will begin to ask questions. One of those mechanisms will be visits, which are a central feature of our approach, but they come after, rather than having a regulatory system which trawls the lands looking under the beds. There are a million contacts with patients every 36 hours. How you would do that through a system dependent utterly on visits and inspectorial visitations, I do not know. So visits which are targeted. Then we listen to patients. They provide us with local intelligence through their complaints, through conversations, letters and whatever else, and then we actually listen to groups representing patients and the public. MENCAP were the ones who alerted us to Cornwall Partnership Trust and the treatment of those with learning disabilities. Then we listen to local government through their oversight and scrutiny committees, and all of that is added to our final view of performance. It is not just self-assessment, self-assessment is the first step, and because the boards know that we are going to do the other stuff, having attempted in the first year, as it were, to try it on, they have now learned that trying it on does not work because we have these other ways of cross-checking and we get a better dialogue when they admit sometimes, “We have a problem over here”, and recognition of that is the first step to doing something about it, because we would then say, “SHA”, or whatever, “Monitor, can you please go in and help?”, and that is in the interests of patients.

Q708 Dr Stoate: You mentioned organisations such as SHAs, you have mentioned patient groups and you have mentioned OSCs (Oversight Scrutiny Committees). How can you be sure that those really have brought to light all the issues that you would wish to be brought to light?

Professor Sir Ian Kennedy: You cannot be sure of anything in this life, but the point I would make is that the larger the number of sources of information you have, the greater the possibility that through that cross-checking mechanism you will identify things that are not right and then be able to do something about it. If you simply relied upon published data or self-assessment as the only thing, you would seriously be in trouble.
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Q709 Dr Stoate: What I am asking is: are there any gaps? As you know, I am involved in general practice, and I still do general practice to a certain extent. I have just been through my annual appraisal, in fact, this week, which is an interesting and edifying experience. However, my appraiser can only appraise the information that I have effectively provided. So when the appraiser says to me, “Can you tell me examples of patient safety incidents occurring in the practice?”, all she will find out is those that I have reported. It does not make it easy to plug any gaps.

Professor Sir Ian Kennedy: You are absolutely right. If that were the case and we were operating that system, I would be pretty ashamed of myself because you would say, “I have done this.” I would want to go, and I have a deal with the General Medical Council and the Nursing and Midwifery Council, and I would say, “Is this the case? Has Stoate told us the truth?”

Q710 Jim Dowd: Highly unlikely!

Professor Sir Ian Kennedy: Then, if there were dissidence between what you say and what we discover, that provokes a conversation. It may be that there is an explanation—there may not be—and then we escalate it to the SHA, or whatever.

Q711 Dr Stoate: What I am really asking is whether you think the system is sufficiently robust? It sounds to me as though you think it is.

Professor Sir Ian Kennedy: I am persuaded that there is always room for manoeuvre, for improvement, and it has been improved over the three years we have run it, but it is pretty robust. I think Barbara will be operating a different system, but the mentality behind it will not be too different.

Baroness Young of Old Scone: Can I comment on the primary care issue?

Q712 Chairman: Very briefly, because we are slipping on time here. We have got three sessions this morning. I am afraid, so I am going to have to speed things up.

Baroness Young of Old Scone: To highlight the importance, we believe, of primary care, if you look at the amount of information that is available, it is not as good as other services. For example, even on the reporting of errors and incidents, it is far lower than you would expect, and so we are very pleased that the Government is intending, we hope, to bring primary care services, including general practice, into registration from 2011 because we believe that that will give us a framework within which the professional accreditation systems that the College of General Practitioners is working on and the regulation system can produce a much more rounded risk profile of general practice than currently exists, and we know that is an issue that the public are particularly keen to see happen.

Q713 Dr Naysmith: I have a couple of questions for Sir Ian but, first of all, I would like to welcome him back to this committee. You have helped us in the past with a number of our investigations and, as I suspect this may be your last appearance before the committee, given your change of circumstances, I just wanted to say thank you for all the help you have given us. The Healthcare Commission has conducted a number of what one might call landmark investigations into major lapses of patient safety, such as Maidstone and Tunbridge Wells Trusts. What were the key shortcomings that you uncovered in these investigations? Dr Moyes has already made reference to the important role of the board. Perhaps you could make sure that you cover the role of the board as well in these shortcomings and see what you can elicit about that?

Professor Sir Ian Kennedy: I am very conscious of time, so thank you for your very kind remarks. It has been my pleasure to appear. We published a document called Learning from Investigations in 2008. If we have not given it to you, we will. On page 39 through to page 45 there are both the general themes we have learned from all of our investigations and some specific themes. I just make two other points. First of all, things will always be going wrong somewhere in a very large organisation. Modern healthcare is risky and the job of all of us is to try and minimise or mitigate those risks. We have had about 320 requests to do investigations. We have actually only done 14, with about three pending. We have chosen the ones which we think will allow us to generalise about problems which are not specific but national: vulnerable people with learning disabilities, maternity care, hospital-acquired infections, dignity and care of the elderly, and so on. We have found leadership, priorities in management, structural changes and mergers and general governance and information about what is going on, recurring themes, and that is where Bill is quite right to say that the buck starts and stops with the board.

Q714 Dr Naysmith: Can we organise the board and ensure it operates properly to make sure that it takes safety seriously?

Professor Sir Ian Kennedy: I would take a completely different tack. Yes, the board has to be stronger, and there is an initiative that Bill and I started with Sir William Wells some time ago about how you educate modern boards, and so on and so forth, and that, I think, is very important, but I would say that the future is not investigations, the future is surveillance and what I described earlier. We should be in the business of preventing Baby P, preventing Bristol, by identifying things going wrong before they get to the point where you have a tragedy and you have to investigate. We in the Healthcare Commission are seeking to shift the centre of gravity away from post-op investigations to surveillance.

Q715 Dr Naysmith: Is it a good idea to make one member of the board responsible for safety matters, or should everyone have a role?

Professor Sir Ian Kennedy: Everyone.
Q716 Dr Naysmith: Everyone?  
Professor Sir Ian Kennedy: It is the job of everybody. It should be part of the job description of everybody, from the cleaner to the chairman of the board.

Q717 Dr Naysmith: I think Dr Moyes wants to come in, but I will ask you one more question before I ask Dr Moyes. You were due to publish a study today, in fact, of patient safety in 30 trusts. We understand that it has been put back for a week. I do not know if you want to tell us why it has been put back for a week, but the question I was going to ask: does the study tell us anything about how widespread the failings are in patient safety?  
Professor Sir Ian Kennedy: I apologise that it is not before you today; it will be before you by the end of the week. This is because we are suffering from indigestion in the Healthcare Commission. We have to publish a lot of reports and we have three weeks to do it.

Q718 Dr Naysmith: I find it surprising how often the Government publishes a document the day before they appear at this committee! You have not taken that opportunity?  
Professor Sir Ian Kennedy: I would hope that you would not accuse me of in any way seeking other than to be open with you, as you already indicated in your encomium earlier. You will have copies of that. It does identify—I will make two short points—that trusts are now paying greater attention, and still they seem to be giving insufficient attention, focusing more on targets and finance and mergers, and so on, than on safety, and non-executives, in particular, describe themselves as being passive recipients, not really able to get into the granularity of what is going on in their trusts.

Q719 Dr Naysmith: I was not going to ask you about this, Bill, particularly, but you obviously want to come in and have a word or two.  
Dr Moyes: Perhaps just one quick comment, if I may. When I talk to boards about their role, there are five things I really stress to them. They have to have proper information on safety and performance—that is the work with William Wells, the intelligence board that Ian referred to—there has to be transparent reporting within the board, within the hospital. The clinical teams have to report to the board. There has to be challenge. The non-executives have a legitimate role to ask the medical director questions. There has to be clear accountability, and there has to be a proper risk assessment done in the board of the decisions that they take. Investment decisions sometimes have safety aspects, and that has to be thought about. That is the only comment I wanted to make.

Q720 Charlotte Atkins: What went wrong with Mid Staffordshire Foundation Trust?  
Dr Moyes: I think what happened with Mid Staffordshire was that at the point where we authorised it, they did meet our criteria. We were quite clear about that.

Q721 Charlotte Atkins: When did you authorise it?  
Dr Moyes: We authorised Mid Staffordshire in February 2008, after quite a lengthy assessment. We were aware at that stage that Dr Foster’s work had identified a high SMR (standardised mortality rate), it was 127, but it was declining. There had been work commissioned by the trust itself, by CHKS, to look into that. There had been meetings with the SHA and the PCT and all of that seemed to indicate that the issue was about the very, very poor quality of coding. So at the point when we authorised the trust in February, the consensus around the system was that the trust had a serious problem with its coding and that was leading to a misleading set of SMR data. When the Healthcare Commission decided to investigate, it was on the back of that, that they had an outlier, as Ian said, in relation to SMR that caused them to investigate. Now that they are in the trust, now that they have been in the trust and we have been kept very closely informed by the Healthcare Commission as this investigation has proceeded, they have identified a number of areas where clinical staffing levels had been very poor, clinical leader strip had been very poor, nurse staffing levels had been very poor; there had been aspects of privacy and dignity that had not been given proper priority. So, to answer your question, I think that the points I have just made are probably the things that have gone wrong. I do not think the board has always had good information; I do not think the board has always had good reporting. I do not think they have challenged, I do not think they have always asked the right questions, or, when they have, they have always been behind the curve; they have been reacting. To their credit, as the Healthcare Commission started to uncover problems, I do think the board started to try very hard to rectify them; they did not simply watch and see a body of evidence building up. Clinical staffing levels in A&E, for example, have been hugely increased, nurse staffing levels have been increased, but the reason why the chair woman has stepped down is that she has recognised that leadership of the board needed to be changed, needed to be stronger. The reason that we used our formal powers of intervention to put in an interim chair, and now an interim chief executive, is that we think they need much stronger leadership to tackle the problems that the Healthcare Commission has identified, which are real problems, to get this hospital back on its feet. So that would be my answer to your question.

Q722 Charlotte Atkins: But it was less than a year ago that you authorised them as a foundation trust. Surely you are not suggesting that at that point they should have got that status?  
Dr Moyes: At that point the criteria that we had, financially viable and well governable, were the criteria they met, and at that point there were a lot of aspects of the performance of the hospital that we did not look at because, like all regulators, we were under pressure to be proportionate and not excessive. Since Mid Staffs, we have expanded our assessment process, so we do take a look at local press cuttings, for example, we do ask the Healthcare
Commission, not just at local level, but at national level. "Is there anything you want to tell us?" We ask the investigation team in the Healthcare Commission, "Are you".

Q723 Charlotte Atkins: But less than a year ago, when you authorised the fact they should have foundation status, now we are hearing we have high rates of mortality for emergency admissions and concerns of poor nursing care at the trust. That does not happen over one year, it must have been there a year ago when you authorised them to have a level of independence which would assume that you had confidence, not only in the chief executive and the chair person, but also in the board. A lot of hospitals now are rushing towards foundation status, so much so, in fact, that they are beginning to neglect things going on in the hospital, and I am talking about a hospital very close to me, North Staffordshire University Hospital Trust, and what worries me is that it appears from the evidence of Mid Staffordshire that it is relatively easy to get foundation status when there are clearly significant problems within the trust and that maybe we are scattering this independence far too widely without proper scrutiny.

Dr Moyes: I do not accept that for a second. I do not think it is at all easy to become a foundation trust. One applicant in three does not get authorised the first time. My memory is that North Staffordshire has already had a go at becoming a foundation trust and we sent them back because we were not satisfied; so I am not accepting that it is easy. What I will accept is that at the time that we authorised Mid Staffs our assessment process was relatively narrow, and that was because we relied on the fact that the Secretary of State supports the candidates when they come before us, we also relied on the extent of work that had been done by the trust itself to try and understand its high mortality rates. It was not that we did not know about them, but we were persuaded by the external scrutiny of SHAs, by the work that the SHA did, by the PCT’s view that this was a coding problem and not an indicator of really seriously deficient care. As I say, we have learned lessons in Mid Staffs. We do a much wider scrutiny of other sources of information: the Healthcare Commission, local press reports, trends in complaints, trends in serious untoward incidents, patient surveys, patient satisfaction data, all that kind of thing. We look at all that now, whereas at the time we did the Mid Staffs assessment we did not. So there are certain lessons we have taken and our process will continue to evolve in the assessment, but I do not think it is an easy process.

Q724 Charlotte Atkins: But potentially people may have died as a result of not considering the core problem and considering it is just a coding problem. What worries me is that it puts into doubt the whole process of self-assessment, if you were convinced that actually it was just a coding problem and not a significant problem within the trust.

Dr Moyes: Do not forget that, for a good part of the time when we now know that there were problems in this trust, it was not a foundation trust, it was directly managed by the SHA, ultimately, so it was part of the previous system in which, in my view, the board’s responsibility was very fuzzy. The Healthcare Commission’s investigation has spanned four financial years, in two of which this was not a foundation trust and in two of which it is a foundation trust; so I do not think one can draw any conclusions from this about foundation trust status.

Q725 Charlotte Atkins: I think you can draw the conclusion that perhaps they should not have been given foundation status in the first place.

Dr Moyes: Well, at the time we authorised them they met our published criteria, and we have to stick to those criteria, but, as I say, we have learned lessons and we have expanded the range of data we bring to bear, and I think that is important.

Dr Taylor: This is to Jan, and I have been instructed to be brief. Like Doug, I have greatly appreciated your thoughtful and open contributions, and I am looking for an open contribution on this. The new NHS complaints process has removed the Healthcare Commission from the process and has not put the Care Quality Commission there, so complainants automatically lose the automatic independent review. Do you agree with me that this is a disaster; that it has implications for patient safety?

Chairman: We do not ask leading questions, you know!

Q726 Dr Taylor: I want a straight answer.

Professor Sir Ian Kennedy: When the Healthcare Commission was being set up I asked the then Minister not to give to the regulator the responsibility of adjudicating on complaints but, rather, give the regulator the responsibility of monitoring what complaints were coming through, what they were telling us, particularly as regards safety, so that action could be taken. The Government and Parliament took other views. We then had to build a system at some point. Talking about the cost of regulation, it was commanding 14% of our annual budget building a system and for a while we were behind the curve, using Bill’s language. We got ahead of the curve, we learned an enormous amount and we fed that back, so the experience was valuable. I refer you to our document which is called Spotlight on Complaints 2008—I am not going to go through it again—in which we identify the recurring themes which come through complaints, and they are recurring and they remain more or less consistently the same. What the taking away of the responsibilities of second-tier complaints from the regulator will do, we will have to wait to see. Critically, it will mean that trusts will have to deal with them more effectively at local level, and historically they have not done so. If we get the same rate of appeals as the Healthcare Commission had to deal with, the ombudsman will be dealing...
with 8-9,000 a year. That cannot be the case; that cannot happen. So there has to be some way, and Barbara, through CQC, will have some mechanism whereby she will monitor—and it may be a regulation requirement that they deal adequately with them—but without sanctions against individual trusts, it is my experience that trusts still do not sufficiently take seriously complaints. Good ones do, and, indeed, good ones welcome complaints. I was talking to the Chief Executive of UCLH. They have a lot of complaints. That is an index of good performance, in my view, providing they deal with them, but if they are not dealt with, we will have a lot of unhappy patients and we will have a lot of issues of safety. After all, 23% of complaints had to do with safety in the context of GPs and 38% of all our complaints were about GPs and 0.3% of incidents collected by the NPSA came from GPs.

Q727 Dr Taylor: Have you been able to form any impression about the effectiveness of PALS and ICAS?

Professor Sir Ian Kennedy: PALS have been useful to patients, and we have certainly found in the context of complaints that they have helped patients. If I were to accept your invitation to be a bit open for a moment just to say one thing, I think mechanisms which are reactive for hospitals waiting to hear about PALS while you are waiting to hear about ICAS, waiting to hear about other things, is the wrong way of doing it. What I would like to see is hospital trusts, PCTs and GP practices develop more active, rather than reactive, mechanisms, talking to patients in a consistent way, doing surveys, finding out mechanisms for feedback from patients in a consistent way and then showing what they have done about it so they close the curve. Reactive mode is fine, but it does not get us anywhere near where we need to be.

Q728 Dr Taylor: So good communication can prevent lots of complaints?

Professor Sir Ian Kennedy: And the initiative from the trust rather than expecting the patient to do it.

Baroness Young of Old Scone: I know you are pushed for time, but would it be useful to briefly hear what we are planning to do to plug the gap, to some extent, of the transition? We will be, through the registration system, requiring all providers to engage within trusts on healthcare acquired infection. We will also be bringing GPs into registration, which will give us an opportunity to look at an area where safety as yet is not hugely examined. The Healthcare Commission has done in the past to know that they are all improving, that the rates of infection are going down, there is a much stronger engagement within trusts on healthcare acquired infection issues now, but there are still a few that need a bit of a push to get to the level of the rest.

Mr Scott: Thank you. With your psychic powers, you have answered the supplementary as well!

Chairman: We will move on then. Charlotte.

Q732 Charlotte Atkins: Baroness Young, the Patients Association have told us that they have a great concern that the Care Quality Commission will not be as robust as the Healthcare Commission in reporting on safety. What is your view to that?

Baroness Young of Old Scone: I think I am probably going to leave this room and phone the Patients Association, because we have not met them yet, so it is kind of weird that they have got this impression. I would quite like to see their evidence, and it would be worrying if they did not have concrete evidence. We certainly have made an absolute commitment to safety as a fundamental part of our manifesto as the most important element of our model of quality. We are going to be in a better position to look after safety issues than the Healthcare Commission was or the Commission for Social Care Inspection, because we do have this ability to move across health and social care and it is often in the gaps between services that some of the big safety issues do arise. We will also be bringing GPs into registration, which will give us an opportunity to look at an area where safety as yet is not hugely examined. The information that is available on GP issues of error and omission is not as well developed as it is in, for example, acute provision, and we have also got...
stronger enforcement powers. So I would find it really difficult to understand how the Patients Association feel that we are going to be a kind of limp rag. The other commitment we have got right at the heart of what we do, of course, is to involve users and patients and carers and families. So we will be hot-footing it to the Patients Association to make sure that they have a full opportunity to explore with us what we are going to be doing and have an opportunity to influence if they are feeling concerned about it.

Q733 Charlotte Atkins: But your own memorandum says that the proposed registration requirements regarding patient safety, as currently worded, are in some ways not as comprehensive as the standards for better health that underpin the Annual Health Check. What did you mean that by that? Will that hinder your ability to address patient safety issues?

Baroness Young of Old Scone: We need to correct that, because the discussions that have been happening on the registration requirements have moved on. In fact the concern, which was about one criterion, which was that there was not an explicit requirement to put in place changes as a result of local learning from incidents, has now been reworded. In fact, about 75% of the registration requirements are directly about issues of safety, so there is safety threaded right through the registration requirements and we no longer have a concern about that particular criterion because it has been reworded.

Q734 Charlotte Atkins: But something that has been raised with me is that there are some outcomes that the CQC might rely too heavily on data and paper-based reviews at the expense of on-site inspections by well trained and experienced inspectors. Is that a concern that you can understand?

Baroness Young of Old Scone: No. One of the joys, I think—and with 25 days to go I am having quite a lot of bother finding joys right now—of bringing together the Social Care Inspection Commission and the Healthcare Commission is that they have got very different models, and I think that by combining the two we can get the best of all worlds, a good process of the sort that Ian has described of taking data and particularly beginning to predict risk situations. What are the indicators that show that providers are actually getting into the risk zone but, at the same time, having quite a rich inspection process that allows us to sniff the breeze and to reality check as well as reality checking from a whole variety of other information providers, including local communities, local authorities, patients, various other regulatory bodies? So I think we get the benefit of both, and I would be very anxious, as indeed you are, if we were overly reliant on one or the other. I think it is the combination of both that is the important thing.

Q735 Charlotte Atkins: I think that Haringey Children’s Services probably demonstrated that on-site inspections are really important, but there is also a concern that there might be reductions in staffing associated with light-touch regulation. Again, I do not know if that is justified or not, but clearly, it is important that you have the qualified staff that are able to carry out these inspections in a way which would be robust.

Baroness Young of Old Scone: Not being a saint, before I took the job as Chairman of the Care Quality Commission, I did check that we were not scheduled for mammoth reductions post setting up, and I think the reality is that were the three existing commissions to be on trajectory, and I think the Healthcare Commission is not necessarily the case but certainly with their other two commissions there are still some remaining streamlining reductions that they were due to make that will not now be completed until after we come on the scene, so there will still be some streamlining. Our commitment in setting up the new organisation was to protect the front line as far as possible and to bring across as many of the inspectors that are currently in the Healthcare Commission and Social Care Inspection Commission as were willing to come to us and to make sure that that ability to be there on the ground is as rich as it was previously. But we want to go further than that because we have got the opportunity of looking at two very different field work forces, two very different recruitment and training processes, two very different inspection methodologies, and I think we can learn from the good stuff that is in each of the three commissions and produce a united cross social and health and mental health care inspection and local process that is exactly what you describe: well targeted, risk-based inspection by people who know what they are talking about.

Professor Sir Ian Kennedy: May I, with your indulgence, Chairman, very quickly say as regards healthcare, I am not sure, though I am an adherent to the need for visits and inspection, that they ought to be, as it were, targeted. I am not sure going to visit any particular location would have done anything for the healthcare of Baby P, because one of the problems was, as I recall the facts, he was moved around into this A&E and into that doctor, and so, if we were able to have proper electronic recording of the relationship between children at risk and doctors being able to have access to that and then record that they have just seen a child, that would be, in my view, something to think about as to how we look at the situation of children like that: because there is a lot of what lawyers call ‘forum shopping’ and what parents such as this might call ‘doctor shopping’, where you move from one doctor to the other, so that unless you have some consistent way of capturing that information nobody knows that this is happening.

Q736 Dr Taylor: This is specifically to Baroness Young. Almost four years ago to the day this Committee did a report on prevention of venous thromboembolism in hospitalised patients and, to our horror, we discovered that between 25,000 and 32,000 deaths per year occurred from this. The cost
was estimated at 640 million, and what makes it even worse is that these deaths are largely preventable, and we actually said that thousands of lives could be saved by the use of a tried and tested treatment and all one needs is a risk assessment and then you know which patients have to have the prophylaxis and where you are. We understood also, which makes it rather worse, that the Healthcare Commission and the CMO’s VTE Implementation Working Group had pretty well agreed that this was going to be a feature in the Annual Health Check for 2009–10, which would have been tremendously important and saved lives if every trust was doing this risk assessment, which is easy—it is only a few extra questions on a route—and we understand that it is not in among your proposed indicators for the periodic review. Why not?

Baroness Young of Old Scone: We share your view. If you think about it, there are more people dying from venous thromboembolism than there are from healthcare acquired infections, probably, and so it is an important issue. We did, indeed, in our draft proposals that went to the department have venous thromboembolism as one of the fields that we wanted to look at in the periodic assessment in the Annual Health Check. We have, under the Act that establishes a requirement for the periodic review, to seek the Secretary of State’s approval, and we did not get that for this line. The view was that we should not be adding into the requirements we were placing on trusts anything that was not already in the operating framework which had previously been agreed and launched upon the NHS. The commitment is that, though there is not a specific indicator in for this year, for the 2009–10 periodic review, that the department will look very favourably on it being in for the following year. In the meantime we are not just sitting back and doing nothing. In the 2008–09 Health Check there will be a process of looking at implementation of NICE guidelines and, of course, one of the NICE guidelines is on venous thromboembolism and we will be looking at venous thromboembolism as part of that process. So there is one more than one way of skinning a cat, but I think there is a point of principle here, however, and that is that I arrived at the Care Quality Commission as the bill was virtually through the House. The only part of our regulatory framework that we have to get the Secretary of State’s permission for as opposed to consult with the Secretary of State is the periodic assessment process, and I would like to believe that the department will not put that into a box that says we may only look at things that the NHS has agreed are important, because I think that really does seriously infringe the independence of the regulator and the public have the right to expect that we will be able to look at things that we are seriously worried about.

Q738 Dr Taylor: In a parliamentary question in November 2008, the minister responding did say, “We will be monitoring the position closely and formally reviewing the policy in time.” It does not go on to say how many more deaths might occur in that year. Are they going to be monitoring it or are you monitoring it for them?

Baroness Young of Old Scone: I cannot speak for the department and the NHS itself, but certainly we, through the 2008–09 Health Check, the one that is underway at the moment, will be using our ability to look at implementation and the NICE guidelines to raise the venous thromboembolism issue.

Dr Taylor: I think you should check, because the NICE guidelines, from my memory, only apply to surgical patients, and this applies to medical patients very definitely as well.

Q739 Dr Naysmith: A couple of questions for you, Dr Moyes. We have already touched on them when you were talking with Charlotte about Mid Staffordshire. It sounded then as if your remit for deciding who should be a foundation trust and who should not was rather narrow at the time you made the judgment for Mid Staffordshire. What responsibility does your remit give for patient safety issues for foundation trusts now? It may have changed since Mid Staffordshire, I do not know. You were indicating that you had learnt some lessons.

Dr Moyes: We learnt some lessons about the volume of data, the breadth of issues that we should look at in the assessment process. Now, when we are assessing foundation trusts, as I said earlier on, we do ask the Healthcare Commission quite explicitly, nationally and locally, “Is there anything you want to tell us?” We do look at press cuttings, we do look at trends and serious untoward incidents and complaints and lots of other things that we bring in, where previously we did take probably a slightly too narrow focus. So in the assessment process we try to make sure that we have some understanding of the quality of governance in the hospital as well as its financial strength.

Q740 Dr Naysmith: The safety figure really.

Dr Moyes: We regard safety as a key indicator of governance. We do regard boards as responsible for everything in the hospital and we want to understand: is there a problem with safety? Are there untoward incidents or are there clinical failures that the board should know about and they do not know about, or, if they do know about them, are they doing the right thing about them? Medway, for example, we identified quite a high SMR, and, again, we delayed the authorisation of Medway for several months to force them to get to the point where they understood what was going on and they could explain it to us, and I think that led to quite substantial changes in the clinical governance processes in Medway which I think was to the good. So, yes, we do make sure, as best we can, that we identify potential or actual problems of safety and that we have got confidence that the board will deal with them.

Q737 Dr Taylor: So really we have got to work on ministers?

Baroness Young of Old Scone: I would suggest that the Minister is the man to talk to.
Q741 Dr Naysmith: I move on to a different topic now. In evidence to the Public Bill Committee on the Health and Social Care Bill when it was being considered by Parliament, Monitor stated—I do not know whether this was in evidence or whether it was a written statement—“The creation of a new regulator, the Care Quality Commission, with statutory powers over NHS foundation trusts puts the success of the financial trust regulatory regime at risk. Giving two regulators powers of intervention over the same bodies risks confusion, duplication and loss of accountability.” Do you still hold that view?

Dr Moyes: It is still an area I am anxious about. Monitor has been consistent throughout, quite openly saying that we believe that the strength of the system is that we have the responsibility to intervene in circumstances of failure where other mechanisms such as the Commission’s pressure, and so on, has not had an effect. As Barbara said earlier on, the Care Quality Commission has a power to register and, therefore, to deregister and, therefore, to vary the registration conditions, and I think we both recognise that that is an area where, once the CQC comes into being properly, we are going to have to work quite carefully together to identify who does what in what circumstances. But it is an obvious issue that has to be sorted. We both recognise it has to be sorted. We are developing a memorandum of understanding between our two organisations which tries to make sure that we can describe to the world in language the world can understand, how our compliance system and the CQC’s registration system will bolt together. It is not an insuperable problem but at the point when we made those comments it was very strongly felt by us.

Q742 Dr Naysmith: There is another area of possible confusion and that is in the area of performance management, the role of strategic health authorities in respect of non foundation trusts. Are strategic health authorities doing something different? Are they going wrong in some of the things they do, that we need to have another two bodies involved?

Dr Moyes: The point about strategic health authorities for us is that they are obviously responsible to the Secretary of State. The Secretary of State has no powers of direction over foundation trusts. Therefore we would like to persuade the strategic health authorities that their focus should be on commissioning and what commissioners are doing and whether commissioners are commissioning effective health care or not. In cases where foundations trusts have not responded to commissioners properly, are not co-operating, not delivering and not doing the right thing, then it is our job to come in and make sure that the foundation trust performs properly. I think that way of working is gradually being teased out and accepted as the right way to get the system operating efficiently.

Baroness Young of Old Scone: Our distinctive role is that we are there to give the public assurance. We are to some extent standing slightly apart from the system. We are not part of the management or the performance management or the commissioning system, we are there to assess quality and help drive improvement but mostly to give the public assurance. I think that independent role is required in a system, no matter how heavily performance managed or commissioned it is.

Q743 Chairman: Dr Moyes, I think it was Alan Milburn when he was in office who said that all hospitals would be foundation trusts within three years or something like that. It has not quite turned out like that. If they were at some stage in the future, what would be the implications on your budget? How much extra money would you need to do your job?

Dr Moyes: I very much hope and believe that all hospitals will eventually be foundation trusts, although not necessarily all hospitals in their present form. In the long run I do not see Monitor as being a large organisation with a huge budget. We have invested a lot in technology—a lot in our terms, but in national terms not very much—in order to produce a system that can collect in a lot of data and process a lot of data very efficiently, without a huge increase in staff, so we would have a period, and the Department recognises this, where our assessment teams would have to continue in existence, but as we get more foundation trusts, we have to add to our compliance function. There is a bit of double running there. In the longer run, when hospitals are all foundation trusts, our assessment effort should largely wind down and we would be primarily a compliance organisation. I expect our budget to go through a bulge and then decline again, but we are 90 people or thereabouts today, and a budget of £15/16 million. I am expecting next year a budget of around £17 million and perhaps one or two more people, but I do not see us as being an enormous organisation and I do not think it is necessary.

Q744 Chairman: Thank you. Sir Ian, could I echo what Doug Naysmith said earlier and thank you personally for the co-operation that this Committee has had from you and from the Commission over many years now. I do not know where your future lies, but I hope you will be very happy there. I hope that we can, as a Committee, get the same co-operation from your successor Commission, as it were. It is vital in terms of overseeing health care in this country that we have co-operation from organisations like that in our day-to-day work and not just when we are sat in witness sessions as we are this morning. I would like to thank all three of you very much for coming along and assisting for this inquiry.

Professor Sir Ian Kennedy: Thank you very much.

Chairman: Thank you.
Witnesses: Mr Finlay Scott, Chief Executive, General Medical Council, and Mr Steve Walker, Chief Executive, NHS Litigation Authority, gave evidence.

Q745 Chairman: Good morning. Thank you for coming along to help us with this evidence session in relation to patient safety. For the record, could I ask you to give your name and the current position you hold, please.

Mr Scott: I am Finlay Scott. I am the Chief Executive of the General Medical Council.

Mr Walker: I am Steve Walker. I am Chief Executive of the NHS Litigation Authority.

Q746 Chairman: It might be the case that I will be exiting before the end of this particular evidence session. I have another important engagement in my diary and Doug Naysmith is going to take over. Absolutely nothing personal is intended. I have no interest to declare now, Finlay, in terms of my ex membership of the General Medical Council, but perhaps I could start with you because we have heard evidence from junior doctors that patient safety was not an overt theme in their undergraduate training. How should the undergraduate medical curriculum change to ensure patient safety?

Mr Scott: I understand that this has been said. As I think you are aware, at the moment we are in the middle of a consultation on a new edition of Tomorrow’s Doctors, our guidelines for medical schools. Among other things, the draft guidelines identify nine domains, the first of which is patient safety. We will be reflecting in the course of the consultation on whether that yet makes it sufficiently clear that patient safety should be an important element of the early education given to all undergraduates in this country.

Q747 Chairman: Professor David Webb told us that patients are being harmed by prescribing errors as a result of inadequate pharmacology education for doctors. He said that the GMC has acknowledged that there is a problem there. We saw some statistics on prescribing errors of new doctors, as it were, which were a bit alarming, although new doctors do not work in isolation. Are you going to amend Tomorrow’s Doctors accordingly to make sure that we do have proper education in that part?

Mr Scott: The draft on which we are currently consulting is very clear about the importance of prescribing. In the course of the consultation we will consider whether more has to be done to make that plain, both in the light of what has been said to this Committee and in the light of other responses. I think it is important to try to ensure that we understand the reasons for prescribing error, and I am not sure that those reasons are genuinely well understood. We have commissioned two pieces of relevant research, the results of which are already understood. We have commissioned two pieces of research, the results of which are already perceived problem lies in more teaching of pharmacology per se, we need to be sure that we understand the causes. The second piece of research which I will mention briefly is a study being undertaken by Dr Tim Norman. That study is looking at the causes of prescribing error in hospitals as distinct from general practice. Again that will help us to understand better the causes of prescribing errors, so that we can take appropriate action.

Q748 Chairman: You do not have a time scale of when they are likely to be finished at all, do you?

Mr Scott: I think that research is reporting later this year. Because I am aware of evidence about errors in core training, the next stage in our research programme will go on to look at the probability that prescribing errors can be better explained in primary care, leading us to take appropriate action.

Q749 Chairman: The other thing on the undergraduate curriculum is to take account of non-technical skills, issues around human factors training (communication and team work skills, situation awareness, etc). You will have seen the Darzi Review on the next stage and the need for team work in particular. Can you give us any idea of how you think that might improve. Are they able to provide that kind of teaching in terms of not just the technical side but the human factors side as well?

Mr Scott: As I think the Committee is aware, when we launched the first edition of Tomorrow’s Doctors in 1993 it marked a shift away from the acquisition of knowledge to be recited by rote at your finals and then promptly forgotten. It tried to move the education of new doctors more on to the acquisition of non technical skills—not ignoring the technical skills but taking full account of non technical skills—with greater emphasis on communications and the ability to keep oneself up-to-date in the course of a 35 or 40 year career. By common consent, I think, today’s new doctors are able to communicate more effectively than their predecessors. However, I think there remain major challenges around ensuring that today’s new doctors are not able to operate effectively in teams, which is an important aspect of the non technical skills. I think it is less about what we write in Tomorrow's Doctors—the messages are plainly there—and about understanding better through research and analysis what leads to more effective team working and the
avoidance of some of the tragedies that this Committee has heard about. Again we have that very firmly in our sights. The core messages about effective team working and communications and non technical skills more generally are already there.

**Q750 Dr Stoate:** Previous witnesses, the Medical Decision-Making Research Group at Birmingham University, expressed real concern about the extent of diagnostic errors in general practice in primary care. The recommendation from them was that “The General Medical Council should require medical schools to place much greater emphasis on the teaching of decision making, including diagnosis.” Is that something the GMC is likely to respond to?

**Mr Scott:** If I may say, I think we were all a little surprised to read elements of that evidence, because from your own experience—and I do not believe much has changed—the ability to take a history and to communicate effectively with the patient, to diagnose differentially, is at the heart of medical practice. Dr Jan Illing’s report, to which I earlier referred, does not give us any reason to believe that today’s emerging doctors are poorly prepared in that sense, subject to two qualifications. It is possible that the evidence you heard was less to do with whether we are teaching students how to produce differential diagnoses and more about the theoretical aspects of decision making which they feel may be more effectively taught in the course of the curriculum.

That is something we will follow up with them. The second point which Jan Illing’s research has exposed is that today’s new doctors appear to be well equipped in terms of knowledge and skills but they are under-prepared in terms of applying that knowledge and those skills in a clinical setting. We have tried to reflect that in the new draft of *Tomorrow’s Doctors*, the essential argument being that much earlier in their undergraduate training and before they take up positions of responsibility within the NHS, they should be confident that they can apply their knowledge and skills in actual practice and then gain confidence and competence in order to deal with some of the issues that you have heard about.

**Q751 Dr Stoate:** Several of our witnesses have also expressed concern about the level of missed diagnosis and delayed diagnosis in general practice. Is that not a cause for concern that the GMC might wish to take up?

**Mr Scott:** Yes. Again I think it is really important, as the regulator, that we work with others to try to understand why that should be. Generally speaking, as you know, the GMC has been recognised as—what I call the taxi driver test—“The organisation that strikes doctors off”. That is usually the response that I get from a taxi driver if I tell them what I do. In fact our most important contributions to patient safety are through education and training and standards and ethics, and of course ensuring that only good doctors are registered in the first place. To come back to your question, I think it is important that we work with others, including the Postgraduate Medical Education and Training Board, to ensure that these issues are pursued. If I may talk about the planned merger of PMETB with the GMC, probably from April of next year—a merger that this Committee, I am glad to say, endorsed—that will create for the first time an opportunity to look at how we regulate education and training across all stages of a doctor’s career to ensure that we identify the point at which the risk of error begins to emerge, not necessarily always at the undergraduate stage.

**Dr Stoate:** That is fine. I just wanted to ask the question, but you have covered that point. Thank you very much. Thank you, Chairman.

**Q752 Sandra Gidley:** We are told frequently that the NHS aspires to a “fair blame” culture and that the point is to look at systems rather than blame individuals when something goes wrong. Clearly there will be cases when it is incompetent practice by an individual and you have to draw the line somewhere. Where does the GMC draw that line?

**Mr Scott:** I think we all have to start from the point that doctors are human beings and they make mistakes. There is a widespread literature, both in the healthcare industry, our economy and in other industries, that demonstrates the relevance to error of systems. We tend to approach it from this point of view, that there are two key requirements of doctors. Their conduct should not step outside the guidelines that we lay down—they should not behave inappropriately with patients and so forth—and when they transgress in relation to those guidelines, it is right that their conduct should be properly examined. But we also require doctors to practise within the limits of their knowledge and skills and within their competence, and that leads to the kind of distinction to which you were pointing. Perhaps I can illustrate it by reference to the figures that we publish. We receive about 5,000 inquiries, complaints or allegations each year about individual doctors, and they fall into broadly three groups. The first is a group which could not conceivably engage our procedures. I do not want to trivialise the point, but we do get complaints about where doctors park their cars and so on, so we can pretty quickly decide that that group does not deserve our attention. There is a second group, which for internal reasons we call Stream 2, where on the face of the complaint it would not be just to take action against a doctor’s registration but it is possible that put in a broader context there might be a possible concern. With our Stream 2 cases, therefore, we immediately engage with those who employ the doctor or contract with the doctor for medical services. In the great majority of cases the allegation or complaint does not sit in a context that requires us to take action, and we can leave, therefore, the employer or contractor to deal with it. I think that enables us to stand apart, largely, from single incident clinical events or omissions, which might be regarded in a different parlance as mistakes, where we do not unduly bear down on the doctor. The third category is where on the face of it we need to investigate further, or, having contacted
the doctor’s employer, there is a context that requires us to take action. So I think we are moderately effective but no doubt we could do better at trying to distinguish between the deep-seated fundamental problems where we need to take action and those where they reflect the fact of mistakes or systems that fail.

Q753 Sandra Gidley: To be absolutely clear, if a doctor makes one mistake, that could be human error. If a pattern starts to emerge, then that is when you would intervene.

Mr Scott: Yes. Not to exclude the possibility that some mistakes might require us to take action, but in the normal course of events the distinction you have drawn is extremely helpful. May I make a supplementary point? I think there is a real tension in the way in which we operate our procedures, which is this: the philosophy that we have just espoused is easy to describe here and to intellectualise, but in fact many of those who contact us, many patients or relatives or friends who contact us, would not necessarily accept the distinction that we have just drawn, and they do not distinguish so readily between the mistakes that unfortunately do happen and the more deep-seated problem. One of the challenges we face if we are to move towards a fair blame approach is to try to have a better public understanding of the function of our procedures, which is not always to bear down upon doctors who make mistakes.

Q754 Sandra Gidley: Is the National Clinical Assessment Service effective? If not, how could it be improved?

Mr Scott: It is probably not for me to say whether they are effective or not.

Q755 Sandra Gidley: Go on.

Mr Scott: What I can say is that we work very constructively with them. I think the NCAS performs an extremely useful role. Despite what I started by saying, I think it does so effectively. It enables engagement by the doctors, employer or contractor with a process that can be less threatening to the doctor than inevitably our procedures will appear to be. One of the great strengths of the NCAS approach has been to provide advice and guidance to trusts and others on how actual or emerging problems might be handled. I think there is a great opportunity in the future, with the introduction by the Government of Responsible Officers in every trust and also by the pilots that we are pursuing at the moment of what are rather inelegantly called GMC Affiliates, to ensure that it is a joined-up approach. As part of the two pilots that we are running in North Yorkshire and in London to explore the concept of Affiliates, we have set up with others within the strategic health authority what is called a Regional Medical Regulatory Support Team, involving the NCAS and others, in order to try to ensure a more joined-up approach to the patient safety agenda.

Q756 Sandra Gidley: Revalidation is coming up. How will that fit in with what we were talking about earlier?

Mr Scott: Perhaps I could start by referring to the evidence you have just heard. Dr Moyes stressed the importance of boards, trust boards but, indeed, primary care trusts, accepting their responsibility for patient safety. The second important point was made by Sir Ian Kennedy, when he stressed the importance of surveillance, as distinct from investigation after the event. We have now a good track record in relation to after-the-event investigation and dealing with doctors whose fitness to practise is impaired. The thrust of revalidation is to make our contribution to preventing things going wrong in the first place. It is very much about the quality agenda, it is not about dealing with bad apples, but, inevitably, our ability to introduce revalidation without imposing a huge bureaucratic burden upon doctors, distracting doctors from their frontline responsibilities and thereby damaging patients, inevitably depends on local systems of clinical governance and of appraisal. We have already heard this morning an example of how the appraisal system may not be as robust as it might be, and that is why, together with the Chief Medical Officer for England, Sir Liam Donaldson, and the Department of Health for England, and, indeed, all four health departments, there is a commitment, reflected in the White Paper, to make appraisal more robust. If we can introduce or develop robust clinical governance and fully effective appraisal, then I believe revalidation will add considerable value to the quality agenda but at a very low marginal cost and greatly to the benefit of patients.

Q757 Dr Naysmith: You talked about your three streams: the trivial; the one incident which gives cause for concern; and then the more serious investigation. You said that with the second stream you would get in touch with the employers and let them know. You presumably then say to them, “You sort it out,” and they say, “We will sort it out.” Do you ever follow that up? Do you regularly follow that up, maybe a few weeks later, and say, “Have you sorted this out or not?”

Mr Scott: Yes. We have tried both approaches, one of complete radio silence on the assumption that they would do something effective, and we have also followed up. The general conclusion from the second approach is that trusts and other health care organisations take their responsibilities seriously and do deal with the issue.

Q758 Dr Naysmith: But you do not do it routinely?

Mr Scott: If I could come back to the burden of regulation, although Sir Ian did not much like the word, the cost of regulation, we have to be sensitive to the fact that each time we interact with a doctor or with a trust there is an effect which is not necessarily beneficial. We have reflected on our experience with both approaches and the result is that we do not now always follow up, simply because it was not an effective use of resource at our end or within the trust.
Q759 Stephen Hesford: Could I first of all, Chairman, apologise to the Committee for not being with you for the first session. I had other House duties. Would you accept that in times gone by the GMC did not approach its task to doctor regulation as robustly as it might have done and that led to a certain lack of confidence in that process? I see you nodding. That might engender a lapse in culture with doctors, because they understood the process and Big Brother was not watching them as carefully as it could have done. Are you confident now that the GMC is in a position not only to have reversed that culture but to lead the culture in a different direction whereby the public can now be satisfied that the GMC is in a position to undertake that role in a way that I am sure we all like to think it does?

Mr Scott: We have acknowledged in other places, including before the Shipman Inquiry, that the ways in which we operated what are called our Fitness to Practise Procedures were not as robust as they should have been. It is for discussion whether that had a real practical effect, but in a sense I do not want to deviate from the honest position we have taken—and of course that was one of the reasons we launched the fundamental programme of reform which has led to the introduction of a completely overhauled system of fitness to practise. I am today satisfied that the risk based approach we try to take where we weigh the information that reaches us, we consult with doctors, employers or contractors, we have a more thorough investigation upfront before we make the preliminary decision: all of those improvements have led to a more robust approach and we can truly say that we live up to the purpose that we espouse, which is to protect, promote and maintain the health and safety of the public. It is really important that the GMC is seen as a regulator for the majority of the profession as well as a regulator of the minority. Important though it will remain to deal quickly and effectively with impairment, increasingly our contribution should be through the work we do on education and training, standards and ethics, and ensuring that only fit to practise doctors are on the register.

Q760 Jim Dowd: You mentioned the Shipman Inquiry. In response to Sandra’s questions about the fair blame culture, the emphasis was on inadequate or incompetent practice. What Shipman brought forward—and let us hope it does remain unique—is the notion of malice in the exercise and the practice of medicine. That had never happened before. I imagine the systems for detecting it were not in place. Are you satisfied that they are now? Without believing for one moment that there is any evidence that anything remotely comparable to Shipman’s practices has gone on anywhere, are you satisfied now that your approach is critical enough?

Mr Scott: I think there are two elements to answering that question. It is incumbent upon us to continue to stress the importance for all doctors of taking action when a colleague’s conduct, performance or health is placing patients at risk. If you analyse not just the Shipman case but the other headline grabbing cases that led to inquiries, Ledward, Neale, Kerr/Haslam, the striking feature is the length of time for which it was recognised locally that there were problems but no effective action was taken. I think we have to squarely acknowledge our own responsibility for ensuring that every registered doctor is ready to act effectively. As it happens, in the tracking surveys that we ran in 2006 and 2008 there was encouraging evidence that doctors increasingly recognised that responsibility, but I think we also have to be realistic. As Dame Janet Smith herself said in her fifth report, even if all her recommendations were implemented, she could not guarantee that the intelligent criminal—because that may be what we are dealing with; the intelligent criminal—might not defeat the regulatory system. Indeed, that was the message from the Beverly Allitt report by Sir Cecil Clothier. I think the key for all of us is to ensure that systems interlock in a way that we deter and detect quickly, so that you reduce the likelihood of these events occurring to as close to zero as you can. The key point for me that emerged from the Shipman Report was the point of strengthening death certification and coroners’ procedures, as distinct from, say, revalidation. Revalidation will make a contribution, but it is not designed to detect intelligent, deliberate criminal behaviour.

Chairman: Thank you for that. We are now moving on to Steve Walker.

Q761 Dr Taylor: I have two questions about the Clinical Negligence Scheme for Trusts. In our extra brief we have been given details of the premium collected, going back to 2000–01, when it was £40 to £50 million. It suddenly jumped in 2008–09 to £396.3 million and the figure for 2009–10 is £713.4 million. Can you explain how you get at this figure and why it has gone up so much?

Mr Walker: I had kind of anticipated someone would ask me that question this morning. The Clinical Negligence Scheme for Trusts is a risk-pooling scheme and we deal with the resolution of claims, whether they have been tested in court (very, very few of those) or by alternative dispute methods, in-year. When we pay the claim, that is when we need the money. We try to leave as much cash as possible with frontline trusts and remember it is trusts only as members at the moment. In fact at the beginning of this period we had surplus cash and felt able to give a rebate to trusts at the beginning. This period of £70 million. In essence, the contribution for the current year should have been about £470 million. It still does not explain the big difference. The big difference came about because we found that during the year we were spending at a much faster rate than we had anticipated. We can only be reactive, obviously—we cannot go out and find people to give compensation to—and we found that for some reason we were faced with a surge of claims, settling at between about £100,000 and £0.5 million in particular. We had not anticipated that and we still have not bottomed the reason for that. They are all legitimate claims, obviously—we do not pay unless there is a liability. We also had held back, either by agreement with claimants or because the courts had stayed them, approximately 120 cases, some of which would have been settled in the previous year, because
of the Thompstone case—the case which changed the basis on which indexation is applied to future care claims. We also were taken by surprise—there is no point in pretending otherwise—by the surge in the number of claims that were being funded by conditional fee agreements. They have been available to claimants for some years now but there has not been a very mature market in insurance. Insurers back the agreement, so that a solicitor can offer a “no win, no fee” arrangement, and insurance is purchased against the risk of you losing the case. That means that in cases that have been selected and do win by claimant lawyers, their costs can now be double what they previously were. The answer is that we had been hopelessly optimistic in giving the rebate we did, although on the knowledge we had at that time I genuinely think we could have been criticised had we not released that back to the service, and we were then faced with a position where we might have run out of money in-year. There were three options available. We could have allowed that to happen, but that would have impacted on patients, which would have been absolutely wrong. We could have gone back to the trusts and said, “We want a second call in-year,” but we had no idea whether they could afford it and we realised that that would massively disrupt their operations in some cases. Or we could do what we actually did, which was to borrow money from the Department of Health. We did that and we have to repay that over the next two years, so £60 million of the uplift is a repayment of debt. The really important message, apart from mea culpa because we got it wrong, which we undoubtedly did, is that that is not a reflection of a deteriorating level of performance in the National Health Service. The claims that we will be paying both this year and next come from events which occurred last year, two years ago, three years ago. We have had claims going back to the 1950s, even though the authority has only been in existence since 1995. It is a function of the payments to be made in-year; it is not a reflection at any given time of levels of negligence (for want of a shorthand word) in the service.

Q762 Dr Taylor: We have been given a table with two columns: total liabilities and actual clinical negligence liabilities. These have shot up from less than £1 billion ten years ago to £11.91 billion now. This has been a fairly steady increase.

Mr Walker: Indeed.

Q763 Dr Taylor: Is there an explanation for this?

Mr Walker: Yes. The provisions figure, the almost £12 billion that you identify, is not a real number; it is an actuarially calculated number. The one thing we know about it is that it will not be right: it may be more or it might be less, but it is actuarially sound at the moment.

Q764 Dr Taylor: Right.

Mr Walker: And it is a reflection of the best modelling we can do. Please forgive me if I am going too far in this explanation. If the National Health Service had stopped trading in its present form on 31 March last year, and all activities that have occurred since then had been undertaken by a new corporation or body, the £12 billion is the best measure we can make of the liabilities that would still come through from previous activities, including children born in the 1980s and 1990s, et cetera, because, as you will appreciate, there is no limitation period applicable to most of those claims. Does that make sense?

Q765 Dr Taylor: Help!

Mr Walker: I am sorry, I am always torn between words of one syllable being patronising and—

Dr Naysmith: Use words of one syllable here!

Q766 Dr Stoate: Do not worry, we are good at bullshit.

Mr Walker: I am sorry, I should know better than to invite this kind of comment.

Dr Stoate: Never bullshit a bullshitter!

Q767 Dr Naysmith: Mr Walker, the NHS Litigation Authority sets standards for patient safety through the Clinical Negligence Scheme for Trusts.

Mr Walker: Yes.

Q768 Dr Naysmith: Should the standard setting not be the job of a body that is not responsible for dealing with litigation?

Mr Walker: That is a good question and it is one which we ask ourselves regularly.

Q769 Dr Naysmith: What answer do you come up with?

Mr Walker: Well, first of all, the background is that the Clinical Negligence Scheme is a risk-pooling scheme. It began during what used to be called the internal market, when trusts were first exploring autonomy and the idea was that risks would be pooled, claims would be settled from the pool, and the rather wise people, I think, who were putting that together recognised that if it were a mutual insurer, for example, that insurer would want to instigate some risk management activity to protect the pool. That is how standards were initially devised.

Q770 Dr Naysmith: That is about risk management, is it not?

Mr Walker: Yes.

Q771 Dr Naysmith: Would the Care Quality Commission, for instance, not do a better job at setting standards?

Mr Walker: I do not know that they would do a better job. I think we do an excellent job of setting in the context of extensive reiterations and subsequent rounds of consultations with all of the interested parties. It is entirely possible that Baroness Young, in her wisdom, might decide that is something that they would want to do. No one has volunteered to take it on historically, I should say, and what has happened is that people like the Healthcare Commission, for example, have used our assessment outcomes and fed them into their own data to produce things like the annual health check. I think that what we do, we do very well, but I am not saying that we are the only people who could do it, nor am I saying that it is not
possible that someone could do it better, but lots of people take our data on the basis of what we do now and make use of it.

Q772 Dr Naysmith: How does it compare with what happens in other countries, for instance? I do not want to go through them all, but is our system unique?

Mr Walker: It is not unique, but there are variations. In other dispensations, as you know, there is a commercial insurance element, and commercial insurers would feel very comfortable about setting standards and they would incorporate that, as it were, into their underwriting, which is something that we do not do. We do discounting, so in a sense it comes into our underwriting of risk. A commercial underwriter, of course, can always refuse to accept a risk. That is inconceivable for us in the context of NHS trusts, so we try to create systems that we know trusts use as a template for their risk management programmes, and we know they use it and welcome it in governance terms. Indeed, we are frequently asked by the private sector if we can sell the service out to them.

Q773 Dr Naysmith: That is interesting in the light of my next question. We understand that the Clinical Negligence Scheme does not cover situations where patients receive NHS care from independent sector providers. Is that true?

Mr Walker: It is not true. We do.

Q774 Dr Naysmith: You do cover situations like that. Mr Walker: Yes, we do. In direct response to government policy, which as you know is to widen the range of providers delivering NHS care, we have, through the ISTC programme, through the first and second wave contracts and through the extended choice network—

Q775 Dr Naysmith: It is widespread throughout the system. Then. That happens.

Mr Walker: Through those programmes.

Q776 Dr Naysmith: It is no wider than these programmes.

Mr Walker: No wider than those programmes, that is correct. That is by agreement with the Department of Health. We deal with those claims so that the patient experience is no different vis-à-vis a claim for compensation should he or she be harmed in an acute trust as compared to in an independent sector treatment centre. We provide that cover through the Commissioner on the assumption that the Commissioner owes a duty of care to the patient.

Q777 Dr Naysmith: Do you think it should be widened to widen the use?

Mr Walker: With respect, the Government thinks it should be widened because of the Health and Social Care Act last year. The Act has received assent but it is only enabling legislation and requires regulation.

Q778 Dr Naysmith: Will that cause problems for your organisation?

Mr Walker: No.

Q779 Dr Naysmith: So you are quite happy with that.

Mr Walker: Well, absolutely happy to do it. We are part of the National Health Service. Our only reason for being there is to help deliver NHS policy, which in turn is presumably always government policy too.

Dr Naysmith: I would not like to make presumptions like that. Thank you.

Chairman: We will not have that debate this morning. (In the absence of the Chairman, Dr Naysmith was called to the Chair)

Q780 Charlotte Atkins: Mr Walker, we are still waiting for the NHS redress scheme some three years after the necessary legislation was passed. When is it going to happen? When and if it does happen, will it make any difference?

Mr Walker: An interesting series of questions. Let me take the first one first. When the Redress Act received assent, the Regulator Impact Assessment that was published at the same time said that it was unlikely that the redress scheme would be up and running before 1 April 2009; in other words, at the end of this month. I believe that subsequently Parliament has been informed—and I just do not know what the mechanism is—that that date will be put back—and remember, that is not a start date; that is a likely earliest start date—to 1 April next year. When regulations are laid, then the redress scheme can kick in. The second part of your question I think is particularly interesting, and I have to say I do not know the answer. I think one of the reasons why perhaps there has not been a rush to implement the Redress Act is that the systems that are currently in place for dealing with claims, particularly the low value claims which are envisaged in redress, may be perceived to be fair, reasonable and equitable now. There will be dispute about that, particularly from those who are not successful in bringing claims, but of course the redress scheme, as many observers seem to have missed, is entirely tort based anyway, and so the same criteria will apply. It will still be necessary to show that there has been a breach of duty or negligence or one of the other factors that would create the liability to succeed under a redress scheme as envisaged by the Act. The word “tort” is expressly mentioned there.

Q781 Charlotte Atkins: Action against Medical Accidents suggests that the process should be changed and that you should have an “avoidability test” rather than a blame culture. What is your view about that?

Mr Walker: I do not think it would make a great deal of difference. I think it would make a difference to certain individuals who were bringing claims, but of course I am trying to answer the question in the round. To the population of people who might want to bring claims, I think that to introduce one test as opposed to another would simply lead to the lawyers focusing on proving the new test, as it were, bringing in their experts to establish that the new test had been met, and I really do not think it would make a dramatic difference.
Q782 Charlotte Atkins: If you have a no blame culture would you not get more co-operation from the medical professions involved? We would go towards a system which happens in aviation—where people are willing to give information on near misses, about things that could have happened, or, indeed, when things have happened, to own up to them—rather than go down the blame culture route, where everybody puts their hands up to say they are innocent.

Mr Walker: I do not think, first of all, that AvMA’s image of everyone denying that they have done anything wrong exists in real life anyway. It certainly is not our experience. There will be examples, of course, because it is human nature to hide from the fact that you have made a mistake, and I do not think any kind of regulation or change in the rules is going to change that. People are very reluctant in any walk of life, whether it is driving a car or whatever else it might be, to own up to their mistakes. In terms of changes in the law, we are currently working within a system that, with all due respect, ladies and gentlemen, is created by Parliament and the courts, and I am not convinced, despite recurrent debates, about moving towards no fault—and I realise you are not talking about going quite that far in terms of compensation. The “no fault” debate always comes down to two issues: the first, in practical terms, is that there is no “no fault” scheme anywhere in the world, because they are all constrained to some extent by the wordings.

Q783 Charlotte Atkins: What about the scheme in New Zealand?

Mr Walker: The scheme in New Zealand is not no fault. That has to be an event within the definition that they describe. I have not been out to New Zealand to test it personally but I have read extensively about the New Zealand scheme. The New Zealand scheme has been constrained at least twice since inception, because initially it was seen to be too wide. When I say “seen to be too wide” that perhaps brings me to my second point. I said there were two things: one is the definition issue and the second is cost. I do not sense that there is a will to fund what a real “no fault” scheme might cost. I do not know what it would cost but it would inevitably mean that a lot of people who do not succeed today would receive compensation. The only way to offset that, it seems to me, is to reduce the benefits that might be available. That might seem attractive to some people: it will not to the people who will feel that they have been denied their right to the larger number, as it were. I think the problem with all of these things, unless we can give everything to everyone, which is clearly impossible—and I am using those words deliberately to exaggerate—is that there will always be people who are just outside the boundary and to them whatever we are delivering will appear arbitrarily unfair. Believe me, this is a subject I have given a lot of time for over the years.

Q784 Charlotte Atkins: In your view, is there a true “no fault” compensation scheme operating anywhere in the world?

Mr Walker: No, I do not think there is.

Charlotte Atkins: Thank you very much.

Dr Naysmith: Thank you both very much indeed for coming along this morning and giving us your evidence.

_Witnesses:_ Mr Geoffrey Podger, Chief Executive, Health and Safety Executive, and Professor Kent Woods, Chief Executive, Medicines and Healthcare Products Regulatory Agency, gave evidence.

Q785 Dr Naysmith: Good afternoon. Welcome to this our sixth evidence session in our patient safety inquiry. I would be grateful if you could identify yourselves and say who you represent for the record.


Mr Podger: I am Geoffrey Podger. I am Chief Executive of the Health and Safety Executive.

Q786 Dr Naysmith: Thank you both for coming. You say in your written evidence, Mr Podger, that “the current regulatory situation can lead to confusion for duty holders, inhibit the establishment of improved management practices and is not necessarily the most effective use of public resources.” That suggests you would like to see something different there. How would you like to see it changed? How should it be changed?

Mr Podger: I think we do take the view that there are improvements that could be made to the present system. I must say I have considerable sympathy with the view that Barbara Young expressed to you, that wholesale restructuring is often not the most sensible way of bringing about improvements. But to give what is perhaps the main issue for the Health and Safety Executive, to put that on the table, we have become concerned that in those cases where we ourselves get called in to investigate, very often we are following on from an investigation which has been done by somebody else. In our view that is not (a) an efficient basis on which to do an investigation, because the basis on which we investigate is different, and (b) clearly it puts all those who are, as it were, to be investigated through the same mill twice. It means a lot of time will be expended on the process, and inherently there is the argument that justice delayed is justice denied.

Q787 Dr Naysmith: What are you saying sounds perfectly reasonable but do you suggest any particular changes?

Mr Podger: Let me say that we would like to see this more generally across the whole area which we investigate, not simply in the health area, but where a case is thought of sufficient seriousness for us to investigate, under section 3 of the Health and Safety at Work Act, not the normal run of cases we would
Mr Geoffrey Podger and Professor Kent Woods

5 March 2009

Mr Podger: Yes.

Professor Toft: as I have great respect for

Mr Podger: Indeed. We first of all have a category of

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under which they were supposed to be acting. I think it is important, therefore, that we should preserve in the healthcare area as elsewhere that there is an issue of individual responsibility. I do not think people should be enabled to, in some way, get out of that if they have really acted in a way which is quite improper, given the instructions under which they were.

Q793 Dr Stoate: Could you see yourself then prosecuting such a person; for example, if there were a significant patient safety issue brought by a physician and the manager effectively ignored it? Could you see that as something you might take up as a prosecution?

Mr Podger: The answer is, as I say, that it cannot be ruled out. As you will well appreciate, doctors may be acting in various capacities in hospitals. They may, in fact, be acting as managers, in which case I would suggest that this possibility does become a real one. I would not see us acting against a clinician on clinical grounds, because, as you know, the system of accountability is different there, and you are well familiar with that. In relation to management, we would not inherently rule it out. The issue in that kind of case that Brian was talking about is inevitably, first of all: was the attention of the right people drawn to it? The discussion you heard this morning about the role of boards is crucial here. Boards need to be made aware of what is going wrong. If people fail to do this, then they do put themselves in a position of individual liability, in my view. Obviously whether you prosecute depends on the circumstances, but the principle is a correct one. Yes, I think managers do have to understand that they do expose themselves potentially to criminal law if they do not in fact make sure that matters of extreme importance are properly brought to the attention of the board and then the board must take responsibility for what it then does.

Dr Stoate: Thank you, that is very helpful.

Q794 Dr Naysmith: Before we leave this area, Mr Podger, I realise you have said that you do not want to be involved in clinical regulation, and that is fair enough, but in the borderline cases to which you make reference, when you were saying, “We need to take action here,” have you found any resistance to taking action? Without naming any particular cases, when you have said, “We want to take this further and prosecute”—and you have said you have a duty to prosecute if you felt you should—have you ever encountered resistance to do that in the National Health Service?

Mr Podger: No, because, in effect, the National Health Service would not be able to mount such resistance. That is perhaps the difference between ourselves and the other regulators you have been talking to, because we are external to the National Health Service. Clearly it is incumbent upon us to investigate fairly and objectively and then to listen very carefully to what people say to us. We have no interest in manic or unreasonable prosecution of any kind. Once we are involved, we have full powers, and it would not, in my view, be possible for people to obstruct us and they do not seek to do so in our experience.

Q795 Dr Taylor: Mr Podger, you have already referred to falls out of windows and scalds. In the Healthcare Commission’s evidence to us they give us a table of the top ten safety incidents reported to national organisations and patient accidents come out way top of this: 230,000 in 2007–08. What can the HSE do to address these sorts of accidents? I am particular thinking of elderly patients who fall out of bed and break their hip and extend their admission time to hospital for ages. What are you doing? What can you do? How do you plan to improve it?

Mr Podger: That is a very fair question and it reflects what I was saying earlier. I think it is important not to regard hospitals as places of total peculiarity as opposed to the problems that arise elsewhere. I want to prosecute such a person; for example, if there were a significant patient safety issue brought by a physician and the manager effectively ignored it? Could you see that as something you might take up as a prosecution?

Mr Podger: The answer is, as I say, that it cannot be ruled out. As you will well appreciate, doctors may be acting in various capacities in hospitals. They may, in fact, be acting as managers, in which case I would suggest that this possibility does become a real one. I would not see us acting against a clinician on clinical grounds, because, as you know, the system of accountability is different there, and you are well familiar with that. In relation to management, we would not inherently rule it out. The issue in that kind of case that Brian was talking about is inevitably, first of all: was the attention of the right people drawn to it? The discussion you heard this morning about the role of boards is crucial here. Boards need to be made aware of what is going wrong. If people fail to do this, then they do put themselves in a position of individual liability, in my view. Obviously whether you prosecute depends on the circumstances, but the principle is a correct one. Yes, I think managers do have to understand that they do expose themselves potentially to criminal law if they do not in fact make sure that matters of extreme importance are properly brought to the attention of the board and then the board must take responsibility for what it then does.

Dr Stoate: Thank you, that is very helpful.

Q796 Dr Taylor: Very often the reason given for an elderly person falling out of bed, even though the cot sides are up and they are confused, is a shortage of staff. Would you ever say anything about that?

Mr Podger: I think that is one of the most difficult areas for us to intervene on. Issues about levels of provision of staff are always inherently difficult. It is clearly a legitimate factor to consider if you then go on to consider whether there is fault. The question has to be asked: Was it reasonable to do in the circumstances? But, equally, that would apply to individual carers. It would not inherently apply to those who are running the organisation, where you would have to ask: Are you able to run this organisation at all on the scale you are with the staff you have? That is a responsibility which, in my view, is a responsibility which is properly held at board level.

Dr Taylor: Thank you for helping us to understand your case. Perhaps I could also say thank you for the calendar that you sent around with the most marvellous cartoons. It helps to dispel the image of HSE as a sort of malignant over-inspector.

Q797 Sandra Gidley: I did not get one.

Mr Podger: I am extremely grateful for your words. Normally I have to offer to submit supplementary memoranda for the things I have forgotten but after this session I could perhaps submit supplementary calendars!
Dr Naysmith: We are going to bring Professor Woods in now.

Q798 Sandra Gidley: Professor Woods, we have had evidence about risks posed by untraceable, unlicensed "named patient" medicines, internet pharmacies and counterfeit medicines. Has MHRA made an assessment of the scale of this?

Professor Woods: Yes, it is an area which has concerned us, particularly in the last five years or so, because, particularly on the counterfeit front there has been evidence worldwide of an increasing interest of criminality in counterfeit medicines. Although the UK has been spared to a large extent, I think there are certain risk factors which mean that we cannot assume that we are going to be fortunate in the future. In hard numbers, we have identified 14 incidents in the last five years where counterfeit medicines have got into the legitimate supply chain. That is 14 too many but, nonetheless, set against 800 million prescriptions a year, that is at the moment a small problem. On the other hand, there is a separate issue which relates to internet distribution and purchase of prescription only medicines. That is a much more vulnerable environment. Our strategy has been to deal with those two, in a way, separately, but sometimes it emerges that the same criminal gang is working in both fields and we have brought 14 prosecutions for counterfeit activities over the years. The main strategies for dealing with those two risks are slightly different. The vulnerabilities in the UK are these. We have a particularly complex distribution system for medicines. We have more wholesale dealers. We have more trading of pharmaceutical products between the manufacturer and the end user, more than in most European countries, and that allows multiple points at which counterfeits could be inserted. We also are seeing the effect of globalisation, in that there are many more countries with manufacturing facilities able to produce very impressive counterfeits, impressive not only in terms of what is in the tablet but impressive in terms of the packaging, the labelling, a very good facsimile of the raw material. As an agency, we have put together an anti-counterfeiting strategy which we launched in November 2007 which has several elements to it. Communication, collaboration and regulation are the themes. We work very closely with our colleagues in other countries because much of this, as I have indicated, is internationally based. We also have identified for our own purposes what we consider to be a risk list of products which for various reasons we think are most likely to be vulnerable to counterfeiting. We have opened a 24-hour counterfeit reporting line. We carry out a routine market surveillance operation, particularly focusing on those products which we have put on to our at-risk list. We have developed new technologies, such as near infra-red spectroscopy, to allow that type of surveillance to be done more easily. We have worked closely with the EU and with global bodies to try to ensure that there is an international perception of the risks that counterfeiting activity poses. It is not a matter of intellectual property; it is a matter of patient safety. I am pleased to say that I think there is a sea change among regulatory agencies who recognise this for the potential hazard it is.

Q799 Sandra Gidley: Is there a bigger risk from counterfeit medicines in the legitimate supply chain or from internet pharmacies?

Professor Woods: Internet sales are particularly worrying because the scale is certainly larger. It is very difficult to regulate for the practical reason that if you have a website offering to sell Viagra, which is nearly always fake, the source of manufacture might be in the far end of Asia, the website itself may be hosted in another country, and the point of sale may be in a third country, and for one regulator working in one jurisdiction to break that network is exceedingly difficult without the participation of other countries. We have set up what we call internet days of action, which happen several times a year, where we assemble evidence we have of illegally operating websites in the United Kingdom. About every four months there is a co-ordinated set of raids which are carried out with as much publicity as possible. The publicity is part of the public health protection. People have to understand that if they buy prescription medicines over the internet it is dangerous. The suppression of criminality is only part of it; we have achieved prosecutions and will continue to seek successful prosecutions, but, in terms of the internet issue, I think that public awareness is the main stay of getting on top of it.

Q800 Sandra Gidley: How do the public know, because there are legitimate internet pharmacies?

Professor Woods: Indeed there are.

Professor Woods: The Royal Pharmaceutical Society has created a scheme with a logo which is displayed on internet pharmacy sites which are doing absolutely legitimate business and communicating prescription medicines against a prescription. That is a scheme we very much welcome. We work closely with the Royal Pharmaceutical Society on this work, and we are very careful to emphasise that we are concerned about the purchase of prescription medicines without a prescription on an unverified pharmacy site.

Q801 Sandra Gidley: How does the public tell one from the other?

Professor Woods: The Royal Pharmaceutical Society has created a scheme with a logo which is displayed on internet pharmacy sites which are doing absolutely legitimate business and communicating prescription medicines against a prescription. That is a scheme we very much welcome. We work closely with the Royal Pharmaceutical Society on this work, and we are very careful to emphasise that we are concerned about the purchase of prescription medicines without a prescription on an unverified pharmacy site.

Q802 Sandra Gidley: We have also heard that bar coding technology is a significant weapon against counterfeiting. Would you agree with this? Or is there a better way?

Professor Woods: It has the potential but it has substantial complications and complexities to it. It is something which is under very active scrutiny at the moment. We contributed substantially to an EU review of this area which is now out to consultation. It went out to consultation in
December. The issue is that an auto-identification system, such as bar coding or auto ID or whatever, would be quite complex to run. It is more than the sort of bar coding that is necessary for, say, stock control or patient safety activities like ensuring that the right patient gets the right blood. Those essentially can be run locally. With an anti-counterfeiting system, first, because we have the global sale of medicines, manufacture can occur in almost any country. An effective auto ID system would have to be internationally agreed, working to international standards. Second, there would have to be a single, large database, so that at any point in the distribution system you could interrogate a package and confirm in that database that that indeed was the pack that had started life in a factory several countries away. The third thing which is different is that it would have to be resistant to forgery. If you have a bar coding system in a hospital to make sure that blood is properly distributed, nobody is going to try to forge that, but if you are trying to produce an anti-counterfeiting system of auto ID, you are looking at standards of non-forgeability that get close to credit cards, and that is a very demanding set of criteria. It may happen, but it will certainly need to be done on an international basis. The consultation that went out in December is also consulting on some proposals which the EU has put forward, but they are only proposals of principle, the nitty-gritty details have not yet been resolved.

Sandra Gidley: Thank you.

Q803 Jim Dowd: Professor Woods, the Royal Pharmaceutical Society in evidence to us stated that the Yellow Card Scheme provides only a “sparse data set and there is an urgent need for more complete information on adverse drug reactions (ADRs) soon after a medicine is licensed.” Do you agree with that statement? If so, what are you doing about it?

Professor Woods: The Yellow Card Scheme has certain intrinsic weaknesses about it, and yet it is an exceedingly valuable scheme which we have been running and our precursor agencies have been running and refining for 40 years now. It is an essential part of medicines safety surveillance and we have worked hard in recent years to increase the utility of that scheme. To give you the scale, we currently have a database of 600,000 adverse drug reaction reports, and if you include foreign reports which are being copied to us, we have one million reports. That is a very valuable resource based on the spontaneous reporting of what individuals consider to be potential adverse drug reactions. Originally the system was set up for doctors and coroners to report, then it was widened to pharmacists, then it was widened to nurses, and our interest in the last year or two has been widening it to the general public. There was a bit of resistance to this initially, from several quarters. The suspicion was that the general public would give us rather trivial reports of low information—
Q805 Jim Dowd: If I understood what you were saying correctly, you were tending to agree with the Royal Pharmaceutical Society that it only presents a sparse data set at the moment.

Professor Woods: It is estimated that something of the range of 5% to 10% of adverse drug reactions get reported—and that is not just our experience, it is true around the world.

Q806 Jim Dowd: Has that figure changed at all with the introduction of direct references from the public to you?

Professor Woods: In so far as we have got more reports, I suspect it has improved to that degree. It is helpful that the reports we do tend to get tend to be the more serious ones. Even so, only a minority of adverse drug reactions are reported to spontaneous systems worldwide. It is an imperfect system but it is a necessary system.

Q807 Jim Dowd: In the reports that you are now getting directly from the public have you noticed any duplication between references which have already been made that may tend to indicate that a professional should have made a reference but did not and the member of the public then had to do it themselves? Or it could indicate a hypochondriac. I am not sure.

Professor Woods: There is a technical issue. We do have a de-duplication procedure inside the system, so if we get a report from the doctor and from the patient we recognise it as a single case. We have done some interesting work last year, again with the Royal Pharmaceutical Society, using community pharmacies as a way of getting across to the public, first, that they can report, and, second, that they or their pharmacist should report. We had quite a large publicity campaign running over six weeks which pharmacists were very active in. It had a dual effect. First, it reminded pharmacists that they could report, but its specific target was the patients who were using those pharmacies. All this, as I say, has pushed up reporting rates. You are trying to optimise a system which is never going to be perfect, but it can certainly be enhanced.

Q808 Jim Dowd: Part of that would be making the existence of the self-referral by patients more widely known.

Professor Woods: Making it widely known and making it easier. They can report on Yellow Cards, they can report over the internet. On our website we have a very easy patient reporting line. All of these things modernise and enhance a system which has been doing this very well over the years but it has scope for improvement.

Jim Dowd: Thank you.

Q809 Dr Naysmith: On one of our previous inquiries some years ago we recommended that the Yellow Card System should be extended to patient reporting.

Professor Woods: Yes.

Dr Naysmith: Even if it is only moderately successful, it is nice to achieve something.

Q810 Charlotte Atkins: Professor Woods, on this Committee we received oral evidence about the appalling case of Bethany Bowen. In that case a medical device, a morcellator, was used inappropriately and it appears to have contributed to her avoidable death. I am surprised that in this situation the MHRA does not appear to have taken a particular role in terms of looking at how this device should have been appropriately used.

Professor Woods: We did, indeed, have a role in that. Perhaps I can suggest that there are three aspects to it. The first and our most immediate concern, our statutory responsibility, is to establish whether the device malfunctioned. We worked with the manufacturer to confirm that that was not in fact the case. A deficiency of the device would include deficiency of the instructions for use. We consider this to be an integral part of the device. We did confirm with the manufacturer that the instructions for use made it very clear that there were certain surgical settings of particular hazard, including vascular sites where the risk of bleeding was obvious. There is the question of the device, and that is our responsibility. There is the question of the procedure in general: Is that way of removing a spleen intrinsically too risky to do, given that there are alternative ways of doing a splenectomy? That is not directly something that we work on, but there is a committee called the Interventional Procedures Advisory Committee at NICE, on which I have sat and on which my senior devices colleague Dr Ludgate still sits, which considers from the procedural point of view: Is that something which trusts should be prepared to see happen in their premises? That is the procedure. The third aspect of it is the training. We have heard from Finlay Scott the issue of the doctor’s responsibility to ensure that they are working within the limits of their competence. There is a clinical governance question about the training and support of people who are carrying out rather innovative or perhaps unusual procedures, whether they have had the training they need. That is something which lies between, as it were, the professional responsibilities of the individual doctor and the corporate clinical responsibility of the institution. We follow that spectrum part of the way. Our prime concern is with the device: Has the instruction with the device made it clear what the hazards are? We are closely involved in other bodies’ scrutiny of procedures, particularly innovative ones. We do not have a role in training, as such. We have adopted some areas of training in relation to devices use, because it seemed to be a rather awkward area, but the reality is that there are 80,000 or so different types of device on the market and we could not possibly provide training support for all of those. It is normally considered to be a part of the manufacture and sale that there should be training in the use for whomever the end user will be, but, nonetheless, as an agency we have put out a certain amount of training material on devices use and we would like to expand that. It tends to be
fairly general issues, like using infusion pumps and so forth, but we have picked those because they crop up as a source of mishap over and over again. Although we cannot train people to use a morcellator, there are so many infusion pumps in use in the NHS and we get back our adverse incident reports which indicate that operator difficulties are very common, so that we felt that we should put out specific advice, and we will do more and more of that as the opportunity presents.

Q811 Charlotte Atkins: Do you think you should be more involved with the procedural issues? I know you are on the Committee, but do you think you should be more directly involved in that, given this particular case?

Professor Woods: I think the right level of engagement is the one we have, and that is to have somebody with deep devices expertise sitting on the advisory committee of NICE which considers the procedure. But then they have to be scrutinised on a procedure-by-procedure basis. It might be that using exactly the same instrument to remove uterine fibroids will be considered acceptably safe but to use that instrument to remove a spleen might not be. Our role is to ensure that the devices expertise and experience is available to another body which makes that judgment.

Charlotte Atkins: Thank you.

Dr Naysmith: Thank you both very much indeed for giving us a lot of useful information and you have done it in a succinct and yet comprehensive manner. Thank you very much.
Thursday 19 March 2009

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins
Mr Peter Bone
Sandra Gidley
Stephen Hesford
Dr Doug Naysmith
Mr Lee Scott
Dr Howard Stoate
Dr Richard Taylor

Witnesses: Professor Sir Michael Rawlins, Chairman, National Institute for Health and Clinical Excellence (NICE), Lord Patel, a Member of the House of Lords, Chairman and Mr Martin Fletcher, Chief Executive, National Patient Safety Agency, gave evidence.

Q812 Chairman: Good morning. Could I welcome you to our seventh evidence session in relation to our inquiry into patient safety? I wonder if I could ask you for the record if you would give us your name and the current position you hold.

Mr Fletcher: I am Martin Fletcher, the Chief Executive of the National Patient Safety Agency.

Lord Patel: Naren Patel, I am Chairman of the National Patient Safety Agency.

Professor Sir Michael Rawlins: Michael Rawlins, Chairman of NICE.

Q813 Chairman: I have a question to start this session which relates to the NPSA. Do you think that your remit has allowed the NPSA to have the maximum possible impact on patient safety or could the government have given you a better job description, perhaps with a broader remit, than your present one?

Lord Patel: Let us first of all address the issue of what is our remit. Our remit is written in words which are not always very clear. If I summarise it, NPSA's role was to coordinate systems wide patient safety by key things: by promoting a culture of reporting and learning from adverse events in the health service; to devise, implement and monitor a reporting system based on relevant national standards to be issued by the Department of Health regarding adverse events and near misses, again to promote a culture of reporting and learning; thirdly, to collect and appraise the information on reporting adverse events, near misses and other material useful for any purpose connected with the promotion of patient safety. The remit itself was fairly wide. What it did not have in it was any role to work in terms of implementation of the learning outcomes or any role of monitoring that implementation was being done or, that matter—although we independently do that—to have a role to test the methodology and, more importantly, it did not have any specified role to work with other NHS organisations such as maybe NICE but also with the regulators. However, we interpreted that job description fairly widely and actually do work closely with the Healthcare Commission and will now do so with the Care Quality Commission and some work with NICE also. If you ask me the question, could a wider role have been given, organisations always say yes. On the other hand, we were able to interpret the roles that we were given in a way that would allow us to more widely interpret that. Implementation was the key. The view we have taken is that it is not our role to be an enforcer or an inspector or a regulator; we are not that. Our role mainly was to promote a culture of patient safety, particularly in providing tools and whatever was needed for people to establish local systems to collect this information and be a national repository and produce the learning from that national repository.

Q814 Chairman: Do you have anything to add, Mr Fletcher?

Mr Fletcher: I think Lord Patel has covered everything.

Q815 Chairman: There is something I want to take up with you and this is about the issue of an independent investigation process for all deaths and serious injuries caused by healthcare. When we look round at air and rail accidents these investigations are actually run by independent bodies. If it were the case that independent bodies looked into deaths and serious injuries, would that not ensure that we get to the bottom of serious incidents without a vested interest getting in the way? What is your view on that?

Lord Patel: That is a good question. You are quite right, in other fields and in other industries they do have a system of independently looking at any serious injuries. Let us just rehearse what happens now. The local organisation where the healthcare is delivered does the investigation in the first place. At times they might feel that they want an independent group, they might invite some experts from outside, for example another trust, to carry out that investigation. The strategic health authorities might decide that they want to conduct an inquiry and that might be independent of the trust where the serious incident occurred. It may be that other agencies such as Parliament or government may get involved sometimes and set up an independent inquiry. The coroners of course do their own inquiries in cases referred to them. The principle of having an independent inquiry for serious untoward incidents, particularly that might lead to serious harm or death, is important. However, the principle also should be important that you would do this inquiry with the primary purpose of learning from it and to get that learning across the NHS rather than doing an inquiry about that particular incident to find
blame or where blame lies (although that may come out). The next thing we need to look at, if you are going to do this, is what is the scale compared to other industries? On the basis of the information we have if you take serious harm and death we are probably talking in terms of numbers of possibly 10,000 or more. If there are going to be large numbers there are quite considerable cost and resource implications. One way to handle that might be to set clear criteria of what incidents you would investigate, in particular they would have to be ones where there is a patient safety issue and there is likely to be learning from it. Secondly, there might be, for instance, a never event—things that should not happen—that could be investigated. That way you are setting clear criteria. That does not mean that these criteria cannot be violated; there may be others which fall outside that you still wish to investigate. The concept of local ownership of this investigation is correct; whether the independence should come from the SHAs and not individual trusts might also be right. What is important though is that you have the right people with the right skills carrying out these investigations. That is where we need to have some training and some tools so that the trusts and others understand clearly the clear criteria of what needs investigation. Before that, to make the care safer, there are other issues that we need to address. For instance, if a hospital has a higher number of serious untoward incidents than the average then we need to go round and look at our systems in this hospital. Is there something fundamentally wrong with those systems? Let us not start discussing the report of two days ago. I do not know whether that helps.

Q816 Chairman: In part it does but at the very beginning there were a lot of “mights”: it might be an inquiry; it might be by a neighbouring trust that would come in and do the inquiry. Really the issue is that there are no mights in terms of rail of air; there are independent inquiries into what happened and lessons learned. We are obviously doing a comparator between risk assessments in different parts of the economy, as it were, in relation to what is happening in health. Would you like to see the “mights” being replaced by “will” or “should”?

Lord Patel: “Should”.

Q817 Mr Bone: Lord Patel, I think you said in your opening remarks that there were 10,000 possible deaths a year that are untoward or needing investigation.

Lord Patel: Serious incidents and deaths.

Q818 Mr Bone: Let us take that as being a hundred additional air crashes in this country. If there were a hundred additional air crashes in this country the government would be absolutely criticised if they were not independently investigated. Is the problem that we are letting the NHS cover up these things by not having an independent investigation; independent investigation, not NHS investigation?

Lord Patel: Let us address the concept of 10,000 serious incidents including deaths where we are going to do in-depth, independent investigation. As a concept of independent investigation I sign up to it. What we need to look at is the feasibility of doing this and whether it is necessary to do it in all 10,000 because the learning that may come from two may apply across the board of the healthcare and you do not need to do more than two, depending on what the investigation is about. It is a systems failure that we normally try to pick up, not individual deaths. I think that has to be clearly understood.

Mr Bone: I am afraid you would investigate air crash; you would not just say, “It’s like the other one”.

Q819 Chairman: They all fell out of the sky.

Lord Patel: That is if the analogy of air crashes is always going to apply to healthcare which we can have another debate about.

Mr Fletcher: Just to add to Lord Patel’s comments, I think that the key point around investigation is firstly the point about why we are doing it and we are really doing it for learning. What we are interested in is that the investigation is robust and credible and gets to the issues that have led to the harm in a way that we can then take action on those in terms of national learning across the NHS. One of the things we have done is to work very closely with each of the ten strategic health authorities in England to set up patient safety action teams. We have transferred the patient safety management resource from our agency to those SHA hosted action teams and a major focus of those action teams is on improving the quality and robustness of local investigation of patient safety incidents. We have also done a lot of work to develop standardised tools for trusts so we have a whole series of templates that are now available on our website that are aiming to standardise to a level of quality the types of investigations that are done and training associated with that. One of the other issues that we have considered and one of the areas where we may do more is actually to think about whether we convene some sort of national panel of experts that may be available for trusts to call upon if there was an investigation that potentially had national significance in terms of learning.

Q820 Dr Naysmith: What about a body like the Independent Police Complaints Authority which must deal with almost as many incidents as you are talking about and yet is independent of any police force? Would that not be a model that might be useful in this situation for investigating incidents?

Mr Fletcher: If we went down the road of a national panel of experts it would be very much about people who had expertise in clinical areas and safety who could provide the independent perspective on any investigation. The second point I would make is that from our end in terms of national learning we do individually review every incident report that we receive where there is a report of a patient death or serious harm. We would often go back to the trust and seek their own investigation report of that; we
would look at the literature and we would talk to experts. So I think there is a process that we have in place to make sure that from the point of view of national learning that where these events are reported we are really getting to the heart of what the risks are that might need action across the NHS.

Mr Fletcher: I think it is more a question of how we build on those we have rather than setting up something different.

Q822 Stephen Hesford: Lord Patel and Mr Fletcher, it has taken a lot of time and effort to set up the National Reporting and Learning System. What would you say have been its successes and its failures?

Mr Fletcher: Let me start with the successes of which there have been a number. The first thing to say is that the National Reporting and Learning System makes it possible for every NHS staff member to report to the system in every care sector across England and Wales, so every organisation has a connection to the system. Not only that, when they prepare a report for local purposes it also is the report that we use for national purposes because the data are transferred electronically so we have been able to have both local systems and national systems where there is not a requirement to report separately. Our trend in terms of reporting is upwards so more staff than ever are reporting, more organisations are regularly sending us data and we believe that high reporting is more likely to indicate organisations that have a strong culture of safety and openness. We think that is a good thing. We have regular systems of feedback now in place to organisations so, for example, every six months we provide feedback reports to organisations on their profile and rate of reporting and we have been doing that now for three years. Two weeks ago we published for the majority of NHS organisations in England and Wales organisational level data about the profile and nature of their incident reporting. We have just produced our eleventh quarterly data summary which we produce separately for England and Wales. So I think we have regular mechanisms of feedback well-established. We are using the data to learn for patient safety improvement and there are a number of ways we do that. We do that through identification of new risks so there may be an event that looks like a one off event at a trust level but when we look at the national data we can see a pattern in that and an example would be work we did looking at a series of patient deaths where there was a theme around patients who were deteriorating; it was not being identified or, if it was being identified, it was not being well-managed so we were able to identify that as a theme and actually work quite closely with NICE on taking action forward on that. We have done a lot of work on looking at overall patterns and trends in data and feeding that back to the service so, for example, we produced a big report on patient falls which is one of our major topic areas reported.

Q823 Stephen Hesford: You said about reporting back to the service but who, in that circumstance, would you actually report back to? Who would you send this stuff to?

Mr Fletcher: The organisational feedback that I talked about before—for example the confidential feedback report—would go to the people responsible for clinical governance and risk management within the organisation. We would then also separately write to the chief executives of the organisation to alert them to the fact that these data are available in their organisation.

Q824 Stephen Hesford: Not at the level of the Department of Health.

Mr Fletcher: Not directly to the Department of Health. The data we published two weeks ago—which was a summary for every organisation in the NHS in England and Wales who had reported to us—names the organisation and is searchable on the website. You can go on, put the name of the organisation and you will get a summary of their data.

Q825 Stephen Hesford: In another life you are a politician because you have not answered the failures part of the question.

Mr Fletcher: I will get to those. There are a couple more successes, if you will allow me. We have done a lot of work around speciality based learning as well. We have worked very closely, for example, with the College of Anaesthetists, the College of Surgeons, looking at the data that relates to their speciality and what we can use from that for improvement. We have done a lot of work around common contributing factors so, for example, we looked at nearly 25,000 incidents where there were problems associated with correct identification of a patient or some element of their care (they got the wrong drug or the wrong procedure because of weaknesses in the identification of the patient) and that has resulted in a whole programme around standardising use of wrist bands, use of the NHS number and technologies that improve accuracy. As I said earlier, the other two areas I have mentioned in terms of successes are that we now have a very robust system of reviewing individually all reports of deaths and serious injuries. That is around 1,500 to 2,000 reports a month where we would individually review those reports and, as needed, go back to the trust for information, look at the international literature, talk to relevant experts to identify where national learning is needed. I have to say I think the other indicator of success is that we have had huge international interest in our work and we get a lot of people wanting to come and see what we are doing and looking at what the lessons are that could be learned from reporting systems in other countries. For us they are the successes. In terms of what you call failures, I think the sense, as you said in your question, is that the system has perhaps taken longer and has been slower to reap some of these benefits. With hindsight there would be a recognition that an undertaking of this scale was a lot more complex than anybody had perhaps at first realised. You have
to remember that when this system was set up five years ago it was the first of its type in the world. There was not a recipe book to pull of the shelf and there was no international experience to look at. There has been a lot of learning as we have gone on but I believe we are now at a point where the system is delivering a lot of benefit to the NHS. I am not for a moment saying it is perfect and I am not saying that there are not areas that can be improved; however I think we have a very strong platform in place to support national learning.

Q826 Stephen Hesford: It is suggested to us that basically what you do is busy yourselves with minor incidents from acute hospitals. Is that fair?  
Mr Fletcher: No. Let me tell you why I think it is not fair. I presume this is perhaps a comment about the fact that around two-thirds of our data relate to incident reports where there is either no harm or low harm to patients. We believe that those incident reports are very important for two reasons. One reason is because what it is telling us is that staff across the NHS are much more aware of safety and are not waiting until a patient is harmed before they are raising a concern. We think that is a good thing in terms of being able to take preventative action. Secondly, from the point of view of the way that we work, it is often the patterns in those data that are actually very important in terms of being able to contextualise a serious event. If I can give you the example of amphotericin, there has been a lot of publicity recently about a coronal inquiry where there were two deaths relating to amphotericin in one trust. When we went back into our data when there were two deaths relating to amphotericin in non-paediatric areas but we often get reports on medicine safety issues without knowing the name of the medicine. Another example would be that we often do not get the age of the patient in the data. We are aware that there are some emerging themes in our data around the treatment of children in non-paediatric areas but we obviously need the age to be able to focus our understanding of the incident reports. Where we need to do more around the data is actually about getting through incident reports both for local review purposes as well as national purposes is as accurate and complete as it can possibly be.

Q827 Stephen Hesford: Given that part of your function is an educative function to inform the service and trusts, underreporting is still very substantial. Would you accept that?  
Mr Fletcher: What we know is that if it is hard for people to report, if it is not relevant to the patient care they are providing and if we do not provide feedback, there is little benefit in reporting. We know that if we can address the issues of making it simple, relevant and giving feedback then we can improve reporting. We know from our data, as has already been mentioned, that we get a lot more reports from the acute care sector than the primary care sector so we think that is an area where more needs to be done in terms of reporting. We have had some recent success. I will give you one example where we worked very closely with the College of Anaesthetists to design with them a specialty reporting system for anaesthesia. The electronic form was designed in a way that was very relevant to their specialty. The College was very involved with us in analysing the data and providing feedback. In the pilot of that which involved 13 trusts across England, in the first 150 reports more than 100 of those were from senior consultants. We believe that if we can get these things right that means we can make reporting very much more worthwhile.

Q828 Stephen Hesford: You have touched on a few areas there. Doctors underreport in relation to other healthcare workers, so there is an issue. There is almost no reporting from primary care—it is a sort of reporting desert—so after five years there is an issue there. Adverse drug events are still underreported. What can we do and what are you doing about those three particular areas?  
Mr Fletcher: To take those one by one I will start with primary care. The picture in primary care is mixed. What we know is that there is underreporting from general practice. When we look, for example, at our mental health data we get quite good reporting from community based mental health services. It is absolutely clear that general practice is underreporting and that is why we are currently working with general practice along the lines of what I have talked about with anaesthesia, of designing a specialist electronic form, working closely with the college on the analysis and feedback of that data. We have a number of pilot sites about to get under way in the NHS South West to actually test this and look at how we can improve general practice reporting. In general practice we have also done quite a lot of work with the college around significant event audit which is a well-established methodology in general practice for learning from things that go wrong as well as things that work well. What we have done is to develop a tool kit with the college around using significant event audit as a more meaningful tool for learning. I think that is very much in our focus.
Q829 Stephen Hesford: Is that for GPs?
Mr Fletcher: Yes. The other quick point I would make is that as a result of Lord Darzi’s High Quality Care for All report we have support to establish something that we are calling Patient Safety Direct and that will build on the National Reporting and Learning System and create a single portal nationally for reporting and learning. We are very much targeting that effort on the bigger issue of doctors reporting as much as we see nurses reporting.

Q830 Stephen Hesford: What about drugs?
Mr Fletcher: We get around 8,000 or 9,000 medicine safety incident reports a month. It is one of our top three areas of reporting (falls is the other one I mentioned) so I think we get a lot of data and are very actively using that.

Q831 Dr Taylor: Still sticking with Lord Patel and Mr Fletcher, you have told us that you have pretty good systems for collecting reports and for promoting safety messages but there seems to be an absolutely stark divorce between these messages and the people who should take note of them. The Committee of Public Accounts in 2006 we are told found that “Patient safety alerts and other solutions are not always complied with though trusts self-certify that they have implemented them”. Would you agree that there is this huge gap? You have said that staff are becoming more aware of safety; are they really? We cannot avoid talking about what has been happening in Staffordshire; the Department of Health have said it is down to the Healthcare Commission and strategic health authorities to check compliance. The strategic health authority involved in this case certainly did not check compliance. How can you bridge this gap between your immense amount of knowledge about the risks to patient safety and actually getting it across to the people who are doing the work?

Lord Patel: I will make an initial comment and then I will let Martin come in. You are absolutely right; this is the crux of the whole issue, that we can have a mechanism from which we get a lot of learning but unless there is are clear processes to make sure that that learning gets implemented, monitored, tested and it makes a difference to patient care we are not going to get very far. The crucial issue is: how do we get this learning implemented?

Mr Fletcher: Perhaps I could set some context in terms of how the mechanism works. Basically, as I said in my earlier comments, having analysed the data if we had identified some risks that we thought were important for the NHS to know about and some actions that we felt needed to be taken at a local level, we would issue an alert or a rapid response report. That is done through a system called the central alerting system which is managed by the Department of Health in England and that goes electronically to every trust. We can specify who it goes to in the trust—whether it might be the medical director or the pharmacy director or the chief executive—depending on what the nature of the alert is. When we issue an alert we set a date for compliance to be reported. By that date trusts are required to report their compliance with the alert fully, partially or not as the case may be. We obviously look at those data from the point of view of whether there is more that we can do to help support implementation. Obviously the Healthcare Commission looks at those data as part of its annual health check and in fact we have gone further in our partnership with the Healthcare Commission where we have actually identified particular alert areas that we think are important for them to look at. The alert we issued around high risk medicines was a particular topic focus for the Healthcare Commission’s last health check and they were able to look much more closely at compliance around that.

Q832 Dr Taylor: You have said we can look on the web for alerts from each trust. Did you actually have alerts about Mid-Staffordshire?
Mr Fletcher: Sorry?

Q833 Dr Taylor: One of you said that we can look up our own trusts for a summary on the web for alerts that you have had. What I want to get at is had you had alerts about Mid-Staffordshire?
Lord Patel: I think we need to clarify the distinction between alerts. I think what you are referring to is what Martin spoke about earlier on about the comparative data from different trusts that we published two weeks ago in several areas. Was Mid-Staffordshire one of them? Yes, it was.

Q834 Dr Taylor: So you did have a number of alerts about that particular trust.
Mr Fletcher: Not so much alerts. What we published in these organisational data reports was essentially a profile of the incidents that that trust had reported to the National Reporting and Learning System. So we profiled the incident type—patient accidents, medication, et cetera—the degree of harm that was associated with those incident reports; we gave feedback on the rate of reporting and consistency of reporting and we also gave comparative feedback on the number of reports as compared to other trusts like them in order for a trust to look at whether they felt their reporting rate was as it should be.

Lord Patel: Dr Taylor, if I answer specifically, what it indicated was that Mid-Staffordshire was a relatively low reporting trust and it had a higher incidence of severe harm and death.

Q835 Dr Taylor: Did you convey that to the Healthcare Commission? What did you do with that?
Lord Patel: The Healthcare Commission would be aware of it because everybody was made aware of it.

Mr Fletcher: On an annual basis we provide data on reporting rates of trusts to the Healthcare Commission and they use that as part of their screening process in the annual health check.

Q836 Dr Taylor: The fact that there were more serious incidents there than other places did not mean you really felt you had to alert somebody specifically to that?
Lord Patel: This is the first time we have published this data transparently. Before, the arrangement—an arrangement that I did not approve of ever since the
day I became the Chairman of the NPSA—was that this data was kept confidential and should be available to the trust itself. We have broken that rule this time.

**Q837 Dr Taylor:** So it is now, for the first time, available widely.

**Lord Patel:** Correct. That is the intention from now onwards, not to have this data confidential. That is why we broke the rule.

**Q838 Dr Taylor:** In future, if one particular trust was standing out, would you jump up and down about it more than you did before?

**Lord Patel:** We need to develop a relationship of working with the new CQC—Care Quality Commission—as to how the new agenda in quality can be inclusive of all this information that we might have. I was going to refer to this later on because I know you might ask me a question about the priorities in NHS.

**Q839 Dr Naysmith:** You just said that everybody had this information.

**Lord Patel:** When we published it, yes.

**Q840 Dr Naysmith:** Did Monitor know about it when they gave the trust foundation status?

**Lord Patel:** Probably not.

**Q841 Dr Naysmith:** Why did Monitor not know about it?

**Mr Fletcher:** I think we have to be a little bit cautious because one of the things we know is that there is wide variation in how trusts report because they use different definitions. Part of the whole point of us publishing the data trust by trust is to actually look at how we can get greater consistency in comparing the data because it may be that a higher number of events is because this is a trust that has a better culture of reporting. It may also indicate that it is a trust where there are problems. The key audience for these sorts of publications is really the board of that organisation. In the organisational data summary what we have done is made a number of recommendations to boards about looking at this data, understanding them and making sure that they think this is right for their organisation. Whether over time these data could become some sort of early warning sign of an organisation where there were concerns, I think it is too early to say.

**Lord Patel:** What we should be doing—and we are trying to address this—is to have a reporting system which has some kind of uniformity in what is reported and consistency so you can use comparative data, not only when you publish the data but develop indicators or early markers of a problem developing long before it actually becomes something like what happened in Mid-Staffordshire. That is the challenge.

**Q842 Dr Naysmith:** What do you do about a board that is in denial, it is being given the information but is refusing to act on it?

**Lord Patel:** What I told Dr Taylor was an observation based on information we have. We have to accept that that is crude information. The observation on that crude information is that this trust comes in the bracket of a lower reporting trust and when you look at serious harm and death incidents it is higher. We can make a hypothesis about it but we cannot be accurate. However we can make this kind of data more robust but to do that we will have to do some work on it. What do you do when the data is robust and a board ignores it? Clearly there needs to be some kind of sanctions available; without sanctions it cannot work. That is a personal view; that is not a board view or an NPSA view.

**Q843 Dr Taylor:** When did you put the Patient Safety Action Team into the West Midlands SHA?

**Mr Fletcher:** The first of April of last year, 2008. That is when the teams were officially established.

**Q844 Chairman:** Is one of the major issues in this, what was highlighted by the Committee of Public Accounts Report in 2006, that “Patient safety alerts and other solutions are not always complied with though trusts self-certify that they have implemented them”?

**Q845 Chairman:** Is it safe to allow self-certification when alerts have been issued in terms of an institution?

**Lord Patel:** It is a good question; the problem is that if I am providing care to the patient as an obstetrician and I am sent an alert of some system failure that harms patients and I do not implement that or my management does not implement that, what is the sanction?

**Q846 Chairman:** Garden leave.

**Lord Patel:** I have never had any experience.

**Q847 Chairman:** Let us hope you never do.

**Lord Patel:** If you are going to make a recommendation we should explore what are the mechanisms in place that makes an institution implement them. Whether that is a guidance or an alert from us or whether it is guidance from NICE or any other organisation, what happens and who monitors it? We do not have that monitoring role, neither do we have a role of enforcing implementation.

**Q848 Mr Bone:** I have it in my mind that when you publish an alert that is now in the public domain. If there was an air crash they would say, “You have to fix this widget because a hundred people died”, is that happening or is that something new? I am not quite clear on that point. Is it in the public domain?

**Mr Fletcher:** Yes.
Mr Bone: So the newspapers and media can get it.

Mr Fletcher: Yes.

Q850 Mr Bone: Moving on then, I have certainly had this experience from constituents where a loved one has been harmed or maybe killed by a failure in the hospital to do with patient safety. Instead of having an open, warm and sympathetic reception to these people you go into spin doctor mode where the whole thing is to protect the hospital from any damaging comment and to protect the hospital from being sued. There are whole departments of bureaucrats to this. I am not saying that happens in every hospital because I have no evidence of that, but we have had evidence of this happening in some. Do you accept that that does happen in some places?

Mr Fletcher: There is no doubt that organisations often react in a very defensive way when things have gone wrong. This concept of being open or having greater openness is something the NPSA has championed for a number of years. Essentially what we have argued is that what patients want is an apology, an explanation, a commitment that some sort of investigation will occur to look at what has happened and why it has happened, and they want feedback on what changes are being made to prevent it happening to other patients. We have done a lot of work to develop guidance, training and resources to help trusts do it because I think it is easier said than done in practice. As you are probably aware, the Department of Health commissioned a review of the implementation of the guidance by Albert Wu, an expert from the United States. We welcome that review because I think he has made some very helpful recommendations about how we can further strengthen implementation of this for example through more targeted training of senior clinicians to really make sure that this is happening much more in practice than it is at the moment.

Q851 Mr Bone: That is all to be welcomed and what you are doing is greatly appreciated. However, do you think that the actual practical pressures on my foundation hospital are more to be defensive and to protect their interests of the hospital’s PR and to save it being sued? Do you think that pressure is greater? It should be more open so how, in practical terms, can we get them to be more open?

Mr Fletcher: To give you one example in terms of the point you make about litigation, we have worked very recently with the NHS Litigation Authority on the circular that they sent out explaining what you should do when something has gone wrong to make sure that that has very strong and clear messages about the importance of openness and links to the guidance and tools that are available through the work that we have done. There has been a very strong partnership not only with the Litigation Authority but also with a number of medical protection societies as well. The message is that openness is probably a better approach—even where there is threat of litigation—than defensiveness—because we know when we talk to people about why they litigate it is often because they had a sense that people were not telling them and were not being honest and open with them.

Q852 Mr Bone: Do those guidelines apply to foundation hospitals?

Mr Fletcher: Yes.

Q853 Mr Bone: If you found someone who was really not being open what would the sanction be in that case? Would it be name and shame?

Lord Patel: We do not have any sanctions. All we do is issue guidance about being open and transparent.

Q854 Mr Scott: Lord Patel, what do you think the top priorities should be for improving patient safety?

Lord Patel: The Chairman and Dr Taylor referred to it and I emphasise it again: the key issue here is about implementation of learning. It is the implementation of the learning that identifies where there is system failure that leads to harm to patients or something that happens in one trust—a system they operate—that leads to harm. If the learning that comes is not implemented then we are never going to see the improvements in patient care that we are after. That would be one of my priorities, a systematic approach to patient safety that the local organisation must address. Secondly, I think there needs to be a greater engagement of the board—whether it is a foundation trust or whether it is a non-foundation trust—in the quality of patient care and the safety of patient care rather than a focus on the agendas of targets and finances. Targets and finances are important, but the issue about patient safety and quality needs to be on the board agenda on a regular basis. I personally believe there ought to be a non-executive director who gets appropriate training on what quality and safety means in healthcare and that would be the person who takes the role of governance in every trust, focussing on safety and quality. Senior clinical involvement is extremely important. The question was asked earlier on about involvement with doctors and I think what we require is a senior clinical involvement, whether that is in acute trusts or in primary care. Reporting of patient safety incidents is important and implementation of learning outcomes is important, and a demonstration that they are being implemented and not just a tick chart approach to it. If there was a monitoring system they could demonstrate that they had implemented them. That is important for us too because we need to have this learning tested to find out that it works. Not every alert we produce might be appropriate and demonstrate the good outcome that you might think it might do. There is another issue at trust level about an in-depth understanding of serious incidents and deaths to ensure we get to the root causes and appropriate lessons are learned. The trust we were discussing earlier, from the report that I have read it is quite clear they did probably have higher incidents of untoward deaths. They should themselves have been going round asking the question why and looking at their systems. The independent inquiry and Healthcare Commission has done that, but we are moving onto the new agenda of Quality Accounts.
think Quality Accounts might be one way to embed patient safety; patient safety becomes part of the Quality Accounts. A demonstration by the trust and primary care to make sure that safety is part of the Quality Accounts that could be monitored. So there are several things that could bring patient safety more to the action level rather than the level where we are sitting just now which is more information, possibly doing good, but not knowing whether it is doing good.

Q855 Dr Stoate: Professor Rawlins, I want to pick up on a point from your recommendations in Safety First published in 2006. One of the recommendations was that, “A pilot should be established to examine the option of NICE developing technical patient safety solutions”. Can you tell me where you have got the option of NICE developing technical patient safety solutions. A pilot should be established to examine

Professor Sir Michael Rawlins: We did this jointly with the NPSA; it was very much a joint venture looking at costs of interventions to prevent serious safety problems. We used two examples, one was ventilator-associated pneumonia and the prevention of and the second one was medicines reconciliation (which is a funny way of putting, making sure when you go into hospital everyone knows what medicines you were on before you came in and you are continued on the ones that are appropriate). We did these; they were very satisfactory. We produced reports and advice to the service. We know that our ventilator-associated proposals have been taken up to 90% of patients in intensive care units; it was 50% before and it has gone up to 90%. On medicines reconciliation it is a bit slower because it needs the input of pharmacists and there are not enough of them necessarily—there is a financial implication—but 40% of hospitals have actually got it sorted out and another 40% are apparently making good progress. It was a very successful venture. We have not continued it. To be honest with you I do not think the NICE necessarily needs to be involved; I think the NPSA are perfectly capable of doing that sort of thing themselves. We did it jointly so we have not set up any special programme at NICE. Indeed it was a wise decision not to take any more on at NICE in view of what has happened within the last few months when we have been given a whole host of other things to do. The arrangement for the NPSA to do this sort of thing is that they come to us if they want to, we get on very well. Lord Patel and I often meet and Martin often meets with Andrew Dillon so it is an easy relationship.

Lord Patel: I would just add that every trust will implement this ventilator-associated pneumonia package and we will soon introduce central venous line infection reduction. As far as reconciliation of medicine is concerned, the good trusts have come down from 40% failure on reconciliation of medicine to as low as 8% or 9%.

Q856 Dr Stoate: Professor Rawlins, you will know from our previous conversations that I am quite keen on technical solutions in patient safety cases. Last week some of us went to Charing Cross Hospital Pharmacy Department and we were very impressed with their automated dispensing arrangements and the fact that they showed clear reductions in patient safety incidents and medication errors but—and it is a big “but”—in their clinical systems they have turned off their drug interaction programmes because they say that they are confusing, they are unhelpful and in fact they increase the risk of errors being made because of different doctors interacting with them differently. I am very concerned about this. Is this something that NICE has looked into?

Professor Sir Michael Rawlins: Not really, no; not into the prescribing systems. Those are really being looked after by the Connecting for Health programme.

Q857 Dr Stoate: The next question—as you probably anticipated—is that I am extremely keen for interactive expert programmes with NICE guidelines because I believe NICE guidelines are a huge bonus to patient safety. The big problem I have is that they are not available in a form that GPs can use.

Professor Sir Michael Rawlins: I am afraid that will be a big “but”–in their clinical systems they have turned off their drug interaction programmes because they say that they are confusing, they are unhelpful and in fact they increase the risk of errors being made because of different doctors interacting with them differently. I am very concerned about this. Is this something that NICE has looked into?

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Q858 Dr Stoate: I would love to be. Actually, I want you to go further and I want to put this on the record. I want your system, your NICE guidelines, to interact directly with the clinical records so that when I type in, for example, asthma, into a patient’s read code in a corner of my screen I want a box to say that this person should be on this, this and this and have you done the following tests?

Professor Sir Michael Rawlins: I am very concerned about this. Is this something that NICE has looked into?

Professor Sir Michael Rawlins: I am afraid that will be a big “but”–in their clinical systems they have turned off their drug interaction programmes because they say that they are confusing, they are unhelpful and in fact they increase the risk of errors being made because of different doctors interacting with them differently. I am very concerned about this. Is this something that NICE has looked into?

Q859 Dr Naysmith: Lord Patel, you said a few moments ago that you thought there should be at board level a responsibility and it should be a priority for boards. Is there currently any guidance telling boards, whether they are ordinary trusts or foundation trusts, that this should be the case or could that be one of our recommendations?

Lord Patel: We have worked with both Monitor and the Appointments Commission to help produce guidance about boards and we also work with the Appointments Commission to see non-executive directors and do seminars for them.

Q860 Dr Naysmith: All I am asking you is whether it is documented at the moment, that this is something that should be a responsibility of a board?

Lord Patel: No.
Q861 **Dr Naysmith:** So we need to strengthen your arm in this.  

**Professor Lord Darzi:** That would be helpful.

**Chairman:** I think all three of our witnesses very much indeed for coming along and helping us with our inquiry this morning. Thank you.

**Witnesses:** **Professor Lord Darzi of Denham KBE,** a Member of the House of Lords, Parliamentary Under Secretary of State; **Ann Keen MP,** Parliamentary Under Secretary of State for Health Services and **Sir Liam Donaldson KB,** Chief Medical Officer, Department of Health, gave evidence.

**Q862 Chairman:** Good morning. Could I welcome you to what is our seventh evidence session in relation to our inquiry into patient safety? I wonder if I could ask you for the sake of the record if you could introduce yourselves and the current position that you hold.  

**Professor Lord Darzi of Denham:** Ara Darzi. I am the Parliamentary Under Secretary for Health.  

**Ann Keen:** Ann Keen, Parliamentary Under Secretary of State for Health.  

**Sir Liam Donaldson:** Liam Donaldson, Chief Medical Officer in the Department of Health.

**Q863 Chairman:** I am going to start with a question for you, Sir Liam. What effect has *An Organisation with a Memory* had on safety in the NHS? How much better is patient safety now compared with a decade ago?  

**Sir Liam Donaldson:** I think *An Organisation with a Memory* started the journey that the NHS has been on to make patient safety central to how healthcare is delivered as it is now with Lord Darzi’s report, but I think it is a journey that every health system needs to go on if it is to get patient safety in that central position. Just touching briefly on the areas where I think major progress has been made, we have seen much greater awareness of safety as an issue when *An Organisation with a Memory* was published. It was not something that people talked about; the terminology was not even used. I think there is also a much better understanding of some of the sources and causes of risk in healthcare. At the time *An Organisation with a Memory* was published I think most people would say that when harm occurred to patients it was as a result of incompetent doctors. There were a small number of incompetent doctors and we need to ensure that we keep the number of people who are in that category down to a minimum. However, the vast majority of things that go wrong in healthcare are errors made by good people in weak systems, as you will have heard from other witnesses. The point there I think is the Swiss cheese—which is the metaphor for all of this—is well understood by a large proportion of staff in the NHS. One of the things that we initiated very early on was the setting up of a reporting system. That has been successful; it is certainly bigger than anywhere else in the world. There are things that need to be done to make it more useful and effective. To a certain extent we have been slightly victims of our success in setting that so early; we now have a huge number of incidents and the key to it is how to successfully analyse that huge database. I think also we have commitment at the top of the NHS. Going back to my time in the regions as well, I have worked with many chief executives of the NHS and unless the chief executive of the NHS is espousing and promoting a priority then it tends not to be taken seriously. That level of commitment is there now. We have not seen all this commitment at board level. I said many years ago that boards are more concerned with money and activity than they are about quality and safety, but again with changes through the Next Stage Review that is changing and is a major necessity. If you look at the other tests which *An Organisation with a Memory* set out—I will be brief with some of these—greater openness about errors, getting rid of the blame culture where the solution to anything that goes wrong is to chop somebody’s head off and believe you have solved the problem. That is not to say that people should not be held to account in serious circumstances, but in many circumstances the emphasis should be on learning and not judgment and if you continue to punish people who make errors—nurses, others—then people will be too frightened to report errors and you will kill many more patients. We have also seen research. One of the areas I think has gone less well—this is not a feature only of our system, it is a feature also of many healthcare systems around the world—is that we do not yet have enough examples of solutions where we have seen something go wrong, we have learned from it and we have put in a solution that has effectively eliminated or reduced that risk. Around the world there have been many alerts issued about wrong-site surgery but wrong-site surgery continues to occur. We need to find ways of developing more effective solutions.

**Q864 Chairman:** How do we compare with the rest of the world?  

**Sir Liam Donaldson:** As far as having a programme in place, being committed, having a large amount of information that we can learn from, we are probably the only whole healthcare system that is in that position. We can see around the world individual institutions—large hospitals, groups of hospitals—who are further ahead in some ways than we are, but nobody that has tried to do it on this scale across a whole healthcare system. I think we are very much in the forefront in that respect. I think more needs to be done on education and training. Finally I would say that involving patients and family members, which has been done very successfully in the initiative I have run through the World Health Organisation, listening to somebody who has risen above their own personal tragedy to speak powerfully about the need for safer care is a way of moving hearts and minds in...
Sir Liam Donaldson: a way that somebody like me could not hope to do. Getting those patients into the medical schools, the nursing schools, the management schools, to tell their stories is probably something that is as powerful as anything and we need to do more of that.

Q865 Chairman: We will be covering one or two of those areas in the next few minutes, but one of the things we have been told in this inquiry is that there is no reliable data on how many patients are actually harmed by the National Health Service each year. If there is no reliable data, how can we be sure that things have changed?

Sir Liam Donaldson: We cannot yet be sure that things have changed but you would be hard pressed to find any healthcare system in the world that could tell you that. We do have data on patients being harmed through the reporting system that you will have heard a lot about. We believe there is underreporting. However, the prediction when An Organisation with a Memory was published was that nobody would report. We have had a massive level of reporting but the weaknesses are that we are probably not hearing as much about the serious errors as we should and we are not hearing enough about primary care. If we can get those right then I think we will really have something to be not just encouraged about but proud of.

Q866 Dr Naysmith: Sir Liam, we have just been hearing from the National Patient Safety Agency and it is clear that the people involved and the staff generally are obviously dedicated and hardworking people. Are you confident that the NPSA’s current remit allows it to have the maximum possible impact on patient safety?

Sir Liam Donaldson: I think I would say, “Yes, but . . . ”. I think it has shown over the last couple of years remarkable leadership. It has engaged local NHS services in a way that they did not perhaps do in the first phase of the NPSA. They are feeding back information which the airline industry tells us is very, very important to give to people, a sense that their information is being used and acted upon and is coming back to them. I feel that the area that needs debate—I am not sure what the right answer to it is—is that when an air crash occurs you see an accident investigation team going straight out and getting to the root causes of the problem and making a report. I do not want to prolong the Committee’s time, but having been in post a long time I have seen many, many forms of inquiry and most of them grind the whole system to a halt. Worse still, lawyers get involved. Any investigative mechanism which would be—the one that initiates that sort of investigation. When you look at the sort of incidents like Mid-Staffordshire which are more to do with the functioning of the whole organisation then I think a body like the Care Quality Commission and the Healthcare Commission is better placed to do that provided that the public have confidence in its independence.

Q867 Dr Naysmith: There is probably quite a lot of involvement by lawyers in any case at the moment in the National Health Service. Do you think having an independent inquiry would make that much more likely?

Sir Liam Donaldson: How could you run 50 independent inquiries in the country at the same time? The whole system would grind to a halt. I say that because I do believe an in-depth investigation done rapidly is very, very important but I would say to you as parliamentarians, can you write a law for us that will prevent that from becoming turgid, bureaucratic, lengthy and legalistic? Can you do it in such a way as it is not a blame and retribution exercise because otherwise you are back to square one killing people whose lives could be saved if you had a different culture?

Q868 Dr Naysmith: If we could, would you think it would be a good thing to have something totally independent of the National Health Service? At the moment we have local inquiries and sometimes strategic health authorities get involved and then they move on up and now, like we have in Mid-Stafford, there is this question of bringing in from outside, but still from within the National Health Service, an expert to look at accident and emergency. This is a muddle. If you have a purely independent step that you take when the circumstances justify it, such as happens with the Police Complaints Commission (I know it is not on the same sort of level of importance, although sometimes it is) then you can have this independent look at things which people think does not happen at the moment.

Sir Liam Donaldson: I am broadly in agreement that something needs to change. I would see a conceptual distinction between an accident type incident which is the majority of situations that we are talking about in the field of patient safety where you need a rapid investigation that learns quickly. It would not seem logical, given that the NPSA has in-depth from all its incident reports of more minor matters not to let it be the one that initiates that sort of investigation. If I could take you back to the process of the Next Stage Review, one of the challenges for me was when I asked people what you mean by quality. That was an interesting question because you got a different response from the clinical staff, you got a different response from the patients and the public and you also got a different response from management in relation to what quality means. If you remember I said this in July, having an evidence based review I went back to
look at what we mean by quality in healthcare. There are many, many academics and policy makers and probably the most famous one was Donabedian in 1990 who essentially said that quality has seven pillars ranging from efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy and finally equity. That was 1990 and if you look at the debate that moves on and so contemporary healthcare’s definition of quality now is effectiveness, safety and patient experience. There are more—we can talk about productivity and cost effectiveness and I agree with that—but we picked up these three because we wanted a clear framework that the NHS understands; the three domains of quality within that framework are safety, effectiveness and patient experience. These are interrelated but that is the framework that we put together. Based on that framework we are taking the bill through Parliament—I am taking it through the House of Lords at the moment, it will come to you soon—we hope to use indicators that measure safety, effectiveness and patient experience and every provider organisation through legislation will be publishing annually their Quality Accounts which would include indicators reflecting safety—

Q870 Sandra Gidley: Would these be self-reported? How is that scrutinised?
Professor Lord Darzi of Denham: Within the Quality Accounts there are three sections. The first section is what the Healthcare Commission—CQC in the future—tends to measure in relation to, for example, safety. We have a number of safety indicators; that is a given, that has to be in the Quality Accounts because it is already reported to the Healthcare Commission. Then, as you know, the Department of Health publishes annually the operating framework and it has a number of different tiers of indicators. The compulsory ones are called the vital signs and will be in another section of the Quality Accounts. Then there is the third section. There is a huge amount of information in the NHS but that information does not necessarily have the ownership of the clinicians and staff who are working with it. We have just been through a terribly long consultation and we have what we call a short menu which is about 200 indicators. Many of these are safety indicators like hospital acquired infections, which is part of the CQC. The whole purpose of this is at different levels of the system. The first purpose of this for me is that as a clinical team if you want to improve your service, if you want to know where you are, you have to take ownership of measurement and then see where you are and constantly improve. The board has to sign this quality account off. You have to be accountable to the quality of care which includes safety, effectiveness and patient experience to the local population that you serve. At a regional level commissioners have to have that data before they start doing proper commissioning. You cannot commission a service if you do not know what the output of that service is. At a national level we want these indicators to monitor the progress of the NHS on a year by year basis. That is the driving principle behind this ownership of the data and the publication of the Quality Accounts.

Q871 Sandra Gidley: Having to pass legislation to make the board accountable, is this an acknowledgement, if you like, that boards have not been fully accountable in the past and have not paid enough attention to patient safety at the expense of balancing books and some of the other indicators?
Professor Lord Darzi of Denham: I did sit on a board many years ago where most of the discussions were on other issues rather than what matters to clinicians and patients, which is the quality of care and I am bringing the Quality Accounts at the level of the board. The board has to sign these off because ultimately the business we are in is to provide high quality care. We know that. The money is the enabler and the government has doubled the amount of money invested in the NHS to make sure that we achieve that. If you look at the NHS plan in itself—we have debated that many times—we have areas of focus which, at the time, were very bad. The major killers in this country were cardiovascular disease and cancer. Let us take cardiovascular disease. In six years we have dropped the mortality rate of cardiovascular disease by 50%; that is a great, great achievement. We set out to do something and we did it. That was based on setting an outcome as a target and we changed everything to make sure that we met that. The Next Stage Review is: how do we make that systemic? How do we make that for end of life? How do we make that in long term conditions? That is the transition that I am talking about and the only way you can achieve that is to have ownership of all of these pathways with the indicators that measure them within hospital settings. Let us not forget that Quality Accounts is not just for acute hospitals; it is about primary care, it is about community services. It is a bold statement to say that quality will be the organising principle of the NHS and that is exactly where we want to head.

Q872 Sandra Gidley: Back to patient safety, how will the Commissioning for Quality and Innovation allow patient safety issues to be addressed?
Professor Lord Darzi of Denham: CQUIN, which is the Commissioning for Quality and Innovation, was another enabler in High Quality Care for All. It is purely to give the commissioners a lever for quality improvements. Contractually the PCT will have to contract with the provider and say, “Right, we need to identify your priorities in these three domains” (let us not forget, safety, effectiveness and patient experience). So when they are contracting with the provider they will look at their safety indicators and they may decide that these are the areas we need to improve in your provision. That would be part of the contract between the PCT and the provider. At the moment we started with 0.5% of the uplift of the tariff; we hope to increase that. My ultimate aim initially, for the first year the message I want to try to get out to the PCTs is: please concentrate on
improving the quality of reporting and please assure the data. After that we start concentrating on quality improvements.

Q873 Sandra Gidley: You are also going to be recording Patient-Reported Outcome Measures. How will that influence safety?

Professor Lord Darzi of Denham: Something we should be very proud of is the creation of PROMS (Patient-Reported Outcome Measures) because these are high risk indicators that measure effectiveness as the patient sees it, not the doctor, and what the patient experience is. A good example is that someone could come to me with groin pain, I would say, “You have a hernia”. I repair that; he comes back and says, “I still have the same pain”. As far as the patient is concerned that procedure did not meet their expectation. If I could give you an example of safety within that, I have no doubt that if there is a safety issue which will reflect on the outcome or the experience of the procedure, that will be captured through the PROMS. A good example is that you come in and have a hip replacement and you may get deep venous thrombosis prophylaxis. You had a good operation but you ended up with a clot which delayed your discharge, it means you have to be on warfarin for six months. The patient’s experience reflects very much on that; it is one way of capturing the whole experience of safety effectiveness and the patient’s experience.

Q874 Dr Stoate: Bruce Keogh, the NHS Medical Director and Martin Fletcher told us last year that PCTs could withhold payments in the result of a never event. You mentioned never events earlier on; have we got anywhere with that yet?

Professor Lord Darzi of Denham: Yes, we have. If I could give you the background to the policy itself, again this was evidence based because it has been used in the United States and I think the discussions you had with Bruce were based on the evidence in the US where insurers withhold payment to the provider if there is a never event. Our approach to this is slightly different; we want to phase this. Firstly, you are right and I think if you happen to be the commissioner on behalf of the PCT there is no reason why you cannot bring parts to the answer. Firstly, you are right and I think if you happen to be the commissioner on behalf of the PCT there is no reason why you cannot bring other never events locally.

Q875 Dr Stoate: I understand that—that is quite straightforward—but what about the should not events? What about the patient who goes into hospital with a UTI (I am quoting now from patients I know about), catches a hospital acquired, ends up staying in hospital three months and then falls out of bed or has a fall and breaks something. All that time that is happening not only is that a disaster from the patient’s point of view but the meter is running and the PCT ends up with a bill for many, many tens of thousands of pounds. As I say, I have examples of actual patients where that has happened. Surely that is an example of things you should be stamping out. If that person went into hospital with a UTI we should be paying for the UTI, we should not be paying for the C.diff, the hip replacement, the month in intensive care which happens as a direct result of a patient error.

Q876 Dr Stoate: These are should not events; they should not happen but they are nevertheless patient safety events and effectively the PCT ends up with the bill.

Professor Lord Darzi of Denham: Absolutely, but let us not forget that healthcare—Sir Liam was mentioning this earlier—used to be an art but it is now science, but it is not the perfect science. We are quite clear, we all make errors and the question is how do we create a culture in which we capture these errors, we learn from them and we do something about them.

Q877 Dr Stoate: My question is slightly narrower than that. My question is, should the PCTs not say, “Your problem, you pay because we are not going to”. I know insurers in America would take that view. They would say they would not pay for that because it is nothing to do with the condition the patient went in with. I think that might focus the mind rather well at board level if the hospital did not get payment for having somebody in the hospital for
three months when they should have been in hospital for three days. That might focus the mind. Why are we not going down that route?

Professor Lord Darzi of Denham: That is a reasonable point. I am starting with things that we are absolutely sure should never happen. If your policy idea captures the minds of PCTs and they wish to contract with their providers to add other things—should not events, as you call them—then I think that is a local issue that needs to be decided. Let us not forget that those who are involved in the delivery of healthcare are professionals, they have professional values in doing what they are doing and I think changing the culture and behaviour locally in preventing mishaps and errors that lead to harm is exactly what we are trying to achieve in the NHS.

Q878 Dr Stoate: What I am saying is that there are no financial incentives for hospitals to crack down on that sort of thing. If the centre were to say to hospitals, “You are going to have some very large bills unless you change your culture, I think that might get the board focussing in a way that they did not just focus on things that perhaps were not so critical for patient care.

Professor Lord Darzi of Denham: I think that is correct to a point; financial incentives are one, but it is not everything. What we have seen through the Next Stage Review and what I have seen out there and most of your hospitals and primary care providers, clinicians go to work to provide high quality care, they do not go to work to make mistakes intentionally. I do not think the financial incentives are going to change that. What we need to do is work from board to the ward in making sure that the culture is changing where there is vigilance rather than complacency; there is resilience; there is learning culture and whatever way we look at this we will always have errors in healthcare provision. Our ultimate aim is to learn from them and constantly reduce them. Financial incentives may be one, but I think there are other factors in which we will make this happen. Leadership is the one which I mentioned to you the last time I was here; I think that in itself is the one that I personally think we should focus on.

Q879 Mr Bone: Lord Darzi, I understand how incentives could work in a commercial situation; I do not see how it works in a health service because all you are doing in reducing the money going into my primary care and my hospital is reducing the service to my constituents.

Professor Lord Darzi of Denham: I agree; it is not everything.

Q880 Stephen Hesford: Lord Darzi, what role does Patient Choice have in driving up safety standards?

Professor Lord Darzi of Denham: A lot, and you know my commitment to Choice because, although the government introduced Choice about four years ago, some clinicians were a bit critical about Choice because Choice in those days was about access (where could you get the quickest waiting time and things). As I have explained it in the Next Stage Review. Choice is informed choice: the type of choice you all exercise in this room: where to go, what is the best care, what is the information you need before you have that. That is where we need to go to. Informed choice is based on safety, effectiveness and also the patient experience. If I can give you one example on a personal basis, three years ago when I was seeing patients in the clinic, you do your consultation, you finish your counselling, the patient needs an operation and the first question they will ask you is, “What is the MRSA rate here?” That is a choice based on safety. When clinicians are operating or even physicians sit down at the end of the consultation and describe to the patient risk benefits. That is the world we are living in; everything has a risk. The idea that we are going to reduce risk to zero in healthcare is not going to happen in our lifetime and patients do appreciate that discussion of risk benefits. Within those risks you talk about safety issues that may happen and most informed patients, at the end of that consultation, make the judgment call whether it is the choice of provider and choice of treatment because some treatments could be more radical and could be actually less safe. I see this in cancer surgery. Safety is very much part of the discussion you have with a patient.

Q881 Stephen Hesford: We have just heard that the NPSA have started publishing statistics on reported patient safety incidents which is a new departure. Is that to inform patient choice? If it is, is there not a tension between publishing that data and creating a risk that if it is published people will stop reporting?

Professor Lord Darzi of Denham: This is an NPSA decision, as you know. They are independent. I was delighted to see that. It is part of what we are trying to bring in, that is transparency. You have it in Parliament. Transparency of healthcare providers in this country use taxpayers money; we are talking about transparency within the system. If you look at what they have done recently, there are a number of ways in which they are reporting what these incidents are (some of them are minor errors). I think the message out of that to the public when you see an organisation reporting a high error rate it is not necessarily a problem; we should actually trust these organisations because they are reporting it, they have a culture of reporting, they are learning from it and they are doing something about that. I would be more concerned if there was one that is not reporting anything. That is the clear message there. As I said, I have not met a patient who believes that we can do everything one hundred per cent risk free, but they know what it is and that is another set of information that empowers them, what these issues might be when they discuss it with their clinician.

Q882 Chairman: In the first evidence session we had here a health provisional told us they were concerned about how things do get out of our hospitals, particularly in the local media. There was one story about one incident that can demoralise the workforce, as it were. Do you think there is any risk, with the publications of PROMS—which is not the
NPSA decision but your decision—that the Patient
Related Outcome Measures may in some senses
bring on this type of debate in localities?

Professor Lord Darzi of Denham: I do not think so.
I think we all have responsibility here. We want to
bring this transparency. All clinicians in the NHS are
very proud to publish what they do. The media also
has a responsibility and I think they will appreciate
the transparency; that is what the media wants. We
are not talking about single individuals here, we are
talking about the organisation itself and if that in
itself could drive improvements then so be it.

Q883 Dr Taylor: It seems to be that it is largely non-
technical skills that will improve the patient
experience. I am thinking of leadership, delegation,
team working, compassion, communication. Has
the NHS been very slow to recognise this compared
with the aviation industry? Why is this and how are
we going to promote these sort of non-technical
skills that are absolutely vital for communication?

Professor Lord Darzi of Denham: I could not agree
more with you and this is something that I have
declared to the Chairman. I have a research interest
in this area and we have published a large amount on
non-technical skills or human factors (another term
being used). I think that is very important, certainly
in the environment that I work in, like the operating
theatre which is very complex and is getting more
complex by the day. I believe it is even more complex
than a cockpit now. You need non-technical skills
and there is the evidence base to support that. I think
there is another leader in this field who is advising
you and I am delighted to see that. Ultimately it is
not the Department of Health who decides what is
the curriculum of a trainee working in the NHS or
even a senior. It is very much a local issue and what
we need is to focus more on improving the
commissioning of education and training. In a high
quality workforce we have said we will split the
commissioner provider functional deaneries and
that will happen soon. Commissioners will start
using evidence based commissioning for education
and training. Providers will move into so-called
health, innovation, education clusters which I
mentioned to you before. We need more universities
involved in this and provide more leadership. Then
we need to work at a national level with the
leadership of the profession. The colleges have a
huge role to play here in really trying to get these
skills integrated into the curriculum of postgraduate
trainees. We also need to work on these as part of
the curriculum of the undergraduate trainees. Then
you get the regulator—I am talking about a very big
landscape here—which is the GMC that holds the
universities into account as to whether they are
doing this, or the postgraduate providers of training
(which, as you know, we combine GMC and
PMETB together) in seeing whether these bits of
competencies are met. This is a big story.

Q884 Dr Taylor: Do you think communication skills
can always be taught and always acquired?

Professor Lord Darzi of Denham: I think it will be
easier acquired in some than others. There is a degree
of self-selection also when we decide which speciality
to go to.

Q885 Dr Taylor: We have heard in the first session
that the NPSA are very good at collecting the reports
and promoting the messages but there seems to be a
divorce between the messages and the messages
actually getting through. You have been closely
involved with the WHO Surgical Safety Checklist.
The NPSA is now saying this should be used
throughout the NHS.

Professor Lord Darzi of Denham: Yes.

Q886 Dr Taylor: How can that be enforced?

Professor Lord Darzi of Denham: There is an alert
and if there is an alert from NPSA that needs to be
enforced by every NHS organisation. My
understanding is that it will be February next year
before the Checklist is enforced in every operating
theatre.

Q887 Dr Taylor: So if a surgeon does not use it he
will be in trouble.

Professor Lord Darzi of Denham: No, we will not
even get that far. If he does not use it, the operation
does not happen. It is very simple; the plane would
do not take off.

Q888 Chairman: Who stops it?

Professor Lord Darzi of Denham: The team.
Surgeons are not the only people running the
theatre, they are not; there is a team there.
Ann Keen: It is usually the sister. We could talk at
length about behaviour in theatre but we will not.

Q889 Dr Taylor: So the team sister would
completely stop the arrogant surgeon or physician
doing something they should not do.

Professor Lord Darzi of Denham: The reverse is true
as well. A surgeon would not start the operation if
the kit is not available, the nurse does not have
everything right and ready. The reverse is true and, I
promise you, the reverse is as important.

Q890 Sandra Gidley: Just coming back to that, how
will you know afterwards that the check was done?

Professor Lord Darzi of Denham: There will be a
check list in the operating theatres.

Q891 Sandra Gidley: Yes, but I have worked for
organisations where you have to do fridge checks,
for example, and people used to just go and tick
them off and sign them at the end of the day. How is
it going to be monitored?

Ann Keen: You have to introduce yourself. You have
to announce that you are now doing this checklist.

Professor Lord Darzi of Denham: Are you asking
whether we could make an error doing the checklist?
Yes, there are errors doing the checklist but I promise
you those errors are minute if you compare the errors
made without a checklist.
Q892 Dr Naysmith: I must just say that we have had some evidence to the Committee that it does not happen in every operating theatre even though it should and even though the system should be there. Lord Darzi, this is probably the last question for you for a least a while, but I would like to quote something that was said to the Committee by John Black, President of the Royal College of Surgeon. He said that the new European Working Time Directive rules are “the biggest threat to patient safety and, not only that, to delivery of service for a long, long time”. Do you agree with that? If you do not, does it not worry you that the leading representative of your surgical colleagues believes that that is the case?

Professor Lord Darzi of Denham: John is not just the President of the College he is a good friend of mine, he has been a mentor of mine and I go back many, many years operating with him when the laparoscopy or keyhole surgery came in. Firstly I will talk about the safety aspect and then I will talk about the training aspect.

Q893 Dr Naysmith: He really believes it to be a real threat to safety.

Professor Lord Darzi of Denham: Let us firstly decide why we have a Working Time Directive. We have the Working Time Directive because people like me and him in our training days did 72 hours on a weekend and then back to work doing one or two on call because my boss felt that the only person who could see his patients was me every second night. We were working like zombies and there was an evidence base why the Working Time Directive was brought in.

Sir Liam Donaldson: If I could interrupt, I started life as a surgeon and on three occasions when I was training I saw people falling asleep in the operating theatre, quite literally.

Q894 Dr Naysmith: You will trigger Howard off to tell you in a minute about his experience! I do not think there are many people round the table who do not think that the Working Time Directive in principle is a good thing, but the way it is being applied now in some hospitals, according to John, is a real threat to safety.

Professor Lord Darzi of Denham: It is a health and safety act; it is purely to protect patient safety. All patients ask me the night before their complex surgery, “I hope you are getting a good night’s sleep tonight”. That is exactly what they ask; that is quite common to any surgeon. Where I sympathise with John is the debate: could you train a surgeon in 48 hours a week over a period of five or six years.

Q895 Dr Naysmith: That is another point.

Professor Lord Darzi of Denham: Yes, that is another point and I have sympathy for that. The question is, if we are to use the same way I was trained—which was an apprenticeship system—then we should all be concerned. What we need to challenge is not the number of hours; it is the quality of an hour training, what we put in that hour of training. We were talking about human factors earlier. We have simulations now: we need to challenge ourselves on the training tools, the training culture. The idea that training is done on the side is no longer; not everyone should be doing training. Training itself is a very important thing; we are training our future surgeons who will be operating on us. It is very important that we have the culture right, we have consultants with the right PAs in their contract to train; we have dedicated lists for surgeons to train and ultimately we need to look at the curriculum. We are working with John and the College of Surgeons looking at what we can do with the curriculum to enhance the quality of the units of training. It is not quantity, it is quality. I think we can then try and see whether at the end of the belt we are producing these competent surgeons.

Q896 Dr Naysmith: We might not know that for a few years. That is the problem, what happens in the interim.

Professor Lord Darzi of Denham: Most trainees finish their training programme, get a competence certification of their ability to do things or not to do things. That is a very important part of the trainee’s assessment on a year by year basis. If there is a trainee who has not yet met the competencies that the college have put together at a local level then that person will have to do an extra year or two years. That is nothing new, I know and you know that some people take longer than others.

Q897 Dr Naysmith: Is this a possible outcome of the directive, that there will be a lengthening of training?

Professor Lord Darzi of Denham: We will know that in due course. Americans historically trained competent surgeons in five years; before the Working Time Directive we used to take 12 or 15 years before you became a consultant. How did they do it? They really concentrate on the units of training time. You have someone there supervising you during the day; you have someone supervising you at night. If you expand these hours to night hours, night hours are not the hours that you train.

Q898 Mr Scott: We have been told about the continuing lack of openness, reporting and learning culture in the National Health Service. What is the government doing about it?

Ann Keen: It is the basic question really in relation to safety because it does depend on the culture that you work with. It depends on the organisation’s ability to show that sort of leadership that really will encourage people—all clinicians, all members of that health unit—to be open about their practice. To do that they have to feel very safe. Patient Safety is the title and it sounds huge and we wonder how we can deal with that because we are doing all these other things. It is really about being honest, showing leadership that has gone throughout our contribution this morning already. Really strong leadership is about openness and not about secrets, and it is not about a blame culture. Most of us would never be able to operate in that sort of environment, that is blaming someone else always for something that has gone wrong. To start with you have to get that culture right and you have to have an
organisation that is willing to say, “Be open with us and we will be fair back with you”. To provide that we have different steps. You can take small steps and show improvement. There is nothing worse, having done this myself when I was practising as a nurse, than to go to a conference or a study day and come back and try to change something only to have someone say, “No, we don’t do it like that here; we always do it this way. You might have that idea but you can’t do that because we always do it this way. So-and-so always likes something done in that particular manner.” That is not an organisation that is open and which will progress and develop. With our constitution now in place that also will help very much people to see—whether that is patients or staff—that they have the right to operate in an environment that allows them to say about their practice and allows them to encourage safety as being a priority.

Q899 Mr Scott: To elaborate on that, if we could take for a second a mythical hospital where a patient has had a procedure like a kneecap replacement where the kneecap has been put in the wrong way. I am not talking about blame but is the person who actually made that error then taken to task if retraining is needed? I was told that in those instances it could become maybe a better use of the word never event.

Ann Keen: That should not happen. If you are not able to admit your mistakes you cannot learn from them and it is back to that environment. The past, all of us could acknowledge, is more of a secretive past and people were afraid to say that an error has taken place. There have been examples when junior colleagues have witnessed something taking place and did not feel that they were actually able to speak out and say, “I have to stop you there because you are about to make an error”. If you feel you cannot do that, that tells you everything about the culture that you are working in and that particular environment and leadership that you are working in. I can relate to that. There is no doubt that some people feel that they cannot point out to a senior, in particular, because the team does operate in a hierarchical way. When it does that it is not operating in the best way. It should not have that hierarchical structure other than for respect of knowledge for the team rather than not to be able to say, “You might have got that wrong”.

Q900 Mr Scott: So that culture is being taken away because in some ways, perhaps much like politics, some doctors and some politicians find it much harder to say sorry than others.

Ann Keen: What we are doing in the health service right now is learning the entire environment of a much more openness which is coming through with the transparency. It is not easy for health professionals to say they have something wrong. It is not because they intended to harm therefore how can we say you have something wrong. I think the good leadership and management of that organisation should almost ask the question: did you intend to harm? I am sure the answer would be no, so therefore something must be wrong with that organisation and the system of that organisation. It is back to openness but it is hard to get cultures to change because it is so different within its hierarchy.

Sir Liam Donaldson: I guess we come back to understanding what causes these things. I can imagine three situations in which that could occur: carelessness on the part of the surgeon, the manufacturer of the joint making an error so that it was labelled “right” rather than “left” or the x-ray department was chaotic so the wrong patient’s x-rays were put up on the board when the operation was taking place. I think we have to understand the causation of these things and then put in the appropriate intervention. In some cases it might be retraining.

Q901 Charlotte Atkins: Targets have been criticised in the NHS. We have had some evidence from a surgical care matron who has told us that system failures can occur as a result of making targets the overriding priority. The example given was that meeting the four hour A&E maximum target can mean putting a surgical patient on a geriatric ward and that would have consequences for patient safety. What is your response to that? Are targets to blame for this?

Ann Keen: Speaking as a nurse, I think we would have to use again our knowledge and our skill as to how that surgical patient could be managed equally safely on a ward that was not a surgical ward by asking a surgical ward nurse to accompany the patient to the ward, to see that the patient was still being managed in that particular way. It would not necessarily automatically make the situation unsafe. Certainly going back to the target within four hours, many organisations do it very effectively because it is safer to be seen within four hours and to be transferred. I think the target for A&E in relation to safety is actually the correct one. There is a margin for 98% rather than 100%, but in that particular answer you gave me I think there are ways that the pathway of that patient could still be secured if we did things differently. It is not the ideal, but it can be managed differently in a way that would not necessarily incur that patient to be unsafe.

Q902 Charlotte Atkins: Are boards and managers in the NHS obsesses with access targets rather than with patient safety? Those are the allegations that have been made.

Ann Keen: I would say that that is an excuse. We have to have proper clinical care for patients and prior to targets being set we can all remember the days when it was acceptable to wait for 12, 18, 24 hours in unsafe conditions because how many tests had been carried out, completed and reported back? What expert clinicians had seen that patient in a set time that made the patient exceptionally unsafe with their care? I totally support the targets area. Clinically it has been supported and the board's
primary reason for being there has to be to make sure that the unit or the hospital is safe. To do that you would have to have proper staffing levels, that is absolutely paramount for the targets. It has to be the appropriate workforce, it is the right skill mix and then patient safety within that target will be met and will be met well.

Q903 Charlotte Atkins: You worked in the NHS as a nurse before the targets were set. What was the situation in terms of, say, A&E? What sorts of statistics would have come out of A&E to demonstrate that the hospital was failing in that particular area?

Ann Keen: Many times in A&E it was like a battlefield; you do not know what is coming through the door next. In the days that I worked in it in particular, whatever came out of the ambulance came into the next cubicle and you used your triage really to say, “Who needs life saving now, this instant?” I will go towards that patient and I will see that my team goes towards that patient” rather than to have a much more organised route of care now in relation to chest pain, with possible stroke, with other trauma that should go to other trauma centres. It can be so chaotic and battlefield is the best way of actually describing it. To have systems and pathways of care in the appropriate buildings with the appropriate staff, to actually say after the initial triage that this person needs to see an expert, have the tests run quickly and for them to move on because it was never, ever acceptable to me to look at a patient and their family and see them in a distressed state for hours and hours on end. I am sure my medical colleagues would agree with that.

Q904 Charlotte Atkins: What about the four hour target getting in the way of dealing with the more severely compromised patient? Because you are coming up to the four hour target you have to put in somebody who has actually maybe got a relatively minor complaint compared with somebody who has just come through the door from an ambulance in a real emergency situation? We are told that these targets are getting in the way of dealing with the clinical priorities which would normally be set by the clinicians within that A&E department.

Ann Keen: If that is how they are practising, they are practising totally unsafely and unnecessarily. They need to organise themselves differently.

Q905 Charlotte Atkins: Ara has already given us a good account of the Quality Accounts but I do not think he mentioned the clinical dashboards which I think are also within your ideas. Maybe you could also expand on that.

Professor Lord Darzi of Denham: Just dealing with this targets issue first, I think within four hours you could really sort out the majority of patients coming in through A&E. You could see them, get a history, make a provisional diagnosis and then admit them in a safer and quieter environment. If there is an issue in which there are a very small number of patients—trauma would be a good example—the patients come in, they need a very pro-active treatment. You do not wait four hours for that. They each go to CT scans, they come back and decisions need to be made. I have never felt that that is suppressing my ability to do that. You cannot have a healthcare system that spends £110 billion a year, employs 1.3 million people and say, “There’s the money; get on and do your best”. This is taxpayers’ money. We have to have a degree of standards. Do you expect to take an airline carrier that has a four hour delay? You do not. They fly safely but they actually get you to your destination, 98% of the cases within the time that they have given you. That is what the patients and customers expect, especially if they are actually funding it. It is not for free; our health is funded by the public. I just wanted to say that about the target side of things. Back to the dashboard. I think if we want to take what I described in the Quality Accounts as quality improvements I think we are moving from targeted interventions (like A&E, cardiovascular disease and cancer) into more systemic improvements in everything. To do that you need clinicians to set their own targets themselves and measure what they are doing. The dashboard is for them to display how they are doing when it comes to patient safety, effectiveness and also the patient experience. I could give you one good example. Healthcare in my practice is a team. I could do a very good operation on Friday, I could come in on Saturday morning and, although I am very happy with the patient, the patient is in pain. The reason they are in pain is because their epidural has run out and they have been in pain for two hours. The only way I could capture that is to measure the patient experience, get back to them and have a better pain management service. I do not think we can dictate that from the centre; that is for clinical teams to do. These are professional people. We know what the standards should be and the Quality Accounts and the ability to measure and constantly improve is the purpose of the Next Stage Review.

Q906 Mr Bone: We have two very highly regarded ministers today; I know they talk quite frankly and that is most helpful. It is what happens in practice for the board of directors in some hospitals something like this: you go into a very nice room, you have your tea and coffee; the chairman is paid £45,000 a year for three days a week, the non-executives £18,000 for a day month. The first item is the budget: how are we doing on the budget? There is a report and people say, “That’s very good, we’re keeping within the deficit; we’re not going to have a deficit, that’s rather good”. Then we move on to talk about targets: how are we doing with the targets: “Yes, we’re meeting all these targets, that’s good”. Perhaps they then go on to talk about their trip to investigate something somewhere; then they talk about the internal management (some nurse is complaining about something or other). Do they ever discuss patient safety? Is that not the problem? Are these directors in general terms just not up to the job? Surgeons and doctors have very, very good training: I just do not
think these directors and non-executive directors have that. Am I on to something here or am I just way off the mark?

**Ann Keen:** You do have a point because it varies and that is where now, with the National Patient’s Safety strategy, there is good practice and we have to really develop that good practice. Again it is back to the openness because we do have exemplar organisations which are really leading the way and assisting to get this message across. The strap line of the ward to the board is a serious one. We have examples of where it has not taken place; we have a recent catastrophic example of where it has not taken place. I am saddened to say that because of that event in Mid Staffordshire I am sure that all boards now will be much more alert but it should not have to have happened that way. The reality is that the openness and the safety is only coming through our clinical colleagues to be able to support it, therefore to bring it up to the board level is a new area but it is an area we are concentrating very heavily on and asking people to concentrate very heavily on. David Nicholson, our Chief Executive, has written to all chief executives to make sure that this is a priority as part of the response to the tragedy of Mid Staffordshire.

**Q907 Mr Bone:** The chief executive tends to be well trained. Do you accept that there might be some criticism that the directors on the board—non-executive directors and, I am afraid, chairmen—really just are not up to the job and maybe they need some sort of training or better qualifications to be sitting on these very, very important boards. Many of them would not qualify to sit on boards of public companies where there is less money involved and less danger to people.

**Ann Keen:** Again I do think we do have to do more work in this area. People who come onto our boards do so with the best intention to support their local trusts or PCT in their community. However, because of what we are asking the board to do they have to be assisted, helped and trained and encouraged to do it, but also we need to make it clear that it is their responsibility. Safety is the responsibility of every one of us who is involved with healthcare. There is an NPSA training programme for non-executives through the Appointment’s Commission which I think will have to be strengthened even more so, but there is a lot of international work being done on this as well. The Institute for Health Improvement in Boston, Massachusetts works on virtual schemes that they are doing in America. Back to the openness, chief executives in one of the Boston hospitals has put up for everyone to see how they are performing. That has been quite an opening for other hospitals in the area. The more open we become, the more the reality of this very serious training and responsibility will take place.

**Q908 Dr Stoate:** We have heard from the Health Foundation about their Safer Patients Initiative. Can you tell us what the Department of Health is doing in response to it?

**Ann Keen:** We are actively involved with encouraging organisations to take part, to learn from, to help to launch it. We are involved right in the centre of the organisation and again encouraging all parts of the health service to do the same. We work very much in partnership with the Health Foundation; it is very important for us to do that and we partner them. The work is very well renowned and again learning daily how to bring this into the culture. It is so important that we have this culture change.

**Q909 Dr Stoate:** Is this something the department should have been doing anyway or do you rely on organisations like the Health Foundation to come up with these initiatives?

**Ann Keen:** It is about partnership with Safer Patients and working with the institute in Warwick, with the institute in Boston, the National Patient’s Safety Association and the Health Foundation. They have the ability to communicate with everybody with our support. It is always with the full support and encouragement of the department.

**Q910 Charlotte Atkins:** As a Staffordshire MP you would expect me to ask you about the Mid Staffordshire NHS Trust. Last week we had Bill Moyes here from Monitor, the regulatory body for foundation trusts. He said that in February 2008 the hospital met their criteria, but one month later the Healthcare Commission was so concerned that they started a year long investigation into the hospital. Does this not undermine the whole credibility of the foundation trust status investigation inquiry, that that could possibly happen? There were clearly issues within the hospital which were not picked up by Monitor and were not revealed in the self assessment process.

**Ann Keen:** If I could just say to start, the secretary of state’s statement yesterday apologised and I want to associate myself with that apology to the patients’ relatives and people who suffered in Mid Staffordshire. There was a process that we went through and in April 2007 Dr Foster published and showed high HSMR in that hospital. The SHA and the trust followed this up and were reassured at all times that this was a problem with data collection. Each time those questions were asked it was about data collection. In June 2007 the process of foundation trust was accepted. I have to acknowledge all of the work that the Health Commission has done, but in particular to praise them for not accepting this and to keep pushing to say that this, to them, was not right. They did not want to accept the consensus on the data and they then went in after and I believe that was later than the June 2007 date. It was a series of events where people believed that the data was collected and it was total mis-information. The Health Commission still battled away and to go in and to insist and then to find what we are now all too sadly aware of.

**Q911 Charlotte Atkins:** My concern is that Monitor did not pick it up. If you take one of the conclusions of the Healthcare Commission it says, “Despite a
system that looked good on paper, the trust did not have a clinical governance structure or audit process that worked. It had no effective systems and so failed to identify or understand the cause of high death rates among patients admitted as emergencies.” You cannot get much more damning than that but Monitor did not pick up on this and gave foundation status. Just about 30 miles away in North Staffordshire there is the University Hospital of North Staffordshire that desperately wants foundation status. There are issues within the hospital which, to be honest with you, I do not think the hospital fully recognises. My concern is that in this great headlong rush to get foundation trust status, these things are overlooked. The other issue is that nowadays many of the boards of our hospitals are full of people with financial qualifications and inevitably therefore they look particularly at financial issues rather than patient safety issues.

**Ann Keen:** I should say that many foundation hospitals within the country are performing at excellent standards and providing very innovative clinical practice with a very flexible workforce where, without question, the standard is very, very high indeed and they are leading the way in best practice and encouraging others to do the same. It is very, very complex when you have the tragedy that we have had but I believe now that what the secretary of state has put in and the actions which I am sure the Committee is aware of, that the new leadership of the trust will answer any requests from relatives of patients who died at Stafford Hospital between 2005 and 2008 with a full review of the case notes to determine whether or not the care they received was appropriate. Professor Sir George Alberti will review independently the trust’s procedures for emergency admissions and treatment for their progress against the recommendations in the report and he is going to report to the secretary of state within a month. The chief executive has already written to every NHS organisation in England drawing their attention to these recommendations in this report and setting out the expectations that every board will assure itself that these issues are not occurring within their organisations. Dr David Colin-Thomé will review the circumstances that occurred in Mid-Staffordshire prior to the Healthcare Commission’s investigation to see how nationally the commissioning system totally failed to expose and prevent the failings. Finally, the new National Quality Board will draw on all its expertise to advise the secretary of state by the end of the year on what more should be done to improve the alignment of the national system of regulation and management in the light of these very, very serious findings of Mid-Staffordshire.

**Q912 Charlotte Atkins:** Thank you for that. Were the strategic health authority and, to a less extent, the PCTs asleep on the job? What were they doing? PCTs are commissioning the patient care at the hospital and the SHA, who also cover North Staffordshire Hospital, clearly had not picked up on these problems. It worries me that we have these systems but I am never quite sure, when we have these awful disasters, what they are doing. Why are they not held accountable?

**Ann Keen:** The Healthcare Commission is very clear where the blame lies and it is the board and the trust for systems and shambolic governance. They didn’t take notice of any concerns raised by patients and staff. The SHA and the PCT believe there was a problem with the data collection. The circumstances of those two situations have risen into this tragedy. Believing data was wrong, the SHA and the PCT will have to answer as to why that was the case. The Health Commission puts the blame firmly and squarely with the board of Mid-Staffordshire Trust because of their total shambolic management and total lack of concern. They met in private and there was no patient safety discussed. It is a catalogue of events but a catalogue of some of the events that the PCT and the SHA accepted.

**Professor Lord Darzi of Denham:** I would just like to reinforce what Ann said. I think the problem here was denial; denial of the data as Ann very eloquently explained. That is the whole purpose of what we are trying to do to move on.

**Q913 Charlotte Atkins:** Lastly, can you give me an assurance that there will not be a golden pay off for the sacked chief executive?

**Ann Keen:** The new chair and the new trust are really undertaking a rapid response to this. The suspension has taken place and then we will have to act within the confines of law and with that discussion. I understand totally and empathise totally with the sentiment that that question was asked in.

**Q914 Charlotte Atkins:** Will you be able to write to me if you cannot tell me now about the golden pay off if there is going to be one? I think that people need to know that the state of denial within the trust will not mean that the chief executive will get a golden pay off. Whether we are talking about banks or hospitals, there has to be responsibility at the top.

**Ann Keen:** I totally agree and I accept your question. As that develops I will be very happy to keep you and the Chairman informed of the progress on that. I understand totally the sentiment that that question was asked in.

**Q915 Dr Taylor:** Can I follow up some of those concerns? I also have a trust that is going for foundation trust status and from the complaints I get I am very unhappy that quality may not be taken into account. Following up on the SHA function, they are protected by data but from standardised mortality ratios this trust was the fourth worst for the years 2003 to 2006. We were reassured yesterday by the secretary of state that there was no other trust now in that same state, so that assumes that numbers one, two and three, who were worse than Staffordshire in 2003 to 2006, have been improved. SHAs somewhere or somebody must have been making those other ones improve. Does the West Midlands SHA have
any excuse for not acting on those SMRs for so many years?

**Professor Lord Darzi of Denham:** You are raising the issue about the HSMR, Hospital Standardised Mortality Rate. I know something about this because it was discovered at Imperial College where I work. It is a tool and, like many tools, it has its advantages and it has its disadvantages. It looks at the mortality of the hospital, divides this over the average national mortality and then it gives it weighting against sex, age and the social deprivation, and also on the diagnostic code of that procedure. Then the come up with a figure; a figure above 100 it is slightly higher, below 100 it is where you should be. You have to remember it is comparing organisation to organisation so there will always be people above 100. What we are really talking about is an outlier, not one above 100. The ones you were referring to were above 100 but not outliers. Our reassurance for that is the regulator. It is the Healthcare Commission that picks those alerts and it has what we call an early warning system. If it picks that up it goes in to investigate or alert the SHA in relation to that. An HSMR is like a thermometer which tells you that you have a temperature but not necessarily what the cause is. I think it is a reasonable thing to look at how you are doing and how you are progressing.

**Q916 Dr Taylor:** Should the SHA have picked that up before?

**Professor Lord Darzi of Denham:** They have picked it up and I think we come back to the issue that Ann raised earlier. A debate then started between the SHA and Mid-Staffordshire NHS trust in saying that this data is incorrect because the coding was wrong. There was a period of denial in relation to that until, as Ann pointed out, the Healthcare Commission exercised its leadership and said, “Forget about HSMR, we are going to go in and find out what is going on”.

**Sir Liam Donaldson:** Could I just add that there is quite a dispute now on the validity of these statistics. The strategic health authority commissioned the University of Birmingham to look at it. They have produced a report which is now the subject of a BMJ article tomorrow. Then the team at Imperial College who helped with the Bristol inquiry—Professor Sir Brian Jarman—have issued a rebuttal. So this is an index which itself is the subject of quite a lot of professional dispute amongst statisticians.

**Q917 Chairman:** Maidstone and Tunbridge Wells were also not picked up by the annual health check. Does that concern you?

**Sir Liam Donaldson:** I think any failure to detect these sorts of problems is a major concern. As far as the point that was made earlier about the regulators, we have to be absolutely clear in the future that one of them must have total supremacy on looking at the quality and safety of care and that will be the Care Quality Commission.

**Q918 Dr Taylor:** Would you all agree that the report from the Healthcare Commission is an excellent tribute to that organisation? Following on from that, the CQC has a vast amount more work to do than the Healthcare Commission; do you think it is spread too thin to be able to produce this sort of excellent report?

**Ann Keen:** I would like to put on record the excellent work that the Healthcare Commission has done for us. The case last week showed their courage and determination to bring those standards to everybody’s attention. Building on their skills and expertise will very much be the case and we understand that the Care Quality Commission will also use surveillance and scanning, drawing on a very wide range of already available information sources, including complaints, to highlight where issues may require more in-depth investigation. So they will be building on their work, adding to their work with different skills and different knowledge.

**Q919 Dr Taylor:** You said yourself that hospitals must have proper staffing levels. It has come out very clearly that there were hopelessly inadequate staffing levels in Mid-Staffordshire. Whose fault was that? Was that the fault of management or was it that there just was not enough money for it?

**Ann Keen:** I feel it has to be management and all. If you are operating, as we have discussed, in A&E and you were asked to operate as you were in Mid-Staffordshire with so many people not in that workforce and not in that skill mix it was inevitable that there were going to be these serious problems. The clinicians as well as the managers would be aware of that. At this moment in time I do not know in depth as to how much reporting had gone on internally of the staffing levels within A&E in that particular hospital. We can all have a bad shift but you cannot have a bad year like that. I want to find out if they went through their professional organisations? Did they go to management? How many complaints were taken about the staffing levels? We ask so much of our staff in the NHS and they do, literally, perform miracles, but they have to have the right team to be able to do that appropriately for their clinical skill but also for safety and that is the responsibility of management. The resources were the same as they were for other hospitals that did not have that problem and it was how they chose to use their resources and create a problem within the workforce.

**Q920 Dr Taylor:** How and when are we going to get those answers?

**Ann Keen:** I would expect that to start unfolding now the new chairman and chief executive have the report for the first time on Wednesday. They are now starting their internal inquiry.

**Q921 Dr Taylor:** So there is not an external inquiry into this because Sir George Alberti will not be looking at this sort of aspect.

**Ann Keen:** Sir George Alberti and Colin-Thome will be doing that and they have been asked to report back to the secretary of state within a very short period of time, within a month. I know that other organisations like the Royal College of Nursing are already making those sorts of inquiries and I am sure other professional bodies will be as well.
Q922 Dr Taylor: Will we get the answer why there were inadequate nurses there?
Ann Keen: Yes, most definitely.

Q923 Dr Naysmith: Who at the Department of Health is ultimately responsible for operational issues when it comes to patient safety?
Ann Keen: We are all responsible. We really are all responsible.

Q924 Dr Naysmith: If you say everyone is responsible then no-one is individually responsible. Who is in charge? If something comes up about patient safety on whose desk does it land at the Department of Health?
Ann Keen: If it is in relation to an individual trust for example the sad example this week, the chief executive has written to all and that makes it look like I am saying the chief executive but I am not. I am trying to say that the process of responsibility really is collective, on the ground and right the way through all of the systems.

Q925 Dr Naysmith: You do not have any named person?
Ann Keen: There are named people within organisations throughout the NHS family.

Q926 Dr Naysmith: I am talking about the Department of Health. Sir Liam, do you know the answer?
Sir Liam Donaldson: Essentially the responsibility for all of this falls within the NHS management board which is led by the chief executive with a medical director.

Q927 Dr Naysmith: We have heard it said in this inquiry that we are conducting now in previous sessions and it has come up again this morning already that boards are responsible for safety, senior managers are responsible for safety, senior managers are responsible for safety, commissioners are responsible for safety, regulators can be responsible for safety and performance managers will be responsible for safety. Do you think that all of these roles are currently being performed in a co-ordinated and effective manner?
Ann Keen: Through the regulator and through the National Patient Safety Association that is improving all of the time. Being aware of safety is, as we said at the beginning, something that has only come about in the last ten years of having this responsibility. The collective responsibility has to stay because it is about the practitioner at that time or responsibility. The collective responsibility has to come about in the last ten years of having this improving all of the time. Being aware of safety is, as any other part of care but to dictate the curriculum tomorrow’s doctors, getting into the leaderships of professionals. Worse than that, we heard from our advisors this morning that it is perfectly possible for someone to become medically qualified having never written a prescription before and never having attended a formal qualification or recognition on patient safety. So there are still massive gaps. What are we doing about that?
Ann Keen: The Department of Health is not responsible for the training of doctors or nurses but what we have to do is to bring the patient safety organisations in for modules and really get through to the colleges to say that this aspect of care is as crucial as any other part of care but to dictate the curriculum to them is not in our domain. The paper on Tomorrow’s Doctors, getting into the leaderships of.

Q929 Dr Stoate: Ann, you said earlier that we have to change the culture in the NHS to one of safety. I entirely agree with you and yet we have heard from witness after witness before this session that safety is simply not a core part of the curriculum for training, not just of doctors and nurses but of all health professionals. Worse than that, we heard from our advisors this morning that it is perfectly possible for someone to become medically qualified having never written a prescription before and never having attended a formal qualification or recognition on patient safety. So there are still massive gaps. What are we doing about that?
Ann Keen: The Department of Health is not responsible for the training of doctors or nurses but what we have to do is to bring the patient safety organisations in for modules and really get through to the colleges to say that this aspect of care is as crucial as any other part of care but to dictate the curriculum to them is not in our domain. The paper on Tomorrow’s Doctors, getting into the leaderships of.
the professions and getting them to really lead from the front on how this could be delivered, how important this is, you certainly cannot have a tick box to say you have had half a day on safety somewhere and it was part of your induction course, it was probably about where the fire escapes are and those sorts of aspects of safety. That is where the NHS has done its training in the past. Each time you move hospital or organisation you get a half day induction on safety but it is not the sort of safety that your Committee is discussing today. So it is really getting that through to the leadership of the professions, to the leadership within the royal colleges and to make sure that we are part of that curriculum. Dr Taylor mentioned earlier communication and asked if you could teach communication skills. Well, it is a difficult area to talk about but until it is embodied right the way through everything we think of and do, then it will become the norm and we are not there yet. We are struggling, but we are going to get there.

Sir Liam Donaldson: I would like to make three brief additional points. First of all, the minister mentioned Tomorrow’s Doctors; that is basically the document that determines what the medical curriculum in all our medical schools will be in the next decade. It is currently out to consultation and I am sure the Committee will have looked at that and formed a view on whether it is adequate in patient safety terms to shape the curriculum. Secondly, we need to have more centres of the sort that Lord Darzi has in his hospital, simulation centres where people can be put in teams, trained in a multi-disciplinary way in the sorts of skills of communication that are really necessary. At the moment we do not have enough of those centres and we need to have more of them. The third thing is that we need to ensure that the medical education leaders understand these concepts of patient safety and are committed to instilling them in their students.

Q930 Dr Stoate: I entirely agree with you, but to come back to Ann’s point the rub is that you have already said that ultimately the minister is responsible for patient safety and that is the way it should be and the public will inevitably ask what the government is doing about this and yet we are still getting Mid-Staffordshire, we are still getting Maidstone and Tunbridge Wells. Is it not time that we effectively told the colleges—I know this is going to be difficult for you—that the culture at the moment is not the culture that ministers want to see. We want this culture change; the public expect it of us. As Lord Darzi has said, the money is going in which is fantastic but until we change that culture—and I believe that has to come from the top—we are just not going to change the outcomes.

Ann Keen: I totally agree with you and it is very frustrating when you are in the position of accepting responsibility and the privilege of ministerial responsibility to not always be able to steer the diktat as to how this will be delivered. It is not without passion and it is certainly not without a message. I believe the time is long overdue when we had more influence on that. Again we are back to custom and practice as to how a curriculum has always been delivered but to bring people on board with you within Ara’s colleges, as Liam pointed out, we have to make it interesting. If you talk to some junior nurses and junior doctors today about patient safety, what would they think it was? They would all think it was something different. We have certainly done infection and today’s figures again are showing a reduction which is excellent, so we are getting that message through. However, the message was so basic that did they see that as safety or did they see it as hand washing procedure? To be fair to the practitioners, if we are asking them to practise in a particular way we have to help them do that as well. There is much innovation out there that they are probably not even aware of; that is an exciting change of practice. “The patient is ready to see you, now doctor” rather than the other way round because the patient is now safe for you to see because we have everything in place.

Q931 Dr Stoate: There are examples of safety but that is not the culture of safety and that is what we have to get across.

Ann Keen: It is, “This is what we do to you, we are doing this to you today. I am now going to do this to you”. It is a really holistic approach. “The patient is ready to see you now doctor” rather than the other way round because the patient is now safe for you to see because we have everything in place.

Q932 Chairman: When we asked the chief executive of the NHS Litigation Authority whether their standard-setting role ought to be handled by a body that is not responsible for dealing with litigation, he replied, “That is a good question and it is one which we ask ourselves regularly”. Is it one that the Department of Health ever asks itself?

Ann Keen: Not that I have heard. Being honest with you, I think this is something we really do have to look at and need to look at. We would want to come back to you with those answers because it is a question that has not been addressed in the way you have asked me the question.

Q933 Chairman: I would appreciate it if you could get back to us before the end of this inquiry, before we draft anything up.

Ann Keen: Yes.

Q934 Chairman: One of the things we heard was that the Clinical Negligence Scheme for Trusts does not cover situations where patients receive NHS care from independent sector providers (apart from ISTCs). It seems to me under those circumstances
that we are sending NHS patients into different independent hospitals without cover at this stage. Are you going to do something about that immediately?

**Ann Keen:** I will get back to you on that and you will have more evidence to show what the department will be doing on that.

**Q935 Stephen Hesford:** The NHS Redress Act was passed in 2006 but we are told that there is still no sign of the NHS Redress Scheme. Where is it? What is the delay? Are we going to get it?

**Ann Keen:** Again this ties into your previous question. Apologies to the Committee, but it is something we will have to write to you on because they interlink in actual fact very closely and work is in progress at the moment on that.

**Q936 Dr Taylor:** The NHS complaints process, why ever is the government abolishing the automatic, independent review in that process? At the moment it is internal, then you go to the Healthcare Commission when you do get the automatic independent review and only then onto the ombudsman. That middle stage is being cut out, why?

**Ann Keen:** The NHS complaints procedure has been criticised for being complex and taking too long. The previous requirements were often very inflexible and bureaucratic and more concerned about the process rather than outcome for the complaint. We published Listening, Responding, Improving for NHS organisations to put this into practice based on the NHS constitution and the ombudsman’s principle of good complaint handling. On the first of April of this year these new arrangements for improving the handling will commence. The aim is to improve the quality of people’s experience of services through a much more flexible approach. It has been criticised so badly that we were forced to re-look.

**Q937 Dr Taylor:** Will there be a compulsion on trusts as part of their internal inquiry to involve independent experts? Because that is what patients need.

**Ann Keen:** There will be a one stage independent review process conducted by the parliamentary and health service ombudsman for the NHS and local government.

**Q938 Dr Taylor:** The ombudsman cannot possibly cope. The Healthcare Commission tell us that almost half of their 8,949 complaints were upheld or sent back to the trust for further work. How is the ombudsman going to cope with this number of complaints?

**Ann Keen:** If I could take you back to your previous point, that is a very strong argument. The trusts could also of course conduct an independent review themselves.

**Q939 Dr Taylor:** What I am getting at is, who is going to tell the trust they have to do that? At the moment the only way a patient or a family will get an independent review is when it goes to the ombudsman. They have to have the right to an independent review before it gets to the ombudsman because the ombudsman will not be able to cope.

**Professor Lord Darzi of Denham:** You will probably remember this because it came through the Health and Social Care Act last year as it passed through Parliament; that is when the legislation came through. The problem is that you have had a three tier system when it came to complaints. If you look at the data — this is amazing data — nearing 35% to 40% of the complaints that go to the Healthcare Commission go back to the trust to be dealt with. So you had a huge amount of bureaucracy in the system. The trust, because it is going to be moved up, does not deal with it properly; the Healthcare Commission sends it back to them; you have delays of up to six months to a year and what we try to do is get the trust and the board to be accountable for that, to get this right. As you know and I know, in most complaints patients are purely looking for an apology and have we learned from it. How do we strengthen the dealing of complaint at a local level? The CQC, in their registration purposes, could actually look at the complaint of an organisation and remove their registration if they are not dealing with the complaint. That is much more powerful than it used to be before but we are shifting the responsibility and accountability of dealing with complaints to the NHS provider. That is what went through Parliament last year.

**Q940 Dr Taylor:** How are they going to know that the individual trust is not dealing with complaints? Because of the number that are going to the ombudsman?

**Professor Lord Darzi of Denham:** Yes.

**Q941 Dr Taylor:** So the CQC then can step in.

**Professor Lord Darzi of Denham:** Yes, but they will not be dealing with individual complaints.

**Q942 Dr Taylor:** Is it not the independent aspect of the Healthcare Commission’s part at the moment that tells when the thing has to go back to the trust? What I am getting at is that we are losing the independent review which is so absolutely vital.

**Professor Lord Darzi of Denham:** Most of these complaints go back to the trust.

**Q943 Dr Taylor:** Yes, because of the independent review by the Healthcare Commission, not because.

**Professor Lord Darzi of Denham:** No, because they have not been dealt with properly and the Healthcare Commission send it back and say, “You had better get on and deal with this complaint”.

**Q944 Dr Taylor:** Do we know that that is without the independent—

**Professor Lord Darzi of Denham:** Yes, that is exactly so; we have the figures from the Healthcare Commission.
Q945 Dr Taylor: You are happy then that somehow the new system with just the two stages is going to work and is going to give patients access to independent views of what they believe has gone wrong.

Professor Lord Darzi of Denham: That is correct. If the ombudsman is obviously raising concerns about it then that is something that the CQC needs to look into. It is bringing more transparency, more accountability of ownership of complaint to the actual provider in which a complaint has arisen. If the patient and the public are still unhappy they could go to their PCT with that complaint and the PCT will look into it, or they could send it to their ombudsman.

Ann Keen: Is that generally shared? Do patients largely find the constitution again, the constitution gets through to the public in a manner in which we want them to do so. They will see a totally different set of rights and how they can access, what they are entitled to do, how they are entitled to complain and where they are entitled to get support from. The constitution really will feature as people get more familiar in using it and that is not just public but it is staff ensuring that the public has the rights to the constitution. This is set out very clearly.

Q946 Dr Taylor: Do they have the right to claim an independent review before it gets to the ombudsman?

Professor Lord Darzi of Denham: They could request it from the trust if they wished to see that.

Ann Keen: This is to speed up the process.

Q947 Dr Taylor: Coming on to PALS and ICAS, are they up to the job?

Ann Keen: From our experience and from the feedback we get, PALS supply an excellent service to patients. The reporting on the PALS services is excellent.

Q948 Dr Taylor: I do not suppose you know off the top of your head how many actual PALS personnel there are per trust throughout the country. I can see a parliamentary question coming up. I have the absolute impression that in some places there is perhaps one PALS officer for three hospitals.

Ann Keen: That is not my experience but I feel confident that you will ask the question of me and I will soon know the answer and I will respond to you.

Q949 Dr Taylor: I have a very high opinion of ICAS. Is that generally shared? Do patients largely find ICAS helpful?

Ann Keen: Very much so and of course coming back to the constitution again, the constitution gets through to patients in a manner in which we want them to do so. They will see a totally different set of rights and how they can access, what they are entitled to do, how they are entitled to complain and where they are entitled to get support from. The constitution really will feature as people get more familiar in using it and that is not just public but it is staff ensuring that the public has the rights to the constitution. This is set out very clearly.

Q950 Dr Taylor: I should know and I regret I do not, does the constitution give an automatic right to an independent review of a complaint?

Ann Keen: Yes. It talks you through the process of how to achieve that.

Q951 Dr Taylor: I shall go back and check it, thank you.

Sir Liam Donaldson: I think we do have to weigh into the equation on complaints that the degree of rigour that the ombudsman brings to complaint investigation is much, much higher than ever was the second stage of the complaints procedure. Maybe you sacrifice fewer people getting that, but when they do get it the rigour, the openness, the public reporting of the outcome is very, very high compared to any other element of the complaints procedure.

Q952 Chairman: The last question we have for you is that in 2007 the department published Coding for Success which promoted and supported the use of auto-identification technology (barcoding, et cetera). We saw some of this in action last week in a National Health Service Hospital. The document stated, “The Department of Health will review progress by the end of 2008”. Could you tell us what has happened?

Ann Keen: Every board has a goal to achieve this. Some of the systems at the moment are still quite patchy, I believe, but we continue to work with all of the agencies to achieve this. The implementation of coding requires both manufacturers and the NHS to make significant investment decisions and the progress of how this system is working again is very variable.

Q953 Chairman: Have you published anything in relation to the review?

Ann Keen: Not that I have information on at this moment.

Q954 Chairman: Could you share any information with us about the review?

Ann Keen: At this moment we cannot.

Q955 Chairman: Could I ask you to have a look at that as you are going to look at one or two other things you have been unable to supply evidence for this morning and see if you could give us a synopsis of what the review is going like in relation to this coding system.

Ann Keen: Yes.

Q956 Chairman: I think that is it. Could I thank all three of you very much indeed for coming along. Sir Liam, I do not know if you are aware of this, but we are expecting to call you on the first day when we take evidence on our alcohol inquiry when we get back after the Easter recess.

Sir Liam Donaldson: I will need a stiff drink before then!
Wednesday 3 June 2009

Members present
Mr Kevin Barron, in the Chair
Charlotte Atkins
Jim Dowd
Sandra Gidley
Dr Doug Naysmith
Dr Howard Stoate
Mr Robert Sym
Dr Richard Taylor

Witnesses: Dr Peter Daggett FRCP, Consultant Physician, Stafford Hospital and Mr Howard Catton, Head of Policy and Implementation, Royal College of Nursing, gave evidence.

Q957 Chairman: Good morning, gentlemen. Could I welcome you to the eighth session of the Committee’s inquiry into patient safety? Would you, for the record, introduce yourselves and tell us the current position you hold, please?

Dr Daggett: Good morning, Mr Barron. I am Peter Daggett, I am a consultant physician at Stafford and I have worked there since 1982.

Mr Catton: Good morning. My name is Howard Catton and I am head of policy at the Royal College of Nursing.

Q958 Chairman: Thank you and welcome once again. I have a question to both of you. To your knowledge what efforts were made by staff to draw attention through official channels to the extent of dangerously unsafe care at Mid-Staffordshire?

Dr Daggett: I and my colleagues have been raising concerns with management at all levels for some considerable time and certainly around 2006 when I think the present problems arose. Your clerk has a dossier of some written information, copies of letters and e-mails going back even further than that. We did try consistently and at all levels over an extended period of time and a large number of comments were made. I will quote from one or two things. One of my colleagues, a cardiologist, said, “I have over the last few years completed incident forms highlighting failures of care. These were either downgraded to minor events by nurse managers without discussion with me and they are not investigated. I have persistently complained to the clinical director at meetings that incidents were not properly investigated.” There are many other examples like this. One of my colleagues who is a gastroenterologist wrote a long letter in 2006 to the middle management again indicating that the lack of nurses on his ward was of considerable concern and a danger. There is no doubt that considerable concerns were flagged up over an extended period of time by many people.

Q959 Chairman: Howard, I know you do not work in the hospital itself but how would you approach that question?

Mr Catton: Our experience has been the same. For a long period of time nurses were reporting concerns; between 2005 and 2008 we believe there is in the region of 500 or so incident or accident forms. There was a particular period at the end of 2007 where there were about 200 within a six month period. The concern which has been reported back to us is that people felt those incident forms were going into a black hole or into a waste paper basket. There is one example which was reported to us where a nurse said she did see an incident form in a senior manager’s waste paper basket. People were reporting concerns but they did not feel that those concerns were being taken seriously. I think that led to a loss of confidence in the fact that anything was happening and there was no reporting back mechanism either in terms of incident forms that were put in. There is a particular concern for us in relation to nurse staffing levels because a significant amount of those incident forms, as Dr Daggett has said, related to concerns over shortage of staffing.

Q960 Chairman: Whose fault was it that information from staff went unheeded?

Dr Daggett: I do not think it was an individual’s fault and I do not think it would be helpful to apportion blame. The systematic fault was that information provided to middle management—that is the directorates—was perhaps not acted upon as quickly and as forcibly as it should have been. When it reached the senior management level, ie the chief executive, he took the view that there were other more pressing matters and did not think it was significant.

Q961 Chairman: Was the nature of the trust itself—its size and level of staff turnover and other matters—a factor in making it difficult to raise issues?

Dr Daggett: I think the answer that is yes and the reason I say that is that if I go to one of my medical management colleagues and have a robust discussion with him about some management or political issue and then three hours later I need help in the ICU with patients it is quite awkward. I think because we work in a small hospital closely with clinical colleagues who have taken on this very difficult task of management—I could not do it—we tend to perhaps give them a more gentle ride than we should have done.

Q962 Chairman: I was a lay member of the General Medical Council for a considerable number of years and there is an issue in terms of good medical practice about what a doctor should or should not
do. Do you think in any way that that was compromised by the way the hospital was run from your perspective as a professional?

**Dr Daggett:** I am not aware of anything dangerous happening that would cause me to contact the General Medical Council. I think it was a quality issue, that is patients may not have been treated as well as they should have been in terms of respect and dignity and that is, I think, entirely down to lack of nursing care. The nurses we have got are very good and I have never seen an example of bad nursing, just not enough of it. I do not think the care given by doctors was actually dangerous but it was too fast.

**Q963 Dr Naysmith:** Going back to something you said, Dr Daggett, you said that complaints were being submitted through middle management and at that level they were being thrown in the waste paper basket or discarded in various ways and were disregarded. If that was going on for quite a while there must have been people who knew that that was wrong and that complaints should be treated properly. I know you do not want to blame any individual—that is fair enough—but if at the level of middle management complaints were not being passed on did that not worry you and some of your middle management complaints were not being submitted through middle management and at that level did you not want to do something about it?

**Dr Daggett:** I do not think they knew. I have just seen a staff survey where the question was asked of the staff at the moment, “How many of you have seen feedback from any sort of incident form?” and 80 per cent said “Never”. We have only just realised that this has happened. I think that incident forms, when there was a paper system, went into a black hole, as my colleague said, and I do not think they were acted upon. The system has now changed; it is now electronic and much more transparent. I have recently spoken to the person in charge of this and she assures me they are now acted on and a manager is identified to deal with all electronic incident reports within 48 hours and feedback provided. This is one of the useful changes that has resulted from the HCC report.

**Q964 Dr Stoate:** The Secretary of State recently said in the House that “one of the great mysteries of Stafford” was that nobody went outside the official channels to blow the whistle. You are saying to us that forms were filled in, they were basically set fire to or chucked away or something happened to them and they never went any further. That is almost incredible. Why did nobody say, “This is getting us nowhere; we need to go further. Why are the local press not involved? Why are we not talking to the BMA? Why are we not going to the Royal College of Nursing? Why are we not blowing the whistle outside?” Surely someone thought to do that.

**Dr Daggett:** I will answer that but I would like to raise something that surprises me, that there has been no comment made anywhere else about this problem. The HCC did ask doctors if they had objected and I certainly said I had and there was written evidence of that. I have read the report in some detail and I can see no comment made about that. So the fact that doctors and nurses did raise concerns appears not to have got into the HCC report.

**Q965 Dr Stoate:** That is my point. Doctors and nurses were raising points, they were filling in incident forms, they were passing things on but clearly things were going nowhere and no-one thought to say, “Things are going nowhere; that is unacceptable, we must take it up elsewhere”. No-one, for example, seems to have contacted the local Members of Parliament and said, “We are really frightened and worried about what is happening in our hospital”. As a local Member of Parliament in my district I can assure you I get plenty of contacts from local doctors, nurses, patients and others and if I have concerns I am at the chief executive’s office within hours. That is the way it works; that is what MPs do. Why was nobody doing that in Stafford?

**Dr Daggett:** As regards the correct channel I think those were all followed and gone through.

**Q966 Dr Stoate:** They were not, were they? They went to middle management and then disappeared. **Dr Daggett:** The middle managers did speak to chief executives and that did not result in any satisfactory outcome.

**Q967 Dr Stoate:** Nothing actually happened despite a large number of problems and complaints. **Dr Daggett:** I think that is right, but the whistleblowing policy is actually quite interesting. The hospital PCT and the SHA policy says that there is a provision to disclosure to the prescribed regulator. You can go to the Audit Commission in relation to public sector finance; the Serious Fraud Office, the Health and Safety Executive; the Environment Agency if there are environmental issues; the Charity Commission; the Occupational Pensions Regulatory Authority; and the Data Protection Registrar. There is no mention made of approaching the PCT or the SHA directly. In fact one of my colleagues did approach the PCT directly about lack of staff and other factors and was told that this would be resolved internally within the hospital management. He then went to colleagues he knew who were medical members of the PCT and was told the same thing. One of the very useful things that I hope this Committee can do is to codify the way that consultants and nurses can actually contact the next layer up, the PCT or the SHA, because at present there is no defined route of doing that.

**Q968 Dr Stoate:** I am amazed that nobody anonymously approached somebody outside, for example a Member of Parliament or scrutiny committee of their local council and said, “I am very concerned, do you think you could look into this but I do not want to give my name”. Surely somebody would have done that.

**Dr Daggett:** I think perhaps they did and certainly the Stafford MP Mr David Kidney spent some time working in the hospital and his website indicates that he was very satisfied with what he saw.
Q969 Dr Stoate: He must have been the only one who was. I have a letter here from Dr Pradip Singh who submitted this in evidence. You said earlier that you did not think that patient safety had been particularly compromised by some of these issues, but just to quote from him: “I personally reported dozens of serious adverse clinical incidents resulting from abysmal secretarial support in my department, grossly abnormal result, eg CT scan showed possible pancreatic cancer when not shown to consultants for weeks or months”. How could that not have affected patient safety outcomes if possible pancreatic cancer was not even being reported to the consultant for months?

Dr Daggett: I think that is a very specific case. The large majority of the consultants, in regard to this matter, look at their results as they come in on a day to day basis. Dr Singh’s practice is different; he is a busy man.

Q970 Dr Stoate: He says here, “Many clinicians have felt frustrated for a long time”. He says, “I circulated these issues to my consultant colleagues and I was suspended from work on flimsy ground without following elementary rules of natural justice” et cetera. The point is that he is saying that he did talk to his consultant colleagues and still nothing happened.

Dr Daggett: He most certainly did. We all talk to each other as well as our managers and our nursing colleagues. However, it is a very big step to go from internal dissent to effectively a vote of no confidence in an entire hospital management structure which is what it would have involved.

Q971 Chairman: Howard, the Secretary of State referred to a survey of nurses showing that 87 per cent would blow the whistle even if they suffered reprisals and 77 per cent say that the culture for raising concerns in their work is better than it was three years ago. How does that compare with what your members tell you?

Mr Catton: You are referring to a survey of 5,000 nurses just a few weeks ago before our conference. Out of that 5,000 survey 78 per cent—nearly 80 per cent—said that they were concerned about victimisation or personal reprisal if they were to report their concerns to their employers. Less than half felt confident their employer would protect them if they spoke up and out of those people who did report incidents again half have not had any feedback. I think what our survey showed us—which reflects what has happened at Mid-Staffordshire—were two things. One is a lack of awareness of whistleblowing policies and procedures. People did report incidents but they reported it at the lower end of the policy of procedure, filling out an incident form. The awareness of taking it to a prescribed body or an MP does not appear to have been there. People were concerned about what the implications may be for them. By that I do not mean that people thought it would be as crude as “If you speak out you’ll be fired” although obviously you will be aware of recent Panorama events and there is an issue there in terms of speaking out. I think it is a more subtle and insidious culture, particularly that was prevalent at Mid-Staffordshire. People were told that the big prize was foundation trust status—the organisation’s survival depended on that—I think that contributed, as well as the fact that we in nursing had a particular problem that there were no middle nurse managers. There were very few ward sisters but between ward sisters and the director of nursing there was a virtual vacuum in terms of nursing leadership. If nurses are filling in incident forms that middle tier of nurse managers are absolutely critical to building up a bigger picture about what is happening across the clinical area; they would be integral to dealing with complaints when they were raised. Those staff simply were not there. Then at board level we had a board who were closed, who were focussed on foundation trust status as well. This is partly the question that Dr Stoate raised as well about why were people not speaking out; they were but at a low level. Then there were these really strong forces in terms of leadership, policy, foundation trust status and the culture which constrained against people taking action more publicly.

Q972 Dr Naynsmith: Can I ask why there were no nursing middle managers? Was that a deliberate policy?

Mr Catton: I mentioned the relationship between the staffing levels and incident forms. Almost 40 per cent of incident forms that we were aware of related to staffing levels. Between 2003 and 2008 there was virtually a year on year reduction in the number of nursing staff, somewhere in the region of 200 whole-time equivalents which equates to around about 300 heads. In terms of accident and emergency they took out 17 staff. It is incredible that the board did not undertake some sort of impact assessment about what the implications would be of taking out that number of nursing staff. We provided to the Committee before and could again some very strong evidence from both the UK and around the world about the relationship between nurse staffing numbers and experience and morbidity and other quality care indicators like nutrition and pressure sores and all the rest of it.

Q973 Dr Naynsmith: Was that for financial reasons that they were taken out?

Mr Catton: The £10 million savings that the trust sought to achieve was a greater figure than they needed to achieve foundation trust status and it is our experience in Mid-Staffordshire—but it is also our experience elsewhere—that nurse staffing budgets tend to be close to the top of the list when organisations are looking at financial savings, hence why we make the point about the relationship and the link between nurse staffing levels and patient outcomes. Whilst this is tragic in this case, it does provide an absolute example, in reality, about what that impact is on patient care.
Q974 Chairman: Howard, could I just ask you in view of the circumstances, do you think your members’ professional responsibilities were compromised at Mid-Staffordshire Hospital?

Mr Catton: Our general secretary has visited Mid-Staffordshire on more than one occasion. We also had nurses who work at Mid-Staffordshire who spoke at our conference recently as well. Those nurses spoke very passionately about wanting to provide high quality patient care but they identified three factors: leadership, resources and infrastructure as confining and constraining their ability to deliver high quality patient care. Nurses also have a responsibility to their employer; they also have a responsibility to their professional code of conduct. Their professional code of conduct includes two principles that are pertinent to Mid-Staffordshire and indeed to nursing across the piece. One is about protecting patient confidentiality, the other one is about speaking out when there are risks in the environment of care to patients. They are both absolutely important principles. The patient confidentiality principle is a cardinal principle and therefore to breach that principle nurses have to show that they have tried every other means of raising a concern or an issue before they breach patient confidentiality in terms of the greater public disclosure. I am aware that the Nursing and Midwifery Council have set up a meeting this week to talk about producing more guidance for nurses who have to make those decisions in terms of balancing those two principles. That is difficult enough, but when you are doing that without nursing leadership in a middle management position and when you have a board who appear to have an attitude which is that nurses can stretch and make do or that we can take more out of the nursing budget and more out of nursing staff then I think it puts those nurses in an unenviable position.

Q975 Chairman: I accept that but if anybody fails in their professional duty it is not the system that is taken to their regulatory board, it is the individuals concerned. It struck me, as somebody who has sat on a medical regulatory body for a length of time, that there must have been, without going into detail, a lack of professional responsibility potentially in these patients that did not surface for whatever reason.

Mr Catton: Those nurses who were at the clinical face raised those concerns and nothing happened and there were no senior nurse managers to see that face raised those concerns and nothing happened either.

Q976 Dr Taylor: Peter, in your submission you have said that the Clinical Risk Management Committee was told in March 2001 that staff shortage should no long trigger an incident report. Who said that? Who told you that you could no longer consider staff shortages?

Dr Daggett: This committee met in 2001 and this statement was made. I think you have a copy of that letter there. That directive came from a middle grade medical manager and as far as I know it was not actually rescinded but it was ignored. Even during 2001 the level of staffing was not regarded as a serious matter.

Q977 Dr Taylor: What was the cohesion like between consultants and nursing staff? In the old days if a consultant was bothered about what was going on it would be the ward sister the old fashioned matron he would have gone to. What was the sort of liaison between doctors and nurses?

Dr Daggett: It was actually very good. I have copies of correspondence going back to 2002 and 2003, after this episode. There are sisters writing to me and me writing back and saying, “Look, we are all agreed; it is not good enough” but the mantra from the management has always been that on the one hand there is no money and more recently that there is no gain without pain. We were told that things would improve and indeed following the appointment of the new director of nursing things did improve and they improved before the HCC report. That is one reason I think why many people felt there was no need to take it any further because the trust board and particularly the director of nursing had taken the view that the level of staffing was inadequate therefore our complaints and warnings had been noted. Things were improving and indeed they still are. The HCC report is a great stimulus, if you like. I have always worked very closely with the ward sister on my ward; I need to know her opinion. The doctors and nurses, with very few exceptions, have always got on well as a team.

Q978 Dr Taylor: During post take ward rounds are you able to have a nurse with you?

Dr Daggett: This is a hot potato. I cannot do a post take ward round without having a nurse who can tell
me her view of how the patient is, but because the nursing level has been so very low for such a long time it has become the norm not to have a nurse. The matter that Dr Stoate referred to where a colleague was suspended related directly to that. I am told that this colleague said that he could not safely conduct a ward round without a nurse being present and at that point said, “I will be in my office if I am required” and the next thing I knew he was suspended. I do not know all the background but that is the information I was given and I have no reason to doubt it.

Q979 Dr Taylor: Has the replacement of the director of nursing made a big difference?
Dr Daggett: It has made a remarkable difference. I do not want to embarrass the lady by saying how much we approve of her but we do. She is reliable, she is not a soft touch, she does what she is asked and she initiated the staffing review as a result, I suspect of the trust being aware of the consultant’s concerns. That was in 2006 when she was appointed. Very soon after things started to improve slowly and therefore, as I have indicated, it has achieved the desired effect and her good work continues.

Q980 Dr Taylor: Again from your description and your submission the director of nursing is really the only clinical member who sits on the trust board.
Dr Daggett: There is a medical director. The last medical director was a pathologist but again a respected colleague who was always entirely approachable. The new medical director is a gynaecologist, also a clinician, so there are two clinical members of the trust board.

Q981 Dr Taylor: Could you put your finger on the main things that can be done to reduce harm to patients in general?
Dr Daggett: First of all the incident reports and other expressions of concern from the nurses and doctors should be managed in the same way as complaints from patients, ie taken seriously immediately and actioned in the same way complaints now are. That would go a long way to stop the misappropriation of information which has definitely happened in the past. I think when there is a major concern individual nurses and doctors should have right of access to the trust board. It is true that consultants can go and see the chief executive, but consultants by and large have got fairly thick skins and do not mind going to see an important man who may not approve of them. I think the nurses at present will feel very inhibited going to the chief executive. I think it should be in the letter of appointment that if you do have serious doubts you have right of access to the trust board to put them directly to them. The trust board are honourable and truthful people and I think if they are presented with information in that way they might have acted more quickly. Finally, I have to put my hand up and say “mea culpa”; we should not have accepted the mantra that there is no money and we should have said there has to be otherwise there is going to be a fiasco.

Q982 Dr Taylor: Howard, does the RCN have a policy on nurses accompanying doctors on ward rounds?
Mr Catton: We do not have a specific policy but generally I would say that we would absolutely expect that that would normal practice. The strength of the multi-disciplinary working between doctors and nurses and others is a critical factor in delivering high quality care. The reality of doing a ward round, I suspect, is that medical colleagues would feel limited if they did not have a nursing input into that in relation to the patient’s condition over the previous 24 or 48 hour period. May I also offer some views in terms of what could be done?

Q983 Dr Taylor: Yes.
Mr Catton: Firstly in relation to whistleblowing, we have mentioned that we think there are policies and procedures in place but they are on the shelf and people are not aware of them. We think it would be very helpful if chief executives and boards gave unequivocal guarantees and commitments to their staff that if they speak out in good faith about patient concerns they will not suffer any detriment. I think that would be aided by more directors and chief executives walking the patch and meeting the clinical staff on a regular basis. Organisations need to have a central register of all concerns that are raised, but a register in a format which is accessible and lends itself to scrutiny by executive and non-executive members. Critically there needs to be some mechanism to ensure that there is feedback to staff, that their concerns have been heard and what action has or has not been taken, and the clinical leadership piece which we have already spoken about. More generally in relation to quality, I guess we are very aware at the RCN that we may bang on about nurse staffing levels somewhat and we wanted to try to say something a bit more helpful about how you could an organisation really take notice about nurse staffing levels given the critical link between nurse staffing and patient outcomes. Two relatively simple indicators which would not involve a massive data collection—it is data which is already there—for trusts to be aware of, what your nursing establishment is and what your actual staffing level is so that if there is 15 per cent or 20 per cent discrepancy due to frozen posts or people on sick leave that people are aware of that. Secondly, the ratio between registered nurses and non-registered nurses. For general medical and surgical wards the Royal College of Nursing has said that we think a 65:35 ratio is about where that split should be and was very interested and pleased to see that Dr George Alberti made reference in his report to the fact that that ratio between registered and non-registered slipped to 50:50. In terms of boards having some high level indicators about nurse staffing but which are meaningful and easily collectable, we would propose those two.
Q984 Charlotte Atkins: Dr Daggett, first of all, how were patient complaints dealt with at Mid-Staffordshire? Was there a proper process or were they dumped, just like the staff complaints were dumped?

Dr Daggett: I am not an expert on that but I can give you an opinion.

Q985 Charlotte Atkins: Please do.

Dr Daggett: Until, I guess, 20 years ago complaints came to the hospital and were sent directly from the chief executive to the consultant and in my case I dealt with that within 48 hours because I could get the notes out. If there was a problem I rang the patient up and said, “Look, I’m very sorry, come and talk to me”. The large majority of complaints were just a request for information, misunderstandings. In the days when consultants had the autonomy to do that I think that was actually dealt with much better because sitting down with a patient with a cup of tea, apologising if necessary and explaining if something had been done wrong was the way forward. At the moment I think the complaints go first to the chief executive, they are then sent into PALS, the letter is then sent to the consultant concerned who then calls for the notes and is required to respond within two weeks which I think is too long. The system I think is universal throughout the country and I do not think the Mid-Staffordshire system is likely to be different from anywhere else in the country but it is too unwieldy and bureaucratic and it certainly prevents complaints being ignored. There is a temptation, if something unpleasant lands on your desk, to put it in your in-tray and deal with it later. The majority of consultants do take complaints seriously and act much more quickly than the PALS system allows them to.

Q986 Charlotte Atkins: Were you aware of a large number of complaints coming in either from individual patients or relatives or indeed from the local MPs?

Dr Daggett: I do not have that information. All I do know is that if a complaint comes to me directly I deal with it straight away. I will probably live to regret this, but recently I have not had complaints. I work on a ward that has been partially immune from what has been happening where we have a rather different ethos and although clearly we get things wrong and we do get complaints, I have not had a large number so I cannot really make any comment on that.

Q987 Charlotte Atkins: You mentioned the issue about the complaint going to PALS (the Patient Advice and Liaison Service). Do you think the fact that PALS is part of the hospital rather than being independent of the trust is a problem here?

Dr Daggett: I would doubt it. The person in charge has worked in the hospital for a long time and we regard her as being independent. I know she is paid by the trust and owes loyalty to it, but she acts as a patient’s advocate and I have never known the PALS service come down firmly on the side of the doctors without a very good reason. The other problem I think with the PALS service is that once the consultant has provided a report that is then transcribed by a manager and signed by the chief executive. The manager knows a little about the case because he has read the report; the chief executive, with few exceptions, knows nothing about the case, he is just asked to sign the letter. That seems to me to be a recipe for dissatisfaction.

Q988 Charlotte Atkins: I know as a Staffordshire MP that the Local Involvement Networks (LINks) are not working effectively in Staffordshire. Do you think that would be a factor in terms of not giving support to patients who may be raising complaints?

Dr Daggett: Again I am afraid that is outside my experience. Everybody deals with complaints and unpleasant episodes in a different way. I have always done it my way which I accept may not be entirely approved of, but I believe it works. I cannot answer a question about LINks I am afraid.

Q989 Charlotte Atkins: Howard, can I just ask you to comment about the issue of how you would expect patient complaints to be dealt with at hospital level?

Mr Catton: We would expect there to be a very clear governance process with identified lead officers, with a governance committee for scrutiny for overview, for seeing patterns and themes that emerge, for reporting to a board level with clear standards in terms of action that people are either required to take in terms of investigation or dealing with the problem but also feedback and liaison with whoever the complainant may be, and the principles informing both patient and staff complaints or incident forms to be similar obviously because you would want to read across between the two. I have mentioned the fact that there were no modern matrons—whether we call them modern matrons or not—or that tier of nurse management would play a critical part in terms of investigating complaints, dealing with them and making sure that they were followed through. There is a real capacity deficit there in terms of dealing with complaints because those staff were not in place.

Q990 Charlotte Atkins: So the lack of middle management in the nursing structure would impact on the effectiveness of dealing with patient complaints.

Mr Catton: Absolutely because I think that a lot of those complaints that were raised at a ward level may then normally be passed through to that middle management structure and then equally the investigation of those complaints and any action that comes out of them, that nursing management structure would be integral to leading on that and to report back.

Q991 Charlotte Atkins: Are you aware of any issues around complaints from your own membership within the hospital?

Mr Catton: The general comment that I would make is that as valuable as PALS are, nurses talk to us about PALS providing services more around
signposting information and advice and support, it is not about providing the necessary independence that goes with the scrutiny of health services. Equally the variability in what LINKS are doing and their effectiveness is something that has been reported back to us.

Q992 Charlotte Atkins: Were your members raising with you any issue about the fact that they felt that patient complaints were being suppressed in any way?

Mr Catton: I am not aware that that was raised directly with us.

Dr Daggett: If I could just come back on that, as regards the patient complaints I think far from it. The PALS service (which we regard as independent but internal) pursues complaints until they have been dealt with. I would be most surprised if any are being suppressed.

Q993 Charlotte Atkins: I was not suggesting that PALS would suppress, I was talking about the hospital management suppressing it, ie that they were swept aside and not taken seriously. The very point you made yourself about the chief executive signing off a letter without actually knowing anything about the substance of the complaint is worrying I think.

Dr Daggett: I agree.

Q994 Mr Symes: We have gone through several changes in patient complaints and the government, in their wisdom, decided to get rid of the community health councils. Do you think that we would have learned about what was going on earlier had that structure stayed?

Dr Daggett: I never quite understood what community health councils were for. They gave people a chance to let off steam and were a useful safety valve, but if you look in the local newspapers they are full of observations about the hospital for years and years and actually the local newspaper I think fulfils pretty much the same function as community health councils.

Q995 Mr Symes: Would you have a view, Mr Catton?

Mr Catton: I think there was variability in relation to community health councils as well since the variability we have got with LINKS. I think that effective public/patient involvement needs a degree of independence. I think it needs access to information in the first place and it needs to be presented in a way which is understandable and can be scrutinised. I think that if you want genuine and meaningful public/patient involvement you need to resource it as well and there are currently weaknesses across those issues.

Q996 Mr Symes: Dr Daggett, you have worked in a hospital for a number of years. We have heard from ministers that things are improving and one accepts that. However, there are also many calls for a public inquiry. How do you feel about that? Do you think a public inquiry would be helpful for the community?

Dr Daggett: I think it would. It would lance the boil and given people a chance to say what they need to say. I think it would be a good thing and I have a sense of déjà vu. I started my career 25 years ago representing the hospital at the legionnaire’s disease inquiry and I was asked to go because I was young and vigorous; I will leave you to decide why they have asked me this time.

Mr Catton: We have called for an independent inquiry but which is held in private. The reason for that is that I have referred to the deeply engrained and insidious culture that we believe staff have been working under for a number of years. We think if an independent inquiry were held in private it would provide an arena in which staff would feel able to speak much more fully and frankly about their experiences, but the findings of that inquiry should be made public.

Q997 Dr Naysmith: Dr Daggett, what role do you think the board played at Mid-Staffordshire? Could I ask you first of all, is there any kind of formal organisation for senior clinicians and consultants like yourself to make your views known to the board?

Dr Daggett: We have directorates of medicine, surgery and so forth. There is a hospital management board, the Hospital Modernisation Board. There is also a Consultant Staff Committee which is the equivalent of a community health council—it is a talking shop—where we are able to go and give our opinions and let off steam, but that has no right of access to the trust board. As far as I know, nobody has right of access to the trust board and coming back to the point I made earlier I think perhaps they should. The chief executives that I have worked with over the years have been approachable to various degrees and I have spoken to them informally as have my colleagues, but there is no right of access for the consultant body or indeed the nursing body directly to the trust board.

Q998 Dr Naysmith: Are your colleagues happy with that? My experience of senior hospital doctors is that they can be fairly forceful in making sure that their opinions get heard at the place where decisions are made. Is that not happening at all at Mid-Staffordshire?

Dr Daggett: It comes back to the fact that it is a small hospital. Because we have to work in a small community I think we argue rather than fight and perhaps in retrospect we should have fought.

Q999 Dr Naysmith: Do you get any feedback at all from board meetings? Do you know what goes on at board meetings and do you get an indication that any of your concerns have been dealt with?

Dr Daggett: Again it is sent back down the chain of command. Information from the trust board is provided, I guess, when necessary to the hospital management board on which the clinical directors sit and they then pass it down to the individual consultants usually by sending out the minutes of the hospital management board which clogs up your mail box for three weeks.
Q1000 Dr Naysmith: So the minutes were circulated. Dr Daggett: Yes.

Q1001 Dr Naysmith: There is no question of secrecy. Dr Daggett: No. Everything from the hospital management board was circulated. I do not think anything from the trust board directly was circulated.

Q1002 Dr Naysmith: Has the foundation trust governance model made any difference? Or does it not make any difference at all? Dr Daggett: I have not seen any difference but I am not a political animal. Many of my colleagues take a greater interest in that but I have not seen any changes so far.

Q1003 Dr Naysmith: You have not seen any difference? Dr Daggett: No.

Q1004 Dr Naysmith: Do you agree with the Healthcare Commission that the board was too concerned with finance and targets? Dr Daggett: Yes, I agree with them.

Q1005 Dr Naysmith: You agree wholeheartedly with that statement. Dr Daggett: I do not agree with the entire HCC report, but I agree with that statement.

Q1006 Dr Naysmith: Howard, do you have any observations? Mr Catton: Yes, we do. We undertook a survey of members working in foundation trusts back in 2007 (we can provide more details to the Committee afterwards) but the headline from that was that at that point in 2007 of the 46 foundation trusts that we talked to nurses in, they were concerned that the big business ethos was squeezing out patient care. That is how they described it and they were concerned about lack of transparency, the justification being that matters were commercially sensitive. They also make an interesting observation that foundation trusts appeared to fear Monitor more than they did strategic health authorities. That focus on achieving foundation trust status, it being the ultimate prize and organisational survival being dependent on it, was absolutely for us evident within Mid-Staffordshire along with the lack of transparency, the commercial confidentiality and the lack of clinical leadership issues. The other thing I think I would add is that there were mixed messages to staff. When the £10 million was announced staff were told there really would not be clinical posts cut; there were. When clinical floors were introduced people were told that this was for effectiveness and for efficiency and it would not undermine patient care. We had a situation with one ward sister in charge of three wards—nearly 80 beds—and patient care was affected. I think the messages that the trust board gave did not match the reality of the experience of nursing staff. You obviously saw the impact that had

Q1007 Sandra Gidley: Dr Daggett, can you just clarify something you said earlier? You said that information to middle management was not acted on. Can you clarify what you mean by “middle management”? I thought you then went on to say “the board” as though you were referring to the board as middle management. Dr Daggett: When I use the expression “the board” I mean the trust board, the chief executive, the director of nursing, the medical director and so forth. The next layer down is called the hospital management board.

Q1008 Sandra Gidley: So it is the hospital management board you were referring to. Dr Daggett: Yes.

Q1009 Sandra Gidley: You also said that you have not witnessed examples of poor nursing care; it was a quality issue. Would you care to elaborate on that? Dr Daggett: I have never seen a nurse on a ward deliberately neglect a patient or mistreat them. I have seen patients left, as the report suggests, un-nursed because there is no nurse and in the past it has been possible, as we have just heard, to have one ward sister looking after 80 beds. That sister and her two or three staff nurses cannot properly nurse 80 patients; they cannot even nurse 40 patients. I have never seen a patient deliberately mistreated or deliberately ignored.

Q1010 Sandra Gidley: Would you take issue then with the submission we have had from an organisation called Cure the NHS? I will quote from it: “During the eight weeks I cared for my mother I had to feed vulnerable patients as there was no-one else to feed them”. I think you have probably explained that. “I saw confused patients physically and verbally abused daily. Patients continually fell and no-one was around to help them. Staff did not seem to understand the risk and how to manage it.” The bit that worries me there is, “I saw confused patients physically and verbally abused daily”. That is not a lack of nursing; that is poor nursing care. That is abysmal nursing care if that is true. Dr Daggett: If true that would be cause for concern but I doubt very much that it is true.

Q1011 Sandra Gidley: Why would you doubt this person’s submission? Dr Daggett: I have never come across any suggestion, apart from this, that that is the case.

Q1012 Sandra Gidley: You have personally never witnessed anything of that nature. Dr Daggett: I have personally never witnessed anything other than a few nurses doing their best in difficult circumstances.
Q1013 Sandra Gidley: So reports we have had the tablets and medication were not given on time, that bathrooms and commodes were not always cleaned, that patients were neglected and left soaking in their own urine developing sores, that is all down to lack of nurses.

Dr Daggett: That is a sin of omission; I have never seen a sin of commission.

Q1014 Sandra Gidley: Is it not sometimes easy to excuse that with lack of nurses? Surely some of these patients and some of their representatives would have said something, would have raised complaints to consultants. I cannot believe the nurses were happy with this and you say you were not happy with this, but why did this not go anywhere?

Dr Daggett: All I can say is that on my ward that has never happened.

Q1015 Sandra Gidley: Are you able to answer for the other wards?

Dr Daggett: I cannot answer for other wards.

Q1016 Sandra Gidley: In fairness I do not think your ward is one of the ones which is featured heavily in the report, which is probably why you are here and not somebody else.

Dr Daggett: No, it is because I am old and expendable!

Q1017 Sandra Gidley: The point I am coming to here is that surely every health professional has a professional responsibility—be they a nurse, be they a doctor—to do their best for their patients and this clearly was not happening. We have been to other hospitals which have a regular system of case reviews. This is not something that is allowed or disallowed by management; this is something the clinicians themselves decided to do because it was good practice but this does not seem to happen in this hospital. Why is that? Why did clinicians themselves not take some sort of lead on this? There are some things the clinicians could have done themselves, why did they not?

Dr Daggett: I think they should have done and we have now changed our system. We will now be having such reviews.

Q1018 Sandra Gidley: Surely the doctors and consultants do not exist in isolation. A lot of them must have practised in hospitals that did have these good systems in place. Why did this suddenly all disappear into the ether when they came to work in Staffordshire?

Dr Daggett: I cannot answer that.

Q1019 Sandra Gidley: Can I just ask a question of Howard Catton? I cannot believe that the nurses were happy with leaving patients in these conditions. We continually hear that it is all about clinical leadership and we did not have this tier of leadership, but I am sorry, I just do not buy that. Surely the nurses too had some sort of personal and professional responsibility and they should have been doing something. If the board would not listen, is there not a mechanism through the RCN or somewhere else where the RCN can act as advocate? Did that happen? Were you listened to?

Mr Catton: The type of nursing care that you have described is unacceptable and I would not for one minute try to condone that. I think that there were a range of factors at play here. I have talked about staffing levels, I think that was critical; there is only so much you can stretch and make do. If you do not have the staff with the experience then that is a problem. We have not talked about training and development either. There was a lack of training and development.

Q1020 Sandra Gidley: You do not need to be trained and developed to know that it is wrong to have a patient in a urine soaked bed. I am sorry, that is basic training, it is not development.

Mr Catton: Absolutely.

Q1021 Sandra Gidley: My question to you was, should there be some other mechanism for nurses to raise these problems?

Mr Catton: Yes.

Q1022 Sandra Gidley: Was there? Was it used? If not, should there be something?

Mr Catton: As I said, that nursing care is unacceptable. There is a really powerful concoction of ingredients here in terms of the oppressive culture, staffing levels, training, lack of leadership, lack of resources as well which came together; it is not just one of them. There were staff who left during this time because of the environment that was there. I think there have been lessons for the Royal College of Nursing as well as for other organisations as a result of Mid-Staffordshire. We have recently set up our own whistleblowing lines so that nurses can phone us directly with concerns which they might have. I think the other issue here as well—it is an issue about wider policy—is that if the trust had focussed on quality as much as they did finance then we would probably not be sitting here today. There are some big policy levers that you could use to get them to focus on quality; pay them more for quality rather than just volume; make sure that it is a commissioning contract; make sure it is part of SHA’s performance management processes and procedures. I am slightly concerned that we are hearing now that quality accounts may not be accounts but may be quality reports as well. I think there are some big things that we can do with the policy levers that are available to us to make quality be at least an equal partner to finance as well.

Q1023 Sandra Gidley: I do get concerned when I hear people talking about policy levers because I think a lot of this stuff is basic. My final question is, do you think there has been a lot of buck passing by everybody in this and that the clinicians themselves must take a portion of the blame for what has happened.
Mr Catton: From what I have heard from the nurses, as I said, at congress, from what I know the discussions our general secretary has had, those nurses have stood up and have said that there has been unacceptable care here as well. I do not think that nurses are trying to duck it, but I do not think it is fair, right or proper just to say that doctors should have spoken out and nurses should have spoken out without looking at what the other responsibilities of significant bodies were as well.

Q1024 Sandra Gidley: It is certainly part of the picture and that is the part of the picture we are looking at at the moment.
Mr Catton: I think it will be enormously helpful if the nursing and midwifery regulator provide further guidance and advice to nurses about how to speak out and if we get trust boards giving that categorical and unequivocal commitment to support people who speak out.

Q1025 Sandra Gidley: Dr Daggett, have doctors said sorry?
Dr Daggett: Have doctors said sorry?

Q1026 Sandra Gidley: Yes.
Dr Daggett: No, because we have done nothing wrong.

Q1027 Sandra Gidley: We have heard the nurses have said they are sorry, why have the doctors not said sorry?
Dr Daggett: I do not think we have done anything wrong; there is nothing to apologise for.
Sandra Gidley: Others can judge whether they agree with that comment.

Q1028 Chairman: Dr Daggett, could I ask you about your call for a public inquiry? What would we learn from a public inquiry that we have not learned from the Healthcare Commission report and the subsequent reviews that have been done of the different parts of the hospital that were having problems?
Dr Daggett: Mainly so we can find the genesis of the financial problems. This whole sorry business has resulted from the hospital having insufficient resources and I have never understood how that arose. I think some sort of inquiry might get to the root of that.

Q1029 Chairman: You said it would be so that people could get it off their chests, so that they could talk out.
Dr Daggett: Again I think that would be helpful and if people who feel aggrieved can come and give an opinion in public there is much to be said for that. What interests me is to establish the genesis of the financial difficulties. I do not understand because I am not an accountant, but somebody must understand it and be able to work out exactly where the money went and indeed where it is coming from now.

Q1030 Chairman: We would not learn any more about how the patients were treated.
Dr Daggett: No.

Q1031 Chairman: Howard then replied about the issue of a public inquiry and he said he did not think there should be a public inquiry but that nurses would be happy to talk out not in a public inquiry but to talk privately and confidentially and then let that come out to the public about what they felt about the situation. There seems to be a conflict here. They do not want to get it off their chest in a public inquiry. What do you say to that?
Dr Daggett: I think that Howard’s suggestion is perfectly sensible but the virtue of a public inquiry is that relatives and patients who have been affected will be able to speak in public.
Mr Catton: To be clear, an independent inquiry held in private for the reasons we have said but with the findings made public.

Q1032 Dr Naysmith: Dr Daggett, there is evidence that the money that went to Mid-Staffordshire was not all that different from money that went to other hospitals and they managed to provide good care on a similar budget. Why do you think it is that Mid-Staffordshire did not manage to do that?
Dr Daggett: We were told that there had to be a £10 million saving for reasons which I do not understand.

Q1033 Dr Naysmith: Why did you not ask what the £10 million was for?
Dr Daggett: We were told that it was because other agencies required the funds to distribute to other hospitals. Whether that is true or not I do not know and that is why some sort of inquiry might be helpful.
Chairman: Could I thank you both very much indeed for coming along and helping us with this inquiry this morning.
Witnesses: Mr Ben Bradshaw MP, Minister of State for Health Services, Department of Health, Professor Sir Bruce Keogh, NHS Medical Director and Mr David Flory, Director General, NHS Performance and Operations, gave evidence.

Q1034 Chairman: Good morning gentleman. Could I thank you for coming along. I have to say that you are the third minister we have had in front of us on this inquiry. Could I first of all ask you if you could give us your name and the current position that you hold?

Mr Bradshaw: On my right is David Flory who is the Director of NHS Performance and Operations and on my left is Sir Bruce Keogh who is the NHS Medical Director. I am the Minister of State.

Q1035 Chairman: Mid-Staffordshire’s annual health check ratings for quality of service between 2005 and 2008 were “fair”, “fair” and “good”. Given that the annual health check completely failed to bring to light unsafe care in this particular case, how do you know there are nor other trusts doing just as badly?

Mr Bradshaw: On those ratings themselves, for the period you referred to the trust only scored “fair” on quality, which is the second lowest. It was only in 2007–08 that they were given a provisional rating of “good” and I had a conversation with Anna Walker (the outgoing chief executive of the Healthcare Commission) about this because I asked her exactly the same question as you have just me and she said it was made clear in that report that it was a provisional rating because they were already under investigation and it was subsequently reduced to “weak”. One has to accept that the Healthcare Commission ratings are based on a range of measurements, not just restricted to emergency care and one of the things that has been overlooked in a lot of the discussion about Mid-Staffordshire Trust is that no-one, as far as we are aware, is making any serious complaints about the quality of elective procedures, for example, a large bulk of a hospital’s work. I think it is also fair to say that the procedures of the Healthcare Commission and now the Care Quality Commission have been constantly evolving, they have been constantly improving and they have constantly been becoming more sophisticated. It was indeed the growing sophistication of the Healthcare Commission’s procedures with use of HSMRs and other alert systems that finally alerted them to the potential problems that were there at the hospital.

Q1036 Chairman: Do you think the new check by the Care Quality Commission—we are going to have registration as opposed to these annual checks—is going to strengthen the situation in terms of trusts doing what they say they are doing?

Mr Bradshaw: I think it is part of a significant strengthening of the regulatory framework that was established by the setting up of the Care Quality Commission, the first integrated regulator in this country with much stronger powers than the Healthcare Commission (powers of intervention, powers of suspension, of removal of registration, of closure of wards and even whole hospitals if they see fit). I think it is also very important to remember that the Healthcare Commission could have put Mid-Staffordshire Hospital into special measures if at any stage it had found—not only before but during its investigation—that it felt that patients were in danger. It did not do that although it has used those powers, as I am sure the Committee is aware, in three other cases.

Q1037 Chairman: You said about the powers that the CQC has got; will they be able to do a deep investigation into a situation if it ever came to light as in Mid-Staffordshire?

Mr Bradshaw: Absolutely. It would be able to do such an investigation and it has already, as I am sure you are aware, committed to going back into Mid-Staffordshire in three months’ time to have a full re-investigation, in six months’ time and there is even discussion of a year’s time re-visit as well.

Q1038 Chairman: How does registration differ from the tick list we have had in terms of asking trusts how well they are doing?

Mr Bradshaw: Bruce may want to outline some of the details in terms of clinical quality and other requirements that will have to be met for a hospital or providers not just in healthcare but in social care for the first time to be registered with the ultimate sanction of loss of registration which is loss of right to practise. I do not know whether Bruce would like to spell out some of the particular clinical measurements that you might be interested in.

Professor Sir Bruce Keogh: I think the Care Quality Commission are in the process of working out some of the details of that, but one of the things that became clear—as you will know from Lord Darzi’s review—is that we needed to have a very clear definition of quality. We have that and that is around the three domains of clinical effectiveness (that is essentially clinical outcomes for patients), patient experience and safety. The Care Quality Commission have also added access into that in terms of the way that they assess these organisations. So all of these four domains will be assessed with respect to defining quality for registration. The details of those questions still have to be resolved.

Q1039 Dr Taylor: Minister, some of us visited Luton and Dunstable Hospital a week or so ago and we were very impressed by their achievements. They are one of the pilot sites for the Safer Patients Initiative. Certainly I got the impression that there they have a chief executive who worked extremely well with a medical director who has the confidence of the staff and nursing chiefs who again were working together. So you have there real cooperation between the three key elements. From what we have heard about Mid-Staffordshire this same sort of cooperation certainly did not exist and there were blockages between messages getting to chief executive level from both nurses and medical people. What can you do to ensure that hospitals work like Luton and Dunstable where it really seems to be working with high quality care?

Mr Bradshaw: If anything your description of what went wrong at Mid-Staffordshire was an under-assessment of how dysfunctional and dreadful that
hospital was managed. You are right about Luton and Dunstable but I would not regard Luton and Dunstable as an isolated case. The vast majority of hospitals and their boards perform their roles properly and effectively. However, you are right about the work that is going on at Luton and Dunstable; it is a model that is being rolled out across the NHS and it is one that we very much welcome.

Q1040 Dr Taylor: How can you get the personalities that do not appear to want to work together to work together? I am looking at Bruce really about this. How can you ensure that there are medical directors that take their staff with them and are really able to talk to the nurses, talk to the chief executives? How do you do that?

Professor Sir Bruce Keogh: It is not always an easy issue but I think it boils down to good leadership at a managerial and a clinical level. I think leadership is about aligning people to a set of common goals. Liam Donaldson did a good piece of work looking at the characteristics of high performing clinical teams. The first thing was that they had good clinical leadership. The second thing was that their managerial targets were expressed as clinical benefits so that there was a relationship between the two. The third thing was that they measured what they did. The fourth thing was that they compared what they did with others so that they knew what they were doing so that there was an alignment within the managerial and clinical community within the organisation. I do not think we have seen that alignment in Mid Staffordshire. I think there were uncharacteristic reporting lines, particularly from the divisional structure. The medical director is in a fairly isolated position. The heads of the divisions do not have direct accountability to the medical director, they report to the chief operating officer. That deprives the clinical community of an easy access, if you like, into the trust board. In a sense there are issues around attitude and professional culture which need to be coupled with organisational structures. I think it has been a combination of both of those breaking down in Mid Staffordshire. There are other issues about Luton and Dunstable and I have to say that a lot of credit for what goes on in Luton and Dunstable has to be down to Stephen Ramsden the Chief Executive whom I think has displayed exceptional leadership. He was one of the first to engage with the health foundation and the Patient Safety Campaign which is sponsored by the NHS Institute, the NPSA and the Health Foundation. Stephen has led that, if you like, from the bottom up so that now 92 per cent of trusts are part of the Patient Safety Campaign. There are only up to a year next week so they will be announcing the progress that they have made at the NHS Confederation in Liverpool next week. I think what is very important about what Stephen has done is that he has set about embarking on a culture change so this safety initiative is led from the bottom up. That will bring long term sustainability; it will bring clinical and managerial ownership, enthusiasm and I hope will lead to innovation.

Mr Bradshaw: I just want to add one thing which may be obvious but it is adherence to guidance. There is clear and comprehensive guidance out there for trusts as to what their duties are and it is that guidance that needs to be adhered to and was not adhered to in the case of Mid Staffordshire.

Mr Brady: This issue of whether Mid Staffordshire was an isolated incident was dealt with by the Healthcare Commission itself, by the independent regulator, who made clear both in the report and subsequently to it that they went back and did a very careful check of other trusts that had similar high levels of hospital standardised mortality rates and other indicators that may be a cause for concern and they satisfied themselves (Anna Walker is on the record as having said this; she may well have said it in her evidence to your Committee) that there were not any other trusts that gave rise to similar concerns. The Care Quality Commission subsequently confirmed that.

Mr Flory: This links back to the point that was made earlier which is that the role of the Care Quality Commission is not simply one of a periodic review, an annual inspection based on an element of self-assessment. Registration is a constant thing; when it is awarded it is not for the whole year, it needs to be maintained and the standards that underpin it need to be maintained. Alongside that the Care Quality Commission will continue to run in the way that the Healthcare Commission did with alert systems with more real time data to flag up when there are potential problems—that is what triggered the work at Mid Staffordshire—and indeed the Care Quality Commission are undertaking across the country a range of risk summits with all relevant NHS organisations and other relevant stakeholders in order to take a view, based on the evidence available, on where they need to potentially keep a closer eye, where there are maybe some early signs and questions that need to be followed through. Their role is not one about turning up once a year and going away; it is much more continuous in that sense and the alert system is a really important part of it.

Mr Bradshaw: They have committed to publishing those alerts on a quarterly basis.

Q1042 Dr Taylor: The standardised mortality rates are obviously one thing that alerts; what are the other things that alert you to a hospital that is not performing adequately?

Mr Bradshaw: These are questions that you may also want to put to the Care Quality Commission if you have not already, but in the example of Mid Staffordshire what alerted the Healthcare
Commission was not just the high HSMRs because I think everybody accepts that HSMRs in isolation are not enough to tell you that there is a problem. That is one of the reasons that they have not been used in a way that we have now decided to use them and publicise them because they can be skewed for particular reasons. However, in combination with other alerts the system is becoming ever more sophisticated. It was the combination of the level of patient complaints, the level of patient complaints upheld and the staff survey and more that finally caused the Healthcare Commission to begin asking searching questions. As you know from their report, having not been satisfied with the answers they go they eventually decided to have a full investigation. The Care Quality Commission is using, as I understand it, an even more sophisticated suite of alerts and these are developing all the time. As far as I understand it, it is probably the most sophisticated alert system of any healthcare system in the world.

Mr Bradshaw: I would love you to put that question to the PCTs because I think they would throw their hands up in absolute horror to have world-class commissioning described as a tick-box exercise.

Q1045 Dr Naysmith: Some people have described it as that.

Mr Bradshaw: It is an extremely rigorous system in order to address the problem that we have acknowledged has been there.

Q1046 Dr Naysmith: What happened to world-class commissioning then at Mid-Staffordshire?

Mr Bradshaw: It did not exist. World-class commissioning is only a year old.

Q1047 Dr Naysmith: They knew about it; they knew it was coming in. Bristol have been preparing for it for the last 18 months.

Mr Bradshaw: Indeed, and the preparation and the introduction of world-class commissioning has been because of the recognition that commissioning has traditionally been a weakness across the NHS and that is being addressed through world-class commissioning. If you look at the assurance ratings that were published a couple of months ago—which I am sure you have or, if not, they are available in public—it has been a very gruelling and demanding process. The assurance and performance framework that accompanies it will mean that failing and weak PCTs' performance is rigorously addressed by SHAs and in extreme, rather like failing providers, those PCTs will face takeover. We have been absolutely clear about that.

Q1048 Dr Naysmith: The criticism has also been made that the SHAs are more focussed on pushing trusts into becoming foundation trusts than on performance management of them. There seems to be some evidence coming out of Mid-Staffordshire that that was the problem there, that the SHA wanted the hospital trust to become a foundation trust and that is what it was focussing on.

Mr Bradshaw: David will want to say something about the specifics of that, but the SHAs—as the rest of the NHS—has, as their prime responsibility, patient safety and quality. If you are saying to me that SHAs should not be helping and encouraging and supporting trusts that want to become foundation trusts I do not accept that. If you look at the evidence of the overall performance of foundation trusts it is significantly better than the performance of non-foundation trusts. The improvement that we have seen in recent years of performance across the NHS among providers has been among all providers but it has actually been foundation trusts who have improved more quickly than the rest. The vast majority of trusts that scored "double excellent" on the Healthcare Commission health check are foundation trusts. Of course people aspire to become a foundation trust and you would expect the SHA to encourage them. However, you would not expect that process to ignore the absolute overriding importance of patient safety and quality of care.

Q1049 Mr Symes: Nobody has mentioned the strategic health authorities who clearly have a role in the hierarchy. The information must be playing between the hospitals, PCTs and strategic health authority, and we know there are some excellent examples of chief executives, (certainly in the southwest we have a very good one in Ian Carruthers), but they did not seem to pick this up either. I wonder what the Minister feels about that.

Mr Bradshaw: I think we need to be very clear and remind ourselves that both the Healthcare Commission report and the subsequent reports by David Colin-Thome` and George Alberti lay the blame for Mid-Sta`fordshire fairly and squarely with the management of that hospital. It is very important that we do not allow the management of the hospital off the hook for their responsibility. However, David Colin-Thome` did say in his report that he felt that both the SHA and the PCT could have done more. He also made clear that in the performance framework context of that time it would not have been reasonable to have expected them to do more and they did not fail in their duty to do what their job was at the time. However, since then of course the performance management responsibilities of SHAs and PCTs have been considerably enhanced. I think there was no specific criticism of the SHAs or the PCTs in either report, rather an acceptance that they could have done more but it would be unfair to have expected them to have done that. The system has changed and the system changed before Mid-Sta`fordshire came to light and it is part of an evolving improvement of performance management across the NHS.

Q1044 Mr Naysmith: Carrying on in that vein, is world-class commissioning not just another tick-box exercise that people go through without paying a lot of attention to, and is that not part of the reason why the PCT failed as a commissioner?
Mr Flory: It is certainly the case now with 121 foundation trusts in the country that their overall performance has improved significantly in getting that status. In Lord Darzi’s report last summer he emphasised the importance of when organisations are ready and can pass all the tests for them to progress to foundation trust status, the role of governors locally and the membership structure locally brings a whole new local accountability that non-foundation trusts do not have. There are a lot of reasons why the organisations themselves and the systems round them want to move to foundation trust. We see different rates of progression to foundation trust status in different parts of the country. In the West Midlands region now—the West Midlands Strategic Health Authority area—of 26 trusts (either hospital trusts or mental health trusts which are eligible to go to foundation trust status) 11 of them already are foundation trusts and there are still 11 hospital trusts and four mental health trusts to make that journey. The evidence in the West Midlands is not one of rushing through to foundation trust at all costs; it is a more measured process. Indeed, I have had conversations with them about bringing forward perhaps more quickly some of the high performing organisations that are not yet foundation trusts. In that region I would not say it is a question of pushing everybody to foundation trust at all costs.

Q1049 Dr Naysmith: Do you not think it has any validity, the suggestion that in Mid-Staффordshire at least part of the problem was that the focus was on getting the finances right and neglecting some other matters?

Mr Flory: I think that getting the finances right is a crucial and essential part of getting trusts to foundation trust status and what we observed is that clinical viability and excellence and improvement tends to go hand in hand with financial viability and improvement and excellence; the two things are side by side. However, what is really important as trusts are assessed now is that a lot of improvements have been made to the process of assessing trusts and approving them for foundation trust status all through the system. I think that process now absolutely considers non-financial issues.

Q1050 Dr Naysmith: It cannot possibly be right that you only look at finances and neglect other matters.

Mr Flory: We accept what you say. It is in the Healthcare Commission report. The Healthcare Commission made that specific criticism of the management of Mid-Staффordshire Hospital but at the same time it said it was absolutely no excuse for failing to provide quality clinical care. There are hospitals going through the foundation trust application and approval process all over the country that are getting their finances in order and doing all of that while at the same time providing steadily improving, excellent and safe care to their patients. That is the distinction you have to make, not to let this management off the hook. Yes, they were paying too much attention to the foundation trust application and disregarding other important things, but that is not what they should have been doing; it is not an excuse.

Q1051 Charlotte Atkins: The South Staffordshire PCT is paying for those patients to go into that hospital. Why were they not picking up on the fact that they were not getting value for money, that they were not getting the proper nursing care and they that they were not getting the outcomes they would expect from a good hospital? What I do not understand is why they seem to be blinded themselves to what was clear from patients that there were real shortcomings? What is wrong with the route which demonstrates that PCTs are not picking up on these problems? They should be the front line here because they are the ones who are actually spending their money on patients in the hospital and if they are not getting appropriate care they should be the first organisation to pick up on it. I do not buy this idea that it is just because PCTs were being reorganised at the time.

Mr Bradshaw: I absolutely agree with you and so did David Colin-Thomé in this report. There are two separate issues here. There is the specific issue of why Stafford PCT and PCTs in general are not better and tougher commissioners which we have also discussed in some detail. There is also the kind of broader issue which we may come onto later as to why there was not more noise around about this hospital. One of the things that has struck me—and I am sure every member of this Committee—is that if this level of service was going on in my hospital there would be the most extraordinary noise both in the media landscape locally, in Parliament, in the health community locally and in local government. What was going on at this hospital, until the Healthcare Commission decided to launch its investigation, was not what you would have expected given what we now know about the level of care there. Maybe that is an answer that only a political geographer can really provide answers to but that is one of the great things that has mystified all of us through this.

Q1052 Charlotte Atkins: Should we also be looking at the failings of the PCT alongside the failings of the hospital?

Mr Bradshaw: David Colin-Thomé dealt with this in his report about the failings of the PCT in that he thought they could have done more. If there had been more noise around before the Healthcare Commission investigation began then you might have expected them, in order for them to fulfill their duties at the time, to have done that but I do not think that he found any evidence that they had failed in their then existing duties to commission better or more properly.

Q1053 Charlotte Atkins: I would not expect the PCT to wait for noise. I would expect the PCT to be in there investigating and challenging rather than
waiting for noise from newspapers or the media. I would expect the PCT to be in there long before there is any noise at all.

Mr Bradshaw: That is the expectation on the world-class commissioning.

Q1054 Dr Stoate: Minister, it is quite clear from the evidence we have received—which has been a huge amount—that this board failed and that it had been failing for some time. You, like me, have already expressed the disbelief really that there was not more noise, that people were not blowing the whistle and were not phoning the local Member of Parliament who, I entirely agree with you, would have taken action if he or she had known exactly what was going on. I also accept your reassurances that it seemed that this particular failure was an isolated case but I do not see how we could know that. My worry is that if this were happening in other parts of the country and if the local health economy were not blowing any whistles, I am not sure how we would know. I want to tease out how you can be sure that this is an isolated case and that we are not going to see more things coming out of the woodwork in the future.

Mr Bradshaw: I do not want to repeat what I have already said about what the Healthcare Commission said about it being an isolated case. The Healthcare Commission, as regulator—and now the Care Quality Commission—have their own systems in place to satisfy themselves as the independent regulator that that is the case. I suppose as far as we are concerned as the performance managers—although not strictly the performance managers of foundation trusts—we would say that the performance management systems that are now in place and were in place before the Mid-Staffordshire investigation both around the increased and clearer responsibility on primary care trusts (which we have just described), the clearer responsibility and the assurance framework for strategic health authorities to performance manage hospitals should give reassurance that from the performance management side the SHAs and the PCTs would have a handle if such a situation were to arise now. Both the combination of a better performance management system and a better, rigorous, more powerful regulatory system I suggest should provide confidence that this was and is an isolated case.

Q1055 Dr Stoate: I am pleased about that but surely it still relies on a system. What we were hearing this morning was that where complaints were being made and where incident forms were being filled in they were effectively being buried by middle management. Are you confident that the new regulatory systems can prevent that happening? Reports are being passed up by nurses and doctors that are utterly ignored or lost.

Mr Bradshaw: I think that is a very important question because it is not just about performance management, it is not just about regulation, it is about changing the culture in and around the health service. One of the things that I do not think has really been paid enough attention to was the government’s response to both the David Colin-Thomé and the George Alberti reports which are content rich, a lot of new stuff in there including issues around complaints. One of the biggest concerns we have—this came through in the Healthcare Commission report and in the subsequent reports—is the way that this hospital completely failed to deal with complaints properly and how complaints were not taken seriously. Just the changes that have already been introduced previously but also since those reports on complaints (that every trust has to publish the number of complaints they have, the number that are upheld, the number that are resolved, the figures are now being put on the NHS website so that people can compare how individual hospitals perform on complaints, duties on primary care trusts to satisfy themselves that hospitals are dealing with complaints properly and so on) I think will help change the culture. The new absolute legal protection for whistleblowers (not so new, it has been there for several years but it is still bedding in); the trends are improving every year on the number of people using that new legal protection and the role of public protection at work (the independent charity that we have contracted to provide independent advice to people). All of this will help change the culture but it is also about inquiries like this encouraging that culture change.

Q1056 Dr Stoate: You are absolutely right that we need a culture change—nobody denies that—but why therefore can it be justified for the vast majority of foundation trusts to have their board meetings in secret?

Mr Bradshaw: We have made quite clear in our response to the David Colin-Thomé and George Alberti reports which we think boards should meet in public. We are absolutely explicit in our response. I am sure you have read our response, it is not very content rich, a lot of new stuff in there including the ministerial team has always made quite clear that our view is that NHS boards should meet in public.

Q1057 Dr Stoate: That is your view and it is certainly my view as well, but why is not a requirement—apart from very sensitive or financially commercially sensitive issues—that they meet in public?

Mr Bradshaw: We do not have the power to require that of foundation trust boards.

Q1058 Dr Stoate: Should we not have? I am very concerned that if they want to they can lock the doors and get on with it and I am not sure that that is the culture you are looking for.

Mr Bradshaw: We have been as clear as we can be as to what our views are and I think Monitor have been as clear as they can be. If there are still foundation trust boards that are not or never
meeting in public then that is something that those boards themselves need to address. However, we are considering at the moment—not just in the context of foundation trust boards meeting in public or private but also in relation to some other issues we may come to discuss in a moment about personnel matters and foundation trust management and boards—whether we may need to take further powers.

Q1059 Dr Stoate: Are you prepared to take further powers if necessary to ensure that they do open up?  
Mr Bradshaw: We are prepared to consider what extra powers we think the government may need to take to ensure that we have a system where, given that ministers are responsible and accountable to Parliament as I am here today, yet we do not currently have the powers to make the effects and the changes that we might need to do to satisfy committees like this.

Q1060 Sandra Gidley: Just to back to your comment, Minister, about the lack of noise about this, the submission from the Cure the NHS group says, “In January 2008, we contacted the Secretary of State, Alan Johnson, David Kidney MP, Tony Wright MP, Bill Cash MP. We wrote and told them that patients were being denied their basic human rights. Their advice was to talk to the hospital management and the board of governors.” So it was flagged up at quite a senior level. Was it just kicked back by the secretary of state at the time?  
Mr Bradshaw: No, it was responded to in the way you would expect a secretary of state to respond to any representation like that. The point I was making—and I will make more explicitly now—is that one of the first things we did of course when we knew that there was a problem with Mid-Staffordshire was to do a check of all of the correspondence that we had received in the department, all the parliamentary questions that were asked, the debates (there were no debates) and all the local media reporting of this. It was quite clear to us that the vast majority of the noise—as we are calling it—only began when the Healthcare Commission launched its investigation. The vast majority of the complaints, the representations, the campaigning groups and so forth got up steam after the Healthcare Commission investigation began. Before that—and this is one of the things that I think is very odd about this—there was nothing untoward about the volume or nature of the complaints and representations that were made.

Q1061 Sandra Gidley: So this was a single complaint which was probably akin to others you received from time to time about other hospitals in the country. It did not ring any alarm bells.  
Mr Bradshaw: There was nothing unusual about the nature or the volume of complaints that we received about Mid-Staffordshire before the Healthcare Commission began its investigation.

Q1062 Sandra Gidley: There was nothing usual about it?

Mr Bradshaw: The nature and the volume of the complaints and representations that we received before the Healthcare Commission began its investigations were not out of kilter with the number, volume and nature we receive about other trusts.

Q1063 Sandra Gidley: How many complaints about a hospital would a minister have to receive before it raises alarm bells?  
Mr Bradshaw: You are asking me to put a figure on it. What we can do is to provide this Committee, if it would be helpful, with the details of exactly how many MPs’ letters, exactly how many representations, exactly how many complaints or letters we had from members of the public and we can give you those figures. We can also give you comparative figures with other hospital trusts in the country. I am happy to do that.8

Q1064 Sandra Gidley: Does the government not have to take some responsibility? There was a big focus on the financial balance and achieving targets and any chief executive knows which are the hanging offences and which are not. For a number of years the most important thing was that a trust should achieve financial balance. Has that not sent a message to trusts such as Mid-Staffordshire that patient safety is not a top a priority?  
Mr Bradshaw: No, I totally reject this argument that it is all about targets and financial balance. That is to completely let the management of this hospital off the hook. The vast majority of hospitals in this country—including mine and including probably the honourable lady’s—do an excellent job of balancing their books, an excellent job of providing care. They do not do so by compromising patient safety or the quality of care. As David intimated earlier, there is a very, very strong correlation between hospitals that are well-run, that are well-run financially and the quality and safety of the care provided. There is a very strong correlation indeed. This is not an either/or, it is a both.

Q1065 Sandra Gidley: So are you saying they just did not look at the financial pressures in the round, they just took an easy step and cut the staff? Clearly the nursing levels were unacceptable. Again, are there no mechanisms anywhere for ensuring that there is an adequate level of staffing because what we have just heard—one nurse in charge of 80 patients—is clearly unacceptable and yet nobody anywhere seems to have picked this up? Do you not have the right mechanisms in place that would trigger concerns on this?  
Mr Bradshaw: There are countless mechanisms in place and there are masses of guidance in place. The guidance was totally ignored by this hospital management and the mechanisms, such as they were, were not used or deployed.

8 See Ev 189
Q1066 Sandra Gidley: Who should be able to pick up if the guidance is ignored?

*Mr Bradshaw:* That ultimately is the responsibility of the hospital board, for goodness’ sake. The hospital board has a legal duty to comply with clinical guidance and they failed to do so.

Q1067 Sandra Gidley: Who picks up when the hospital board is ignoring it? There seems to be no management here by the strategic health authority. Should they not be overseeing this?

*Mr Bradshaw:* That is again not the case. The Healthcare Commission report was very explicitly not critical of the role performed by the strategic health authority; neither was David Colin-Thomé’s report. I am sorry to have to say this to the honourable lady, but she, by her questioning, would be letting the management of that hospital off.

Q1068 Sandra Gidley: I am not letting anybody off.

*Mr Bradshaw:* Excellent.

Q1069 Sandra Gidley: If the report did not criticise the strategic health authority then who should have picked up the lack of adherence to the guidance? I am trying to get this clear; did the strategic health authority monitor it and pick it up or was it not their responsibility?

*Mr Bradshaw:* There are multiple roles here, are there not? I will go through them all but David and Bruce may want to elaborate in more detail. The prime responsibility for running a hospital is that of the hospital board. I think the honourable lady would accept that. This hospital board failed catastrophically to fulfil its legal and moral duty on all of these things. There is the professional responsibility—I think there was some questioning on this in the session before this one—of NHS staff who, if they feel that patient safety is being jeopardised, if they feel that the quality of care in their hospital or elsewhere is not up to scratch, they have a moral and professional duty to report that. There is the role of the royal colleges; where were the royal colleges? There is the role of the unions. We have already discussed the commissioning role of the primary care trust and the strategic health authority. There is also the regulator and in the end the regulator did its job in this case. Of course we did not used to have an independent regulator; we had a system where something like this would probably never have been uncovered before the life of independent regulation. We have a whole range of people performing a role here. I am afraid to say that the prime responsibility for what happened at Mid-Staffordshire—this is abundantly clear in the Healthcare Commission report which I think was an excellent report—lies with the management and board of the hospital.

Q1070 Sandra Gidley: I do not disagree with anything the Minister says, but he still has not answered my very, very simple question. It is important in case there is another Mid-Staffordshire waiting in the wings, although we all hope there is not. If the board is ignoring DH guidance, who is in a position to pick that up? Who should pick that up? Or does the buck stop with the board? Are you saying there is no mechanism to pick up a dysfunctional board?

*Mr Bradshaw:* If it is a foundation trust, then Monitor; if it is a non-foundation trust then ultimately the NHS has the power to remove the board.

Q1071 Sandra Gidley: So it is the failure of Monitor.

*Mr Bradshaw:* Monitor were only responsible for this hospital for the last year.

*Mr Flory:* I think the question you asked relates to the earlier question about the role of the service commissioner and the primary care trust. Whilst the responsibilities for delivering care safely and to the right standards is absolutely in the remit of the trust board and that is a buck that cannot be passed to anybody else (which is where the core of the problem was here) nonetheless the service commissioner has highlighted in David Colin-Thomé’s report that the PCT could have been less reliant on other systems to detect problems. As David Colin-Thomé says in his report, there are lessons to be learned for primary care trusts about the way in which they hear, take note and involve patients and the public. There are issues for primary care trusts in the way that they receive, interpret and look at data which tells them the way in which the services they commission are performing. There are issues for the primary care trust in the way that their own medical leadership—not just the primary care trust board but through them into practice based commissioners, in the professional executives committees—get involved in an understanding of the way in which services are being delivered and the quality to which they are being delivered. In fact, the David Colin-Thomé report spells all this out very clearly. In fact most of the things that he recommends in there are in train, if you like, from the post-Mid-Staffordshire era both from Lord Darzi’s report (Bruce might to say more about quality as the overriding principle) and also in world-class commissioning where in the past we tended to judge organisations (commissioners and strategic health authorities) on the aggregate performance of organisations that they relate with. What the big change in world-class commissioning is, is this explicit competencies that PCTs are required to have. It is all laid out along the lines that David Colin-Thomé re-emphasises in his report and it is by being competent in that way and meeting the requirements of the world-class commissioning framework that we would expect primary care trusts to be more proactive in their engagement and challenge when such as this happens.

Q1072 Sandra Gidley: World-class commissioning was not an issue then so that does not explain any of the failures. I think we need to move on. Minister, do you think the focus on reducing elective waiting times when it comes to Mid-Staffordshire jeopardised the safety of emergency admissions?

*Mr Bradshaw:* No. Again, apart from the fact that reducing elective waiting times to 18 weeks has been a very important achievement and is one of the
public’s main priorities when this government was elected given the dreadful legacy of long waits that we inherited, there has also been a massive improvement in capacity and performance in accident and emergency departments. We have more than doubled expenditure. There has been a huge increase in the number of A&E consultants. There is absolutely no reason why any hospital should have allowed its accident and emergency services to deteriorate because of its drive to reduce waiting times for elective treatment. As I said before, the vast majority of hospitals now meet the 18 week target times for elective treatment. As I said before, the vast majority also meet the A&E target.

Q1073 Sandra Gidley: As you are aware this is actually a larger inquiry on patient safety and throughout the inquiry we have heard from numerous witnesses about the importance of an open reporting culture. Clearly in this case it is just words. What can the department do to make sure that an open reporting culture is not just words and is actually something that is best practice?

Mr Bradshaw: The honourable lady is absolutely right to say that there was no open reporting culture in this case and in fact that is one of the real reasons and causes for some of the problems of different kinds that we have discussed. There was already guidance in place at the time that this board completely ignored on the importance of transparency, openness, reporting and so forth. That guidance has since been strengthened. There are the announcements that we made in some detail—very far reaching announcements—in response to the David Colin-Thomé and George Alberti reports on further improvements on openness, accountability, transparency and so forth. Bruce may like to say something a little bit more in relation to patient safety in general and the importance of an open reporting culture?

Professor Sir Bruce Keogh: I would like to say two things actually. One, if you do not mind, is about elective waiting time targets and the other is about where safety and things such as open reporting might come on the trust board agenda. I have had to deal in two trusts with elective waiting time targets. In March 2000, so nine years ago, a set of targets were imposed on my speciality which was cardiac surgery. I was working in Birmingham at the time and two people would come into a room to discuss surgery; one would usually be the man who required it and the other would be his wife. We would go through the difficult and complex discussion about a life threatening operation and an operation which, if it was not performed in time, might also be life threatening. Eventually the man would agree to the operation and I would ask if there were any further questions. He would say “No” and his wife would say, “I have just one”. I would say, “What is that?”; knowing what was coming. She would say, “When?” and I would say “Eleven months to two years”. Her face would descend into a look of abject terror and her eyes would cloud over with tears. Believe me, we were functioning in a third world surgical service in a first world country. It was only through hard-nosed performance management coupled with targets that forced that through. We were sending for elective cases at half past seven at night, often not getting out of theatre until eleven; we were operating on Saturdays and other days over the weekend. It was tough; it was hard. It brought us into conflict with the management but solutions had to be found. By the time I stopped practising cardiac surgery just over a year ago at UCLH another couple would come in, same discussion with the man, same question from the woman. This time I would say, “Well, what about next Wednesday or Thursday?” Again she would look aghast and say, “We thought waiting lists were longer; we were planning to go on holiday”. So things have really changed. I think some of these targets, provided they are evidence based and clinically relevant, are very, very powerful. There are issues around targets which are about how the organisation as a whole handles these in a coherent way so that they do not compromise other services. I just felt that I would share that experience with you because I have heard a lot in the press that has implied that somehow or other targets are responsible for many of the problems. Furthermore, I have spent a lot of my working career in intensive care units, often sadly dealing with some pretty destructive wound infections, and if there had not been a hard-nosed target driven culture around MRSA we would not have seen the 50 per cent reduction that we have seen. Again it comes back to choosing very specific targets which are meaningful. That leads me into the next business about where safety and things such as open reporting culture? the Minister has said, is often one that provides the right substrate for good clinical services. On the trust board agenda I believe that quality should be number one and that there should be those three domains of quality: safety, clinical outcomes and patient experience as the sub-headings. I think if we address all of those we will avoid a huge number of problems that have been alluded to during the course of the deliberations of this Committee.

Q1074 Dr Stoate: I just want to examine with the Minister the possible conflict of interest which can be levelled against foundation trusts that there is this risk that they are driven by a commercial culture, they have to in a way suppress bad news and talk up their act. That could possible conflict with their role of providing top quality clinical services to patients in an open and accountable culture. Do you share that as a possibility and how do you think we could put that to rest?

Mr Bradshaw: Under payment by results and free choice all hospitals have to compete for business, not just foundation trusts. There is increasing evidence to show that patients who are exercising their choice and hospitals will attract patients based on their reputation and the quality of care they provide. That is a vital part of the government’s drive to not only give people and the patients more power over the care they receive but also drive up quality across the
service. I would not make the distinction between foundation trusts and non-foundation trusts in that regard.

Q1075 Dr Stoate: Except the foundation trust culture is quite different. They are competing for a different level of financial income. They are putting money aside for future projects. They are managing their finances in a completely different way. They are far more commercially driven than merely effectively going out and winning contracts from PCTs. Surely that must be the case.

Mr Bradshaw: David may have something else to say about that but you are right that the financial structure of foundation trusts is different and its specific aim—the honourable member will know more about this than I do because he was around at the time and probably more engaged in the debate about foundation trust hospitals—was to reward high performing hospitals with more financial freedoms. I think the evidence, as I said earlier, would suggest that the two are not mutually incompatible. If you look objectively at the overall performance of foundation trusts and the rate of improved performance of those hospitals that have gained foundation trust status, it would seem to indicate that having those financial freedoms has helped them improve the quality and safety of their patient care.

Mr Flory: All I would add to that is that choice and competition are hand in hand in that regard. For people to be able to choose where to go to for their care then there is that element of different providers and the competition that creates. What is really important to remember is that part of that competition is not competition on price; the price is fixed through the payment by result system so there is no competitive advantage for a trust in cutting its costs absolutely to the bone to be able to beat the competition by providing at a lower price. That is a very important part of the way the system works, that the price is fixed through the tariff mechanism.

Q1076 Dr Stoate: That is helpful but to go right back, Minister, to what you said right at the very beginning, you said yourself that some of the indicators were “fair” and then they went to “weak” at one point. How was it that the department recommended that this be put forward to Monitor for consideration for foundation trust status if you already had indicators that were showing “fair” or possibly even “weak” in some of their clinical performance?

Mr Bradshaw: I would have to remind myself of the exact chronology, but it was in the June of 2007 that the approval was given by the previous ministerial team for the hospital to go forward to Monitor for consideration. At that time there were no concerns that ministers were aware of that would have justified them refusing that going forward for consideration by Monitor. I cannot recall the exact healthcare check at that time; it would have been the 2007-08 one but it would not have come out until later and it would have been the one that we referred to earlier which the Healthcare Commission said was provisional. That was once the Healthcare Commission was already beginning to ask questions of the trust.

Q1077 Dr Stoate: Yet it was still allowed to go forward and become a foundation trust without too much trouble.

Mr Bradshaw: I do not think it was without too much trouble. There is a process that all trusts have to go through and that process is more rigorous now than it was then but it has become more rigorous irrespective of the experience of Mid-Staffordshire. The decision by Monitor’s board to grant foundation trust status again happened in 2008 before the Healthcare Commission launched its investigation.

Q1078 Dr Stoate: Monitor’s investigation cannot have been that rigorous if they failed to spot anything wrong.

Mr Bradshaw: That is a question you need to put to Monitor. Monitor have explained how they made the decision and they have defended that decision.

Q1079 Dr Stoate: Is it reasonable to keep effectively two regulators? We still have Monitor and now we have CQC. Would it not be better to roll them into one and say that the CQC should just do the whole thing?

Mr Bradshaw: The CQC do do the whole thing in terms of—

Q1080 Dr Stoate: Then why do we need Monitor?

Mr Bradshaw: Their roles are slightly different. Monitor also has what I would describe as a performance management role which we discussed earlier; Monitor has the power ultimately to deal with personnel issues, deal with boards for failing, failed management and so forth. The independent regulator—I think this is a very important distinction not least in terms of public confidence—has to be completely independent from the performance management and from the financial management role that Monitor has in order for the public to have confidence that it is totally independent and its role is across the health and social care sectors. Of course the new one under the CQC not only has more powers but it is integrated across all of those sectors and it has powers that the Healthcare Commission did not have to intervene in hospitals including in foundation trusts.

Q1081 Dr Stoate: I understand that, but you still do not see a case for amalgamating like the three bodies you have turned into the CQC; you do not see a case for putting Monitor into the same umbrella.

Mr Bradshaw: Then who would be responsible for performance managing foundation trusts?
Mr Flory: evidence. simply do not believe that that is borne out by the foundation trust hospitals. I looks objectively at the performance of foundation trust hospitals but the rate of improvement among safety, on patient satisfaction than non-foundation trust hospitals is overwhelmingly faster than it is among non-foundation trust hospitals. I do not think there is any doubt— that the granting of foundation trust status made things worse at the hospital is not actually borne out by the objective evidence because the Healthcare Commission itself said that the quality began to improve as soon as its investigation began, which was a matter of a month or so after the formal approval of foundation trust status.

Mr Bradshaw: No, I do not accept that. At the risk of repeating myself for a third time, if the Committee looks objectively at the performance of foundation trust hospitals it will find that not only do foundation trust hospitals outperform on quality, on safety, on patient satisfaction than non-foundation trust hospitals but the rate of improvement among foundation trust hospitals is overwhelmingly faster than it is among non-foundation trust hospitals. I simply do not believe that that is borne out by the evidence.

Mr Flory: One of the regular pieces of feedback we receive from organisations who have been through the process and become foundation trusts is that it is very, very challenging for the whole board, not just the executive membership. Quite often we look to learn from applications that have gone forward and been considered by Monitor’s board but have been deferred or sent back to do more work. Quite often there are concerns expressed in that, from Monitor’s point of view, about the capability of the board to govern that organisation to the standards that they require and that we would expect. I think the challenge for the board in getting to foundation trust status is very demanding on them. Of course that does not guarantee that things will not subsequently need to change and in this instance—and in one or two other instances that we have seen—Monitor have used their powers to intervene to change key individuals, chair or chief executive at the top of these organisations when things go wrong.

Mr Bradshaw: That is something that certainly will be part of the deliberations that I indicated to this Committee are currently under way within the department at the highest level to consider what legislative changes may be required to address some of the concerns that have arisen out of this case.

Mr Bradshaw: Do you think that the lack of provision in the legislation for the removal or the loss of foundation trust status was, with hindsight, a mistake?

Mr Bradshaw: There is a lot in that, Dr Taylor. I could turn your question around and say what you said about Community Health Councils that a lot of dissatisfaction and much more rapid or is there any other way of opening the door to these sorts of groups? CHCs, where they were effective, did it exactly, which is possibly why they were abolished. Patient forums were beginning to be effective and could have done this. We have now gone to this third group but from the comments we hear from many places they are not being effective in any way. What can you do to drive the LINKs forward to make them work?

Mr Bradshaw: There is a lot in that. Dr Taylor, I could turn your question around and say what you said about Community Health Councils that a lot were not effective which—

Dr Taylor: Yes, there were good and bad ones.

Mr Bradshaw: I do not think there is any doubt—this is abundantly clear in both the Healthcare Commission report and David Colin-Thomé’s report which is very explicit about this—that one of the greatest failings at this hospital was that patients and the public were not listened to. It is all there in the report as to why that was the case and why this happened. I think the point you make is also interesting: where were the overview and scrutiny committees? Who is the democratic regulator of local healthcare? We have already discussed where
Mr Bradshaw: I will certainly have a word with my ministerial colleague who has responsibility in this area.

Mr Bradshaw: I was certainly trying to do a great deal to encourage people to complain. Whenever members of this Committee and other MPs write to me with constituents’ letters saying they were not satisfied with the treatment they had at a hospital or by a GP but they are reluctant to complain, I say, “Please complain because if you do not complain nothing is ever going to change. Hospitals and GPs in the future will be measured on both the level of complaints and how well they handle them and implement the lessons they learn from them.”

Mr Bradshaw: No, I agree with that statement. I think it is extraordinary. There were, as I understand it, two whistleblowers between 2005 and 2008 but they were not related to issues that were contained in the Healthcare Commission report. It is astonishing given what we have discussed earlier about the professional duty of people to raise concerns. If professionals in the NHS do not feel that their concerns are being taken seriously by management they have the unions and the royal colleges as an avenue. If, after that, they are still not satisfied they have total legal protection backed up by the law. Why nobody blew the whistle at Mid-Staffordshire at all. Do you have any comments?

Mr Naysmith: Minister, in your earlier remarks you drew attention to the fact which puzzles us all, the whole mystery about why there was not much in the way of complaints—or noise, as we have called it—until the Healthcare Commission really began to get involved and call for evidence and so on. That is a mystery. The other mystery, given that the secretary of state has assured us that whistleblowers in the NHS are guaranteed full protection backed up by the law, is why nobody blew the whistle at Mid-Staffordshire at all. Do you have any comments?

Mr Bradshaw: No, I agree with that statement. I think it would be accurate to describe the problems that have been faced by Staffordshire LINkS as typically of LINkS around the country. They are specific and they are about the structure, they are about the competence and those things are being addressed.

Mr Bradshaw: The ideal is for that provider to deal satisfactorily with the complaint.

Mr Bradshaw: If it does not, absolutely. One of the first things I did as a minister was insist that all primary care trusts in their annual prospectus which they issue to every household in their areas put the fact that you can complain and there is a system of complaints right up there in a very prominent place with details of how you complain. The vast majority of good hospitals do this themselves. Not only are we doing that, but through the NHS Choices website we are doing what we can to encourage people to complain. Whenever members of this Committee and other MPs write to me with constituents’ letters saying they were not satisfied with the treatment they have had at a hospital or by a GP but they are reluctant to complain, I say, “Please complain because if you do not complain nothing is every going to change. Hospitals and GPs in the future will be measured on both the level of complaints and how well they handle them and implement the lessons they learn from them.”
independent and confidential advice. I have to say, the evidence around the country is very encouraging on this. If you look at the latest staff surveys, if you look at the latest surveys done by one of the nursing magazines there has been a dramatic and constant increase in the number and proportion of NHS staff who say they know how to blow the whistle, that they have done so and it has led to change, and that they would do so again. There has been a year on year improvement in that. You may find it fruitful to ask Public Concern at Work about their experience of the whistleblowing system because they will also say that there has been a huge improvement from the culture of the past. It is a mystery to me why there were not more whistleblowers.

Q1093 Dr Naysmith: It must have had something to do with the culture that was operating at Mid-Staffordshire I suspect. It sounds from what you have just said that you are confident that staff are aware now about what they can do and the protection that is available to them if they do blow the whistle.

Mr Bradshaw: Certainly from the independent surveys—not our surveys—that have been undertaken of NHS staff, that is the case; the vast majority of NHS staff are aware of their whistleblowing rights, that local trusts have an obligation to have clear whistleblowing policies in place and to ensure their staff are aware of them. You are right, Dr Naysmith, there were a whole host of problems in this hospital, one of them was a culture of being a closed institution that clearly did not mitigate in favour of people feeling that they could raise concerns. However, it still does surprise me that, particularly some of the professionals involved, did not go further than they did in terms of raising concerns.

Q1094 Sandra Gidley: I want to probe a bit into this. We heard in the earlier session from Dr Daggett that Mid-Staffordshire does have a whistleblowing charter. He read some of it out to us and it seemed to be quite clear that the staff were allowed to escalate a complaint to a number of agencies which were specified (the Audit Commission and the Environment Agency were mentioned) but there was no mention of a regulator in that. Any member of staff looking at the trust’s whistleblowing charter would not have felt empowered in any way to go to the RCN or the Healthcare Commission. Is there not a case for reviewing those charters? What you have just said is very good but clearly that is not penetrating to the staff on the ground.

Mr Bradshaw: I hope I made clear what I said earlier that I obviously think there has to be a hierarchy of actions. The honourable lady will know more about this being a healthcare professional herself, that you raise it first of all with your manager and then there is a succession of steps you go through. It is right to expect people to go through those steps rather than going immediately to the local media or to the independent regulator. Any hospital should make quite clear that the independent regulator is there specifically for these sorts of issues. To be fair to the Healthcare Commission it was in the end only as a result of the complaints that were brought to its attention that it become involved and engaged in this hospital. So it did happen, even in the case of Mid-Staffordshire. I would expect any good whistleblowing policy to make quite clear what avenues are available to people and that is certainly what we make clear from the centre.

Q1095 Sandra Gidley: Do trusts have to lodge their whistleblowing policies with anybody so that it can be clear that it is adequate? Clearly the policy there was less than adequate.

Mr Bradshaw: Yes.

Q1096 Sandra Gidley: Who do they have to lodge them with?

Mr Bradshaw: They have to have them and they have to make clear to their staff that they have them.

Q1097 Sandra Gidley: Who actually looks at them to make sure they are worth the paper they are written on? Is this back to the board?

Mr Flory: It does come back to the board. Expectation and good practice would be that that policy, like all policies, would be available on the trust’s website.

Mr Bradshaw: If there is a feeling by anyone that a whistleblowing policy in a trust is not satisfactory, then bring it to our attention.

Q1098 Charlotte Atkins: You have been very clear that the buck really is with the hospital management and the chief executive in terms of whether they are delivering good patient care and patient safety. You have also said in the House that there should be no rewards for failure in the NHS. Despite all that we now have a former chief executive of Mid-Staffordshire being allowed to resign without any disciplinary proceedings and also receiving £110,000 since stepping down. I cannot see how this can be justified given that we have a very clear policy that there should be no rewards for failure.

Mr Bradshaw: I share your surprise at the way that has been handled and these are questions you might like to put to the interim chief executive when he appears before you in a moment.

Q1099 Charlotte Atkins: I think we certainly will be doing that because it seems to me that the chief executive presided over massive failures and clearly he should not be allowed to get away with it. You also made it very clear in the House that you expected the report and investigations of the former chief executive to be made public. I wonder when that is going to happen.

Mr Bradshaw: Again that is a question you might want to put to him.

Q1100 Charlotte Atkins: It is not in your power to do that.

Mr Bradshaw: It is not in our power to force it to happen but the secretary of state has written to the board requesting that they publish it.
Q1101 Charlotte Atkins: Talk me through the procedure because clearly this is a matter of huge public concern not just in Stafford but Staffordshire as a whole but clearly right the way through the NHS because we must learn the lessons for the whole of the NHS from the failures of Mid-StAFFORDSHIRE.

Mr Bradshaw: I think the secretary of state has made it abundantly clear since he has been in office that there should be no rewards for failure. If you look at the action we took in regard to Rose Gibb, the former Chief Executive of Maidstone and Tonbridge Wells, where, against legal advice we stopped that payment being made; she took us to court and we won. I think that shows that the secretary of state is absolutely determined to ensure that there is no reward for failure in the NHS. The public will not tolerate rewards being paid to managers who have been responsible for such abject failure. In the case of foundation trusts, as I have already indicated earlier in answer to some other questions, our powers of intervention are limited and that is something that we are considering in the context of what further powers we may need to consider taking in order to ensure that such a situation cannot be repeated.

Q1102 Charlotte Atkins: So the £110,000 was actually awarded by the hospital board, was it?

Mr Bradshaw: These are really questions you need to ask the interim chief executive, both about how the process happened—it is their responsibility—and about the amounts and what the amounts represent.

Charlotte Atkins: Thank you, we will do that.

Q1103 Sandra Gidley: There have been lots of calls for an independent inquiry into Mid-StAFFORDSHIRE; what is the problem with having one?

Mr Bradshaw: I think the secretary of state has summed this up rather well by saying that we have not ruled out a further inquiry but we would need to be convinced that it would add real value. We feel that the reference that is often made to the Bristol heart babies inquiry of course refers to a time before we had an independent regulator. One of the very purposes for setting up independent regulation in the health service which we have only had since 2000 was to obviate the need for full, lengthy, very expensive public inquiries into things that went wrong in the NHS. I also think—and I hope that the Committee shares my view—that the Healthcare Commission did a very good job. I am not aware that its report has been criticised for missing or not putting its finger on what went wrong in this hospital. We have had two subsequent investigations which I think, given the timescale in which they were carried out, have been very thorough and had led to significant action on behalf of the NHS and the Department in its response. If there are issues that people feel have not been addressed and not been properly looked at we have made it quite clear that we are always prepared to consider those. The secretary of state and I also had a meeting with Staffordshire MPs this week on this issue at which representations were made again to the secretary of state and he undertook to reflect further on them. If one looks at the comments of Sir Ian Kennedy who, after all, chaired the Bristol inquiry and was the chair of the Healthcare Commission, his view was very clear. He did not think that a full public inquiry would be sensible or necessary in these circumstances given the independent inquiries that have already been taken. However, we are open to persuasion.

Q1104 Sandra Gidley: Do you think that the independent inquiries fully related with some of the patients and patients’ representatives? That seems to be where the call is coming from. There seems to be a feeling that there have been a lot of reviews, some of these have covered the same ground but I think it comes back to a lack of engagement with the people who use the hospital and their relatives. Is there something that could be done there to give more confidence?

Mr Bradshaw: Again I am not here to defend the Healthcare Commission or the work they did, but I think it is unfair to say that the Healthcare Commission did not engage with patients. If one looks at what happened once the Healthcare Commission announced it was having its investigation it was deluged with evidence, submissions and requests to give evidence and talk to it. It was on the basis of a lot of that evidence that its report was written. Since then I know that the chair of the Care Quality Commission, Barbara Young, has been up to Stafford and has spoken to people. I know that David Colin-Thomé and George Alberti did so as part of their reports and they have also agreed I think to go and to a public meeting in the very near future to discuss their reports in more detail and allow whoever wants to to question them. It is also very important not to ignore the fact that every single patient or family of a patient who feels they may have been the victim of poor or dangerous treatment at that hospital has been offered a completely independent clinical review of their case notes. I am not sure and I do not think the secretary of state is sure what extra value a long and expensive public inquiry may bring. I hope that everybody’s priority now needs to be to ensure that that hospital improves and continues to improve. The danger which I think was articulated very well by one of the other Stafford MPs in the debate, Tony Wright, is that there is a danger that one of the repercussions of a long and expensive public inquiry could be that it actually diverts attention, resources and commitment from the hospital in its immediate job of improving care.

Q1105 Sandra Gidley: You mentioned the independent case note review and the submission we have had from the Cure the NHS organisation makes it clear that they do not feel it is independent because it is set up by the hospital and the hospital’s own board is managing it. Is there any
way, at the very least, that some reassurance could be given that there will not be further cover-ups or problems ignored?

Mr Bradshaw: Yes, and those were concerns that were raised personally with me after one of the adjournment debates we have had on this issue recently. I think I am right in saying that it is no longer the case that the hospital is managing the system; it is being managed by the PCT, but David may want to confirm that.

Q1106 Sandra Gidley: Are there some things we do not know yet, such as the reasons behind the number of avoidable deaths at the trust?

Mr Bradshaw: Yes, but as was made clear in the Healthcare Commission report itself and the very careful statement that was made by Ian Kennedy afterwards, it is not possible—as some people did, including I am afraid, a lot of the media—to extrapolate a number of avoidable deaths from the HSMR figures. We have gone over that in some detail before and in fact it is very misleading to do so. The only way that we will know and that families will know how many avoidable deaths there were is as a result of the individual case note reviews and that is a process that is now underway.

Q1107 Mr Symes: Since 1997, since the Labour Party has been in office, you have had an inquiry into the events of Bloody Sunday in the 1970s in Northern Ireland; you have had an inquiry into BSE under the previous Conservative Government. This is a fairly recent thing. If this was a rail crash involving hundreds of people there would be a public inquiry; I am sure there would be. I understand what the Minister says, but I just think there ought to be some way of allowing the families to actually give evidence and to get to the bottom of things for their peace of mind. I think the government really ought to reconsider this.

Mr Bradshaw: As I have already said, we have not ruled out a further inquiry. I think Mr Symes does not take into account in his question the fact that we have an independent regulator whose job it is to have these investigations. I am not aware that he has any criticisms of the job that is done but, for the reasons I have already articulated, on balance we think at this stage it would be unhelpful to government but actually to this hospital and to the local health community. That is a balanced judgment.

Q1108 Dr Taylor: The last question, Minister, could take several hours so I am going to abbreviate it. It is a question about the European Working Time Directive. We have heard very strident calls from some of the colleges but now other colleges are coming on board with the College of Surgeons and really feeling that we are going to be in big trouble on the first of August. There is a recent work from the College of Physicians looking at what is happening in the USA where they agreed that they will keep it at 80 hours with certain restrictions. All I am asking is will you look at the recent work as well as from the College of Surgeons and the arguments in favour of a speciality opt-out for some specialities and certainly 56 hours rather than 48 hours. It is merely just to raise the question and ask you to bear in mind that it is not only the surgeons who are jumping up and down now, it is the other colleges who have realised how difficult it is going to be.

Mr Bradshaw: Let me say something in general about this then I think Bruce, who is one of the world’s leading experts on this issue, will want to say something I am sure. First of all, people have had ten years to plan for this and the vast majority of hospitals have done so and they have implemented it without any problems. I am afraid to say there is no excuse for not being prepared. I hope the Committee would also agree that tired doctors are not only dangerous for patients but they are dangerous for doctors. I was at a Royal College of General Practitioners dinner last night where one of their officials was telling me of two recent cases of doctors who had died driving home from hospital after very long shifts, having fallen asleep at the wheel. I think there is a very serious issue here and there are details that still need to be worked out, but I am confident that the health service would be in a position to implement this. It will require the re-organisation of services in some hospitals and I think it is not fair to say that George Alberti says that this was a problem or will be a problem at Mid-Staffordshire; I think he said it had the potential to be a problem at lots of places if they did not address some of these organisational issues and work out very clearly whether they needed to be doing X and whether they could share Y with another provider and so forth. Bruce may want to say more about that.

Professor Sir Bruce Keogh: It is a perplexing question. I do not agree that the first of August will be a disaster but I do think that it is going to be very challenging for organisations both managerially and clinically particularly around the areas of training, workforce and perceptions about the impact on safety. I have personal experience of this because my colleagues and I introduced the 48-hour limit at the Heart Hospital in April 2007, so two and a half years ahead of the deadline, as it were. What is absolutely clear in this is that it requires a very significant cultural change. I think that cultural change, if I can be so bold, is perhaps more difficult for senior clinicians who find the concept difficult. I put myself in that category because we have been brought up in a different way. We have been brought up in a way where we have trained for long hours, we have used that to get exposure to rarer and more complex things and you will be very familiar with that argument. What has gone through my mind are a couple of things. Firstly, why does it take six years to train a cardiac surgeon in the UK and only three years in the US? That has to pose a spark, if you like. The second is that we are seeing a big generational difference across the board not just in medicine in the way the
younger generation look at their work life balance. Thirdly, you will be aware that there is a report coming out from the Royal College of Physicians today about feminisation of the workforce. In relatively short order we are going to have more women doctors than male doctors and the social demands on women are different to those on men. I think what may at the moment appear to be quite a threat may actually be the stimulus we need to innovate in the way we train people so that we are adopting a completely new approach and not just a modified approach. If psychologically you adopt the attitude that you are just going to modify what you do now, then this is a very difficult problem. If you disassemble what you are doing now and ask how can reconstruct it in a different way and how can we completely review the way we train doctors and the way we handle handovers at the end of shifts, then I think that puts us in a different place in terms of our attitudes to the European Working Time Directive. The Directive actually applies to individuals; it does not apply to rotas. To get it to apply to rotas is more tricky than getting it to apply to individuals. One of the things I did a few months ago was establish a working group to look at this which has representation from everyone ranging from the royal colleges to the Department of Health and the BMA. I think we are making pretty good progress and out of that has come a working group on derogation. In this country there are about 6,800 rotas. We have applications that are being considered at a meeting tomorrow for derogation of 220 of those. Of those most are legitimate requests for derogation because they are around physical reorganisation of plant or services and some are related to difficulties of recruitment into some specific specialities (neuro-surgery would be an example). Following the derogation meeting tomorrow a report will be sent to David Nicholson, then to the secretary of state and should come to the House before recess so that you will have an opportunity to deliberate on that. In the meantime the secretary of state has also asked Sir Christopher Edwards, the new Chairman of Medical Education England, to commission Postgraduate Medical Education and Training Board (PMETB) to look at the potential impact of the European Working Time Directive on training. I think a lot of this is about whether we are just trying to do more of the same or whether we are actually looking to innovate, to improve the training and to improve the life for those who deliver the service. I have worked a one in two as some other people in this room will have; I know what it is liked to be called multiple times during the night and sometimes feel physically sick because you are so tired and then still have to work the next day. We cannot go back to those days. It is not right. It is not right for the staff; it is not right for the patients. One of the other claims that is being made is that somehow or other they do things differently in Germany. We have looked at this quite closely. The Directive is quite clear; it does not allow for a sectoral or speciality opt-out. We have had our lawyers look at this very, very closely. There are different ways of applying the Directive and it has been applied differently in Germany to here. Here it is enforced by legislation and in Germany it is done through collective agreement. Therein lies the difference. However, in both the individual has to opt out of the European Working Time Directive. The reason why we are very cautious about recommending a mass opt-out, if you like, is that in terms of delivering a clinical service you need to have a good, coherent rota and to do that you need to know exactly who is going to be on which day of the week and what times. We are just worried about people being bullied or harassed into opting out when they really do not want to. That introduces a whole new level of complexity into the rota which itself will pose safety problems. Some of these issues are detailed in a letter to the president of the Royal College of Surgeons on 27 April of this year. Those are some headline views, but when the deadline comes we have to be vigilant because it is difficult and it takes time for the culture to settle in. What I have noticed at the Heart Hospital was that whilst it was difficult initially soon people started to find ways of really making it work for the benefit of both the staff and patients.

Dr Taylor: Thank you. You crammed a vast amount into a short time for which I am very grateful.

Q1109 Jim Dowd: I agree with you very strongly about the length of time it takes to train clinicians in this country compared to elsewhere. In passing I would mention the role of the royal colleges as gatekeepers in all this. I think the concern, certainly that has arisen recently over the impact of the European Working Time Directive, is not so much on the cover issue (I understand what Ben said, that organisations have had a lot of time to prepare for this and should be ready). I think it is more the subtle and nebulous views that are now being expressed about the impact on training and seeing a mix of cases. If that is the case, the time it takes to train clinicians is surely going to increase rather than decrease.

Professor Sir Bruce Keogh: I think in some areas that is true, but I still come back to my question: why in heart surgery does it take three years in the US versus six years here? The answer is: a different culture, a different approach and different methodologies for training. That is the direction we need to go in. It may be that in order to get exposure to rare conditions you need to prolong training and the colleges I am sure will look at that, but there are also other issues. If one feels that this has an impact on training then we need to look at the relationship between senior consultants and newly appointed consultants. That has been an issue in the speciality in which I worked and almost all units now have a good mentoring system and good team work. Again a lot of this comes back to team work and how senior, more experienced clinicians support less experienced clinicians, their younger colleagues who are the future of the NHS.
Mr Morton: I wish!

Mr Morton: I cannot be analytical but I can give you some impressions. Certainly it strikes me as an organisation which has lost its way for a period of time. I do not think it is sudden and if you track back through the history there were clearly concerns about the performance of the trust back in 2001 which tended to go below the water line and then reappear again. I think it potentially suffers from a condition which can affect many district general hospitals around the country. It is very easy, I think, as a DGH to become isolated. I think it is really important that you have linkages with other DGHs and other teaching centres so that you refresh the knowledge and have an awareness when you work in an organisation like Stafford Hospital of what happens in other organisations, how the world moves there. There has certainly not been a strong history of that in this area, unlike the home patch where there are very strong clinical linkages and have been for many years. I do not think it is something you can fix quickly. I think also there is an issue with the staff. They do feel they have been battered and bruised for a long period of time. That means that when you are in that sort of environment very often you accept the status quo as being perceived as the norm and that can potentially dull senses over a long period of time.

Mr Morton: I think we have quite a number of priorities that we are trying to move forward. There is an issue about public confidence; the public in the area have a right to have confidence in their local hospital. For many of us who work in DGHs they tend to be the pride of the local community; it is probably the most precious asset that you have in a local town and it is one that all the public want to succeed, they want to have confidence in it and they want to know that when they need it it is there and it will provide them with not just good clinical care but good general care; it will look after them. We have clearly got a lot of work to do to restore that pride and trust back in the hospital. We have also got to do a lot of work internally. I do think that the staff are pretty battered and bruised over the last two years. They feel that they need some light at the end of the tunnel; I hope we are trying to give them that; I hope we are trying to give them a light at the end of the tunnel. If we do not do that, they feel they need some light at the end of the tunnel; I hope we are trying to give them that and, importantly, take action on the back of that—even if that action is to say, “We hear what you say, but . . .”—then that is the only way an organisation can go forward. It has to change culture and that is not going to be a quick fix, I have to say.
Q1119 Chairman: You may have heard the exchanges earlier in that there has been a debate about whether or not there should be a public inquiry in relation to what happened at the trust. Do you have a view about that?
Mr Morton: From a personal perspective, in the eight weeks I have been there, we seem to have been perpetually under the microscope. From my point of view I want to see the organisation start to look forward. I think the staff need to look to the future. I think it could have a disabling effect looking over their shoulders again for the next inquiry to come. The report that we received from the Healthcare Commission and the subsequent reports, particularly from Professor Alberti, were pretty analytical and they certainly went very public.

Q1120 Chairman: In our first evidence session on patient safety—which is several months ago now—I do recall one of the witnesses saying in part that when things come out as something that has happened inside part of the National Health Service and it becomes public it is very demoralising not just for that department but overall within that institution. Would you say that would be the case?
Mr Morton: I think that is true. I think there is a lot of pride from NHS staff in the organisation within which they work. There is a lot of pride in being part of the NHS. When we get it wrong it hurts because the only way we can improve is to learn from mistakes, to put things right and hopefully ensure that that mistake does not occur again.

Q1121 Dr Naysmith: Could I ask you first of all, Mr Morton, why do you think you got the job of taking over what many would call a failing trust? Was it something you applied for or were you headhunted for the job?
Mr Morton: I received a phone call from Monitor asking me to go in.

Q1122 Dr Naysmith: Was that based on your reputation?
Mr Morton: I have no idea.

Q1123 Dr Naysmith: It just came out of the blue.
Mr Morton: Yes.

Q1124 Dr Naysmith: Good luck to you.
Mr Morton: Thank you.

Q1125 Dr Naysmith: Are you satisfied now that the trust is providing a safe service?
Mr Morton: I do not think we can ever be satisfied that we are providing the safest possible service in any hospital in the country or in any GP practice so it is going to be about constantly learning. I think what we have to have—and we are beginning to get to—is a real awareness that where we make mistakes, where we have potentially a near miss which does not cause damage but where a mistake could have occurred, that we learn from that. One of the things the chairman and I are particularly trying to push over the last six to eight weeks is much more of an open culture, much more of an internal reporting culture, the ability to raise concerns with us as quickly as possible. All members of staff at the trust with their May payslip received a letter from me reminding them of their responsibilities to raise concerns with us, to report incidents, that the organisation would take a non-disciplinary approach to incidents that were reported and the only time we would look potentially less favourably on that would be if it contravened professional regulations, if it involved a police inquiry, if it was not the first time that that error had occurred and we would also, if I am honest, take a fairly dim view of incidents occurring that are not reported.

Q1126 Dr Naysmith: So you are confident that it is safer now than it was.
Mr Morton: I do think it is safer now. I do not think that that is a quick fix since I have been there; I think the culture has started to shift from the day the Healthcare Commission came in. I think that was a very sobering experience; the whole process of the report was an incredibly sobering experience and that has helped us to raise standards and I think it will go beyond the walls of Mid-Staffordshire.

Q1127 Dr Naysmith: Why do you think the Cure the NHS group—I am sure you are aware of them—are still finding so many examples of unsatisfactory care in the trust?
Mr Morton: I think we have a much better reporting culture within Mid-Staffordshire and I may go so far as to say it is probably a more honest reporting culture than we might find in many of the hospitals at the moment because it is very much in the public domain. There are incidents still occurring; there are incidents that are occurring in my local hospital in Chesterfield. There will always be incidents where we have a public service delivered by people to people; we will make errors of judgment, we will make mistakes. The important thing is that we learn from those and we have a structure to minimise the impact of mistakes like that. There is certainly an attraction from the Cure the NHS for people reporting their concerns which I actually welcome and I am keen that they not only report them to Cure the NHS but they report them to me as well.

Q1128 Charlotte Atkins: You are the Interim Chief Executive; are you full time?
Mr Morton: I am sharing my time between Chesterfield and Mid-Staffordshire at the moment.

Q1129 Charlotte Atkins: So you spend 50 per cent of your time—
Mr Morton: A little bit more than 50 per cent in Stafford; it is about three days a week, sometimes four.
Q1130 Charlotte Atkins: What worries me is that you have a hospital in crisis and you have effectively what is a part time chief executive on a temporary basis. Do you think that is the right way forward for a hospital which has suffered so much in the last few years?

Mr Morton: It is difficult for me to answer that because Monitor made the call. There is absolutely not doubt that I think it needed a different pair of eyes in there. It does need to recruit and in fact the date has now closed for applications for the substantive post. The interviews for that I understand are due to be held at the end of June or beginning of July so that a substantive appointment can be made. I would absolutely agree that what the hospital needs is a full time chief executive who has a long term future with the organisation and who will bring it forward and provide the appropriate leadership.

Q1131 Charlotte Atkins: When does your contract end?

Mr Morton: I do not have a fixed term contract until the decision is taken that I go.

Q1132 Charlotte Atkins: So until you have a replacement you will continue.

Mr Morton: It is a flexible contract; I have no idea when it will terminate.

Q1133 Charlotte Atkins: Can you tell us why the former chief executive received £110,000 since he stepped down?

Mr Morton: It is not possible for me to answer because I do not deal with the contractual position of the chief executive; that is dealt with by the chairman and by the non-executive directors. What I do know, as accountable officer, had to reassure myself about was that the payment that was made was no more than the contractual entitlement.

Q1134 Charlotte Atkins: Do you think we could get the detail of that information?

Mr Morton: I would have to refer to the chairman on that.

Q1135 Charlotte Atkins: You could approach the chairman and you will let us know what the chairman says.

Mr Morton: I can ask the chairman on your behalf, yes.10

Q1136 Chairman: So that we can have that information for our report. Will you make the report of the investigation into the former chief executive public?

Mr Morton: I am afraid I cannot answer that one either; the report was to the chairman, it was not to me. Again I can only pass that back to the chairman.11

Q1137 Charlotte Atkins: Are you saying you know nothing about this? We have had this culture in the past of buck passing and we seem to be having more buck passing going on now because we are not getting from the chief executive important information that people want to know about in Staffordshire—particularly in Stafford—as to whether there are going to be rewards for failure within the NHS.

Mr Morton: It would have been quite inappropriate for me to have any involvement in the process around the substantive chief executive as interim. It has to be led by the chairman. The chairmen of hospital boards are responsible for the hiring and dismissal, resignation or whatever of chief executives. It is not a role that I can perform; it has to be the chairman of the non-executives.

Q1138 Charlotte Atkins: The Minister of State, Ben Bradshaw, invited us to ask you on the basis that we might get answers from you.

Mr Morton: I cannot comment on what the Minister said. All I can do is refer you to the fact that the report went to the chairman of the board and not to me.

Q1139 Charlotte Atkins: On the basis of the fact that you cannot answer those questions, do you think that the minister of state and in fact the secretary of state should be looking very carefully at the rules under which foundation trust hospitals run and that we should amend those to ensure that there is more openness and transparency?

Mr Morton: I think you need to look at NHS foundation trusts not as a global entity but individually. You have a particular issue in Mid Staffordshire. There is no doubt that it was a very closed culture and I absolutely accept that. When I arrived and the chairman arrived at the end of March they had no board focus on clinical measures, clinical outcomes, clinical indicators or complaints. I absolutely accept that and we have moved to try to put that right. I think we also need to look at how other NHS foundation trusts have worked who have a very open structure with regular meetings of councils of governors where absolutely the same papers that go to the board of directors also go in

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10 Note by the Interim Chair of the Trust: The former Chief Executive of the Trust received more than his contractual and statutory entitlement, which included payment of six months' notice. No ex-gratia payment was made.

11 Note by the Interim Chair of the Trust: An investigation was undertaken by Peter Garland into the conduct and performance of the former Chief Executive of the Trust. The Trust is not able to release this report as it is restrained by law, it is a confidential report and contains personal data. It does not deal with the expenditure of public money. I am advised that ICO Guidance indicates that information in respect of disciplinary matters would not normally be disclosable. Further, Mr Yeates reasonably expected that the information contained within the report and that which he provided as part of the Peter Garland investigation, would not be disclosed and he has via his solicitor objected to disclosure.
Q1140 Charlotte Atkins: Should we then legislate to make sure that the good practice is the normal practice in all foundation trusts?

Mr Morton: I do not have a view on that.

Q1141 Charlotte Atkins: In your own hospital trust presumably you have this openness and your board meets in public.

Mr Morton: The board in Chesterfield does not meet in public. It has the council of governors which meet in public which take the same reports.

Q1142 Charlotte Atkins: So your board does not meet in public.

Mr Morton: It meets in public annually, not more regularly.

Q1143 Charlotte Atkins: Again the minister in the previous session made it very clear that the secretary of state and himself would regard openness as being vital and for the hospital board to meet in public except for the odd occasions where there might have to be some sort of confidentiality due to contractual reasons.

Mr Morton: Yes and all foundation trusts received a letter to that extent from the minister and all boards are considering it. I can tell you what the position is in Chesterfield now; I am not anticipating what the position might be in the future.

Q1144 Charlotte Atkins: Why did you decide in your trust that you should meet in secret?

Mr Morton: I would not describe it as meeting in secret. The public meeting is the council of governors: that was to give them the prominence with the general public to receive exactly the same reports so that the elected representatives—the majority on the council of governors, as you know, are publicly elected from the membership so that it has a democratic majority within it—receive exactly the same reports, particularly on clinical performance, clinical governance, clinical outcomes, financial reports, service performance. That is, if you like, to all intents and purposes a public meeting in our view.

Q1145 Charlotte Atkins: It may be but the issue is—and we heard it from the minister of state—that the buck stops with the hospital management board. Why, therefore, does the hospital management board not meet in public?

Mr Morton: Are we talking about Chesterfield?

Q1146 Charlotte Atkins: Yes.

Mr Morton: The position in Chesterfield is that the board, when it was established, decided to promote the council of governors as the public meeting. Board members attend that—non-executive directors as well as executive directors—with the council of governors in the same room and with the public there. As I say, it takes exactly the same reports. It was a conscious view to elevate the prominence and the role of the council of governors and to give it real power and real teeth.

Q1147 Charlotte Atkins: It seems to me that a change in the law is necessary. Moving on to other issues, what arrangements are there now in Mid-Staffordshire to allow clinical and other staff and patients to raise their concerns either through LINS or through the PCT? Clearly what we have established from the reports that have been produced and from our interview with the minister of state, there has not been a reporting culture and a lot of the concerns only really came into prominence about the time when the Healthcare Commission investigation started in March/February 2008. What arrangements are there now to ensure that those channels are fully open?

Mr Morton: We have put in place a number of things. First of all, I mentioned that I have written to all members of staff personally along with their May payslip to encourage them and require them to report concerns that we will investigate and we will go back to the individuals with the outcome of those investigations. I have been very public locally in offering to meet personally any patients or any families and relatives of patients who have had a poor experience to understand their concerns. I have met with quite a number of families and relatives and at the conclusion of the meeting we have invited them (because clearly they are very interested and very enthusiastic about speaking to us) to join our patient councils and we have had about a 75 per cent take up of that which I think is really, really promising. We have committees linking into each of the divisions where patients can exercise a voice. The medical director is now a full member of the medical division committee so I hope that we will be able to better engage with the medical staff which has clearly been an area that was weak in the past.

Q1148 Charlotte Atkins: Have you met with Cure the NHS?

Mr Morton: The chairman has met with them on several occasions; I have met with them once. I have offered to meet with them, but they declined.

Q1149 Charlotte Atkins: Why did they decline?

Mr Morton: I have no idea.

Q1150 Charlotte Atkins: Did you use the law firm Carter-Ruck to send a letter to a newspaper than planned to publish information supplied by one of your consultants about unsafe services?

Mr Morton: Yes we did.

Q1151 Charlotte Atkins: Why did you do that?

Mr Morton: Because the report that we had seen a draft of was factually incorrect.
Q1152 Charlotte Atkins: Presumably they went ahead and published.
Mr Morton: They did not publish, no.

Q1153 Charlotte Atkins: Why did you not just ask for a right of reply?
Mr Morton: The damage, I think, would have been in running a report which was factually incorrect. We felt it was better for the report not to be produced in the first place. We did exercise our right to bring that to the attention of the newspaper and on the basis of the information we gave they decided not to print the story.

Q1154 Charlotte Atkins: So the information supplied by the consultants, was that inaccurate? Or was the report that was going to be produced by the newspaper inaccurate?
Mr Morton: I only saw a draft of what they were intending to print. It was one consultant.

Q1155 Charlotte Atkins: What about the information from the consultant? What has happened to that?
Mr Morton: I have not seen the information from the consultant.

Q1156 Charlotte Atkins: Who would see it?
Mr Morton: As far as I understand he spoke to a reporter.

Q1157 Charlotte Atkins: I am assuming it is a he; am I right?
Mr Morton: Yes you are.

Q1158 Charlotte Atkins: Has he raised these issues within the hospital trust?
Mr Morton: He has had discussions with a medical director. We asked a medical director to speak to him to understand his concerns and hopefully he is being reassured about his concerns. There is a particular issue around nurses on ward rounds, as you know.

Q1159 Charlotte Atkins: So he is not being suppressed.
Mr Morton: He is not being suppressed at all, no. What I would say is that the previous medical director excluded him from the premises; when the new medical director arrived we reversed that.

Q1160 Charlotte Atkins: Why was he excluded from the premises originally?
Mr Morton: That was to allow an investigation to take place. It was not necessary to exclude him so we restored him to work.

Q1161 Charlotte Atkins: Why would you exclude him because an investigation is happening? I do not understand. Was it an investigation into him personally?
Mr Morton: There was a separate investigation running into his conduct, yes.

Q1162 Charlotte Atkins: How much did it cost to involve this law firm, Carter-Ruck?
Mr Morton: I cannot remember.

Q1163 Charlotte Atkins: Can you let us know?
Mr Morton: I can let you know, yes.
Charlotte Atkins: Thank you.12

Q1164 Jim Dowd: Mr Morton, I realise you are in an unusual position, pro tem at least. You say you do three days at Mid-Staffordshire and two at Chesterfield. I would be interested to know who runs Mid-Staffordshire on the two days you are not there and what is happening at Chesterfield on the three days you are not there.

Mr Morton: It is a bit more flexible than three and two—I was at Mid-Staffordshire four days last week—but I take the point you are making. The executive team at Chesterfield is fairly long established; it has a very experienced non-exec; it has a very strong board. It is not facing any severe challenges; its performance is good in all respects clinically and performance-wise. That might be one of the reasons why Monitor suggested that I might want to spend some time in Mid-Staffordshire. In terms of the time in Mid-Staffordshire, between three and four days, it is not unusual in any hospital for the chief executive to have external duties for one to two days a week. What I have had to do is cut cloth accordingly so on the days I have been in Mid-Staffordshire and therefore not found the time to be able to engage more widely with the West Midlands health community which you would normally do, and I have had to pull out of some events in the East Midlands to try to spare the time. It has been very much focussing on the time on where I hope it will have the most positive impact.

Q1165 Jim Dowd: Would I be incorrect to adduce from that that the role of a chief executive of a foundation trust is actually just a part-time job?
Mr Bradshaw: I do not think it is a part-time job, no.

Q1166 Jim Dowd: So I would be wrong.
Mr Morton: I think you would be wrong, yes.

Q1167 Jim Dowd: The model of management that you had discussions with Charlotte about previously, you say the board meets privately but the governors meet in public once a year.
Mr Morton: Is this Mid-Staffordshire we are talking about?

Q1168 Jim Dowd: No, Chesterfield, where you have your well-established organisation that runs itself. The directors are at the AGM as well along with the governors. One of the criticisms of foundation trusts is that they look a lot like commercial organisations. If you ask me, that is the way a plc runs.

Mr Morton: I will just make a couple of corrections, if I may. The council of governors at Chesterfield

12 Note by Interim Chair of the Trust: Carter-Ruck’s fees were £3,250 excluding VAT
meets every six weeks in public, not annually. The non-executive directors and the executive directors are invited to attend—most of them do attend—every six weeks. They take exactly the same papers that have been to the meeting of the board which would have taken place a week or two earlier and the main reports they look at are the clinical governance and clinical performance reports and the hospital performance reports.

Q1169 Jim Dowd: That is not now the case in Mid-Staffordshire, is that right? The board does meet in public.

Mr Morton: The board in Mid-Staffordshire met in public last month. At the moment it was planning to meet on a quarterly basis; we have since received a letter from the department and so I am sure that Mid-Staffordshire, along with all other boards, will be reviewing the frequency of its public meetings. The council of governors at Mid-Staffordshire meets about six times a year, so not as regularly as Chesterfield, and that does meet in public.

Q1170 Jim Dowd: If the board is meeting in public now at Mid-Staffordshire and you described Chesterfield where this does not happen as a well-run organisation with no particular threats, how is Mid-Staffordshire disadvantaged by having to do this?

Mr Morton: I do not think it is disadvantaged. I think it has a far less mature public face in terms of its council of governors than Chesterfield and many others. Chesterfield has been a foundation trust for five years so it has had the ability to build its public face within the council of governors and to elevate the role of the governors so that they are providing real scrutiny in public session with the board of directors. Mid-Staffordshire has only been a foundation trust for just over a year. I think frankly it never really got the chance to become a foundation trust because within a month the Healthcare Commission were in. Consequently I do not think it had the ability to reach out into its local community as it should do to try to engage with the wider local population. Certainly those foundation trusts that have been around for a couple of years have built very strong links into local authorities, voluntary groups, partnership agencies, local area agreement fora. Speaking locally for Chesterfield, the hospital is now much more engaged with the local community than it ever was and is seen as a key local partner, as a major employer, a major training agency, a major purchaser of goods and services locally.

Q1171 Jim Dowd: You say there is a clinical director who was there before the trouble started.

Mr Morton: One of the non-executive directors—there is only one remaining—and he has been on the board for about 16 months.

Q1172 Jim Dowd: Most others have come on board since the Healthcare Commission report. Throughout the organisation at Mid-Staffordshire there must be a number of people who were there during the difficult times. Have you detected any sense of recognition of failure amongst them or is it just an embattled minority that the world does not understand?

Mr Morton: I think the staff generally feel a heavy degree of responsibility for the care they have delivered and I would be disappointed if they did not.

Q1173 Jim Dowd: Do they recognise the need to change?

Mr Morton: I think we do recognise the need to change and I think the change started well before I got there and certainly pretty much as soon as the Healthcare Commission arrived. There were major changes made in 2008 to A&E in particular when the Healthcare Commission voiced their concerns about that. They returned in February of this year, unannounced, reviewed the A&E services and gave them a pretty clean bill of health. It was actually quite reassuring to be asked last week to host a visit from a foundation trust in the south of England that was struggling to deliver A&E services and they were pointed in the direction of the A&E department at Mid-Staffordshire to look at how it can be done. We can come out of the position we are in at Mid-Staffordshire and I think when you get into a position that we have been in where we were not providing good care—I am not making any excuses; we did not provide good care for a period of time, we let the local population down—that is something we can come out of, we can build on it and people can come and look at Mid-Staffordshire in the future and hopefully learn lessons.

Q1174 Jim Dowd: Finally, what changes have been put in place or are being considered by the board to ensure there are adequate checks and balances and scrutiny of the way the trust is run overall?

Mr Morton: We have put a number of measures in already. Myself and the chairman were quite surprised when we arrived at Mid-Staffordshire that there was not a focus on clinical governance and clinical performance so we established from the first of April a health governors committee which I guess many other hospitals have had for some years, which is a board level committee, its co-membership is the medical director, director of nursing and the non-executive directors. The non-executive director that is chairing that is Sir Stephen Moss who had a long career as a very senior director of nursing in a major teaching hospital in the East Midlands. That meets monthly. It has with it clinical representation from the hospital and we have also invited a representative from the primary care trust to sit in. As a major commissioner of services they need to understand the care level and the quality of service that we are delivering. That will meet on a monthly basis; it will report to the board, it will develop (and we are hoping to see the first cut of this next month) a clinical performance report which will look at all sorts of issues ranging from mortality performance split between emergency and elective (because the two are very different and we need to concentrate on
the individuals and not look at the bottom right hand). It will look at the reported level of incidents; it will review serious and untoward incidents; it will look at complaints and trend complaints; it will understand lessons to be learned from complaints and it will also look at pretty obvious clinical indicators like lengths of stay, infection rates and so on. What we are going to try to do is build up a portfolio of clinical performance which many other hospitals have done, I have to say, which stands at least equal rank to the harder edge performance of waiting times, financial performance and so on. That will go to the health governors committee and our anticipation is that we will share that publicly with the council of governors and it will also go to public meetings of the board. We have to be more open about clinical performance.

Q1175 Dr Naysmith: I would like to clear up something you said. You said the board meets in confidence and then you meet again later with the governors in public. You said they see the same reports so they have all the information, but the difference is that the main board takes decisions on these reports; these reports will be considered at this wider meeting later, but the decision has already been taken. That seems to be the wrong way round. Would it not be better to meet in public before and then the decisions can be taken with the views of the governors taken into account?

Mr Morton: Are we referring to Chesterfield here?

Q1176 Dr Naysmith: Yes.

Mr Morton: The council of governors meets on a six weekly cycle and the board meets every month so in fact sometimes the council of governors will receive the report before the board, it depends on the sequencing of the papers. What I am absolutely clear about is that it is exactly the same report; we do not do a re-run.

Q1177 Dr Naysmith: I am talking about decisions.

Mr Morton: I absolutely understand that.

Q1178 Dr Naysmith: You cannot do that if the decision has already been taken by the board beforehand. But you were saying that sometimes—

Mr Morton: It depends on how the cycle falls but there can be a very open debate in the council of governors—and there is and we do have members of the public arrive—and the governors feel incredibly engaged because they are seeing exactly the same reports and therefore they can feed their views in for the board to take into consideration, representing their wider membership but, as you say, it is the board that takes decisions which is what the board is there to do.

Q1179 Chairman: Could I thank you very much indeed for coming along and helping us. Good luck with the two jobs.

Mr Morton: Thank you.

Supplementary note by the Minister of State for Health Services

I am writing following the appearance of my predecessor, Ben Bradshaw Minister of State for Health, at the Health Select Committee on Wednesday 3 June. Please accept my apologies for not responding sooner.

Ben answered questions on patient safety with a particular focus on Mid-Staaffordshire NHS FT that was the subject of a report by the Healthcare Commission in March of this year. This report described a catalogue of appalling management and failures at every level for which the previous Secretary of State apologised on behalf of the Government and the NHS. We are determined to learn the lessons of Mid-Staaffordshire, and we look forward to receiving the findings of the Committee’s investigation into patient safety.

During an exchange with Sandra Gidley about correspondence that the Department of Health (DH) had received about Stafford Hospital, Ben undertook to write to the committee with some comparisons with other Trusts. This analysis is attached at annex A.

I hope the committee finds this response helpful.

Mike O’Brien QC MP

Annex A

ANALYSIS OF CORRESPONDENCE RECEIVED BY DH ON STAFFORD HOSPITAL

When the public write to DH with complaints, it is often because they are not aware of the independent complaints procedure. DH responds by referring the correspondents to the NHS complaints procedure and advising of the related appeals process (DH is not allowed to forward letters directly into the complaints system for data protection reasons).

The independent complaints procedure is for NHS service users who are dissatisfied with any services provided by the NHS. The Healthcare Commission published a report about NHS complaints on 1 March 2009, which can be found at:

http://www.cqc.org.uk/newsandevents/newsstories.cfm?wid=Call1=customWidgets.content_view_1&cit_id = 34517
The report shows that:

— the NHS receives about 135,000 complaints per annum;
— 7,500 were received by the Healthcare Commission per annum;
— since 2004 the Healthcare Commission had reviewed 30,000 complaints; and
— around 43% of complaints are about acute services.

In relation to the amount of correspondence with DH, we have looked at correspondence received by DH in the period from September 2005 to March 2008. This is the period from when DH’s correspondence database went live to shortly after the Healthcare Commission enquiry into Stafford Hospital began. For that period, the total number of items of correspondence received for Mid Staffordshire NHS Foundation Trust was 61. This covers the whole of the Trust and not just Stafford Hospital because this enables comparisons to be made with other Trusts that may manage one or more hospitals. Looking at Mid Staffordshire NHS Foundation Trust alongside a random sample of nine other acute Trusts for the same period the average figure for overall correspondence received for each Trust was 62.7.

Further statistical analysis on the sample shows that Mid Staffordshire NHS Foundation Trust is not an outlier on the number of letters per bed, using occupied beds as a measure of the size of the Trust, and that Mid Staffordshire NHS Foundation Trust lies within one standard deviation of the sample mean of the number of letters per bed.

As a direct result of the Mid Staffordshire NHS Foundation Trust case, we have now put in place procedures within DH for reviewing all specific items of correspondence about NHS service providers and intelligence gleaned from this will be shared with Strategic Health Authorities for action as necessary. We will also continue to refer any correspondence to the appropriate independent body. We have no plans to carry out analyses such as the one outlined in this letter on a routine basis.
Written evidence

Supplementary memorandum by the Department of Health (PS 01A)

INFORMATION REQUESTED BY THE COMMITTEE FOLLOWING THE EVIDENCE SESSION ON 30 OCTOBER

It was explained to the Committee that Patient Safety issues could be dealt with by PCTs through “hard-nosed commissioning” using CQUIN. This doesn’t seem to have been spelt out in the references to CQUIN by Lord Darzi in High Quality Care For All (where CQUIN comes over as being about quality rather than safety), and it might be helpful to the Committee to have a bit more information on this.

The Next Stage Review set out visions for high quality services, both nationally and regionally, and outlined new developments to enable and support the NHS to improve quality. The CQUIN payment framework is part of this wider drive to put quality at the heart of all we do. It contributes to the alignment of the system around the same goals of achieving better care by bringing quality improvement into commissioning and contract discussions.

It will support improvement in the three domains of quality highlighted in the Next Stage Review—patient safety, effectiveness of treatment and patient experience. The CQUIN framework should not be seen in isolation and forms just one part of the overall approach on quality, which includes: defining and measuring quality, publishing information, rewarding quality, improving quality, regulating and innovating.

The aim of the new CQUIN payment framework is to support a cultural shift by embedding quality improvement and innovation as part of the commissioner-provider discussion everywhere. The Next Stage Review included a commitment to make a proportion of providers’ income conditional on quality and innovation, through the CQUIN payment framework. The framework will allow PCTs to retain a modest proportion of providers’ contract income, which will be paid to providers based on their achievement of locally agreed goals aimed at improving quality and recognising innovation. These stretching but realistic goals will be discussed between lead commissioners and providers, with SHA support and assurance, and included as part of contracts. This approach makes quality improvement and innovation integral to what commissioners pay for rather than supporting the principle that more money is always needed to drive quality improvement.

The framework has been designed explicitly to allow good existing work to continue and develop. It also seeks to ensure there is local flexibility to develop schemes, within a few broad national parameters where NHS colleagues have advised they are needed. The scheme will build upon best practice found in the NHS and internationally and should give PCTs an opportunity to demonstrate their World Class Commissioning competencies. Commissioners and providers would also be required to publish their CQUIN schemes, both their promised goals for the coming year and their achievement against the previous year’s goal.

The aim will be that all commissioners and providers are focusing on quality improvement—not only in contract discussions, but in year-round quality review conversations—and that this is translating into better quality of care for patients.

Initially, we expect most areas will choose to use the framework to focus on data collection on quality, supporting the wider focus on measuring for improvement. Every organisation will then move to using the framework to reflect real quality improvement and innovation.

The areas to be included in specific local CQUIN schemes will be determined through discussion between PCTs and providers on which areas would most benefit from an additional focus on quality improvement. Local schemes will need to include appropriate indicators in each of the three domains of quality—safety, effectiveness and patient experience.

We would expect the safety focus of CQUIN to be around encouraging continuous improvements in patient safety. While assuring basic standards of safety is highly important, there are other more appropriate mechanisms for achieving this.

We expect to publish more information on the CQUIN payment framework shortly to inform local contract discussions.

It was explained to the Committee that, with effect from 2010–11, commissioners would be able to withhold payment from providers in respect of care that was made necessary by a Never Event occurring in the course of treatment. This doesn’t appear to have been mentioned by Lord Darzi in his discussion of Never Events in High Quality Care For All, and a note on these plans would be useful.

A recommendation in High Quality Care for All proposed that there should be a way of identifying and monitoring “Never Events” in England. These are events that are serious and largely preventable. The purpose of developing a national set of Never Events is to strengthen the focus of commissioning on patient safety, in order to reduce serious incidents and improve transparency. We have described in the recent hearing how Never Events can be indicators of how effective an organisation is at implementing safer practices. Monitoring Never Events as part of the contract between commissioners and providers forms part of the wider patient safety and quality agenda in the NHS.
The National Patient Safety Agency will be taking forward Never Events within England from 1st April 2009 and is currently working with the NHS to develop a suitable national set of Never Events and guidelines for their use during 2009–10. An initial list of Never Events has been developed with the opportunity for comment and feedback from key stakeholders. NPSA’s proposed list of Never Events includes:

- Wrong site surgery.
- Retained instrument post-operation.
- Wrong route administration of chemotherapy.
- Misplaced naso or orogastric tube not detected prior to use.
- Inpatient suicide using non-collapsible rails or whilst on one-to-one observations.
- Abscending of transferred prisoners from medium or high secure mental health services.
- In-hospital maternal death from post-partum haemorrhage after elective Caesarean Section.
- IV administration of concentrated potassium chloride.

In the first phase, it is proposed that PCTs will report on the incidence of these events in the services that they commission.

Primary Care Trusts will be able to use the national set of Never Events as part of their contract agreements with providers during 2009–10. During this first year implementation will focus on promoting clear reporting and management systems for Never Events.

Building on the experience gained during the first year, and emerging international experience, the NHS and Department of Health will work to define whether linkages to payment regimes would be appropriate and effective. Moving to this second phase of Never Events would be a possibility from the financial year 2010–11 onward.

Commissioning/provider regulation/performance management of providers—These three functions are all very relevant to Patient Safety, but it didn’t seem to be clearly explained on Thursday how they (and the bodies performing them) relate to each other. We think we understand how this works, but are not entirely sure. Clearly, PCTs commission services from providers and monitor performance as part of that role. The HCC, as we understand it, regulates and (where necessary) inspects NHS providers, and has some regulatory role in respect of Independent Sector providers (from April 2009 the CQC will take on these roles; and from April 2010 it will preside over a new unified regulatory system covering NHS and IS providers alike). The SHAs, it appears, performance manage non-FT NHS providers (this function is distinct from regulating/inspecting, in that it’s a continuous and quite “hands-on” process). Monitor, we gather, effectively performance manages FTs—whilst it’s primarily a financial regulator, it has a statutory duty under the Health and Social Care (Community Health and Standards) Act 2003 to assess, authorise, monitor and regulate FTs “in a manner consistent with the performance by the Secretary of State of his duties under sections 1, 3 and 51 of the National Health Service Act 1977”, which is being interpreted as meaning that Monitor has a performance management role cognate to that of the SHAs in respect of non-FT NHS providers. A note from the Department clarifying these issues would be most helpful.

The management and regulation of the healthcare system is spread across the roles and functions of regulators, strategic health authorities and commissioners. The overriding aim is to achieve safety, quality, responsiveness, fairness and efficiency. The emphasis is on driving service improvement through national standards, world class commissioning, competition and co-operation between providers.

Good system management will help to ensure that commissioners achieve value for money by giving them leverage through improved contracting to ensure providers offer care that is patient-centred, innovative and targeted at commissioners’ priorities. Choice and competition will give patients greater choice between providers of clinical services and models of care, and empower them to influence and shape the commissioning of healthcare services that they want and need.

**Commissioning**

The Department of Health (DH) has signalled a shift in focus towards commissioning over the past few years, including setting out the “Commissioning framework for health and well being.” To deliver the improvements signalled in the NHS Next Stage Review, there was an urgent need to build capacity for commissioning in the NHS. World class commissioning will be one of the ways in which this vision can be realised.

World class commissioning is a five-year plus programme and we expect to see year on year improvements in commissioning across the governance, process and outcomes that are delivered. PCTs will be held to account through a rigorous assessment system, the assurance process, which aims to be as tough as Monitor is in assessing Foundation Trusts.

The assurance system, with its annual assessment cycle, which PCTs are currently reviewing at the moment, has created a robust process for holding PCTs to account and rewarding their development as they progress towards becoming world class commissioners. It does not replace or cut across the existing system of performance management between SHAs and PCTs.
The system has three elements; outcomes, competencies and governance.

The assurance process will deliver improvements in commissioning year on year, and the speed at which PCTs become world class commissioners is likely to be similar to the process of acute trusts becoming FTs reflecting the challenging nature of the system and the step changes it is seeking to achieve.

PCTs displaying high levels of performance or improvement will be rewarded through certain freedoms from monitoring or regulation while those performing least well and not improving will have interventions applied in line with the NHS Performance regime.

**Regulation of NHS Providers**

Whilst DH holds the final line of accountability for PCTs, regulatory bodies have statutory obligations to assess PCTs for different purposes. The purpose of commissioning assurance is to specifically understand whether PCTs are improving as commissioners. Insights drawn from current regulatory assessments will be part of the supporting evidence used in the assurance system. In particular, ratings from the Audit Commission and Health Care Commission will inform ratings. This will ensure consistency across regimes and will create a coherent overall story about PCT performance.

Regulation provides an essential safeguard for patients. Patients and the public look to the regulators and managers of the health and adult social care systems to ensure the services they use are safe and of good quality and that the money they pay through taxes is used efficiently and effectively to provide the best possible services.

The Health and Social Care Act 2008 legislated for the establishment of the Care Quality Commission. The Commission was established in October 2008 and takes up its responsibilities for the quality of health and social care in April 2009. The Commission will bring together the work of the Commission for Social Care Inspection, the Healthcare Commission, and the Mental Health Act Commission.

From April 2010 the Commission will register all providers of health and social care (including NHS bodies), to assure a bedrock of safe and effective practice. Organisations will not be allowed to provide health and social care unless they are registered. The Commission will conduct annual reviews of providers and commissioners of health and social care as well as special reviews into any issue of particular interest or concern.

The Care Quality Commission will be a key contributor to the quality framework set out in the Next Stage Review and will be very focused on the needs of people who use health and social care services. It will be independent and have flexibility to act in the most appropriate way. The Commission will be an authoritative and independent source of information on how well health and adult social care services are being provided. Experience shows that an open system of reporting and accountability is a real incentive to continuous improvement in the organisations being reported on.

As part of their Annual Health Check, the Healthcare Commission assesses the performance of the NHS against centrally set core standards—Standards for Better Health—published by the Department of Health. Under current legislation, private and voluntary healthcare providers are required to register with, and are subject to inspection by, the Healthcare Commission. Providers pay registration and annual fees and are assessed against a set of National Minimum Standards. The Commission sets the level of fees it charges and will shortly be consulting on fees for 2009-10. In calculating fee levels, the Commission is required to work towards a position of full cost recovery, where the fee income matches the cost of the regulatory work. Fee income in 2007-08 was £7.863 million.

The Health and Social Care Act 2008 allows the Care Quality Commission to set fees for registered providers and for the Secretary of State to make regulations on this topic. The legislation allows different circumstances and different persons to be treated in different ways. Any structure for registration fees will be consulted on in due course.

**Independent Healthcare**

As outlined above, Independent Healthcare is currently regulated under the Care Services Act 2000 and the Private and Healthcare Regulations 2001. The Healthcare Commission registers independent healthcare establishments—indeterminate hospitals, independent clinics and independent medical agencies—and ensures that they adhere to the requirements of this legislation. As far as safety is concerned, the legislation provides for:

- premises and equipment to be suitable for their purpose and properly maintained;
- treatments are provided which meet patients’ individual needs and are based on published research evidence;
- medicines are ordered, handled, stored and disposed of safely;
- arrangements are made to minimise the risk of infection;
- there are sufficient staff, and all staff have the appropriate qualifications, skills and expertise.
The Care Quality Commission will operate the Care Standards Act 2000 and the Private and Voluntary Healthcare Regulations 2001 from 1 April 2009 until 31 March 2010. From April 2010 independent healthcare will be regulated under the Health and Social Care Act 2008.

**NHS Foundation Trusts/Monitor**

NHS foundation trusts (FTs) have independent status in the NHS and were created as a key component of the Government’s plans to decentralise healthcare provision in the NHS and deliver high quality, patient-led services to better reflect local needs and priorities. Unlike NHS Trusts, FTs are not directly performance managed by DH through Strategic Health Authorities—they are accountable to their local communities through governors and members, their commissioners through their contracts for service delivery and to Monitor. FTs are free from the Secretary of State’s powers of direction, and as such Monitor cannot replicate those powers or have any role in performance managing FTs.

Monitor was set up in 2004 under the Health and Social Care Act 2003 (consolidated by the NHS Act 2006). It operates within a discrete statutory framework to authorise, monitor and regulate FTs, but specifically to ensure FTs have maximum freedom to operate while safeguarding the interests of NHS service users. Monitor has developed a system of regulation which is able to identify actual and potential financial and non-financial problems, and can use its formal powers of intervention in cases of significant failure.

Legislation sets out Monitor’s statutory obligations. Essentially, its role is to:

- assess FT applicants and authorise new FTs;
- oversee FTs’ compliance against the requirements for financial stability, governance (including national healthcare standards and targets), delivery of essential NHS services in their Terms of Authorisation (licence to operate), by applying a regulatory regime and intervening in cases of significant non-compliance to ensure FTs act on Monitor’s concerns;
- undertake a number of other powers, including:
  - carrying out its functions in a manner consistent with the SoS’s general duties under the NHS Act 1977 eg to promote and provide a comprehensive health service in England, provide clinical facilities to universities with medical and dental schools etc;
  - defining a prudential borrowing code and setting a limit on the borrowing of FTs;
  - limiting the proportion of income generated by FTs through private patient activity;
  - preventing unauthorised disposal of protected assets required for the provision of essential NHS services;
  - ensuring FTs take steps to have a representative membership base.

While Monitor does not play a direct role in defining patient safety, it does have an important part to play in ensuring that FTs are effectively governed, including meeting the required standards in relation to clinical quality and patient safety.

*Information on the use of barcoding in New Zealand (in response to a question asked by the Chairman)*

The Department of Health, NHS PASA and the NPSA did consider international examples when developing the current policy framework (Coding for Success). However, to encourage further uptake in England we were keen to highlight existing good practice here, which including the e-prescribing and dispensing system being used at the Charing Cross Hospital, which has been shown to reduce errors.

The NPSA’s work on the use of barcoding and other technologies such as radio frequency identification (RFID) in patient identification began with researching what was being done in healthcare in this area within the UK and internationally. A summary of that work was published as *Right patient, right care* in 2004. There has been considerable international interest in this work. For example, since then, we have presented our work abroad including in Amsterdam, Italy and Turkey. Much of our guidance on patient identification, including the use of technologies, has been used for the guidance issued by the Australian Commission on Safety and Quality in Health Care.

One other significant factor in considering international examples was that many are linked to health insurance schemes to simplify the process of reclaiming costs. Patient safety does not commonly feature, although it was the key driver for work in the NHS.

The majority of published work in this arena comes from the US where the requirement to include barcodes on medicines was announced by the FDA in 2004. The majority of the ePrescribing system vendors in the US now include functionality to support the administration of medicines using barcode technology.

Some of the initial evidence to support the use of barcodes came from the Veterans Association (VA) in the US. A study at the VA Health Centres reported that mediation errors made during the administration of medicines were reduced by 82.6%. Improvements were seen in the following:

- Wrong medicine being administered to the patient.
- Incorrect dose being administered.
— Wrong patient having medicines administered.
— Medicines given at the wrong time.
— Medicines scheduled that were not given.

New Zealand is pursuing a parallel strategy to that adopted in England but started slightly earlier with regard to Coding for Success. We will continue to work with our counterparts in New Zealand and other international stakeholders where relevant as a means of ensuring that our systems and policies remain effective, efficacious and up-to-date ad infinitum.

The NPSA, in collaboration with the Royal College of Anaesthetists is currently undertaking a qualitative study into the feasibility of introducing double checking procedures to improve the safety of the administration of injectable anaesthetic drugs. As part of this study bar coding technology that has been developed by Professor Alan Merry in New Zealand is being piloted in two hospitals in the UK. The technology is designed to improve the safety of the administration and recording of anaesthetic drugs as well as other key activities undertaken during anaesthesia. It is anticipated that a report of this study will be issued in early 2009. The technology is also currently being evaluated in New Zealand through a study funded by the New Zealand Research Council.

Professor Keogh was going to let the Committee have a note on Lord Darzi’s work regarding the possible use of “black box” data-recording technology in operating theatres (in response to a question asked by Dr Taylor).

The use of “black box” data-recording technology in operating theatres is an innovation that has been developed at Imperial College London. Its primary function has been to record live operations for Human Factors research in complex environments such as operating theatres.

Such technology has also been used in Operating Theatres Simulations where full-scale life-like manikins can simulate a wide variety of clinical situations for the purposes of training. Simulation is a growing area and one that the Department of Health supports.

17 November 2008

Supplementary memorandum by the Department of Health (PS 01B)

PATIENT SAFETY

I was grateful for the opportunity to give evidence to the Health Select Committee’s inquiry into Patient Safety on 19 March 2009, and both my colleague Lord Darzi of Denham and the Chief Medical Officer Sir Liam Donaldson wish to pass on their thanks for your invitation.

During the hearing the Committee and its members asked for a written addendum to the oral evidence on a few specific areas.

You asked whether the NHS Litigation Authority’s (NHSLA) standard setting role ought to be handled by a body not responsible for dealing with litigation such as the Care Quality Commission. As you know, the NHSLA’s risk management standards have been shown to be a successful tool in helping NHS trusts to reduce risks and to improve the protection of patients.

The Department is satisfied with the work undertaken by the NHSLA on standard setting. We agree with the NHSLA that the promotion of good risk management is an integral component of its schemes, and the framework encourages effective risk management activity. The NHSLA standards reflect issues that the NHSLA sees arising in clinical negligence claims, and the NHSLA is therefore well placed to undertake this task.

We have established the Care Quality Commission (CQC) to play a clear and vital statutory role within the emerging Quality Framework and in our reform agenda more broadly. The Commission also plays a crucial role in bridging health and social care. It already has a big task ahead of it. We see no compelling case for asking it to take on an additional role at this stage.

Information held by the NHSLA for its own functions may well feed into CQC’s own processes to help assure the safety and quality of care. We, of course, look to CQC and NHSLA to cooperate to minimise burdens on front line providers of care in their respective roles.

You commented that you had heard that the Clinical Negligence Scheme for Trusts (CNST) does not cover situations where patients receive NHS care from independent sector providers (apart from Independent Sector Treatment Centres (ISTCs)). You were concerned that under those circumstances we may be sending NHS patients into different independent hospitals without cover at this stage and asked if we are going to do something about that immediately.

On the first point, this should not be the case. NHS bodies that commission services from the independent sector have a responsibility to their patients to ensure that those services are appropriately indemnified if something goes wrong. On this basis, contracts with independent providers should be indemnified or insured in respect of all NHS work. If the Committee knows of instances where this is not happening then I would be interested in any relevant information you are able to provide.
Turning to the second point about immediate action, with an increasingly diverse range of providers across the NHS, we are looking to extend the indemnity arrangements in place for the NHS so that other providers of NHS care can benefit from these arrangements if they so choose. We will shortly be consulting on extending CNST to allow independent sector providers to join CNST in their own right. This will be done by using the provisions within the Health and Social Care Act 2008. Currently, we have agreed national arrangements to provide cover for the ISTC programme, but these will be superseded by the new arrangements once introduced. Many independent healthcare providers, of course, do have comprehensive liability insurance. There is a provision in the Private and Voluntary Health Care Regulations that allows the regulator, currently the Healthcare Commission, to confirm that this is available.

You also asked about implementation of the NHS Redress Act 2006. The proposed NHS Redress Scheme would aim to speed up the medical negligence claim process and encourage a move away from the blame culture inherent in the NHS, promoting openness with the emphasis on learning from mistakes. The scheme would also aim to target the money spent on litigation to redirecting it for the benefit of the injured patients. We have strengthened to this principle by including a key pledge in the NHS Constitution. This requires:

"when mistakes happen, to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively (pledge); and to ensure that the organisation learns lessons from complaints and claims and uses these to improve NHS services (pledge)."

Other key elements of the proposed NHS Redress Scheme include the provision for patients to receive redress in the form of care, a duty on all scheme members to appoint an appropriate person responsible for learning from mistakes and a more proactive approach to clinical negligence, with the onus no longer on the patient to initiate a claim. All scheme members would be required to review adverse incidents and trigger the scheme themselves, where appropriate.

However, we believe that initially focussing on complaints reform, rather than the introduction of the NHS Redress Scheme, will be of wider immediate benefit to users of all NHS services, and will also be more effective in embedding the general principles of redress across the NHS. When the reformed complaints arrangements are embedded, we can consider further the matter of financial redress.

You will be aware that a major reform of the complaints system is now underway and will be implemented from April 2009. It will:

- put the patient or service user at the heart of any complaints process and ensuring that it will be easier and simpler for people wishing to make a complaint;
- move to a more open, accessible, flexible and sensitive approach to responding to complaints, ensuring robust and appropriate investigation;
- emphasise the benefits of responding to complaints properly to help improve services and to; and
- learn from mistakes.

Once the above principles are embedded across health and social care organisations, applying redress measures more specifically to any particular scheme or initiative (for example, in the area of clinical negligence cases) can be considered further.

You have also asked whether the NHS Redress Scheme should be based on the avoidability test. It is our view that by introducing one test as opposed to another would simply not lead to a significant or meaningful change. Nonetheless, this is something the Department would like to keep under review.

With regard to our original policy document, “Coding for Success”, published in February 2007, as you know we made recommendations for the NHS and industry on implementation of auto-identification. We set out a programme of co-ordinated action involving Connecting for Health, NHS Purchasing and Supply Agency and the National Patient Safety Agency, with the GS1 coding standards organisation also having a significant role. The aims of this programme were two-fold: firstly, to get the NHS up to speed with understanding the potential benefits of coding and making the necessary investment to use coding; and secondly, to work with manufacturers of healthcare supplies (both pharmaceutical and devices) to put appropriate codes on products that do not already carry them.

Although significant progress is now being made within the current policy framework, some very helpful developments were not envisaged when Coding for Success was written, including, for example, the development of the NHS Procurement e-Enablement Programme (NPEP). Others, such as the work of GS1 and the Connecting for Health programme have now built up significant momentum.

We will continue to work with these agencies and stakeholders across NHS and industry, to ensure that the policy is reviewed and updated in a timely fashion.

Implementation of coding requires both manufacturers and the NHS to make significant investment decisions, often linked to major re-design of systems and re-training of staff. We therefore need to encourage bottom-up development, facilitating with practical guidance and support where we can.

The early emphasis has been on the NHS, as many hospitals were not using coding in any way, despite many products coming to them from manufacturers with usable codes. Some 150 hospitals have registered for GS1 membership, giving access to coding resources and support, and more are joining all the time.
We have decided that it was no longer appropriate to conduct a review in 2008. Part of the reasoning for this decision was that the implementation programme has built up significant momentum and is making good progress—the NPEP programme in particular is one which was not envisaged at the time of publication but which is starting to drive uptake of coding. Furthermore, the current policy framework is not blocking progress in any aspect of coding. If we were to announce a formal review then this would create uncertainty and may slow progress as the NHS and industry might perceive this as a potential risk, ie that the recommendations might change as a result of the review.

However, we are continuously looking into relevant ways of reviewing progress being made by ensuring at the same time that we do not hamper or slow implementation.

I hope that this satisfactorily answers the questions raised in the oral evidence session on 19 March, and I look forward to reading the findings of the inquiry into patient safety when they are published.

Ann Keen MP
Parliamentary Under Secretary of State for Health

31 March 2009

Supplementary memorandum by the Department of Health ((PS 01C))

INFORMATION TECHNOLOGY

Clearly, information technology is a vital tool in the delivery of health care services, helping to provide services at the greater speed. Its use in NHS commercial and procurement activities has been established for many years and has recently led the NHS Purchasing and Supply Agency (NHS PaSA) working in conjunction with NHS Trusts to put together an NHS Procurement eEnablement Strategy as a means of covering eBusiness, eProcurement and eCommerce efficaciously.

The objective of this strategy is not to replace existing systems but to put into place the essential enablers, such as common coding systems, that will enable the NHS to effectively exploit procurement eEnablement technologies and achieve the significant benefits they deliver. Although this structured approach to driving forward the implementation of relevant coding was not in place when Coding for Success was published in February 2007, it is anticipated that the effective use of eEnablement technologies in procurement can deliver for the NHS a range of significant benefits that contribute directly to patient safety.

Specifically, in order to implement the abovementioned strategy the NHS Procurement eEnablement Programme (NPEP) was established, following extensive consultation with stakeholders from the NHS, suppliers and technology providers to the NHS, and it is expected to run up to 2011–12. It is worth noting that NPEP does not provide systems to the NHS, it is about putting common data standards into NHS supply chain systems and driving capability into the NHS.

The programme consists of two types of deliverables, base deliverables¹ and accelerated delivery projects (ADPs)² but also GS1 Global Trade Item Numbers (GTINs) have also been set as the NHS data standard for products in line with Coding for Success. We foresee that by implementing the latter, we will drive the application of GS1 GTINs by manufacturers onto their products and provide a NHS environment that is able to support through its supply chain systems the use of GS1 GTINs. Currently this is not the case and even where products do carry a GTIN (for example in pharmacy) the NHS are not using the coding to manage the supply chain and for identification of the product through to the patient.

Furthermore, there are a number of NPEP deliverables, which directly drive the adoption of GS1 GTINs by suppliers. Specifically, under the ADPs we are putting together a structured programme to work across the top 100 NHS suppliers which is due to commence in May 2009 but we are also working with NHS organisations to put in place action plans so that they can create compliant systems and include procurement eEnablement in their business objectives; a start has been made with the NHS pharmacy. Moreover, under the base deliverables good progress is being made in relation to including the requirement to use NHS standards in the terms and conditions of NHS organisations, as well as producing guidance on the application of GS1 GTINs in the NHS supply chain for suppliers and the NHS. Both tasks are expected to be completed by the end of 09/10.

We think that that these are significant steps in ensuring the successful uptake of coding. Although it is early to provide evidence of uptake being driven through NPEP activity; it is anticipated that NPEP will be able to provide an overview of the position with regard to the adoption of coding by the top 500 relevant product suppliers in the NHS by next autumn. The programme will also be able to report the current position with regard to the capability of NHS supply chain systems being able to support coding during the first

¹ Base deliverables—these provide the foundations (such as standards and guidance) that are required to be in place before capability to effectively utilise procurement eEnablement technologies can be driven into NHS organisations.
² Accelerated delivery projects (ADPs)—these projects drive capability into NHS organisations, NHS suppliers and technology providers and provide once-only tools for the NHS. This provides a significant capability for the NHS, drives standardisation and implements good practice.
quarter of 2010. These will be important in assessing the effectiveness and efficacy of our new programme and how they contributed to the uptake of coding. I would be happy to share with you our findings when these are readily available.

You have asked about the benefits of Electronic Records, particularly you mentioned Cerner’s Millennium Release 0 patient administration system. Although there has been widespread use of electronic patient records in primary care in the UK, there have been very few studies conducted from the quality and safety perspective. Therefore evidence is lacking but “absence of evidence is not evidence of absence”. A study by Fernando3 and colleagues highlighted that although there are safety features in GP systems, these are not so well developed in some areas, specifically the lack of selectivity of prompts and alerts.

Most of the research on benefits comes from published work from the United States—significant studies4 were presented by David Bates, Medical Director of Clinical and Quality Analysis, Partners Healthcare; and Board Chair, American Medical Informatics Association, in his presentation to the Health Service Journal Patient Safety Congress on 1 May 2009.

The reason there is little evidence to date from the UK is most probably because there have been relatively few deployments in the acute setting and where there have been few, if any, studies reported in major peer-reviewed journals.

Finally, it is important to mention here the NHS Care Records Service (NHS CRS) a valuable tool aimed at helping us improve the way we manage patients’ treatment. The purpose of NHS CRS is to allow information about patients to be accessed more quickly, and gradually to phase out paper and film records which can be more difficult to access. The Summary Care Record, one element of the NHS CRS, is an integral part of supporting Lord Darzi’s Next Stage Review vision in relation to patient access, increased choice, achieving a higher quality of care and efficiency in patient services.

22 May 2009

Correspondence between the Rt Hon Alan Johnson MP, Secretary of State for Health, and Mr John Black, President, The Royal College of Surgeons of England (PS 01D)

EUROPEAN WORKING TIME DIRECTIVE

Dear John

I understand the challenge that the European Working Time Directive presents to your members and I am pleased that we were able to discuss College concerns in a constructive way. I appreciate your acknowledgement that the College is not in conflict in any way with the Department over this issue. This reflects the fact that we all have patient safety as our highest concern.

You have called for an opt-out for all surgeons from the application of EWTD with flexibility to work a maximum of 65 hours a week. You stressed that this is particularly important for surgeons in order for trainees to gain the necessary clinical exposure and experience for a good training. I promised to respond fully following our meeting when I had had time to reflect upon our discussion.

I have carefully considered the arguments you presented when we met, and in subsequent correspondence with other government departments, but as I explained, I do not accept your argument that surgeons need to work longer hours than any other group of doctors in the NHS. The UK Government will continue to defend the right of individuals to opt-out if they so choose, but I cannot agree that a blanket opt-out for surgeons is desirable.

More specifically, a sector-wide opt out is simply not possible under the terms of the Directive. The right to the individual opt-out is not automatic under the Directive. The Directive gives EU member states the option to legislate that individuals can opt-out, a course we have followed in the UK, or to deal with the issue via collective agreements in order to enshrine the same individual rights.

In Germany, for instance, unions and industry representatives have collective agreements to use the opt out in specific professions, including doctors, enabling those covered by the agreement to work 54 to 60 hours a week. But within these agreements, staff are still required to make an individual decision to opt-out.


It has been claimed that there are sectoral exemptions for employees working in the armed forces, the fire service and the police. This is incorrect. The police and the armed forces are only exempt in times of national emergency.

Furthermore, I reject the premise that requiring surgeons to work longer hours will improve patient safety. There is inescapable evidence that doctors who are required to work long hours are more likely to make mistakes.

There are challenges for surgery, as there are for other 24/7 specialist services, in moving to the final stage of an average 48 hour week. We understand that and we have listened carefully to concerns raised by doctors, including those of your fellow Royal College Presidents. We are providing a great deal of financial and expert support to help Trusts and clinicians manage these changes safely and effectively. The Government assessment is that it may not be possible for all services to reach 48 hours by August this year. This is why I have written to the European Commission setting out our intention to apply a derogation to work up to 52 hours, for those services that will need more time to implement the Directive in full.

I believe that clinical leadership from both individuals and clinical professional organisations is the key to moving towards full compliance. Many of your own members have already led the way in introducing new working practices and better handover procedures, so that they can assure patient safety whilst providing their junior doctors with a healthier work/life balance. The quality assurance process that SHAs are leading is identifying those services that may require additional support or a different approach. Patient safety and the quality of patient care come first for everyone involved and I am pleased that those Royal Colleges most concerned with 24/7 care will be working closely with the SHAs over the next few months to bring their expertise and leadership to bear.

I am surprised and somewhat disappointed, following your assurances at our meeting, that the Royal College of Surgeons has not taken the opportunity to fully support this partnership working. I would also urge you to follow up the opportunity that came out of your last meeting with David Nicholson, to undertake joint work with the Department to identify key risks and work through solutions that would support Trusts.

Finally, I wanted to address your concerns that reducing the hours junior doctors work will reduce the quality of surgical training. There is no evidence that training is any less effective since the gradual reduction in junior doctor’s hours over the last 10 years training. The numbers who fail training has remained static and the new competency based system that your College has pioneered, ensures that junior doctor progress as they demonstrate the competencies required.

I naturally support the College in wanting to improve the quality of their training and I understand how important experiential learning is in surgery. Night cover poses a particular tension. On the one hand it is important to ensure adequate emergency surgical and post-operative care, and on the other hand night work for trainee surgeons eats into the more beneficial day-time training. Whilst recognising these tensions, I believe that with good professional leadership, solutions will be developed among those delivering surgical services at the front line in our NHS.

Having trainee surgeons on call at night does not afford more opportunities for training or necessarily mean better training—very little training takes place during night-time hours when only very urgent surgery is carried out. The way in which surgeons are training is evolving. The surgeons of the future will face different demands from those who trained 10 years ago and we need to harness all the latest technology such as virtual reality surgical simulators, to allow trainees to practise their skills.

In this respect, I agree with Lord Darzi and his advice to the Health Select Committee when asked about surgical training in relation to their Inquiry in to Patient Safety. What we need to challenge is not the number of hours; it is the quality of an hour of training. It is important that we have the right training tools and the right training culture. We want to work with the College to look at the curriculum and ways to enhance and evaluate the quality of units of training. Dr Patricia Hamilton, Director of Medical Education at the Department would like to meet with you to discuss this further and I have asked her to contact you to take this forward.

Yours sincerely

Alan Johnson

27 April 2009

Dear Alan

Thank you for your letter of 27 April 2009 relating to the European Working Time Directive. I appreciate your full response to a number of issues I raised when we met on 10 February 2009 and I am glad to have a clear statement of your position.

I am sorry that the clear evidence that we presented to you, and we have continued to gather on this issue, has not persuaded you to take action to enable surgeons to work up to 65 hours a week after August. It is incorrect to suggest that we are not working with the Department to try and deal with the effect that the introduction of EWTD will have on patient care. We are currently reviewing the data recently forwarded by DH and have identified surgeons from the SHAs to analyse and comment. We have declined the offer of
government funding to do this work as I do not believe it would be appropriate to use public funds in an attempt to identify solutions to be applied across SHAs that will not solve the problems resulting from the implementation of the directive.

There is no evidence that surgeons who work up to 65 hours a week are more likely to make mistakes. In fact there is clear evidence that the introduction of shift working, necessary under EWTD, would have an effect on patient safety. Mistakes are made by individuals who work shifts and there are mistakes made during the extra handovers introduced to maintain 24 hour cover.

You refer to the importance of clinical leadership in addressing this issue. It is quite clear to me from the supportive responses of surgeons and indeed doctors from across the spectrum of specialties, from representatives of the public and patients and from many independent commentators that the College is demonstrating effective leadership on an issue of wide interest and concern. It would be immoral for me to support the full implementation of EWTD when I have clear evidence that it will damage quality of patient care and diminish patient safety.

There is now overwhelming evidence that the quality of surgical training is being affected by reduced hours. The College has the experience of consultants and surgeons—in-training in every specialty across the country to demonstrate the profound implications of this directive for training now and surgical standards in the future. We have hard data from the log books of trainee surgeons that they are not getting enough training experience.

I should be happy to meet you, your fellow ministers or departmental officials at any stage if you feel further discussion would be useful and constructive but I would do so on the basis that, once again in relation to a major crisis facing the NHS, I believe those providing the service rather than officials in DH are best placed to identify the problems faced and the solutions required.

Kind regards
Yours sincerely
John Black
8 May 2009

Further memorandum by the Health Foundation (PS 21A)

PATIENT SAFETY

1. INTRODUCTION

1.1 Ensuring safety relies on the ability to assess risk and mitigate against it as well as attempt to prevent risk happening.

1.2 Hospitals, like industry, put layers of defence in place to prevent errors happening. However, most of these defensive layers have some weakness. Adverse events can occur when these defences around a particular situation have been circumvented by many errors. Professor James Reason explains this in his swiss cheese model—each layer of defence is a slice of swiss cheese, when the weaknesses or holes in each layer of cheese align, the result can be catastrophic harm.

1.3 Safer Clinical Systems is The Health Foundation’s new five year programme. It will look at systems that encompass each layer of defence. While the Safer Patients Initiative looked at interventions at the point of clinical care, our new programme will look at whole systems of care encompassing many layers of defence.

2. PROGRAMME AIM

2.1 In launching a new demonstration programme focused on building safer clinical systems, The Health Foundation aims to bring a shift in application of continuous improvement methodologies from the current focus around efficiency and flow to a focus on safety. The Foundation’s ability to make a significant investment over the long term allows it to demonstrate the impact of these methodologies at scale.

2.2 By working with a number of NHS organisations and other technical experts the Safer Clinical Systems programme will:

— develop a new suite of strategies to improve safety that complement and enhance the approaches developed through the Safer Patients Initiative and other patient safety programmes;
— fill the current gap in the evidence base;
— develop a set of standard shared measures against which to demonstrate impact;
— enable faster learning and progress through supporting a collaborative approach;
— work with an explicit goal of sharing knowledge and learning with the wider service.

5 Reason, J. Human error: models and management. BMJ. 2000;320:768–70.
2.3 Through this programme we can start to challenge the perception that failures in patient safety are a product of bad clinicians rather than one where clinical processes and systems are seen as major contributors to breakdowns in patient safety.

3. Programme Structure

3.1 Safer Clinical Systems will be a three-phased programme over five years.

3.2 Phase-1 will operate from October 2008-May 2010 and will seek to obtain “proof of concept” by designing and testing systems-improvement approaches to improve patient safety. This phase will involve teams from five UK healthcare organisations, experienced in applying systems improvement approaches, working closely with expert advisers to co-design and test a range of clinical systems interventions.

3.3 Phase-2 will operate until early 2012 and will demonstrate lessons and successes from phase-1 on a larger scale. There will be an expectation that individuals participating in phase-1 will continue working as an expert faculty in phase-2 to support up to a further 16 UK healthcare organisations to implement and monitor the successful interventions tested in phase-1.

3.4 Phase-3 will operate until spring 2013 and will seek to accelerate UK-wide spread of systems-approaches to patient safety and build an infrastructure for longterm sustainability. The expert faculty drawn from phase-1 participants would continue to play a key role.

4. Participating Organisations (Phase 1)

4.1 The following organisations have been selected to participate in phase 1:

— Bolton Primary Care Trust and Bolton Hospitals Trust who will focus on improving communication throughout the urgent care pathway to reduce clinical risk.
— Hereford Hospitals Trust who will focus on reducing medications errors for in-patient treatment.
— Plymouth Hospitals Trust who will focus on the hand over between medical wards’ patient care.
— NHS Lothian who will focus on the provision of accurate and timely clinical information to support patient pathways.

4.2 The expert technical support team will be provided by a consortium from Warwick University with expertise in safety and reliability, human factors, lean methodology, industry as well as the involvement of senior clinicians from within the National Health Service.

Stephen Thornton
The Health Foundation
November 2008

Supplementary memorandum by the Health Foundation (PS 21B)

PATIENT SAFETY

1. Introduction

1.1 Thank you for the opportunity to attend the Committee’s meeting on 5 February as a witness to the inquiry into patient safety. Further to this oral evidence session, the Health Foundation would like to provide additional information about the techniques that have been implemented in the 24 UK hospitals that have participated in our Safer Patients Initiative (SPI).

2. Supporting Cultural Change

2.1 Ingraining safety in the behaviour and motivation of all staff brings real change in organisations. Senior leaders set safety as a priority and help to create a climate where staff can challenge others to change their behaviour, anticipate risk before it happens, and change their practices and processes to start to build a safety-minded culture.

2.2 The Health Foundation’s Safer Patients Initiative introduces a range of interventions to promote behavioural change. These include safety briefings, the Situation—Background—Assessment—Recommendation tool and executive WalkRounds.
2.3 Safety briefings

Safety briefings are a simple tool designed to help multidisciplinary teams share potential safety problems and concerns. They increase staff awareness of safety, encourage more open communication about safety issues, and over time help an organisation create a culture of safety and reduce errors.

2.4 In South Devon Healthcare NHS Foundation Trust handover briefings are now part of daily practice on wards. The introduction of daily ward safety briefings has really helped staff focus on the patients who are most at risk on the ward during that day. Staff report feeling greater assurance that patients are safer because those who are potentially at risk are highlighted to the whole team during each shift.

2.5 There is considerable interest in implementing the World Health Organization surgical briefing which has been successfully used to improve team working and tackle patient safety issues in surgery. The surgical teams participating in SPI are now experienced in using briefings and are beginning to see the advantages that they bring. Simply telling people to implement the briefing can result in it being conducted as a tick box exercise, performed by only certain groups of staff, rather than as a team effort that provides benefits for all. The major challenges that the SPI teams have overcome are engaging staff from all professions and ensuring that a briefing is done reliably for every patient every time.

2.6 Airedale General Hospital at Airedale NHS Trust has reached 100% compliance with surgical briefings for urology patients since their introduction in April 2007. For all surgical patients across the hospital, 90% now have a surgical briefing; this is from a starting point of 20%.

2.7 The SPI’s surgical briefing involves anaesthetists, surgeons, perioperative practitioners and support staff. The precise content of the briefings can be amended to suit local circumstances, but they cover the following as standard: staff introduce themselves, check that they have all the relevant equipment and patient information and are ready to perform the procedure, and ensure they are free to raise any safety concerns. For example in orthopaedic wards the surgical briefing can be used to help staff identify patients who require prophylactic antibiotics to help reduce infections and compression treatment to help prevent blood clots so that these can be given or arranged before the first surgical incision is made.

2.8 SBAR

SBAR tool acts as a reminder to health professionals to describe the situation, the background, their assessment and their recommendation. The tool gives a structured format that allows essential patient information to be clearly communicated and then questioned by the listener, with the conversation resulting in a decision on the best course of action. It can be used when communicating in person, over the phone or even online.

2.9 In Bradford Teaching Hospitals NHS Foundation Trust, SBAR has now been implemented within all general ward areas within the medical directorates (12 wards in total) and is used during handover as a clear concise process to ensure all information is provided. Within those medical directorates that have been audited, 80% of staff in the general wards are using SBAR during handover to the outreach team. Across the trust, 18.3% of staff are now trained in SBAR and this continues to rise as training is rolled out more widely.

2.10 Executive WalkRounds

The chief executive, the executive team and the board all have a major role to play in establishing a culture of safety. One highly effective way of demonstrating commitment is through executive WalkRounds, where senior executives go to clinical areas and discuss with frontline staff concerns for the safety of their patients. The visits are planned and involve groups of available staff in structured conversations to help raise their issues and concerns in a non-judgemental environment. The issues raised are documented at the time of the visit. The crucial next step is to take those concerns and plan actions to resolve them, showing a commitment and an executive responsibility for patient safety.

2.11 At the WalkRound staff are encouraged to share their key patient safety concerns, any recent incidents and the lesson learned. how easy it is for them to raise and discuss patient safety concerns and what the executive team could do to help address these issues.

2.12 Common to all hospitals are issues such as quality of patient identification, patients being treated on wards in a way that is different to the specialist treatment that they need, delays in transfer and discharge of patients, and delays in receiving supplies. The solutions that are often implemented at ward level will only go so far to addressing the problems. By focusing executive-level attention on wider issues across the hospital there is a better prospect of change taking place.

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7 Figures correct as at December 2008
2.13 Justin Phillips, a consultant anaesthetist and clinical lead for the SPI perioperative care group at Musgrove Park Hospital tells us that a “success factor for SPI is the executive buy-in: having non-medical people within an organisation who are quite senior expecting it to happen, so you’re not pushing against a closed door. If you’re having problems or issues with a particular area or an individual, they can help things happen, and they’ll drive the whole process.”

2.14 The Health Foundation would be happy to provide the Committee with further information about these techniques and the experiences of the trusts we are supporting through the Safer Patients Initiative.

Jo Bibby
The Health Foundation
March 2009

Further memorandum by the National Patient Safety Agency (PS 39A)

PATIENT SAFETY

The Committee has asked the NPSA about the collection and understanding with regard to near misses.

The NPSA has defined patient safety incidents as any event which did or could cause harm to patients. This includes near misses. Within the field of “no harm”, reporters are required to state whether the incident happened and caused no harm, or where the incident did not reach the patient (classic near miss). However, we do not present these in regular official statistics at the present time because there is variable coding of this field, and in practice the distinction can be difficult to apply for staff.

With regard to your comment on the underreporting of near misses from various sources the estimates of underreporting come from casenote review studies. Given the level of underreporting generally, the NPSA considers that it is likely that near misses are also underreported, often not recognised, or not seen as an incident (eg medication errors routinely corrected by pharmacists). On the other hand there are many subsets of incidents in the reporting and learning system (RLS) which are made up mostly of near misses or hazards (eg reports of staff shortages, documentation incidents).

Currently there are a number of ways in which we learn from near misses and ways in which we want to strengthen this.

Firstly, we use near miss information whenever we “drill down” to particular safety issues. Examples include our medication analysis and our work to develop rapid response reports. A typical near miss incident with free text was quoted in supporting information on the rapid response report for heparin flushes as shown below:

When administering Intravenous (IV) antibiotic through an IV line, the line was flushed with Heparin 25,000 units in 5 mls instead of Hepsal 50 units in 5mls. This was noticed immediately. 20 mls was withdrawn and the line then flushed with Hepsal. Outcome: No harm.

Secondly, our ongoing development of the RLS aims to strengthen the information about serious near misses. We are interested in these because a) they are serious events which do not harm patients, but could have eg overdose of gentamicin in a baby and b) we can learn from barriers which prevented that incident harming the patient—which we’re likely only to get from detailed free text or going back to the organisation for more information.

Thirdly, our current work to refresh the dataset and improve the quality of information within the RLS will clarify the value of this information for national learning through specific analyses. We continue to encourage trusts to report serious events, including near misses, in a timely manner.

Fourthly, our work in specialty reporting has helped us understand ways in which we can clarify and help reporters identify and learn from near misses. For example, the anaesthetic reporting form (shown at our meeting with you) allows more clear reporting of near misses and hazards. For this eForm we make a clear distinction between near misses and no harm incidents. You will have seen this in the copy of the summary of incidents from the eForm pilot that we gave you. For your interest, in the reports collected by the anaesthetic reporting pilot we identified around 10% as near misses ie 15 out of 149 incidents.

We hope this is helpful. Please let us know if there are further questions where we could help you.

Dr Tanya Huehns DM MRCP
Patient Safety Strategy Advisor
27 November 2008
Further note by the National Patient Safety Agency (PS 39B)

OUR PLANS FOR IMPLEMENTING ALBERT WU’S RECOMMENDATIONS ON BEING OPEN

The NPSA has been asked by the Department of Health to lead nationally on implementing the recommendations of Albert Wu’s review.

By autumn 2009, we plan to release a Patient Safety Alert for action by trusts. The Alert will be based on Wu’s recommendations and revitalise existing Being open guidance.

We will support trusts to further embed Being open by offering a revised Being open training programme, encouraging a community of Being open experts, providing events to share best practice, and offering other resources through a range of mediums.

22 May 2009

Further memorandum by the Care Quality Commission (PS 41A)

PATIENT SAFETY

INTRODUCTION

1. Following the Healthcare Commission’s report into Mid-Staﬀordshire NHS Foundation Trust and the subsequent reports from Professor George Alberti and Dr David Colin-Thome, the Health Select Committee has agreed to an additional oral evidence session in relation to its patient safety inquiry entitled “Patient Safety: the lessons from Mid-Staﬀordshire”.

2. The Care Quality Commission has already submitted written evidence to the Committee in relation to its inquiry into patient safety. The written submission provided a general guide to CQC’s emerging regulatory approach and highlighted the potential this has to improve the safety and quality of care. The submission also included a description of how safety might be viewed within a broad and integrated model of quality of care. Following the submission of written evidence our Chairman, Barbara Young, gave oral evidence to the Committee on 5 March 2009.

3. In the context of the additional oral evidence session on the lessons of Mid-Staﬀordshire NHS Foundation Trust the Commission now submits the following written evidence, on this aspect, as an additional memorandum to the Committee.

SECTION 1: CQC’S APPROACH TO PATIENT SAFETY

4. As highlighted in our original written submission, CQC’s remit, tools and powers, building on the work of our predecessor Commissions, gives us a comprehensive opportunity to promote safety, as part of wider care quality, across the whole health and adult social care system.

5. CQC will take a broad view of safety. This will be integrated within an overall regulatory model which recognises all aspects of quality, and which takes a risk-based view of potential issues. Governing legislation also gives CQC a range of new enforcement powers against non-compliance with registration criteria.

6. For example, when needed, formal enforcement powers include formal warning notices, prosecution for breach of registration requirements, or a penalty notice in lieu of prosecution. CQC can also impose conditions on, temporarily suspend, or cancel, a provider’s registration. This will constrain the services they are able to provide (in case of conditions), or prevent them from operating altogether. Cancellation can be regarded as the ultimate sanction as it makes a provider unviable. CQC’s approach to patient safety will therefore be aided by the new suite of enforcement powers that were not available to the Healthcare Commission.

SECTION 2: THE NATIONAL PICTURE AND LESSONS FOR OTHER ORGANISATIONS ON PATIENT SAFETY

7. In the particular case of Mid-Staﬀordshire NHS Foundation Trust the Healthcare Commission investigation found a number of findings in respect of acute hospital care and patient safety as potentially relevant to the whole NHS. These include the need, in particular, for:

— Trusts to be able to access timely and reliable information on mortality and other outcomes, and for trusts to conduct objective and robust reviews of mortality rates and individual cases.

— Trusts to recognise if the quality of care provided to patients admitted as emergencies falls below acceptable standards and to ensure that a focus on elective work and targets is not to the detriment of emergency admissions.

— Trusts to ensure that a preoccupation with finances and strategic objectives does not cause insufficient focus on the quality of patient care.

— Trusts to ensure that systems for governance that look good on paper actually work in practice, and the need to consider whether the information presented to boards on performance (including
complaints and incidents) is so summarised that it does not properly convey the experience of patients and puts non-executives at a disadvantage in being able to perform their role to scrutinise and challenge on issues relating to patient care.

— Senior clinical staff to be personally involved in the management of vulnerable patients and in the training of junior members of staff, who manage so much of the hour-by-hour care of patients.

— Trusts to identify and resolve shortcomings in the quality of nursing care relating to hygiene, provision of medication, nutrition and hydration, use of equipment, and compassion, empathy and communication.

— Good handovers when reorganisations and mergers occur in the NHS.

— PCTs to ensure that they have effective mechanisms to find out about the experience of patients and the quality of care in services they commission.

SECTION 3: THE ACTION PLAN IN RELATION TO MID-STAFFORDSHIRE NHS FOUNDATION TRUST

8. After taking on its full legal powers on 1 April 2009 CQC has been proactively taking forward work with the trust and Monitor to finalise an action plan to rapidly improve performance and to agree the follow up arrangements to ensure that the trust is addressing the recommendations.

9. CQC has also been in contact with Professor Sir George Alberti and Dr David Colin-Thomé in connection with their work at Mid Staffordshire. In addition, the CQC’s Chairman visited Stafford on 1 May 2009 and met the acting chairman of the trust, the local MP and the Cure the NHS group. CQC regards the work around the trust as an immediate priority.

10. CQC is also keen to ensure that the action plan is not simply a bureaucratic exercise that generates lots of reporting but little change. To this end CQC has commented in detail on versions of the action plan to encourage a focus on outcomes rather than on process.

11. The action plan also has to incorporate the recommendations of the investigation report and also those of Professor Sir George Alberti and Dr David Colin-Thomé. We are currently in the process of finalising the main elements for the trust to focus on in the first six months.

12. CQC’s follow up arrangements include a stocktaking meeting with the trust, PCT and Monitor at three months, a review of the trust at six months and a further follow up six months after that.

SECTION 4: CQC’S NEW REGULATORY MODEL

13. CQC is currently developing its new regulatory model which will have a key impact on how it deals with issues including both the quality and safety of care. A number of key themes have been highlighted in building and developing our regulatory approach. These are:

— Giving more emphasis to the views of people using services, carers and families in our work. This will mean developing new ways of involving people in our work more systematically and make sure that commissioner and provider organisations are involving people in decisions about their care.

— Working effectively with others in the health and social care system so that we are working together to drive improvement. We want to work with organisations to make sure that everyone in the sector takes on the responsibility of driving improvement—one of the ways we’ll do this is to expand on the idea of risk summits, where regulators and other bodies share information and make sure that action is being taken.

14. Our third theme is especially relevant to our approach to issues raised by Mid-Staffordshire, namely that our new regulatory model will involve:

— Acting to identify problems early and intervening swiftly so that there is fast, effective action where things have gone wrong. We will be building quality and risk profiles and better surveillance systems that will enable us to identify when organisations are struggling or performing poorly to help us intervene faster when we see something isn’t right. Coupled with our stronger enforcement powers, we’ll be responding swiftly to help protect people.

15. As part of that work we have been developing an approach as to how we will use mortality outliers to highlight potential problems in patient care speedily so that action can be taken. As part of this we have designed a mortality alert programme to ensure we keep strongly abreast of these issues on behalf of patients and the people who use services.

16. Our outliers programme was started by one of our predecessors and uses measures of mortality rates. The statistical technique we use is known as statistical process control (SPC) which measures where there has been an increase in mortality rates which is greater than could be explained by random variation over time. These measures may be indicative of potential problems in the quality of care so they are of interest to us as a regulator, and the reasons for the outlier need to be understood. We intend to expand this programme and are developing a variety of methods and ways in which we will investigate such outliers in order to take swift action where this is needed.
17. We are also developing further work on “risk summits”. A risk summit is a focused meeting attended by a mix of staff from regulators, SHAs and inspectorates in each region facilitated by CQC. The purpose of such “summits” is to share information to identify early warning signs of patients receiving sub-standard care, including high mortality rates, medical complications and complaints. The rapid response system is being introduced in order to share information at the earliest possible moment, putting all the pieces together to see what pattern emerges and trigger regulatory action in order to safeguard patients and the people who use services.

18. When we find poor quality care we will intervene. The nature of this intervention will depend upon the precise nature of the issue. In the past interventions have ranged from agreement and monitoring of action plans to address the identified issue, to the highlighted investigation at Mid Staffordshire. The Care Quality Commission has a wider range of enforcement powers available to it than its predecessor bodies and will use these to ensure improvements in quality. In addition to regulatory powers, we will work with other local NHS bodies, such as SHAs, Monitor and PCTs to make sure that other available tools, including performance management and commissioning, are used to address shortcomings in quality and safety.

SECTION 5: CONCLUSION

19. The investigation into Mid Staffordshire NHS Foundation Trust and the subsequent reports by Professor Alberti and Dr Colin-Thome have thrown into sharp relief what can happen to patient safety when organisations fail. It is important that when incidents like this occur, all parts of the system learn from the experience so that systems and approaches can be improved. CQC has taken specific proactive action in this particular case since taking on its legal powers and is determined to work with other regulators and local performance managers—and the trust itself—to ensure rapid improvement in both the quality and safety of care in Mid Staffordshire. CQC has also looked at its new regulatory approach through the prism of these events and as outlined in this additional memorandum is working hard to ensure the new approach is firmly embedded on behalf of the patients, the people who use services, their families and carers.

May 2009

Further memorandum by the Royal College of Nursing (PS 44A)

PATIENT SAFETY

1.0 EXECUTIVE SUMMARY

1.1 The appalling failings at Mid Staffordshire NHS Foundation Trust are a clear indication of what can happen if Trusts cut staffing numbers, fail to provide leadership and put money-saving measures in front of quality patient care. The RCN believes poor nursing practice is unacceptable, but there is often a wider reason for poor quality of care, whether it is a working culture where patient safety is not the top priority or a finance driven agenda of staff cuts.

1.2 Nursing staff raised their concerns with Mid Staffordshire NHS Foundation Trust both formally and informally. However, despite nursing staff completing numerous incident forms about the low staffing levels and the impact this had on the level of care these complaints were never acted upon.

1.3 Despite these failings Mid Staffordshire NHS Foundation Trust has made some progress since the Healthcare Commission first investigated the Trust regarding these issues. The RCN is now engaged with the Trust in scoping a package of work to support the improvement of patient care and safety and nursing development. This involves the RCN working at a regional and national level.

1.4 The focus on achieving financial targets at Mid Staffordshire NHS Foundation Trust was at the expense of appropriate and safe staffing levels. The importance of safe staffing levels and strong clinical leadership cannot be over-emphasised and it is vital that all NHS Trusts take note of the devastating consequences of placing money-saving measures before patient care.

1.5 The cuts in staff made by the Trust board in order to try to save £10 million resulted in insufficient nursing staff to provide quality care. The reduced staff numbers left those at the Trust overworked and highly strained and, as with other professions, if staff are overworked and overburdened the quality of their work is likely to suffer.

1.6 All trusts need to put patient safety and care at the top of their agenda and the government must support them in achieving this goal. It is clear from the report that the board at Mid Staffordshire NHS Foundation Trust focussed so heavily on meeting targets and reducing costs that patient care and safety suffered.

1.7 Staff working at the Trust have told the RCN that too much time was spent on audits, paperwork and other administrative duties, creating a culture that was “business like” and not patient focused.

1.8 The indifference shown by Mid Staffordshire NHS Foundation Trust toward staff complaints allowed poor care to continue and left staff feeling ignored and demoralised. Staff must feel empowered to raise concerns and to know that when they do they will be taken seriously.
1.9 The RCN has since been told by members working at the trust that communication between senior staff and staff working at grass roots was “closed” and staff felt they were not being listened to. It has also been made clear to the RCN that staff made numerous reports relating to low staffing levels that were ignored with no response or effect.

1.10 The RCN has also been told that some staff at Mid Staffordshire NHS Foundation Trust expressed fear of speaking out in case of reprisal as they felt it could affect their job security. In a recent RCN survey of 5,000 members across the UK 78% of respondents said they would be concerned about victimisation, personal reprisals or a negative effect on their career if they were to report concerns to their employers.

1.11 The RCN is calling on all healthcare employers to make a public pledge that gives a categorical commitment that staff will be protected from victimisation and reprisals if they speak out. Employers should also take urgent action to make sure that all employees are fully aware of whistleblowing policies and procedures.

1.12 The RCN is concerned that Mid Staffordshire NHS Foundation Trust achieved Foundation Trust status despite failings in patient care. It is simply not right that Trusts are able to achieve Foundation status by putting the health of their budgets over the care of their patients.

1.13 The RCN is concerned that other NHS Trusts are reported to be making cuts to nursing posts and patient services in order to save money in the pursuit of Foundation trust status.

2.0 INTRODUCTION

2.1 With a membership of almost 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

2.2 On Tuesday 17 March 2009 the Healthcare Commission published its findings from an investigation into Mid Staffordshire NHS Foundation Trust. The report found the Trust had significant failings across emergency healthcare, leadership and management.

2.3 The appalling failings at the Trust are a clear indication of what can happen if Trusts cut staffing numbers, fail to provide leadership and put money-saving measures in front of quality patient care. The RCN believes poor nursing practice is unacceptable, but there is often a wider reason for poor quality of care, whether it is a working culture where patient safety is not the top priority or a finance driven agenda of staff cuts.

2.4 Nurses want to be able to provide their patients with excellent quality care. However, if staff numbers are reduced so much that they have to rely on Accident and Emergency Department receptionists to assess patients, as at Mid Staffordshire NHS Foundation Trust, there are clear barriers to providing the level of care staff would wish to provide.

2.5 Nursing staff raised their concerns with the Trust both formally and informally. However, despite nursing staff completing numerous incident forms about the low staffing levels and the impact this had on the level of care these complaints were never acted upon.

2.6 Despite these failings Mid Staffordshire NHS Foundation Trust has made some progress since the Healthcare Commission first investigated the Trust regarding these issues. The RCN is now engaged with the Trust in scoping a package of work to support the improvement of patient care and safety and nursing development. This involves the RCN regional office, nursing department and learning and development institute.

2.7 The failings at Mid Staffordshire NHS Foundation Trust were significant and had severe consequences. In light of this the RCN welcomes this opportunity to submit further evidence to the Health Select Committee inquiry on patient safety.

2.8 Below we will set out the factors we believe led to the failings at Mid Staffordshire NHS Trust at a local level and from a wider national setting.

3.0 STAFFING

3.1 The focus on achieving financial targets at Mid Staffordshire NHS Foundation Trust was at the expense of appropriate and safe staffing levels. The importance of safe staffing levels and strong clinical leadership cannot be over-emphasised and it is vital that all NHS Trusts take note of the devastating consequences of placing money-saving measures before patient care.

3.2 During the time period covered by the report Mid Staffordshire NHS Foundation Trust was 120 full time equivalent nurses short of the full complement the Trust should have been operating under. The cuts in staff made by the Trust board in order to try to save £10 million resulted in insufficient nursing staff to
provide quality care. The reduced staff numbers left those at the Trust overworked and highly strained and, as with other professions, if staff are overworked and overburdened the quality of their work is likely to suffer.

3.3 Furthermore, those at the Trust had little or no protected time for training and the further development of their skills. Staff working at the Trust have told the RCN that there was insufficient nurse training to develop and maintain nurses competences. The Healthcare Commission’s report indicated that sickness rates were high amongst staff at the Trust which is likely to be a result of the immense pressure placed on them to meet the demands suitable for a far larger workforce.9

3.4 In a survey of RCN members conducted in 2007 only a quarter of NHS nurses surveyed considered that there were sufficient staff to provide a good standard of care at their place of work, and 55% reported feeling too busy to provide the care they would like to. The survey also demonstrated that nurses working in wards with higher nurse to patient ratios were more likely to regard the standard of care as good.9 In light of this, the staffing levels at Mid Staffordshire NHS Foundation Trust were unacceptable.

3.5 An independent review published in 2006 put forward convincing evidence of a direct relationship between the registered nurse workforce and patient outcomes in acute hospital settings. The paper surveyed nearly four thousand nurses and looked at 118,752 patient episodes of care in 30 hospital Trusts in England. The research found that wards with lower nurse to patient ratios had a 26% higher patient mortality rate. The research also suggested that higher numbers of registered nurses and a higher proportion of registered nurses within the nursing workforce are associated with reductions in patient mortality, incidence of respiratory, wound and urinary tract infections, number of patient falls, incidence of pressure sores and medication errors.10

3.6 In addition to appropriate staffing numbers, skill mix, deployment of registered nurses, education and training, culture of the ward/clinical area and clinical leadership all impact on the standard of care delivered. It is clear from the Healthcare Commission’s report of the Accident and Emergency Department at Stafford Hospital that there was poor clinical leadership at the Trust with very few Band 7 (senior) nurses.11 The RCN’s report: Breaking down barriers, driving up standards: the role of the ward sister and charge nurse, demonstrates that strong clinical leadership is essential to ensuring authority of care delivery in the care setting and in getting messages to board level.12

3.7 Indeed the Healthcare Commission report: Ward staffing, emphasised the importance of ward leadership. It showed that strong clinical leadership at ward level coupled with investment by the Trust in nurses’ careers, welfare and education creates a committed and stable workforce which is more likely to provide high standards of care.13

4.0 TARGETS

4.1 All trusts need to put patient safety and care at the top of their agenda and the government must support them in achieving this goal. It is clear from the report that the board at Mid Staffordshire NHS Foundation Trust focussed so heavily on meeting targets and reducing costs that patient care and safety suffered.

4.2 While the RCN believes targets can, and have, led to improvements in patient care, we have particular concerns with the four-hour target for emergency care admissions. A survey conducted by the RCN in April 2008 of over 500 frontline Accident & Emergency (A&E) nursing staff showed that nine out of 10 (93%) A&E nurses have felt unduly pressured to meet the four-hour waiting target.

4.3 The RCN survey revealed that the pressure to meet the four-hour waiting time has had negative consequences for the quality of patient care. Three quarters (75%) of nurses said that patients were regularly admitted to inappropriate wards14 just to meet the target.

4.4 Although reducing the time spent in A&E has generally improved the experience of most patients, there is evidence that some groups of patients are receiving less than satisfactory care in order to achieve the target. This appears to have been the case with Mid Staffordshire NHS Trust where staff reported feeling that the care of patients had become secondary to achieving targets and minimising breaches. The RCN would like to see greater focus on the quality of the care delivered.

4.5 Staff working at the Trust have told the RCN that too much time was spent on audits, paperwork and other administrative duties, creating a culture that was “business like” and not patient focused.

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8 Healthcare Commission, Investigation into Mid Staffordshire NHS Foundation Trust, pg. 126–7, (March 2009)
9 Employment Research Ltd. commissioned by the RCN, Holding On: Nurses’ Employment and Morale in 2007 (2007), pg. 64.
10 Professor Anne Marie Rafferty of Kings College, University of London, Outcomes of variation in hospital nurse staffing in English hospitals: Cross-sectional analysis of survey data and discharge records (International Journal of Nursing Studies, October 2006)
11 Healthcare Commission, Investigation into Mid Staffordshire NHS Foundation Trust, pg. 48, (March 2009)
12 Royal College of Nursing, Breaking down barriers, driving up standards: the role of the ward sister and charge nurse (2009)
13 Healthcare Commission, Ward Staffing, pg. 25 (June 2005)
14 This means anywhere outside the Accident & Emergency Department. Once a patient is across the threshold of the A&E department, they have officially been discharged and they are off the A&E waiting list.
5.0 COMMUNICATION, EMPOWERING STAFF AND WHISTLE BLOWING

5.1 The indifference shown by Mid Staffordshire NHS Foundation Trust toward staff complaints allowed poor care to continue and left staff feeling ignored and demoralised. Staff must feel empowered to raise concerns and to know that when they do they will be taken seriously.

5.2 The Healthcare Commission’s report clearly documents that staff at the Trust raised their concerns over inadequate staffing levels and the impact this was having on patient care on numerous occasions. However, it is also documented that these complaints were not acted upon and that incident forms and patient complaints were rarely considered at board level. The clinical audit processes did not work at the Trust, demonstrated by the Trust Audit Committee not meeting for over a year.

The RCN has been told by members working at the trust that communication between senior staff and staff working at grass roots was “closed” and staff felt they were not being listened to. It has also been made clear to the RCN that staff made numerous reports relating to low staffing levels that were ignored with no response or effect.

5.3 The report highlighted that a staff survey in 2007 showed the Trust was in the highest 20% across the country for staff witnessing near misses, errors or incidents. The survey also asked whether staff who reported incidents were treated fairly, whether the Trust took effective action to prevent recurrence and whether staff received feedback. Again, the Trust was in the worst 20% of Trusts across the country.

5.4 Research carried out by the Healthcare Commission: Analysis of results of the NHS staff survey and the patient survey for NHS acute trusts in England to see if there is an association, showed a clear link between patient experience and how staff feel about their working environment. The research demonstrated the importance of management and management systems and stressed the importance of communication between managers and their staff. The research showed a positive correlation between patients being treated with respect and dignity with staff reporting that they enjoyed managerial support. The findings into Mid Staffordshire NHS Foundation Trust showed a sharp contrast to this cooperative approach with one consultant at the Trust describing the managerial style as an attempt to “dictate and impose”. The RCN has been told by staff that they felt decisions were sometimes made, without any discussion or debate on their part and that changes were frequently imposed upon them, at short notice, without their involvement.

5.5 The RCN has also been told that some staff at Mid Staffordshire NHS Foundation Trust expressed fear of speaking out in case of reprisal as they felt it could affect their job security.

5.6 The RCN has also been told that some staff at Mid Staffordshire NHS Foundation Trust expressed fear of speaking out in case of reprisal as they felt it could affect their job security.

5.7 A recent RCN survey of 5,000 members which looked at attitudes towards reporting worries about patient safety found that:

— 78% of respondents said they would be concerned about victimisation, personal reprisals or a negative effect on their career if they were to report concerns to their employers;
— 21% had been discouraged or told directly not to report concerns at their workplace;
— 46% felt confident their employer would protect them if they spoke up;
— 99% of registered nurses understood their professional responsibility to report worries about patient safety but fears about personal reprisals meant that only 43% would be confident to report concerns without thinking twice;
— 29% said their employers had taken immediate action to resolve the situation after concerns had been reported;
— 35% said no action was ever taken by employers after concerns had been reported;
— 45% didn’t know if their employer had a whistleblowing policy.

5.8 The RCN is concerned that the results from this survey show that staff do not feel comfortable whistleblowing and in many cases are not aware that they can. In the light of this the RCN believes that all healthcare organisations should be required to hold a register of staff concerns that must be reported to their Board regularly. For NHS organisations, this register should be inspected by the Strategic Health Authority and should be made accessible to local patient groups.

5.9 The RCN is also calling on all healthcare employers to make a public pledge that gives a categorical commitment that staff will be protected from victimisation and reprisals if they speak out. Employers should also take urgent action to make sure that all employees are fully aware of whistleblowing policies and procedures.

15 Healthcare Commission, Investigation into Mid Staffordshire NHS Foundation Trust, pg. 98, (March 2009)
16 Ibid., pg. 37
18 Healthcare Commission, Investigation into Mid Staffordshire NHS Foundation Trust, pg. 105, (March 2009)
19 The RCN surveyed 5,428 members via the RCN website between 24 April and 1 May 2009
5.10 The RCN has recently launched a dedicated telephone service, “Raising concerns raising standards”, to allow RCN members to talk in confidence about serious and immediate worries that patient safety is being put at risk in their workplace. This information will be used to support the nurse to raise concerns and, if needed, the RCN will step in swiftly to investigate concerns directly with employers.

6.0 NHS Foundation Trust Status

6.1 The RCN is concerned that Mid Staffordshire NHS Foundation Trust achieved Foundation Trust status despite failings in patient care. It is simply not right that Trusts are able to achieve Foundation status by putting the health of their budgets over the care of their patients.

6.2 Created as legal entities following the publication of the Health and Social Care (Standards and Regulations Act) 2003, NHS Foundation Trusts, have a number of advantages over traditional NHS Trusts. These include increased levels of autonomy, the right to retain financial surplus and the right to use commercial funding to finance service developments. As achieving Foundation Trust status brings a number of benefits it is perhaps not surprising that some Trusts are heavily focussed on achieving the financial targets needed to gain Foundation status.

6.3 In a survey of RCN members in 2007 respondents expressed concern that profit and politics were becoming more important than services to patients in existing NHS Foundation Trusts. Moreover, the survey found there was a tension in Foundation Trusts between the need to generate income whilst also trying to prioritise essential services and this was a recurring issue for respondents.20

6.4 While many respondents from our survey saw benefits in Foundation Trusts from adopting a more business-like approach to organisational development and service management, the survey also reported that where NHS Foundation Trusts were disproportionately focused on costs, this had a detrimental impact on staff morale and clinical engagement.21

6.5 The RCN is concerned that there are reports that other Trusts are making cuts to nursing posts and patient services in order to save money in the pursuit of Foundation trust status. A recent Nursing Standard report found that Leeds Teaching Hospitals NHS Trust has restricted recruitment in order to save £37.5 million this year whilst Oxford Radcliffe NHS Trust is to cut £11 million from its staff pay budget. Both Trusts are applying for Foundation Trust status.22

Royal College of Nursing

May 2009

Supplementary memorandum by the Royal College of Nursing (PS 44B)

MEETING OF HEALTH SELECT COMMITTEE 3 JUNE 2009

Thank you very much for the opportunity for the Royal College of Nursing to contribute to the Committee’s work on patient safety and in particular to the evidence session on the Mid Staffordshire Trust. We were very pleased to be able to put on record our evidence on the impact of unbalanced staffing levels and uncoordinated savings plans on patient care.

I have visited the Trust and met nurses and other staff on a number of occasions and I have also had a meeting with the Cure the NHS group. One of their insights, especially from nursing staff, is that the problems at the Mid Staff Trust have their origins in 2001. This point does not figure strongly in the Healthcare Commission report and I believe it is worth further examination in an independent inquiry.

At my most recent visit to the hospital I visited several wards and spoke with a large number of staff and patients; and in the afternoon held an hour and a half open session which was attended by nearly one hundred nurses and health care assistants. A number of key themes emerged.

Staff at the Trust are of the view that it had historically balanced its books and met its financial targets. However in the early part of this decade savings were requested to contribute to solving problems elsewhere in the health economy. It also appears that both the previous and the current regime felt compelled to realise savings whilst at the same time struggling to provide the same level of service. There is no evidence of upward pressure being applied to the PCTs to either cut services if there were insufficient funds, or to resist pressure from the SHA to realise savings.

It appears that many of the people at the Trust and the PCTs who bear responsibility for the Mid Staffs Trust have walked away from the problems and have effectively been insulated from accountability as only those currently in post have been held to account.

20 Royal College of Nursing Policy Unit, NHS Foundation Trusts Survey (www.rcn.org.uk/__data/assets/pdf_file/0013/230710/NHS_Foundation_Trusts_Survey_2008.pdf)
21 Ibid.
22 “Pressure mounts on staff levels as trusts chase foundation status”, Nursing Standard, May 27, vol23, no38, 2009
I was very interested to hear a great deal of sympathy for the recently departed Chair and Chief Executive as nursing staff felt they were held responsible for the situation they inherited but which was not of their making. During my one to one meetings and in the open forum many nurses felt that senior managers from 2001 to 2005-06 should also be held to account for their significant contribution into the events that have resulted in the 2009 Healthcare Commission report.

Nursing staff talked about the year on year cuts in staffing levels starting in 2001 which culminated in a situation in 2005 where one ward sister was responsible for three wards of nearly 80 beds. They feel that the situation in which they found themselves working was so precarious that they were unable to provide the same level of care as they had prior to 2001—and that they have been strongly criticised for this.

In order to bring these issues to the fore and to ensure that everyone culpable is held to account, the RCN believes that a further inquiry is needed. We recognise that this might be a barrier to the Trust moving forward but in our view, progress will inevitably be slow anyway as there is a lack of confidence from partner agencies, relatives, carers and the general public. However, whilst we believe that an inquiry would be the best way forward, many of the nurses I talked with, who could make a valuable contribution, would not feel comfortable in a public setting. A closed inquiry with the findings made public would be a positive way forward and we have written to the Minister to express this view.

Once again, we are grateful for the opportunity to contribute to this very important HSC inquiry. It is essential that lessons are learned and I very much hope that the Committee will consider the call for an inquiry.

Professor Peter Carter  
Chief Executive and General Secretary  
9 June 2009

Further memorandum by the Royal College of Physicians (PS 47A)  
USING PROFESSIONAL NETWORKS IN SUPPORT OF PATIENT SAFETY

The appearance of Dr Daggett and subsequently the Health Minister, Ben Bradshaw MP, at the Health Select Committee on Patient Safety, provided the opportunity for some searching questions about the role of professional networks in cases where internal governance systems persistently fail to address clinical concerns. The minister put this in the context of wider traditional sources of external scrutiny, such as local media and MP attention, but we are concerned about channels available through the medical profession.

With this in mind I am writing to your Committee with a few points for consideration before you finalise your report. I will restrict my analysis to the national situation. While the HSC investigation suggests a particularly profound communications breakdown took place at Mid-StaVs, we know from our membership that many hospital doctors frequently feel frustrated in their attempts to raise concerns about standards of care.

There is no doubt in our view that most concerns about patient safety should be dealt with at local level. There are sufficient policy levers in place to encourage regular measurement of care through audit and in most cases senior management pay close attention to these results and act upon them when major issues arise.

However, inevitably, there will be a minority of cases where for a combination of reasons patient care issues are not actively addressed in a satisfactory manner. In these cases the national regulator may not be alerted. It is in these minority of instances that we believe professional networks can potentially serve a very valuable role.

We believe that the networks established by Medical Royal Colleges have been severely weakened by the loss of so-called “hospital visiting” in the early part of this decade. As part of their regulatory role for ensuring quality of medical training, Medical Colleges, through their local representative structure attended hospitals, meeting with trainees, consultants and senior management. Although the objective was to ensure quality of training, the nature and standard of service was inevitably also a recurring contextual factor to be fully understood. As a consequence there was a strong appreciation of patient care and safety matters, and intelligence gained provided the source of often hard-hitting reports to management with associated plans for improvement. Perhaps these interventions became too strong in the changing world of the NHS, but there is not doubt in our view, that a valuable resource of profession external scrutiny has been lost and the Colleges’ professional network has been significantly weakened to the detriment of patient care and medical training.

NHS management were critical of the hospital visiting function for being too frequent, fragmented and perhaps excessively threatening in their view. However, since the changes to the regulatory framework for medical training with the end of the Strategic Training Authority and the transfer of these responsibilities to the Postgraduate Medical Education and Training Board, “hospital visiting” ceased and as a consequence
professional networks have been weakened. Colleges recognised the negative consequences of this change and have been seeking to re-establish effective lines of communication to fulfill the valuable function of external professional monitoring that has been lost, but in some other form.

Firstly, we have reorganised our local network structure to provide specialist physicianly support through a regional advisory network with representation for service and training matters. Secondly, we are taking opportunities to re-engage this network with the crucial service issues of the day. For example, we have been part of the SHA process that is reviewing the detailed implication of the European Working Time Regulation in hospitals. In this respect we undertake a professional scrutiny and advisory role providing independent external professional comment to the NHS management bodies based on local knowledge, whilst recognising it is ultimately the responsibility of employers to implement and manage safe medical rotas.

Thirdly, we are ensuring that our regional advisors are an integral part of the medical revalidation exercise, again to provide professional assurance of process and appropriate availability and use of information. Fourthly, we are conscious that although clinicians and the professions allied to medicine work closely together on the ground and share common concerns, their professional networks are not well aligned. Consequently information does not pass through the professional hierarchies in a consistent way. We believe that we need to align medical and nursing professional networks to ensure commonality of information and approach.

While the College is able to progress its professional network development to a substantial degree, we believe that there are a number of specific areas that the Committee may consider as recommendations in its final report:

1. The Care Quality Commission has set out clear intentions in the field of registration for institutions and services providing healthcare. We believe that in carrying out this function the CQC should be required to seek information about patient care and safety issues from the Royal Colleges as part of the assessment process. Normally this would require liaison with the relevant College regional adviser.

2. Appointment Committees for senior clinicians must have a College representative in the relevant medical field to approve the job descriptions and actively contribute to the selection process. This requires an understanding of the service and its needs for patient care. Currently this is not a requirement for Foundation Trusts, although most do follow this mechanism as a matter of best practice. This should be a universal requirement.

3. The Royal College of Physicians provides an Invited Service Review service. Similar independent professional scrutiny activities are also available from other large Colleges. These provide an opportunity for a confidential external assessment with recommendations of services that are of concern to local management. Currently this requires invitation from the Chief Executive and/or Medical Director. The HSC may wish to endorse this as a further opportunity for professional networks to engage with local services and provide greater assurance of patient care and safety issues.

I believe that there is a tremendous opportunity for the HSC to use the lessons from the tragedy at Mid-Staffs to reinvigorate the professional contribution for the benefit of patient safety. To be clear, I am not advocating a return to the formal regulatory role the College's previously held. We value our independence and it is precisely that function that must be fully exploited. We have lost something of this in recent years and it needs to be re-built with all the benefits that it confers without the bureaucratic encumbrances.

I do hope that our points will feature in your report and I would, of course, be delighted to expand on them if you wish.

Professor Ian Gilmore MD, PRCP
President
Royal College of Physicians
12 June 2009

Further memorandum by the Patients Association (PS 50A)

PATIENT SAFETY: THE LESSONS OF MID-STAFFORDSHIRE

EXECUTIVE SUMMARY

1.1 In terms of patient safety, the Patients Association considers the case of Mid-Staffordshire NHS Foundation Trust to be of equal if not greater importance to the NHS than the case of Harold Shipman.

1.2 This case illustrates the complete failure, over many years, of every single measure in place designed to detect such appalling standards of care.

1.3 The premise of accountability in public life and collective accountability for NHS Boards is at risk of being undermined by the lack of public account being given by various professionals involved in the failings of care either at Mid Staffordshire NHS Foundation Trust or through other regional and national publicly funded organisations.
The Patients Association now has serious doubts about the robustness and probity of the Foundation Trust applications process because this Trust, now shown to be completely unsuitable for Foundation Trust status, was able to achieve it.

Monitor, West Midlands Strategic Health Authority, the Healthcare Commission and any of the local PCTs that commissioned services from Mid Staffordshire NHS Foundation Trust had a responsibility to investigate warning signs such as the results of the 2006 and 2007 national inpatients surveys, in which the trust had been in the worst 20% on the question about whether there were enough nurses.

The Patients Association would like to highlight a number of other bodies that either have a role in safeguarding patients or potentially would have been made aware of problems at the Trust. All of them should be required to give a full and frank account of any contact they had with patients or patient data from Mid Staffordshire NHS Foundation Trust.

In light of the numerous questions outlined in this document that we feel remain unanswered and because of the need for full public accountability, the Patients Association believes a public inquiry is necessary into the failings of care at Mid Staffordshire NHS Foundation Trust. As well as fulfilling the duty of accountability placed upon public servants, such an inquiry would also ensure all the lessons are learned to ensure this is never allowed to happen again.

INTRODUCTION

In terms of patient safety, the Patients Association considers the case of Mid Staffordshire NHS Foundation Trust to be of equal if not greater importance to the NHS than the case of Harold Shipman. The Shipman case and the subsequent public inquiry highlighted serious systemic failures of the systems designed to protect patients from lone doctors working in the community. The case of Mid Staffordshire NHS Foundation Trust has highlighted serious systemic failures of the systems designed to protect patients receiving hospital care.

We cannot overestimate our concern. This case illustrates the complete failure, over many years, of every single measure in place designed to detect such appalling standards of care. In fact, the unacceptable standards of care that may well have remained undiscovered were it not for the statistical analysis of a private company Dr Foster Intelligence. The Healthcare Commission (HC) report states that high mortality rates at Mid Staffordshire NHS Foundation Trust date back to 2003–04. The Commission for Healthcare Improvement (CHI) highlighted concerns about the quality of care at the Trust in 2002. It is now apparent that these concerns were not sufficiently addressed.

We have reviewed in detail the HC report and subsequent Department of Health (DH) reviews. In addition we have also considered press releases and public assurances from those NHS bodies involved and answers given in Parliament by the Department of Health. Our submission of evidence will focus on those questions the Patients Association still left unanswered by any of these aforementioned responses, divided up into key topic areas

ACCOUNTABILITY

As part of the drive to improve the reporting of adverse incidents and create a culture of openness amongst clinical staff the Patients Association supports the “no blame culture” in relation to adverse incidents that occur during patient care. We feel that this philosophy was intended to apply to frontline clinical staff that will inevitably make mistakes.

It should not apply to those holding senior managerial positions (such as Director of Nursing (DN), Medical Director (MD), Strategic Health Authority Chief Executive, NHS Board members) that are responsible for ensuring safe care for patients in hospitals. They should be held accountable for significant failings in care, especially when, as is the case at Mid Staffordshire, those failings have led to hundreds of patients deaths.

The Codes of Accountability and Conduct for NHS Boards (DH 1994) states that:

Accountability—everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgments on propriety and professional codes of conduct.

And

NHS boards comprise executive board members and part-time non-executive board members under a part-time chairman appointed by the Secretary of State. Together they share corporate responsibility for all decisions of the board.

Governing the NHS-A guide for NHS Boards (DOH/Appointments Commission 2003) states that:

"Legally there is no distinction between the Board duties of executive and non-executive directors, they both share responsibility for the direction and control of the organisation. All directors are required to act in the best interest of the NHS. There are also statutory obligations such as health and safety that Board members need to meet. Each director has a role in ensuring the probity of the organisation’s activities and contributing to the achievement of its objectives in the best interest of patients and the wider public.”
3.8 The Nolan Committee’s First Report on Standards in Public Life gives the following definition of accountability:

3.9 Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

3.10 This premise is threatened when, as it stands, of all those NHS professionals, both clinical and managerial, who failed in their duty of care to patients at Mid Staffordshire NHS Foundation Trust leading to between 400–1,200 patient deaths, only two people, the Chair and Chief Executive have been held to account to any extent.

3.11 This has in fact only involved those two persons resigning, without being subject to disciplinary procedures of any kind or being required to give a detailed account to either Parliament or the public.

3.12 This sends a very worrying message to not only patients and the public, but the Boards of other NHS organisations. Accountability is not just about ensuring openness and transparency for patients.

3.13 The HC report and the two DH reviews contain significant criticism for bodies across the NHS. It destroys public trust in the safety of the health service when there is a large amount of criticism with so little accountability. It is simply not acceptable for those involved to claim ignorance of failure when they have a duty of care to patients and accept public money to ensure safe high quality care for patients using the NHS.

3.14 Concerns were raised about the poor quality of care being provided on a number of wards, but if we reflect on the Accident and Emergency Department alone, serious questions must be answered about whether the Board, the MD and the DN fulfilled their duties to provide high quality safe care.

3.15 The Patients Association would have difficulty accepting that the MD and DN and in fact the Board as a whole were unaware of the severe staff shortages, lack of equipment and insufficient staff training (as reported by the HC) in the A and E Department. In light of this we believe patients and the public have the right to know answers to the following questions:

— At any point was the MD/DN/Board aware of a shortage of staff at the A&E?
— At any point was the MD/DN/Board aware of a shortage of equipment at the A&E?
— At any point was the MD/DN/Board aware that staff were appropriately trained in the use of basic equipment?
— At any point was the MD/DN/Board aware that receptionists were triaging patients?
— If they were aware of any of the above failings, did MD/DN/Board have reasonable grounds to believe that this was having a negative impact on patient care and what did they do to rectify the problems?
— If the MD/DN/Board were not aware of any of the above failings, as the failings in care being provided were so severe and took place over such a sustained period of time, does not knowing highlight a failure in their responsibility to ensure suitable medical and nursing care was being provided in the A and E Department?

FOUNDATION TRUST STATUS & MONITOR

4.1 The fact that this Trust received Foundation Trust status at a time when it was giving such poor care is of great concern to the Patients Association.

4.2 It is worth highlighting the basics of the Foundation Trust application process according to Monitors own guide, Applying for NHS Foundation Trust Status: A Guide for Applicants, as it illustrates the layers of scrutiny the Trust was able to successfully bypass.

4.3 This process is split into three phases: the SHA phase, the DoH phase and the Monitor phase. Each body is required to make their own independent assessment before giving their support for the application to move forward.

4.4 The SHA must confirm, amongst other things, that the Trust has “robust, comprehensive and effective risk management and performance management systems in place, which are proven to effect decision-making” and that there is no evidence of “issues, concerns, or reports from third parties.”

4.5 The DoH Applications Committee must review the assurances of the SHA and “test” them before making a recommendation to the Secretary of State for Health (SoSfH) who must personally support the Trusts application.

4.6 After this, Monitor, the independent regulator of Foundation Trusts, conducts its own assessment of the Trust. They must “be confident and able to provide assurance to Parliament and a wide range of stakeholders that NHS foundation trusts will be legally constituted, financially sustainable, effectively governed and locally representative.”

4.7 How a Trust with such a poor standard of care, longstanding issues with its mortality rates and consistently high complaints levels was able to progress successfully is a question that requires a full and frank answer. The Patients Association now has serious doubts about the robustness and probity of the Foundation Trust applications process because this Trust, now shown to be completely unsuitable for Foundation Trust status, was able to achieve it.
4.8 We understand that Monitor have put forward the argument that FT status is not about quality of care at any particular time, but strategy and the ability of the Trust to improve its standing in the future. Whether this is the case or not, this Trust should have failed the application process irrespective of whether the criteria is providing good quality of care or being capable of good governance— it was capable of providing neither.

4.9 Furthermore, if FT status is about effective governance and not quality of care, the Patients Association would argue that this is not the impression that has been given to the public since the introduction of FTs, nor the impression given by numerous press releases by Trusts that have achieved FT status, stating for example, that FT status puts the hospital in the “premier league”. It is difficult for Monitor to now make this argument when they have done nothing to refute the impression given to the public over the meaning of FT status.

4.10 The issue of accountability also arises for Monitor and those involved in supporting the FT application process of Mid Staffordshire NHS Foundation Trust. We would argue that a duty of care arises when a body such as Monitor is put in a position where, if it had been fulfilling its duties properly, it would have detected the problems at Mid Staffordshire NHS Foundation Trust and been in a position to alert relevant authorities to them. Once again, it is worth noting that between 400–1,200 patients died as a result of this failure and many others suffered as a result of appalling standards of care.

5.1 According to the NHS Statement of Accountability (DH 2009) states that

5.2 Primary care trusts can ask the regulators to step in if the providers are not meeting the expected standards.

And

5.3 It is important that primary care trusts engage with their local populations and their partner organisations to take account of local views.

5.4 Dr David Colin-Thome’s report, A review of lessons learnt for commissioners and performance managers following the Healthcare Commission investigation (2009), states that

5.5 Although the main responsibility for such poor patient care clearly rests with the hospital staff and its board of management, including the professional responsibility of clinicians for the care of individuals, the PCTs and SHAs also had a role to play.

And

5.6 However, locally the PCTs and SHAs did not seek out data to ensure quality of outcomes, either in their roles as commissioner, performance manager or with responsibility for oversight of the local health system. It is of concern for instance that reporting to the hospital trust board on patient complaints was suspended in 2003 until 2006, but the PCTs of the time were not aware of this and therefore did not provide a challenge.

And

5.7 The role of the PCT as commissioner, performance manager and guardian of high quality care for their local populations remains unchanged when hospitals become Foundation Trusts.
And

5.8 Prior to 2006, the quality agenda of the hospital was addressed at board level in the PCTs only to a limited degree as data on access and waiting times were given higher importance.

And

5.9 PCTs as local leaders of the NHS must assume ultimate responsibility for commissioning safe services and improving the health of their patients and populations.

5.10 In light of the above, again the question of accountability arises. We have acknowledged failings but without any opportunity for public scrutiny of those senior professionals responsible. Whilst it may only have been a small part of the failure, when that failure is thought to have led to the deaths of between 400 and 1,200 patients it is critical that the public anxiety is fully addressed. It is not enough for a DH official to privately investigate the issue and take accounts from those involved.

5.11 As with Monitor, the SHA and the HC any of the local PCTs that commissioned services from Mid Staffordshire NHS Foundation Trust had a responsibility to investigate warning signs such as the results of the 2006 and 2007 national inpatients surveys, in which the trust had been in the worst 20% on the question about whether there were enough nurses. The trust was worst out of five local trusts for the number of complaints about nursing care and the second worst out of 24 small trusts outside London. In light of this, the public deserve answers to the following questions:

— Did any of the PCTs commissioning services from Mid Staffordshire NHS Foundation—Trust review the results of the 2006 and 2007 national inpatient surveys?

— Did any of the PCTs commissioning services from Mid Staffordshire NHS Foundation Trust make note of the Trusts poor performance in the 2006 and 2007 national inpatient surveys?

— Did any of the PCTs make any assessment of whether the results of the 2006 and 2007 national inpatient survey results indicated poor care was being provided at the Trust and if so, what was done to address this by them?

HEALTHCARE COMMISSION

6.1 The HC has deservedly received widespread praise for its investigation and subsequent report into the failings of care at Mid Staffordshire NHS Foundation Trust. However, the Patients Association must raise the issue of previous assessments of the Trust that failed to give an accurate picture of the care being provided.

6.2 In particular, the Annual Health Check (AHC) carried out by the HC is designed to review the performance of all NHS Trusts and provide a rating on which patients can base their choice of provider. In the 2005–06 AHC, the trust was rated by the HC as having “fair” quality of services and in the following year (2006–07), the trust received “fair” for its quality of services once more. In the same review, the core standards score was “fully met”. This raises serious concerns over the assessments made by the HC since its inception in 2004.

6.3 According to the Healthcare Commission report, in the 2006 and 2007 national inpatients surveys, the trust had been in the worst 20% on the question about whether there were enough nurses. A review in 2004/05 showed the trust had a high overall number of complaints. The trust was worst out of five local trusts for the number of complaints about nursing care and the second worst out of 24 small trusts outside London. In light of this, it is reasonable to ask how the Trust was able to achieve relatively positive ratings from the HC.

6.4 The Patients Association is gravely concerned that, in spite of these consistent alarm bells, such poor standards of care were not uncovered sooner. The HC and the other relevant authorities were only prompted to investigate the Trust after Dr Foster, a private company, published worrying mortality statistics from the hospital. It is now clear that in fact there were long standing concerns about care at the hospital, none of which were sufficiently addressed.

6.5 Furthermore, the HC made no effort to halt the Foundation Trust application process underway for Mid Staffordshire NHS Foundation Trust, claiming they were unaware of its application. The Patients Association would point out that there is a freely accessible online list of those Trusts that have received approval from their SHA and the DH Applications Committee to move forward to Monitor to apply for FT status.

6.6 http://www.monitor-nhsft.gov.uk/home/becoming-nhs-foundation-trust/current-applicants

6.7 It is difficult to understand why a simple check was not made to see whether Mid Staffordshire was on this list and then contact made with Monitor to ask them whether the Trust was actually undergoing assessment presently.
6.8 As we feel the above raises reasonable questions over the performance of the Healthcare Commission, the Patients Association feels this gives sufficient ground to question the argument currently being made by the Department of Health that there is no need for an independent inquiry into the failings at Mid Staffordshire because, whilst the HC might be independent of the DH, it is not independent from the failings itself. In light of the above we believe patients and the public have the right to have answers to the following questions:

— Why did the Healthcare Commission not uncover long standing problems at the Trust during its previous assessments through the Annual Health Check or address the high complaint levels and poor inpatient survey results?

— What action did the Healthcare Commission take to investigate why this Trust, and others, had been consistently performing poorly in national inpatient surveys?

— If the ratings of the AHC have proven to be so inaccurate at Mid Staffordshire NHS Foundation Trust, what, in details is being done to make sure the Care Quality Commission does not make similar mistakes?

OTHER BODIES

7.1 The Patients Association would like to highlight a number of other bodies that either have a role in safeguarding patients or potentially would have been made aware of problems at the Trust. All of them should be required to give a full and frank account of any contact they had with patients or patient data from Mid Staffordshire NHS Foundation Trust.

— National Confidential Enquiry into Patient Outcome and Death.

— Independent Complaints Advocacy Service.

— National Patient Safety Agency.

— Parliamentary Health Service Ombudsman.

— Coroner.

— Health Protection Agency (of particular concern following review of the contents of a leaked email obtained by the Mirror newspaper that shows that the HPA had concerns about the Trust both this year and last).

RECOMMENDATIONS

8.1 In light of the numerous questions outlined in this document that we feel remain unanswered and because of the need for full public accountability, the Patients Association believes a public inquiry is necessary into the failings of care at Mid Staffordshire NHS Foundation Trust. As well as fulfilling the duty of accountability placed upon public servants, such an inquiry would also ensure all the lessons are learned to ensure this is never allowed to happen again.

8.2 Cure the NHS, the campaign group composed of friends and relatives of those thought to have received poor care at Mid Staffordshire NHS Foundation Trust, also want a public inquiry. As they have experienced directly the poor care provided and lost loved ones as a result they are the most able to say whether they feel their questions have been answered.

ABOUT THE PATIENTS ASSOCIATION

9.1 The Patients Association is a healthcare charity which for more than 40 years has advocated for greater and equitable access to high quality, accurate and independent information for patients, for greater and equitable access to high quality care and for involvement in decision making as a right.

9.2 The charity provides an opportunity for patients to share their experiences of healthcare so that the Patients Association can use this knowledge to press for improved services and assist people in accessing the best treatment. Through our Helpline and website we are “listening to patients, and speaking up for change”.

Our Helpline acts an informed and independent source of information for patients.

May 2009
THE SAFETY OF CARE: WHAT CONTRIBUTION CAN REGULATION MAKE?

1. Regulation in the architecture of health and healthcare

As regards the NHS, the government’s policies of decentralisation and localism, the establishment of national standards of performance coupled to local decision-making, a budget in excess of £100 billion of taxpayers’ money, and the performance management cascaded from the centre in Whitehall through regional Strategic Health Authorities, and Monitor in the case of Foundation Trusts, to individual trusts; and as regards the independent sector, its interaction with the NHS and the principle of consumer protection, all combine to create the need for:

— an independent watchdog

  — to provide assurance to the public about the safety and quality of care, currently through the Healthcare Commission’s various activities and in the future through the Care Quality Commission’s system of registration review and assessment;
  — to hold the system to account;
  — to promote improvement;
  — to publish information allowing for comparisons across the system;

all of these to be achieved through the assessment of the performance of providers and commissioners of care; reviews of services and of care for certain groups of patients; and investigations, backed by powers and sanctions.

2. The aim of regulation in relation to safe care

Healthcare is intrinsically risky. Mistakes will inevitably be made. A proportion of patients (though the number and identity are not known) will inevitably be harmed, of whom some will die. These are the facts of modern healthcare, as are the remarkable benefits now enjoyed by patients. In a significant number of the cases in which patients are harmed, the harm could have been avoided.

The regulator, working with others, particularly the National Patient Safety Agency (NPSA), should be concerned to:

— emphasise the particular importance of seeking to secure ever safer care for patients;
— contribute to the prevention and mitigation of unsafe behaviour.

3. How should the regulator achieve these aims?

The regulator should seek to ensure that the safety of care is the highest priority in the system of registration and continuing assessment and review.

Assuming an information-led, risk-based system of regulation, for the regulator to contribute to improvements in the safety of care, the following requirements need to be met:

— an analysis of what constitutes safe care in the various settings in which care is provided;
— the agreement of standards of performance which reflect this analysis and describe what good, safe care looks like;
— the design of ways of measuring (metrics) compliance with/departure from these standards;
— the collation and analysis of data (from all sources, formal and informal, including whistleblowers) required to operate these metrics;
— the reporting of what the analysis shows, including intervention, investigation, and any necessary follow-up.

These are the building blocks which, taken together, enable the regulator to play its part in promoting the safe care of patients. If they are not in place, the regulation and the regulator are less effective, and the patient is less protected. Each of the elements requires examination.

AN ANALYSIS OF SAFE CARE

There is a growing body of evidence of what makes healthcare safe, what good care looks like. This needs to be understood, shared and adopted. Much of the evidence relates to the acute sector. There is, perhaps, undue emphasis on the operating theatre and the intensive care unit, as if it were there that the patient is most at risk. But, being more at risk does not necessarily mean that the patient is more likely to be avoidably harmed. This is demonstrated by the extraordinary success in reducing the incidence of avoidable harm in anaesthesia. It remains a high-risk field of healthcare, but through close, detailed analysis, not least of the design of equipment, errors and associated harm to patients have been dramatically reduced. The same analysis needs to be applied to all aspects of care in the acute sector.
An important feature of such analysis should be the adoption of a “systems” approach, whereby care is understood as being provided within a system. Usually, things go wrong and safe care is compromised when systems break down. Crucially, the systems approach sets its face against the notion that unsafe behaviour and any ensuing harm can be explained simply by identifying individuals whose behaviour is the cause and are therefore personally responsible and should be blamed. Instead, it talks in terms of “human factors analysis”: what are the human factors in any particular activity which contribute to things going wrong? They may be the working practices, morale, team-working, incentives, equipment, resources, external pressures, or the interplay of all of these. Individuals may have done something wrong (though rarely intentionally), but to concentrate on this and not to see any individual as part of a larger whole, inevitably affects by a range of other surrounding factors, is to fail to understand how unsafe practices come about and so fail to be able to learn from them. The analysis of what makes care unsafe and how to make care safer must, therefore, be informed by the adoption of a systems approach.

Unfortunately, this approach, associated with the psychologist James Reason, is only just beginning to influence thinking in healthcare. Blaming individuals is still the preferred option of the press and to a certain extent politicians and the public. By contrast “human factors” is well embedded in the approach to safety adopted in a range of other sectors where high-risk, complex activities are the norm, such as aviation, and the petro-chemical, gas, and nuclear industries. Each of these industries now has an impressive safety record.

As has been said, much of the evidence on safe care and much of the current activity directed at improving the safety of care, focuses on the acute sector. At first blush, this seems appropriate. This is where the action is, it is said, and where errors can cost lives. But, it is too unbalanced an emphasis for two reasons. First, around 90% of all contacts between patients and clinicians take place in primary care settings or through care in the community. To focus concerns about the safety of care largely or wholly on the acute sector ignores what happens elsewhere. Second, there is no reason other than to assume that a similar incidence of unsafe practice takes place outside the acute sector. And, if this is so, the incidence of avoidable harm, currently derived almost entirely from what happens in the acute sector, must be much higher than currently estimated. The risks are different, but there nonetheless. The effects, if care is unsafe, may be different but there are effects and they can harm patients.

It is one thing, of course, to assert this as something that must rationally be true. It is another thing to be able to demonstrate and document it. Again, there are at least two reasons. They interact with each other. First, there is a very significant gap in the data: we just do not know the incidence of unsafe practices outside the acute sector which cause avoidable harm. Secondly, not only is there a gap in the data, but the way in which safety of care is conceptualised makes it currently very difficult to fill that gap. We refer here to the over-identification of unsafe care with “incidents” (reported or otherwise) and “near misses”: ie things being done.

In primary care and care in the community, however, unsafe care may take the form of omissions—failures to do something. Examples include a GP’s failure to diagnose a condition warranting treatment, mis-diagnosing what is affecting a patient, such that the wrong treatment is given, or making a diagnosis later than should have been the case, with consequent avoidable harm to the patient. Our work in dealing with complaints against Trusts provides a considerable body of anecdotal evidence that this is so. In none of these circumstances, is there an “incident” in the sense of something being done leading to the harming of a patient, such as giving the wrong medicine, operating on the wrong site, or inserting a breathing tube incorrectly. An approach to safety, therefore, which is posited on the notion that unsafe care takes the form of “incidents” and then proceeds to quantify these incidents, (concentrating on the acute sector), is important in contributing to the analysis and understanding of safe care, but only offers a partial and limited picture. This is now well recognised by the National Patient Safety Agency which is developing ways of capturing data on unsafe care in the form of omissions, with particular reference to general practice.

There is a view that omissions of the sort described are not properly understood as matters of safety, but rather reflect on the quality of care provided. The patient, on this view, suffers harm from a poor quality of care. On one level, this could be a matter of semantics. And, arguably, if it is, safety should have a wider meaning to embrace omissions which put the patient at unacceptable risk. But, it is a view which should be resisted on other grounds. Quality of care exists on a spectrum on which the safety of care is the starting point: to emphasise its importance, it should not be shouldered aside by describing something as “merely” a matter of quality (and, therefore, not requiring the concern devoted to safety). And, secondly, to categorise something as a matter of quality tends to suggest it is a matter of personal failure or competence, calling for some sort of response at the level of an individual. This runs counter to the systems or human factors approach set out earlier.

It follows that a true analysis of the safety of care, of the incidence of unsafe care, and the lessons for the former which can be derived from the latter, depend on coming to terms with what goes on in primary and community care as well as in the acute sector (and not forgetting the ambulance sector), and with omissions as well as commissions.
STANDARDS OF PERFORMANCE

Put simply, the standards relating to the safety of care are the distillation of current opinion as to what constitutes good practice in the relevant area of practice. It is important to recognise that there must be a degree of flexibility in the standards, since it is unhelpful to adopt a position that “one size fits all”. Some flexibility is required so that account may be taken of the context in which the standards are to be operated. In some geographical areas, there may be levels of disadvantage and deprivation such that the standards may have an aspirational element. It may be helpful, in such circumstances, to establish a “benchmark” of current performance, as a way of applying the standards locally, since the term benchmark has within it an implicit assumption that what can be expected by way of performance can, and should, change.

Once the initial benchmark is established, improvement can then be sought, monitored and identified and the benchmark set higher, always with a view to meeting the required standards, albeit through a measured process of improvement. This fits well with the regulatory duty to encourage improvement. What is sought is some standard of performance, a description of what amounts to good practice, derived from observation of practice, not just nationally but internationally, against which actual performance can be assessed. And, in articulating this norm, due account can be taken of the surrounding circumstances in which the performance to be assessed takes place. This allows for a more nuanced approach. It allows due account to be taken of the difference in caring for a population and patients who suffer various levels of deprivation as compared with those who are more affluent and have more opportunities. The fundamental basis of the approach is its reliance on good practice and the avoidance of risk. The question to be asked in arriving at the relevant standard is, what is required by way of performance so that a patient has service of good quality and will not be exposed to a risk of harm greater than could reasonably be expected and which can be avoided. The aim, therefore, is to agree standards of performance which reflect the analysis of what constitutes safe care and which properly take account of the context in which care is provided and the risks involved. The regulator (and everyone else) is then interested in what can reasonably be expected of this or that service, taking account of all relevant circumstances. But, a caveat must be entered immediately. When talking of safety, the safe care of patients, the idea of a standard, developed through a process of benchmarking with its inherent flexibility, cannot be used to justify behaviour which falls below some accepted and agreed minimum of safe care.

What emerges is the notion that standards of safe care consist of three elements—certain non-negotiable requirements: risks that must be avoided, whatever the circumstances; the norms of current good performance as reflected in national and international practice and general understanding of accepted risks; and incremental improvements in the avoidance of risks.

This idea of a scaled or layered approach is also reflected in how standards relating to safe care can be made to operate in practice. There will be certain standards which are generic, applicable in all circumstances, whatever the context and the area of healthcare involved. Then there will be standards particular to the area or specialty of care, child-specific in pediatrics, or specific to the care, for example, of those with diabetes.

From this approach, it will be clear that it becomes absolutely crucial who establishes the standards. Given the highly politicised nature of healthcare, government is an obvious contender. And, certainly, across the broad spectrum of health and healthcare it is entirely appropriate for government to stipulate that certain conditions be met in what the NHS and the independent sector deliver. This has led government to issue targets and the Standards for Better Health, which the Healthcare Commission is statutorily obliged to “take account of”. There are significant drawbacks, from the perspective of the regulator, in the government’s doing more than identifying a small number of targets from time to time, which reflect the declared priorities of an elected government. Going further than this should be avoided for at least two reasons. First, the choice of what to focus on is often (usually) politically driven. It may not, however, address the real challenges to safe care. “Deep cleans” may have some effect on some hospital-associated infections, but are largely irrelevant as regards others, such that, if the time of the regulator were spent in assessing compliance with the programme of cleaning, it would, to that extent, be distracted from contributing to improvements in the safety of care. Equally, by not including the safety of care in its targets until 2004 (and then only as regards some hospital-associated infections), when targets were the medium through which government signalled the really important things that had to be addressed, it could be said that the government failed adequately to signal the importance of the safety of care in the scheme of things. And, again, while creating a significant regulatory machinery to address concerns over hospital-associated infection, other hospital associated conditions, some of which like venous thromboembolism (VTE) cause a much greater toll of avoidable deaths, have gone without mention until very recently, and, thus, from one perspective, perhaps, were seen as being of less importance.

Perhaps the strongest reason why government alone should not establish the standards of performance is that, to be successful in promoting incremental improvement in performance, they need to be recognised as relevant by the clinicians who are to apply them and be assessed by reference to them. It follows that the regulator also is not the body to establish them.23 Certainly, government, and indeed the regulator, have a role to play in the development of standards, but we take the view that their development must be led by

23 NICE is currently seen as the organisation best equipped to develop standards. This accords with the approach taken here, given NICE’s well-developed system of engagement with clinicians and patients.
clinicians (by which we mean the broad spectrum of healthcare professionals), in consultation with patients. Only then will they be accepted as clinically driven (in Lord Darzi’s language), focussed on and agreed by patients and owned by clinicians, rather than seen as imposed from above and outside.

This is why the question who sets the standards is important to the regulator. There are three reasons. First, the standard must reflect professionals’ and patients’ views on what is important as regards the safety of care, since they are the experts. The regulator wants to concern itself with what matters. Secondly, the regulator is, as has been said, part of the overall architectural scheme for delivering increasingly safer and better care. If clinicians do not feel themselves genuinely engaged in the development of standards, they become disengaged. The regulator’s task in promoting improvements becomes that much more difficult: the regulator is seen by clinicians as the agent of external power imposed upon them, rather than as assessing compliance with standards that they and their patients recognise and endorse. Thirdly, regulation, to succeed in the particular culture of healthcare, must be understood and accepted by those regulated, not least clinicians. To work alongside them and others in the development of standards achieves that goal and thereby improves the prospect that patients will be treated more safely. After all, few clinicians would wish to be associated with a quality of care regarded as substandard by their peers.

The Healthcare Commission has worked successfully with clinicians over the past three years in realising the approach set out above. The collaboration has led to a large number of specialist-specific standards, some of which deal with the safety of care. So as to ensure some degree of authority in what emerges, certain principles were agreed and are followed:

- the standard must be grounded in up-to-date evidence;
- it must be accepted by the large majority of clinicians in the relevant field;
- it must have been agreed also by an appropriately constituted sample of patients;
- compliance with it must be measurable through the collection of data;
- a mechanism must exist whereby it can be reviewed and, if necessary, revised periodically.

One final point needs to be made. While there is a strong argument that government alone should not set the standards, neither should it be left to some local free-for-all to decide what standards they prefer to abide by. Apart from anything else, this would leave the regulator with no firm basis on which to assess performance except on the terms set by those being assessed. A mechanism, therefore, is needed whereby the standards which are put forward by the relevant professional groups are agreed nationally, and examined and endorsed, arguably by government and the regulator.

**Measuring Compliance**

Standards are only useful to the regulator (and all others concerned to assess performance) if compliance with them can be readily measured. This is the area described as “metrics”. In an information-led system of regulation, measurement in the first instance is through the analysis of data. The system, crucially, is not wholly based on data. This would make it too mechanistic. It must be supplemented by “softer” local intelligence and, where appropriate, targeted or unannounced visits to hospitals/trusts. The importance of such visits cannot be understated: suitably targeted, they provide an essential further element of insight into what is going on.

The development of metrics is to a large extent a matter of technical expertise, but there are a number of points to be made of a general nature.

First, the data necessary for the relevant analyses to be made must exist. In the case of the safety of care, it has been seen that in primary care there are significant gaps. Across the system of healthcare as a whole, historically, the NHS has collected data relating to finance and the throughput of patients. Then, data to meet the demands of government relating to targets were added. There was also the data necessary to meets the requirements of the regulators, the Healthcare Commission and Monitor. And, with specific reference to safe care, there is the data which the NHS Litigation Authority calls for to set its risk assessment, and that which the National Patient Safety Agency asks for (rather than requires) through its system of reporting “incidents” and “near misses”. As regards the independent sector, the data required by the current regulator (the Healthcare Commission) addresses the question of whether a provider of services should be licensed rather than any specific focus on the safety of care (although serious untoward incidents must be reported).

From this picture, it can be seen that data about safety has not historically been a priority and its collection to a degree the response to external factors rather than a very important end in itself. Evidence is now emerging that healthcare organisations are paying increased attention to safety. There is an increase in the reporting of incidents to the NPSA and the Healthcare Commission’s inspection of compliance with the Hygiene Code has had a significant effect (“what gets measured, gets done!”). But, there remain significant gaps in the data available to assess, as a regulator, or as a manager, how safe care is and what needs to be done by way of improvement, (one example emerged from the Healthcare Commission’s review of maternity services where it was found that only 17% of trusts collected data which would allow them to assess the quality and safety of care that women receive from initial contact with the service to care after birth. One particular challenge as regards data, is the capacity to keep track of patients (and professionals) as they move about and through the system of healthcare. The difficulties in exchanging data across the system remain a significant impediment to safe care and need to be addressed urgently. This was demonstrated once again in
the “care” of Baby P, whereby he was taken to a variety of healthcare organisations, each of which remained largely unaware of previous encounters and, therefore, unable to respond to the unsafe care that he was receiving.

This must change if the safety of care is to improve. The regulator must be able to know how safe services are and whether those commissioning services are insisting on such information, as part of the regulator’s duty to inform the public. The recent resurgence of interest on a national level in audit is an important step. The regulator, as one of the mechanisms available to government to advance government’s strategic goals, can then stipulate that it requires evidence that audit is being carried out, that the safety of care figures prominently in the audit, and that the evidence produced is reported to those needing to know and is then acted upon. One particularly important aspect of this insistence on audit, is the development of a culture among professionals of reporting and learning from things that have gone wrong. Such a culture, championed by NPSA, has been slow to develop, but progress is being made. It is crucial, not only for the critical reflection of professionals, but also for the regulator (as well as others), both as evidence that the safety of care is being addressed, and as a means of determining whether lessons are, in fact, being learned.

Meanwhile, the regulator should not rely solely on data generated by the NHS and the independent sector in its assessment of the safety of care. There are a very large number of organisations which, for one reason or another hold data on health and healthcare. The regulator should, as part of its strategic approach to information-led regulation, continue to identify these sources of data and add them to its data, not least to give a broader and different perspective on the performance of trusts and services in the area of safety. One of the most important sources is, of course, the NPSA. A successful working relationship has now been developed between the Healthcare Commission and the NPSA allowing for the sharing of data, so that the regulator can act promptly and effectively when appropriate. Two sources of data which are worth mentioning, since they are often overlooked, are, first, the views of patients and the public. These should be routinely collected by trusts and shared with the regulator, as they contain insights about safety which might otherwise be lost. Secondly, the regulator should routinely examine the data on complaints made against providers and commissioners of care for the same reason.

Of course, insisting that data exist invites the question, data about what? The answer is of crucial importance. The regulator, to assess the extent to which trusts and services comply with standards of what constitutes safe care, must be interested in outcomes, what was supposed to happen and what did happen. Partly because of what has been seen in other areas as important to measure, namely, outcomes, or another hold data on health and healthcare. The regulator should, as part of its strategic approach to information-led regulation, continue to identify these sources of data and add them to its data, not least to give a broader and different perspective on the performance of trusts and services in the area of safety. One of the most important sources is, of course, the NPSA. A successful working relationship has now been developed between the Healthcare Commission and the NPSA allowing for the sharing of data, so that the regulator can act promptly and effectively when appropriate. Two sources of data which are worth mentioning, since they are often overlooked, are, first, the views of patients and the public. These should be routinely collected by trusts and shared with the regulator, as they contain insights about safety which might otherwise be lost. Secondly, the regulator should routinely examine the data on complaints made against providers and commissioners of care for the same reason.

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There are clear dangers in relying solely or too heavily on data about processes. They reflect what has come to be called a “tick-box” mentality, by which is meant an approach in which following some process or procedure becomes the focus of attention rather than what is happening to the patient. The regulator, if it is to contribute to the improvement of care, must be concerned with what has happened as a consequence of some action or inaction. This is what needs to be measured. There will, undoubtedly, be circumstances in which the outcome will be too difficult to measure. In such cases, looking to processes may, if the right data is sought, serve as a proxy for the outcome. In such cases, data may serve as the basis for the metric. But, the golden rule should be the pursuit of data on outcomes of care, and in the case of safe care, whether the outcome for the patient was that risks were managed and the care was safe. And, to drive home the point, an agreed understanding of what constitutes safe care looks like must be arrived at, as must the opposite, an agreed understanding of what constitutes a departure from the required standard such as to warrant attention (in short, what is, in the current jargon, a “serious untoward incident” and, we would add, “omission”).

The last question as regards metrics is, what are they for? Obviously, in general terms, they are to measure whether the relevant standards have been met; currently, the Standards for Better Health and other related standards, but in future, the requirements for registration. As regards regulation by the Healthcare Commission, there were two distinct purposes. The difference between the two has very great importance in the context of safe care. The first purpose of the metrics is to be able to conduct a retrospective audit of performance. This was the task given to the Healthcare Commission when it was required by Parliament to publish an annual review of the performance of NHS organisations. While important, such an approach is too limited. Certainly, it allows the regulator to describe what has happened, albeit with a time-lag of up to eighteen months. In terms of safety, problems can be identified and calls to learn lessons can be issued. But, from the perspective of the patient who may have been harmed, it all may be rather too late.

So, the second purpose of the metrics is to allow the regulator to engage in regular or continuous surveillance of performance. Here the aim is to identify where patients are being exposed to unacceptable risks, so as to enable prompt action by the relevant body to be taken, before they are harmed rather than report on the harm later. This notion of designing outcome-based metrics and mining the data on a regular basis to identify outcomes outside the expected and tolerated norm is, perhaps, the single most important development in regulation that the Healthcare Commission has been aiming at since its inception. Of course, throughout its existence, it responded to alerts that all was not well. But, these were the product of a variety of sources, some more reliable than others, and if all were followed up, unnecessary burdens can be placed
on those providing services which, on examination, turn out to be perfectly good. The difference now lies in being able to mine data to identify concerns otherwise unnoticed, and to check out those brought to our attention, before taking any action.

The capacity to carry out surveillance through mining data was reflected in the identification of Mid-Staffordshire NHS Foundation Trust as being an “outlier” in terms of the rate of mortality of patients receiving emergency care there. The data, of course, only raises a question (several trusts were identified as outliers, but concerns were allayed after questions were asked. Mid-Staffordshire remained as a cause of concern, however.). The regulator can then go in search of the answer to the question, which is in essence a question about the risks that patients are being exposed to. And, if unsafe care is identified, pre-emptive, preventative action can be taken, not just by the regulator but by all those responsible for managing the performance of the trust or service in question.

When the regulatory system based on registration is introduced by the Care Quality Commission (CQC), it may well be that the same approach to the use of data will be found to be useful. At the stage of registration, CQC will need to be satisfied that registration is justified, and a significant number of the requirements to be satisfied address the safety of care. And, thereafter, CQC will be keen to keep under review, through the use of data among other things, the continued safety of the care provided by those registered.

COLLECTING AND ANALYSING THE DATA

As has been seen, the data required to enable the regulator to do its job will be found in a range of sources. It should not be the responsibility of the regulator to collect data: this is the job of the various organisations, either within the NHS and the independent sector or outside.

The job of the regulator is to ensure that the data on safety which it needs to carry out its analyses is collected by the NHS and the independent sector and made available. As has been said this is not a burdensome requirement since organisations and services should already be collecting data on safety so as to monitor their own performance. As regards data collected by organisations outside the NHS and the independent sector, the regulator should agree a system whereby it has access to what it needs and can influence what is collected, by, for example, a Royal College, the NPSA, the Health and Safety Executive, or the General Medical Council. The NPSA is a crucially important partner and relations between it and the Healthcare Commission continue to flourish.

The analysis of data to produce what the Healthcare Commission termed “intelligent information” in its Vision document (2003) lies at the heart of modern information-led, risk-based regulation. To this end, the regulator must have a significant capacity to carry out such analysis. This calls for investment in Information Technology and in highly skilled analysts. “Informatics” is the brains of the regulator and over time should be warning, reassuring, and continuously monitoring the safety of care. It should be posing questions and prompting, where appropriate, the targeted visits which will lead to answers.

REPORTING, INTERVENCING AND INVESTIGATING

The regulator should work in public. One of its fundamental obligations, reflected in the law, is to make public its findings. Nowhere is this more important than in the case of reporting on the safety of care. Patients and the public are entitled to know how safe their care will be. They are entitled to know that care is safe and to be celebrated. Equally, they are entitled to know if it is not, not least so that they may demand that action be taken. There is a view which says that the regulator’s reporting of unsafe care undermines patients’ confidence in the NHS and the morale of those looking after them. It is not clear what is intended to flow from such an observation: the regulator exists to check up, this is the job it was given by government, and cannot shut its eyes or hold its tongue when it sees patients exposed to unacceptable risks. Moreover, it is clear from surveys of patients and the public that, so far from wanting to be protected from such information, they are anxious to have it, feeling empowered by it. That morale among staff may be dented is, sadly, an inevitable consequence of the reporting of failures. The responsible regulator will ensure that any report is fair and that any action taken as a consequence of its report pays particular attention, where necessary, to rebuilding morale among staff.

What the regulator may do, so as properly to inform the public, is now being supplemented by the decision of the NPSA to make public a profile of the level of risk of harm which attaches to services in every organisation in the NHS. This sits alongside and compliments the contribution of the regulator. It brings ever greater emphasis on safe care. It also can serve as the basis for regulatory action, should analysis of the data warrant it.

Reports of performance can take many forms—from the paper publication to the interactive web-site. The fundamental obligation of the regulator, of particular significance in the case of reports on the safety of care, is that whatever form a report may take, it is fair, accurate and comprehensible. If it is not, the regulator will have failed in its primary duty to the public.

On occasions, the regulator may reach the view that on the basis of the information before it, patients may be, or appear to be at risk. It may do so based on the reports of its regional and local staff who are its eyes and ears. The Healthcare Commission has introduced, for example, monthly “risk summits” at which
representatives of agencies involved in monitoring local public services share concerns and perceptions as to the risks that users of services, including patients, are being exposed to. This is a very important development, allowing the regulator to work with others to form a risk-assessment of local services.

Alternatively, the regulator will reach this view, as has been seen, on the basis of the analysis of the data it has had submitted to it or as a product of its surveillance. Or, it may have had concerns brought to it by a whistle-blower, by staff, by management anxious for an outsider’s view, or by other parts of the machinery of management and governance.

The regulator’s first task is to assess the evidence that it has. It should be a fundamental rule that when safety is concerned, every expression of concern should be examined, however implausible or contentious it may be. The regulator’s second step is to decide on what action to take. If it is clear that patients are at real risk of being harmed, immediate action to remove the risk is required. The precise nature of this action will depend on the circumstances, but the point of departure should be the welfare of patients and members of the public who might be affected. Their needs must be the first concern of all. Then, a plan must be agreed and put into action, the operation and outcome of which should be monitored by the regulator.

If the regulator is satisfied that there is no immediate threat of harm warranting action, the regulator should adopt a graduated response. The criterion should be what will be the most efficient and effective way of securing the safe care of patients. It may involve a visit from the regulator’s staff, a review by outside peers, the drawing up of a plan in conjunction with others, or all of these. It will involve the relevant tier of management in the NHS, including the Strategic Health Authority, and Monitor as regards Foundation Trusts. Only rarely should a full-blown investigation be needed, perhaps because of the severity or scale of the risk and harm to patients, perhaps because of the generalisability of the findings to the national scene or to all similar patients. Clearly, the results of any investigation must be published, not just so that what happened can be understood, but also so that lessons can be learned.

One of the beneficial effects of publishing a report is the opportunity to set out guidance on future conduct designed to secure safe care. In keeping with what has been set out earlier, any such guidance must be the product of engagement with all those involved, and with, the area of concern. The Healthcare Commission has adopted this approach on a number of occasions, for example, in the case of maternity care, arising from the investigation into Northwick Park and the subsequent national review of maternity services. Moreover, in that case, not only was the guidance a prescription for future safer care, but it also brought together the three major professional bodies (the Royal Colleges of Midwives, Obstetrics and Gynaecology, and Nursing) into a collaborative venture, where their previous difficulties in collaboration had been one of the factors contributing to unsafe care. This is a particularly effective way for the regulator to fulfil its public duty to encourage improvement in the provision of care.

March 2009

Annex

The Healthcare Commission has already submitted a paper to the Committee outlining its work in relation to the safety of care. In this Annex we bring together a number of key points, drawn from our experience as a regulator.

1. Only around half of NHS trusts in England comply with all of the Government’s core standards relating to safety as set out in Standards for Better Health. We are concerned that performance has not consistently improved across the three years of the annual health check. (In 2007–08, 49% of trusts met all standards on safe care, compared with 51% in 2006–07 and 46% in 2005–06.)

This apparent lack of improvement may be because boards of trusts now have a greater focus on safety and what is required in order to meet core standards. Hence, they may be judging their performance more harshly in their self-declarations which is the initial stage of the annual health check. For some standards, for example the standard on decontamination, compliance has worsened because assessments are tougher than before.

The overall picture suggests that the systems in place to ensure safer care are not yet strong enough nor universally adopted. Effective systems are not always in place to understand safe care and risk, report and act on individual incidents, and analyse and act on wider lessons from, for example, information contained in audit, complaints and litigation.

2. Boards of trusts need to become more involved: improve the information that they get on safety, their recognition of how this compares to what is good in safety, and their skills to analyse and act on it.

Our work shows the importance of leadership and of making safe care the core of the organisation’s activity. We have been surprised to find that many boards involved in our investigations did not have systems in place routinely to receive key information on a range of factors that affect the safety of care—such as, rates of infection, errors in medication and compliance with good practice. These boards were unable to identify problems and fix them, before they led to further harm.
We carried out research with 30 trusts, asking them how their board managed safety. Key findings, to be published in March, are:

— boards are paying more attention to safe care, largely driven by concern for such matters as infection control, and the aftermath of high-profile investigations;

— control of healthcare-associated infection is given a lot of attention by boards, and rightly so, but this is disproportionate to the priority afforded to other areas of safety;

— most boards receive reports on serious untoward incidents, healthcare-associated infections and complaints, but immediate targets or finances still tend to dominate their priorities, and boards do not regularly receive a range of information on different areas of safety (eg medicine management, suicides) or of safety culture;

— many of those consulted felt strongly that more could and should be done to hear on a regular basis at board level the direct experiences of patients.

— Most non-executive directors described themselves as passive recipients of information on safety, with limited understanding to challenge it effectively.

— Restructuring of services or the application for foundation trust status tended to diminish the priority afforded to safe care. However, such changes often prompted a review of governance and reporting, with positive outcomes.

There is, therefore, a greater need for an understanding, by the board, of what should be happening (what is "good") so that care can be safe. There is also a need for better information and skills to compare the organisation’s performance against what is good. This has in many organisations been achieved for infection control—the approach needs to be broadened to address all areas of care since the safety of patients is at risk, to varying degrees, throughout any period of care.

3. There needs to be better reporting and analysis, at a local level, of when things have gone wrong

Based on our findings, we believe that organisations need to do more to promote a culture of openness and of reporting when things go wrong. They often fail to carry out systematic analysis following incidents and to identify contributory factors and the action required. Our investigations into serious failure of services have often found, as an underlying factor, that staff felt unable to report problems, leading to the problems going unaddressed.

We carried out research which found:

— more needs to be done to encourage reporting from staff, and different groups of staff. It is important to show staff what impact their reports have had. Our survey of NHS staff found that three-quarters of staff felt that they were encouraged to report incidents, a significant improvement, but that they were much less likely (31%) to have been informed about any changes resulting from reporting incidents;

— when an incident is reported, the report is often of poor quality which makes it difficult to learn and make appropriate changes;

— systematic analysis of incidents across a service, to find common patterns and improve care, is often lacking. (Our work on complaints has also found that trusts could do much to improve the way in which they use lessons from complaints to improve services.)

4. Trusts need to ensure that there is a better, more rounded approach to safety across their services: they need to improve training and the information on what has changed across their services

We carried out research (to be published in March) which found:

— staff responsible for particular aspects of safety (eg the implementation of safety alerts) sometimes do not have the appropriate authority to ensure that changes are implemented across different services, because they are not part of the line management structure for those services. This has particular implications for programmes of training and audit. Safety needs to be part of everyone’s job description and people held to account for improvement;

— only a minority of trusts had protected time for training in safety (note: this mirrors our survey of NHS staff which tells us that there are problems in providing mandatory training);

— trusts should actively check whether actions have been taken in order to be assured that they are providing safe care. Routine monitoring or an audit of implementation of actions relating to safety were often lacking; for example, robust monitoring of the implementation of actions required in safety alerts often does not take place. Better information about safe care needs to be generated at the level of the particular service, to give confidence that good practice is being followed and risks are being addressed.
5. **There is need for far greater attention to safety within general practice and community care**

The greatest number of contacts with patients is with GPs; and the largest number of complaints that the Healthcare Commission reviews relate to primary care (38.4% for the year to July 2007). By contrast just 0.3% of incidents reported to the NPSA (relating to England and Wales) during 2007–08 were from general practice.

Twenty-three per cent of the complaints about GPs that we reviewed concerned a failure, or delay, in diagnosing a condition.

Individual GPs are required by the QOF to carry out four “significant event audits” per year. But the outcomes of these audits are often not shared locally to spread learning, and the level of audit cannot realistically reflect the potential level of incidents in general practice. Far better reporting (of both commissions and omissions in care) is needed.

As a first step, those working in primary care should be encouraged to monitor the extent to which they follow good practice, report incidents and departures from practice, and try more regularly to learn from them.

6. **We need a better national picture of safety**

Better information about safe care needs for the purposes of comparison to be generated at national, organisational and service level, to give confidence that good practice is being followed and risks are being addressed.

As already set out, local organisations need to consider a wider range of information on safety and bring together what they learn from incident reports, complaints, litigation, monitoring and audits of safe care, and local review of casenote. This should also take place at a national level.

There is already a range of information available at a national level, eg the NPSA’s reporting system, the various other reporting systems (HSE, HC, STEIS serious incident system, MHRA system), the HPA, litigation, and the complaints system. This needs to be brought together more systematically, particularly in the case of the most serious incidents. We welcome the work of the NPSA to develop a single reporting system, which can help to underpin this.

In some areas good information on safety is missing: data on general practice and community care data is sparse, and we have not been able to assess organisations on the basis of risk in relation to some core standards (even acute trusts) because no good data is available nationally. It may be the case that good information is available locally. But focused new collections of data are needed at a national level.

In the independent sector, work continues to produce a patient-level dataset and indicators which parallel some of those available in the NHS. This is essential in order to build a picture of safe care across all sectors of care.

7. **Sustained, coordinated work with the poorest performers is needed**

CQC will have broader powers of enforcement, and may fine or limit the registration of, as well as assess and investigate, organisations and services that provide poor quality care.

However, as a regulator, it sits alongside a number of organisations which have important and distinct roles in bringing about improvement. Sustained coordinated effort is needed from the commissioners of care, SHAs, Monitor, the NHS Institute for Innovation and Improvement and the Department of Health, to bring about improvement in those organisations that have failed to improve their performance on safety.

8. **HCAI**

The NHS has had significant success in reducing MRSA infections. The overall national target for reducing infections has been met. But, almost half of trusts did not meet their individual targets for reducing or minimizing MRSA infections during 2007–08. C. difficile remains a major problem for the NHS, but there are encouraging signs of improvement in dealing with it.

Trusts are clearly tackling the prevention and control of infection vigorously. However, few trusts fully comply with the hygiene code. That said we have found few breaches of the code that posed an immediate risk to patients.

Our findings from the first 51 inspections of acute NHS trusts (about 30% of the acute sector) to assess their performance in respect of cleanliness and infection control found that only five trusts complied with all the requirements of the hygiene code. More than half of the remainder were required to ensure a clean and well-maintained environment across all their premises. Improvement is needed in some trusts in processes of decontamination, training and supervision, and facilities for isolation. Where we have raised concerns, we have generally been encouraged by the positive and prompt response of trusts.

While almost all lapses (97%) did not represent an immediate risk to the safety of patients, the analysis suggests that almost all acute trusts have more work to do to get systems for the prevention and control of infection in place. Trusts need to ensure they do this, so as to maintain the fall in rates of infection and ensure they are equipped to deal with the range of infections.
9. The role of the Healthcare Commission

The Commission has sought to play a major part in increasing the focus on safety in the NHS.

Our strategic approach is twofold. Firstly, we focus on organisational culture: whether the organisation has a strong corporate approach to safety. This includes the priority given to safety throughout an organisation; and as part of this, whether organisations report when people are harmed or receive care of poor quality and analyse and systematically learn from such incidents and other information, so as to make improvements for the benefit of users of services in general. Secondly, we test if organisations have implemented established practices relating to safer care.

Using available information and engagement with staff and patients, we establish where the highest levels of avoidable harm are arising and why, and then set the priorities our programme of assessment accordingly. In some areas—ionising radiation, controlled drugs and infection control—we have been specifically asked by Government to carry out work, because of particular risks to safety and public concern.

10. The Commission has addresses the safety of care in four ways:

— broad assessment of compliance with core standards, through the annual healthcheck,
— in-depth assessments and studies,
— interventions and investigations, and
— provision of information.

Broad assessment of compliance in the annual healthcheck

The onus is on Boards to assure themselves that their organisation is safe, and under the annual healthcheck, each NHS trust makes a self-assessment and public declaration on whether they are meeting the Government’s core standards. 12 of the 44 standards relate to safety. We systematically assess whether these standards are being met, by cross-checking trusts’ declarations against a range of data and local views, and visiting a proportion of trusts to test whether they have assessed themselves appropriately.

We also assess progress in meeting two safety-related national targets as part of the annual health check. Overall, cases of MRSA bacteraemia and *Clostridium difficile*-associated diarrhoea are falling, but many individual trusts have not met their particular targets.

In-depth assessments and studies

The Healthcare Commission believes that the broad-brush assessment of compliance with standards is not sufficient to assess the safety and quality of care, therefore, complements this assessment with in-depth reviews of areas of concern.

A number of our reviews (eg that of maternity services) cover substantial issues of safety. We also carry out safety-specific in-depth work. Following earlier work on infection control, we addressed in-depth a number of areas of high priority in 2008–09, forming a substantial programme of new work on safety, as follows:

— A review of medicines management at the point of discharge from hospital, (assessments are currently being finalised; reporting summer 2009).
— A study of implementation of safe care, looking at falls by inpatient, acting on safety alerts, and the management of medical devices (March 2009).
— A study of Boards’ governance of safety (March 2009).
— An extension of the programme of inspecting compliance with the Hygiene Code, so that it covered PCTs, mental health trusts and ambulance trusts on a risk basis in addition to covering all acute trusts (inspections of PCTs have just been completed).
— Two studies on how infection control is managed across health and social care, and of the relative risks of infection across settings and groups of people (reporting May 2009).

Interventions and investigations

We take action where cases of serious concern about the safety of the care of patients are raised. The Commission has had over 300 cases referred to it and completed 16 investigations, as well as a wide range of other interventions, covering both NHS and independent healthcare. The publication of the findings of investigations has been found to have a “ripple effect” bring about improvement far beyond the organisation under investigation.
Provision of information

We have extended the range of indicators used to rate the performance of trusts as regards safety in the annual healthcheck. We have also published benchmarking indicators relating to the identification of a culture of safety and key risks for organisations to use to assess their own performance. This set was developed through broad engagement with clinicians and trusts’ managers, both through traditional consultation and through a research project involving 30 trusts.

Further memorandum by the Healthcare Commission (PS 52B)

I write to you out of concern for the public record and because I understand that the Health Select Committee may undertake an inquiry into mid-Staffordshire NHS Foundation Trust. Some misunderstandings have emerged about the Healthcare Commission’s investigation into the trust. In the hope of clarifying matters, I offer the following.

1. The Commission acted immediately once it became aware of potential risks to the safety of patients. Initially, efforts were made to engage the trust in dialogue about its mortality rates. When that failed and the trust held to its view that it was all a matter of coding, we began an investigation in March 2008. When it became clear how serious were the concerns about the safety and quality of care in the A&E department, we had a meeting with the Chief Executive in May 2008, and wrote immediately afterwards, sending copies of the letter widely, requiring certain critical changes to be introduced straightaway. The Commission continued to conduct its investigation, all the while monitoring current activity. The Report may have taken almost a year to produce, which given the scale of the problem and the need for scrupulous accuracy, is unsurprising. But, for the avoidance of doubt, there was no delay in responding: action on the ground could not have been more swift.

2. The history of the performance of Mid-Staffs, before and after it became a Foundation Trust, is a matter of record. In a clinical governance review in January 2002, CHI called for urgent action on levels of staffing, and, among other things drew attention to problems in emergency care. In the annual star ratings for 2002–03, published in July 2003 it was awarded three stars. The Healthcare Commission was established in 2004. In July 2004, the trust was awarded 0 stars. In July, 2005, it was awarded one star and put in the lowest band of performance for capacity and capability. In the Commission’s new system, in October 2006, it was awarded a “fair” (barely adequate and in need of improvement).

3. The Healthcare Commission’s assessments are of the overall performance of the trust, and are general assessments. They will not always spot every area of inadequacy. Problems can, for example, be masked by the bigger picture. It was for this reason that the Commission was during 2007 was developing its more sophisticated tools, based on surveillance of mortality rates referred to in paragraph 6 below.

4. In October 2007, the trust again scored “fair” for quality of services. In October 2008, it was given a score of “good”, but with the proviso published on our website that this score was based on the trust’s self-declaration and was not endorsed by the Commission, given that the investigation that was then underway. We felt we could not allocate a different rating before we had concluded the investigation.

5. CHI and subsequently the Healthcare Commission assessed performance and made public their findings. The responsibility for managing performance, including effecting necessary improvements lay and lies with the trust and its performance manager, the Strategic Health Authority, the commissioning PCT and, after the award of Foundation Trust status, Monitor. These performance managers are able to visit any trust and call for whatever information that they believe is necessary from the trust to carry out their duties.

6. On the specific issue of mortality rates, Dr Fosters Hospitalised Standard Mortality Rates or some early equivalent were available from 2001. These look at higher than expected mortality rates across a hospital. They raise questions but it is generally recognised that the information is very general. A team in the Commission (the mortality outliers team), developed a process for looking at mortality rates in relation to individual conditions or diagnoses. This information is more specific than hospital-wide statistics. The product of this work first became available in the summer of 2007. It was this work that eventually generated 11 “alerts” of higher than expected mortality rates relating to different conditions at Mid-Staffs, all across the pathway of emergency care. The Commission wrote to the trust in August 2007 requesting an explanation. The trust responded in September 2007, saying that they were “investigating and would supply a copy of their review”. Despite our pursuing them they did not do so. The trust did not respond to a letter about a separate “alert” sent in October 2007. In November 2007, the trust presented the Commission with a slide show, which explained the “alerts” as being caused by coding errors. The trust indicated that it had shown the same slide show to the SHA a few days earlier. The mortality outliers team in late November, referred the trust to the Commission’s Investigations Committee for consideration. Following normal practice, efforts were made to liaise with the trust and the SHA to explore what
was needed. The Commission wrote to the Trust in January 2008 requiring information on clinical governance in the light of the “alerts”. This is referred to in our letter indicating our initial consideration of what was happening, a copy of which we sent to the SHA. The Investigation team visited Mid-Staffs unannounced in February 2008. The Commission immediately launched a full-scale investigation. Simultaneously, the group of local patients brought to the attention of the local PCT a number of complaints from patients which had come to the Commission independently through its Helpline.

7. In February 2008, the Trust was granted Foundation Trust status. The investigation team at the Commission did not know that the Trust was being considered for this status and was not asked whether there were concerns about the performance of the Trust in terms of the safety and quality of care (its rating was then “fair”). We understand that Monitor asked the Strategic Health Authority for its views; the SHA was aware of our work on mortality outliers and “alerts” by then.

8. In March 2008, the Trust declared that it was complying with the core standards involved in the Annual Health Check.

9. The Commission’s staff met staff from the SHA in April 2008 because the SHA was an interested party in the investigation. In May, 2008 after a visit to the A&E department, the Commission’s staff met the Trust’s Chief Executive and expressed serious concerns about the safety and quality of care. Copies of the letter were sent to the PCT, SHA, Monitor and the Department of Health. The Commission considered but decided not to recommend that the Secretary of State and Monitor take “special measures”, since all of the relevant parties were already engaged in addressing problems. The Commission again wrote in September 2008 to the Chief Executive with further concerns. It wrote further in October 2008 to the Chief Executive following the completion of formal interviews expressing its concerns. Copies of the letter were sent to the same parties as before. In October 2008, the Commission published a rating of “good” for the Trust, but made it clear on its website that this rating was based on the Trust’s self-declaration and subject to the outcome of the on-going investigation.

10. The Report on Mid-Staffs was published in March 2009.

I hope that the above analysis will be helpful to you.

Professor Sir Ian Kennedy
Chair
31 March 2009

Further memorandum by Action against Medical Accidents (PS 56A)

MID STAFFORDSHIRE NHS FOUNDATION TRUST

Action against Medical Accidents (“AvMA”—the charity for patient safety and justice) was glad to hear that the Health Committee are to consider issues in connection with Mid Staffordshire NHS Foundation Trust at its meeting on 3 June. As you know, AvMA is directly involved in supporting and advising individual patients/families affected by events at Stafford, and is working with the local campaign group “Cure the NHS” to campaign for a public inquiry. We believe that there are important questions to be answered and lessons learnt for the benefit of the NHS and patient safety nationally, not just in Stafford.

We thought it might be useful if we brought to your attention some of the key questions which we believe are not dealt with, or dealt with adequately, by the investigations/reviews which have been held so far.

Firstly, we wish to raise a concern about the current process which has been set up to offer independent case note reviews to bereaved families, which may need urgent attention:

Are the “Independent Case Note Reviews” independent and robust enough?

We have concerns about the proposed method of conducting the “independent case note reviews” which have been offered to anyone who lost a relative at Stafford hospital. We offered our help in devising a suitable approach based on extensive experience in advising families affected by medical harm at the very outset both to the Department of Health and to the Trust itself. Although the review panels will be clinicians who are independent of the Trust itself, the process itself is controlled and overseen by the Trust. Our offer to help has not even received a response. There is no element in the process which is completely independent of the NHS, which is likely to damage it credibility. Furthermore, our offer to provide independent advice and support to families to empower them in this process has so far been ignored. We believe that in order to get the most from this process, families will need to be empowered to set the terms of reference, ask the right questions and to understand and, if necessary, challenge the advice of the panels.
Secondly, there are a number of important questions which are not dealt with in sufficient depth or at all by the Healthcare Commission report or the other reviews ordered by the Secretary of State:

**What were the problems with investigation and handing of complaints and what has happened since?**

It is a huge cause of continuing disappointment that we continue to see examples of patients’/families’ concerns not being taken seriously or acted upon. The Healthcare Commission report said “The investigation and handling of complaints was poor and, when action plans were produced, action often did not follow”. The Thomé report also refers to complaints, but none of the reviews examines the failings in complaints handling in detail or whether these that been put right. The assumption that the new complaints system will somehow deal with whatever was going wrong lacks analysis and is naïve.

**How were patients/families supported in bringing forward their concerns or otherwise, and what lessons can be learnt from this?**

Feedback we have received so far suggests that the role of Patient Advice & Liaison Services (PALS) has been blurred with that of complaints staff. PALS is supposed to be a customer service/troubleshooting role designed to avoid complaints being necessary. There is a danger that complaints/serious issues may be “buried” if this role, and the role of complaints staff, is not clarified and if there are not robust systems in place. Feedback we have received from families suggests that many perceive this to have been the case.

Independent Complaints Advocacy Services (ICAS) have, as far as we can see, not been mentioned in relation to Stafford. This service was supposed to replace the complaints support which had been provided by Community Health Councils (CHCs) before they were abolished. Feedback so far has suggested that complainants were, and staff are, not being routinely informed of the avoidability of independent help with complaints available from ICAS, or from charities such as AvMA. ICAS themselves have been conspicuously silent over their experience of complaints about Stafford.

**How could Patient & Public Involvement help alert the system to problems?**

The Healthcare Commission and Thomé reports refer to failures to listen to patients and the system of patient & public involvement (PPI). However, Professor Thomé’s assumption that the new system of LINKs will address the problem is without any analysis. An average CHC would have been alerted to problems at Stafford through its complaints support role and/or monitoring visits, and have taken action to force the NHS authorities to take note. Our view is that the fragmented system of PPI that we have been left with post-CHCs makes this far less likely to happen. ICAS is not directly connected to the system of PPI at all. LINKs do not have a role in complaints or have their own dedicated staff, or the powers that CHCs had.

**Which managers or other staff are to be held accountable?**

In addition to the well rehearsed questions about the manner and terms of the Chief Executive’s departure, we would expect to see other people held to account for what went on at Stafford. Given the gross failures in clinical leadership that have been reported, and gross failings in nursing care, have any other people been disciplined? Have there been any referrals to the professional bodies (the General Medical Council or Nursing & Midwifery Council)? What about the board and governors—what confidence should patients and the public have in the Trust, and about accountability of the NHS generally, if the board and governors which presided over this scandal are largely unchanged?

**How could the role of the Healthcare Commission (and the Care Quality Commission in the future) have been/better?**

Ben Bradshaw MP said in the debate about a public inquiry on 18th May that it was unnecessary because there was a national watchdog in place (the Care Quality Commission). However, the CQC’s predecessor being in existence did not prevent the events at Stafford occurring. Whilst the Healthcare Commission is to be commended for its hard hitting report, there has been no independent scrutiny of its own role and whether it should have been quicker to identify problems and intervene. These lessons will be crucial for ensuring that the CQC is an effective regulator.

**What role did staff bullying have to play? What has been done about it?**

We have heard reports that staff were bullied to agree to poor patient care and falsifying of documentation in order to “tick the box” when it came to targets (eg the four hour A&E target). To what extent has this been investigated? What action has been taken against those responsible? What lessons are there for avoiding bullying elsewhere?
When and how did the Department of Health hear about the serious problems at Stafford and was its response appropriate?

Julie Bailey of Cure the NHS wrote to the Secretary of State in December 2007 with details of circa fifty cases as examples of serious concern about Stafford hospital. How was this information used? Were there any other intimations of the problems at Stafford which the Department of Health received which could have been acted upon earlier?

Other questions which are well rehearsed/need no explanation but which do require answers, include:

- How were staff supported in “whistle-blowing” and how should they be?
- How far did the pressure to achieve Foundation Trust status contribute to the failure to focus on patient safety and quality and how can this be avoided in future?
- How did Monitor fail to communicate effectively with the other bodies (and vice versa) and how can this be put right?
- Why did the PCT and Strategic Health Authority fail to recognise the problems at Stafford and act appropriately?

We would be pleased if you could take the opportunity to raise some of these questions and would be interested into your conclusion as to whether you believe, as we do, that a public inquiry would be the most suitable way of addressing these issues.

Peter Walsh
Chief Executive

May 2009

Further memorandum by the Royal College of Psychiatrists (PS 68A)

PATIENT SAFETY

The message that keeping people safe needs well trained, well supported staff who communicate effectively in properly designed, comfortable and welcoming environments is not new but always worth repeating. Treating people with respect and dignity and listening to what they say is likely to reduce risk. Staff should be trained in communication which is simple, unambiguous and easy to understand and even more importantly staff, need to have an interpersonal style which is warm, supportive and reassuring. This is often an issue for staff selection but training in this area is worthwhile as well as making sure that staff, undertake a CRB check. A CRB check is particularly relevant if staff, are going to be working with children and children of the mentally ill.

A continuing focus on risk avoidance as a main driver tends to be counterproductive to achieving the above as is the current emphasis on efficiency and short term cost reductions. Excessive focus on immediate risks leads to neglect of the longer term risks of neglect of physical health and marginalization. Similarly having a blame culture and defensive practice is unhelpful in reducing risk. The biggest risk our patients face is early death and the extent to which this is contributed to by the treatments we use. There is probably more that we could be doing to address the metabolic consequences of atypicals’. They are two orders of magnitude more significant in terms of the burden of illness than sudden death from the cardiac effects of typical antipsychotics.

A reactive approach to violence is unhelpful and what works best is developing an environment which reduces the triggers for impulsive behaviors. These tend to be unplanned interactions, whether with peers or staff, which are perceived as aversive by service users who are highly aroused, may be paranoid, easily over-stimulated and sometimes frightened and disoriented. The best ways of avoiding these interactions are by making the day as predictable as possible using meaningful, enjoyable, age-appropriate occupation with rest periods built in at regular intervals. The physical environment should also be geared towards calmness, relaxation and predictability, with a range of areas so highly aroused individuals can be separated from peers.

Reducing risk is about understanding the factors which contribute to risk behaviors at a clinical level and reducing them either by treatment of symptoms, developing alternative coping strategies, or putting appropriate external supports in be provided by ward based staff including HCAs with the right training and supervision. For a younger group activities geared to leisure and relaxation should be provided at weekends and in the evenings. The physical environment should also be geared towards calmness, relaxation and predictability, with a range of areas so highly aroused individuals can be separated from peers.

Reducing risk is about understanding the factors which contribute to risk behaviors at a clinical level and reducing them either by treatment of symptoms, developing alternative coping strategies, or putting appropriate external supports in be provided by ward based staff including HCAs with the right training and supervision. For a younger group activities geared to leisure and relaxation should be provided at weekends and in the evenings. The physical environment should also be geared towards calmness, relaxation and predictability, with a range of areas so highly aroused individuals can be separated from peers.

It should be considered a core role of ward-based staff and as important a function as administering medication. Ward staff should see their role as to interact and “do things” with service users rather than simply to observe and record. They would obtain more relevant clinical information by doing this than by simple observation, would be less bored and less likely to miss subtle but important changes in presentation.
Inpatient facilities are an essential and an important part of care. The poor state of inpatient facilities has resulted from a systematic running down of inpatient beds, fuelled by an outdated and now misconceived notion that inpatient admission was in some ways a “failure of care”. This has in partly been a stigmatised part of the service, as beds have been reduced to the point where they are often limited to those patients admitted under the Mental Health Act. Stigma itself remains a damaging phenomenon for patients, their wellbeing and for psychiatry practice that aims to help them and act as an advocate for patients. For instance, stigma of psychiatric patients and the perception of the risk they pose as depicted in the media needs to be informed by evidence and more research.

Inpatient services desperately need investment in order to make the experience of them healthier, safer and more conducive to proper clinical recovery and rehabilitation. For instance too many patients are left to stay in bed until after midday because staff, focus their attention on those who are more demanding or needing restraint. There is also a desperate lack of occupational facilities that are so essential for recovery. Too often the criticism from patients and carers that the patient is “left with nothing to do” and so “what’s the point in them staying in hospital” is because of the lack of facilities and staff time to spend with patients. Often patient safety is put at risk because of boredom and a lack of “organised and constructive occupation” and individual attention provided for them. In all Acute wards whether single or mixed there are problems with protecting vulnerable people from people who are often at a different stage of illness whose behaviour is bullying or intrusive.

There is often poor liaison between inpatient and outpatient teams, which compounds the problem of safety. For example a loss of notes/clinical information and a lack of diagnosis which, can be made worse by there being separate inpatient and outpatient consultants. The criticisms of inpatient wards will continue to become self-fulfilling prophesies until a major programme of inpatient investment takes place. The criticisms of inpatient wards will continue to become self-fulfilling prophesies until a major programme of inpatient investment takes place. The current focus on errors caused by staff is not the best way to achieve good patient outcomes as a tick box mentality is nonconductive to good medical practice. What is required is good clinical care coordinated within and across clinical teams with clear lines of responsibility to reinforce patient safety.

November 2008

Memorandum by the British Association of Immediate Care (BASICS) (PS 77)

PROVISION OF ADVANCED MEDICAL CARE FOR THE SERIOUSLY ILL AND INJURED OUTSIDE OF HOSPITAL

We are writing to inform the Health Select Committee about an issue we believe relevant to your current enquiry into patient safety.

Contrary to popular belief the country does not have the capacity to provide doctors to attend seriously injured and ill patients outside of hospital. In the event of a road traffic accident, industrial accident, house fire, sporting accident, sudden medical deterioration, rail/train/plane crash, or terrorist incident the NHS cannot provide doctors to give immediate life saving care to patients.

The current standard of NHS care outside of hospital is provided by paramedics. Most patients are treated very well by paramedics; however there are a small number of critically ill and injured patients who are beyond the skills of paramedics. These patients are rushed into hospital to reach doctor-led care in an attempt to save their lives.

This system is failing the most severely ill and injured in the country, resulting in unnecessary deaths outside of hospital and early hospital deaths. The recent National Confidential Enquiry into patient outcomes and deaths (NCEPOD 2007) concluded that:

“The current structure of pre-hospital management is insufficient to meet the needs of the severely injured patient.”

Doctors frustrated at this lack of NHS care have attempted to provide out of hospital advanced medical care to seriously ill and injured patients for the past 30 years through the charity BASICS (British Association of Immediate Care). This system is wholly inadequate, as it relies on volunteer doctors who are only available if not working in their NHS roles.

The patient safety risk is clear—patients are dying unnecessarily across the UK because the NHS does not provide doctors to care for them. We highlight this risk in the accompanying documents answering each of your terms of reference.24
Risks to Patient Safety

1. A sequence of reports25,26,27,28,29,30 culminating in the December 2007 National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD)31 report has shown that pre-hospital care of trauma patients is inadequate in England, Wales and Northern Ireland. 60% of casualties are not adequately managed, and the avoidable mortality is up to 40%.

2. Seriously ill and injured patients require specialist care to support their organ function; this is known as critical care.32 The beginning of the NHS journey for these critically ill patients begins before reaching hospital with the pre-hospital phase; the average duration of this phase in England is 55 minutes.33 Therefore, the crucial first hour of critical care is entirely outside of hospital.

3. A number of validated studies have shown that critically ill and injured patients in the pre-hospital environment need critical care to survive; the competencies required are only attainable by highly trained critical care doctors. Management by such a pre-hospital critical care doctor (as found across Europe) increases patient survival by a factor of 2.8.34

4. Paramedics and other non-medical health care professionals do not possess the required critical care competencies, and cannot be trained to an appropriate level; gaining the necessary skills requires a high standard of medical training and experience. For example—the advanced airway management technique of tracheal intubation has recently been withdrawn from paramedic training as the survival rate is near zero in paramedic’s hands; it is highly effective when performed under anaesthesia by a critical care doctor.35

5. Emergency ambulances have to attend 75% of life-threatening emergencies within eight minutes. There is no target relating to the competence of the crew member attending, and the crew may not even have Paramedic training. Emergencies may be attended by a Technician crew with limited training, or even Emergency Care Assistants (ECAs), who have very minimal training and can offer only basic first aid. The public therefore face a lottery as to whether an appropriately trained and experienced ambulance crew attends them; they are unlikely to get a critical care doctor.

Current National Effectiveness in Ensuring Patient Safety

6. Currently, the essential, doctor led, critical care that seriously ill and injured patients require is incompletely, unpredictably and inconsistently provided across the UK by volunteer doctors from the British Association for Immediate Care (BASICS); these doctors generally work in their own time for no pay, and are equipped and trained with charitable support. Across the country the voluntary provision of prehospital doctors is extremely patchy. Figure 1 demonstrates this for the South Central Strategic Health Authority region and surrounding counties.

7. The daily need for prehospital critical care doctors in the UK is high. As an example, within Hampshire in 2007, the ambulance service called for medical support for serious incidents 1,334 times in the year. BASICS Hampshire doctors were only able to respond to under half of these calls, as they work full time for the NHS and therefore have other clinical commitments from which they cannot be released.

8. The sickest and most vulnerable patients in the UK therefore do not receive the often quoted NHS principle of “the right care in the right time in the right place”. This absence of NHS care is deadly and has been described in detail by the 2007 National Confidential Enquiry into Patient Outcome and Death “Trauma who cares?” report.36 There is no other group of patients who die through lack of appropriate medical care on a regular basis and the NHS urgently needs to recognize this group of patients and provide them clinical care appropriate to their needs.

9. World class pre-hospital critical care is provided in other countries by teams composed of a specially trained doctor and paramedic. The Germans, French, Dutch, Scandinavians, Australians and Americans all provide 24 hour 7 day a week critical care to patients outside of hospitals.37,38,39

27 The British Orthopaedic Association. The Management of Trauma in Great Britain. 1989
31 Findlay G et al., compilers. Trauma; who cares? A report of the National Confidential Enquiry into Patient Outcomes and Deaths 2007 NCEPOD Dec 2007
32 Department of Health. A report by the Critical Care Stakeholder Forum, Quality Critical Care Beyond “Comprehensive Critical Care”. September 2005
33 NCEPOD Dec 2007
36 NCEPOD Dec 2007
10. During the day time in London, an NHS funded critical care doctor/paramedic team is available to attend critically ill patients, utilising the London Air Ambulance as a vehicle. At night time however, pre-hospital critical care provision in London is highly dependent on volunteer BASICS doctors.

11. The Department of Transport Road Accident Report (2006)\textsuperscript{40} demonstrates that there are 3,172 deaths and 28,673 serious injuries across England each year (figure 2). Application of survival rates from published studies\textsuperscript{41,42} shows that a doctor-led pre-hospital critical care service would save an estimated 2,041 lives per year, with a saving of £2.6 billion to the state (figure 3). The scale of the financial savings would markedly outweigh the costs of the service, which would therefore be highly cost effective.

12. Development of a network of regional, doctor-led, pre-hospital, critical care services for critically ill and injured patients across the country would save lives, reduce morbidity of survivors, enable more injured patients to return to a productive life, and save money.

What the NHS should do regarding patient safety?

13. Prehospital critical care services similarly to London, Europe, Australasia and the USA could be provided by teams composed of a critical care doctor and paramedic. The teams could be transported to incident scenes using helicopters or road vehicles as geographically appropriate.

14. Helicopters enable efficient delivery of critical care expertise to incident scenes. In addition, the helicopter can provide stable and rapid transport of patients to appropriate hospitals. To allow pre-hospital critical care services to efficiently operate, we concur with national guidelines recommending helipad access to the emergency department of all acute hospitals.

15. Regional doctor-led pre-hospital critical care services would facilitate the development of regional trauma centres. Doctors, unlike paramedics, are able to stabilise critically ill patients to enable bypass of smaller hospitals and transport directly to the hospital most appropriate for their injuries.

16. Doctor-led prehospital critical care would enable safe transport of critically ill patients directly to regional cardiac and stroke centres, and therefore would support regionalised stroke and Percutaneous Cardiac Intervention (PCI) services currently being developed by Primary Care Trusts.

17. A phased introduction of prehospital critical care services could be achieved by:

A) Funding the crewing of regional air ambulances with critical care doctors and providing landing sites at all acute hospitals. This would be a low cost solution to the problem of day-time critical care provision for seriously ill and injured patients, including care and transfer of those requiring stroke or PCI interventions. The major cost of the service, the helicopters, is already funded by charities, and the paramedics are already funded by the ambulance services.

B) Extending coverage to include night-time. This would utilise road vehicles or helicopters (as regionally appropriate) to transport critical care teams to incident scenes.

Summary

1. Due to an absence of NHS, pre-hospital, critical care provision, patients are exposed daily to serious risks of which the large majority is unaware. This deficit is clearly apparent to those who work within the field, and we feel it is unacceptable.

2. We suggest that the subject is therefore worthy of a Health Select Committee review. Such a review would deservedly cast attention on this vacuum of care and would act as a catalyst for improvements in safety for thousands of patients.

\textit{Dr Philip Hyde}
Paediatric Intensive Care Specialist Registrar
Training officer for BASICS Hampshire

\textit{Dr David Sutton}

\textit{Dr Charles Deakin}

October 2008

\textsuperscript{40} Department of Transport, Road traffic accident report (2006)
\textsuperscript{41} Br J Surg, 2004 Nov;91(11):1520–6
\textsuperscript{42} NCEPOD Dec 2007
Memorandum by the Royal Pharmaceutical Society of Great Britain (PS 78)

We welcome this inquiry into patient safety and the opportunity to submit evidence to it.

BACKGROUND

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession’s policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century, the Society is working towards the de-merger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

SCOPE OF THE RPSGB SUBMISSION

Pharmacy has a long tradition of commitment to patient safety; indeed the profession grew out of the need for safely prepared and used medicines. We have focused in this submission on medicines safety because that is pharmacy’s area of expertise. The RPSGB has commissioned a scoping project on Making Britain a safer place to take medicines from a team of leading patient-safety experts led by Professor Charles Vincent, Professor of Clinical Safety Research, Imperial College London. The report, which is due to be completed by the end of October 2008, will focus on key stages of the “drug journey” from prescribing to medicine taking; areas where pharmacy or pharmacists can make an important contribution to improving medicines safety; areas where RPSGB has a locus or can bring influence to bear on other agencies to achieve change; proven interventions which improve medicines safety; identifying levers at all levels of the health system for implementing proven interventions on a wider scale; and recommendations about next steps for implementation, identifying specific areas where the future professional body for pharmacy (following the RPSGB’s de-merger in 2010) could have an important role (the project brief is attached at Appendix 1). Much of this submission is based on interim findings from the scoping project.

Opportunities for pharmacy to help improve medicines safety are highlighted in the recent pharmacy White Paper Pharmacy in England which will be taken forward in the context of implementation of the NHS Next Stage Review.

1. What the risks to patient safety are and to what extent they are avoidable

Avoidable harm caused by medicines use

1. Medicines-safety research often identifies the harmful effects of medicines. The avoidable harm caused by medicines use is a function of the effects of the medicines themselves, the way they are used, and the way they are monitored.

2. It has been estimated that preventable harm from medicines could cost the NHS more than £750 million each year in England alone. Box 1 summarises some studies of harm, both avoidable and unavoidable, from medicines use in the UK.

— 9 (1%) of 840 inpatients suffered preventable harm due to medication in two UK hospitals. 45
— 265 (6.5%) of 4093 patient admissions were judged to be drug related and 178 (67%) of these were judged to be preventable in a UK hospital. The drugs most commonly implicated were NSAIDs, antiplatelets, antiepileptics, hypoglycaemics, diuretics, inhaled corticosteroids, cardiac glycosides, and beta-blockers. 46
— 6.5% of 18,820 admissions were due to an adverse drug reaction in two large hospitals, with the reaction directly leading to the admission in 80% of these cases. Most reactions were either definitely or possibly avoidable. Drugs most commonly implicated in causing these admissions were low dose aspirin, diuretics, warfarin, and non-steroidal anti-inflammatory drugs, the most common reaction being gastrointestinal bleeding. 47
— 30 (2.7%) of 1,101 emergency admissions to a Scottish hospital were related to an adverse drug reaction. Three (9.7%) of the 30 were associated with non-prescription medicines. The adverse drug reaction was the dominant reason for admission in 17 cases (56.7%) and only four (13.3%) were considered to be unavoidable. 48

Box 1: Key studies of the incidence of medication-related harm in the UK

An overview of medicines safety

3. The safety of medicines has traditionally fallen into three areas:

a) The safety of the medicine itself. This includes manufacturing a product of suitable quality, and assessing the side effects that the medicine produces. The process by which medicines are licensed provides some assurance of safety in these areas. However, safety may become an issue after licensing, or if the drug is used outside its licence. The presence of counterfeit medicines within UK healthcare is also an issue.

b) Safe and appropriate use of the medicine by healthcare professionals and carers. This has traditionally been considered as “medication errors”. It includes errors in prescribing, dispensing, compounding, administering and monitoring medicines.

c) Non-adherence to medicines by patients. This area is complex, as it involves autonomy and free will. In addition, non-adherence may be the correct action by a patient as they may have experienced an adverse reaction. So, we will not take non-adherence as necessarily a bad thing; however, we will focus on the many cases where it reduces the safety and effectiveness of medicines.

Counterfeit medicines

4. Most of our submission is concerned with areas b) and c) above, as the safety of the medicine itself is the responsibility of MHRA. Pharmacists do, however, have a role in the detection of counterfeit medicines: RPSGB and MHRA have produced joint guidance for pharmacists alerting them to the possibility of counterfeit medicines supply-chain and advising them on what to do if they suspect a medicine is counterfeit. 49 RPSGB and MHRA are also preparing guidance for patients on counterfeit medicines.

5. The RPSGB has also set up the Internet Pharmacy Logo—an initiative to assist members of the public to buy medicines over the internet safely and reduce the risk of counterfeit medicines being purchased by a member of the public. 50

6. The process of medicines use generally follows the route of prescribing, dispensing/supplying, sometimes making up the medicine, then administration (whether self administration or administration by others). For some medicines there is a need for monitoring and review to ensure the medicine is effective and acceptable. All these stages need to be communicated clearly and recorded accurately. The process may vary according to the drug and the setting. 80 percent of drug use is in primary care, and Box 2 below shows what we know from research about the error rates at each stage of the process in the UK.

49 http://www.rpsgb.org/pdfs/counterfeitmedsguid.pdf
50 www.internetpharmacylogo.org
7. Examples of the types of medication error include prescribing errors, omitting to give the drug, giving the wrong drug, giving too much or too little, failing to order the drug, preparing it incorrectly and giving it by the wrong route or the wrong rate of administration. In the past the approach to improving medicines safety has been to take one type of error and try to reduce it. However, as patient safety research has shown, it is important that we look at the whole system. To focus on one error type is analogous to polishing one cog in a rusty clock. All the hard work can be undone by errors elsewhere in the system.

1) Patient sees GP
2) Patient is prescribed medication.
   — Prescribing error rate: 7.5% of prescription items written.
3) Prescription taken to community pharmacy.
   — 2.6–5.2% of prescribed items are not “cashed” by patient
4) Medication dispensed.
   — Dispensing error rate: 3.3% of all items dispensed.
5) Patient takes medication.
   — Patient non-adherence: 30–50%
   — Drug related admissions to hospital: 6.7% of all admissions, 69% of which are preventable
6) Prescribing reviewed at least every 6th request
   — Medication not reviewed in 15 months: 72% of medications
7) For patients seen in hospital outpatients:
   — Prescribing error rate: 77.4% of prescribed items
   — Medication details not added to GP records: 5% of prescribed items
   — Dose taken not added to GP records: 13% of consultations
8) For patients admitted to hospital:
   — Unintentional discrepancies in medication prescribed on admission: 58% of patients/60% of prescribed medicines
   — Inpatient prescribing error rate: 1.5–9.2%. Average of 3.5 errors per patient
   — Unintentional discrepancies in discharge medication: 11–27% items
   — Unintentional discrepancies in discharge medication subsequently received from GP: 46–60% of items; 57% of patients

Box 2: Error rates at each stage of the medicines-use process, based on UK studies

8. It can be seen that in primary care the greatest proportion of errors occurs through non-adherence and inadequate monitoring of therapy.

9. In secondary care, medication errors in prescribing and administration (particularly intravenously) probably have a similar frequency. There is a high degree of error when patients are admitted to, and discharged from hospital.

10. Box 3 shows the frequency of error in care homes, based on work commissioned by the DH Policy research initiative: the Patient Safety Research Portfolio.

— Prescribing errors: 8.3% of prescribed items
— Dispensing errors: 9.8% of dispensed items
— Administration errors: 8.4% of doses observed
— Monitoring errors: 14.7% of relevant medicines

Box 3: Summary of error rates identified in UK care homes

11. As can be seen medication errors can occur at any stage of the process and with so many small steps in the chain from prescribing to the patient receiving and taking the drug, there is plenty of scope for error. The history of pharmacy shows that pharmacists have had a consistent role in reducing the risks around medicines: first by ensuring correct ingredients were used in the right way, and more recently by identifying and correcting errors in prescribing, and helping patients improve their adherence.

— Role of human error and poor clinical judgement.
— Systems failures.

51 Based on work by Garfield, Barber, Walley and Willson, commissioned by the National Leadership and Innovation Agency of NHS Wales
Human error versus systems errors

12. Errors and human behaviour cannot be understood in isolation, but only in the context or system in which people are working. Clinical staff who are prescribing, dispensing or administering medicines are influenced by a wide range of systems factors such as the technology available, the team and staffing levels, their hours of work, the design of their work areas (lighting, cramped space etc), distractions in the work place (e.g. interruptions during a drug round) and, of course, patient factors.

— How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare.

13. The complexity of medication safety should not be underestimated. Medicines are a safety intervention for patients who are often in danger of harm from disease. Clinical practice can never be risk free. Precautionary principles can be applied, but they need to be applied both to treatment with medicines, and to the decision not to treat with medicines—there will always be complex trade-offs under great uncertainty.

2. What the current effectiveness is of the following in ensuring patient safety:

a) Local and regional NHS bodies, and other organisations providing NHS services

14. Every day pharmacists make thousands of interventions to improve medicines safety. Pharmacists are involved in ensuring access to safe medicines through local drug and therapeutics committees, and ensuring safe deployment through local systems, procedures and policies. Pharmacists make individual interventions for patients on a daily basis, using their patient medication records (PMRs) to check for interactions, making sure prescribed medicines are at the correct strength and dose and ensuring safe supply of over the counter (OTC) medicines. They are involved in training medical and nursing staff, and their monitoring of errors contributes to improving awareness and good practice. Pharmacists have also been the driving force in the introduction of technologies to improve access to medicines and safer dispensing. Finally, a complex web of purchasing policies ensures medicines are safe as they are of suitable quality; increasingly purchasing is also driving safety by favouring manufacturers who provide safer products (safer packaging, clear use-instructions etc).

b) Systems for incident reporting, risk management and safety improvement

15. Systems for reporting incidents relating to medication safety exist in the NHS at a local level using individual Trusts’ risk management systems. These are then reported nationally to the NPSA in England and Wales. Community pharmacists working in the large retail pharmacy chains similarly have systems to report errors and incidents within their company and to the NPSA. Small independent community pharmacies may report directly to the NPSA or schemes may exist for them to report to their local primary care organisation. There is however no systematic way of encouraging patients and carers—at home or in nursing homes—to report, yet it is here where we know least about medication safety incidents.

16. The “Yellow Card” scheme operated by the MHRA has increased in its effectiveness and provides a useful source of information; however, it is a sparse data set and there is an urgent need for more complete information on adverse drug reactions (ADRs) soon after a medicine is licensed.

c) National policy

Hospital pharmacy policy

17. Pharmacists in hospital have significantly changed practice following the publication of the Audit Commission’s report A Spoonful of Sugar in 2001. Examples include the widespread adoption of admissions policies (e.g. reconciling medicines on admission to hospital), “one stop dispensing” and adoption of automation.

Community pharmacy policy

18. The NHS community pharmacy contract for England and Wales has three service levels: essential services (provided by all pharmacies), advanced services (which can be provided by all contractors once accreditation requirements have been met) and enhanced services (commissioned locally by primary care organisations in response to the needs of local populations). The first “advanced” level service is the Medicines Use Review (MUR) and Prescription Intervention Service. The same consultation format is used for both MURs and Prescription Intervention—the differentiating factor is what prompts the review. The consultation involves an accredited pharmacist undertaking a structured review with a patient who is taking

http://www.audit-commission.gov.uk/reports/NATIONAL-REPORT.asp?CategoryID=&ProdID=E83CS921-6CEA-4b2c-83E7-F80954A80F85
a number of medicines, particularly patients receiving medicines for long-term conditions. The pharmacist attempts to establish a picture of the patient’s use of both prescribed and non-prescribed medicines (i.e. OTC medicines). The review is intended to assist patients to understand their treatment, to identify any problems they are experiencing (by identifying side effects and drug interactions that may affect adherence and the effectiveness of the drugs), and to suggest possible solutions. A report is then provided to the patient and their GP.

19. MURs can be initiated by a pharmacist identifying certain groups of patients who could benefit from MUR such as older people taking several medicines, or people with diabetes or asthma, and inviting those patients for MUR. Alternatively, a target patient group might be highlighted by a PCT as being appropriate for MUR, reflecting local population health needs that the PCT has identified.

20. The trigger for Prescription Intervention is more reactive. It is prompted by significant problems with a patient’s medication—these are likely to be highlighted during the dispensing process. These problems may identify a need for the patient to increase their understanding of their medicines in order to improve their use.53

21. The Pharmacy Practice Research Trust (PPRT) commissioned research to evaluate the impact of the new community pharmacy contract. The research found:

— Participation in MUR/Prescription Intervention by pharmacies is increasing (from 38% in 2005–06 to 64% in 2006–07; the mean number of MURs conducted per pharmacy increased from 36 in 2005–06 to 115 in 2006–07).54

— A need for greater integration with general practice to achieve the potential of MUR: “GPs perceive MUR would be more valuable with a stronger focus on compliance and the reduction of waste. Information flow is almost exclusively from pharmacist to GP and in hard copy, with only one in four pharmacists reporting receiving feedback from GPs. Over 80% of pharmacists providing MUR say it has had no effect on their relationship with local GPs.”

— “Almost all PCOs identified target patient groups for MUR, the most frequently reported being patients with respiratory disease (asthma and/or chronic obstructive pulmonary disease), followed by patients on multiple medication.”

— Just over half of the sample of PCOs surveyed “reported having a strategy for medicines review and just under half of these had a strategy that included both community pharmacy and MUR.”

— “Monitoring of the MUR service currently focuses on process rather than content or outcomes and PCOs want the service to be subject to audit to provide evidence of value for money. The Prescription Intervention element of MUR is currently an invisible service with no data on its incidence or outcomes.”55

“Pharmacy in England”—the pharmacy white paper

22. The Department of Health (England)’s pharmacy white paper contains proposals in regards to safer medication practice. The Government envisages chief pharmacists and other commissioners having a “lead role in ensuring that safe medication practices are embedded in patient care” by working with patients, senior managers, other health professionals and professional bodies, “to identify, introduce and evaluate systems designed to reduce unintended hospital admissions related to medicines.” Chief pharmacists and commissioners are to work “with other senior health professionals and managers and the Safety Alert Broadcast System liaison offices” to ensure that organisations “respond to NPSA and other alerts efficiently, thereby reducing risk to patients.” NPSA has been asked to organise an event to “ensure that learning from best practice in the implementation of safety alerts informs future responses.”56

— The appropriateness of national targets

23. National targets for medicines safety, such as the alerts issued by NPSA and MHRA, are important to maintaining patient safety and RPSGB would expect pharmacists to prioritise their implementation appropriately.

24. It is essential that national targets set by government on broader areas of NHS performance such as waiting times do not detract from or disincentivise a focus on improving patient safety (as happened at Stoke Mandeville and Maidstone & Tunbridge Wells NHS Trusts, resulting in large numbers of avoidable deaths from hospital-acquired infections).

53 PSNC website: http://www.psnc.org.uk/pages/advanced_services.html
e) education for health professionals

25. Pharmacy is a scientific health profession requiring a high level of education and training. The RPSGB approves pharmacy degrees, to ensure that students have received a thorough and appropriate education for their professional registration and subsequent development and careers.57

26. Patient safety is embedded in all areas of the indicative syllabus for UK pharmacy degree courses.58

27. The RPSGB is currently undertaking a quinquennial (five-yearly) review of the standards for undergraduate pharmacy education. Patient and medicines safety will be at the core of the new standards. A Practice Framework, which defines the requirements of an early career pharmacist, is also being developed and it will feature patient and medicines safety.

28. If medicines safety is to be improved, all pharmacists will need to have an understanding of the factors underpinning safe systems of work—the “science of safety”. This includes understanding human error and systems thinking; safety culture and the role of the pharmacist and how this links to the wider NHS team; supporting colleagues in the event of an error; the role of patients and carers; the role of technology; and design and human factors. Pharmacists already have a good understanding of the practical aspects of safe system design (from “Good Manufacturing Practice”); they need the theory to support these pragmatic approaches and go beyond them.

29. Pharmacists also deliver a unique “world view” into medicine that focuses on medicines as a precious but potentially dangerous intervention—what has been called the “Pharmaceutical Gaze”. Their education needs to retain this unique contribution to the healthcare system.

The role of professional regulation

30. In addition to the above mechanisms for ensuring patient safety, professional regulation also contributes to patient safety by monitoring compliance with the requirements for practitioners to be registered to practise and to remain registered; by providing guidance and advice to help registrants to continue to meet the required standards of competence, conduct and practice; and by taking disciplinary action, where appropriate, against registrants who are no longer fit to practise. The RPSGB also registers and inspects pharmacies.

Fitness to Practise

31. The function of the Fitness to Practise section within the RPSGB’s Regulation Directorate is to monitor and ensure compliance with the standards of conduct, performance and fitness to practise set by the RPSGB, and with obligations imposed on the profession of pharmacy by statute. Where an individual or pharmacy registered with the Society fails to comply with those standards and legal obligations, it is for the RPSGB to take the necessary action to protect the public. This is done through:

— Risk-based routine monitoring visits to community pharmacies by the RPSGB inspectors, and investigations into complaints against registered individuals or pharmacy owners.

— Providing registrants with guidance and advice on matters relating to pharmacy law, ethics and professional standards to help them comply with the required standards and thereby improve patient safety.

— Publication of decisions of the Society’s Fitness to Practise Committees (the Investigating Committee, the Disciplinary Committee and the Health Committee).

— Enforcement, which is achieved by bringing proceedings against an individual or pharmacy owner registered with the Society through the Society’s fitness to practise machinery, or through criminal proceedings.

RPSGB’s new regulatory powers

32. The Pharmacists and Pharmacy Technicians Order (“the Order”), came into force in February 2007. It replaced the Pharmacy Act 1954, and modernised and restructured the RPSGB’s disciplinary and regulatory framework.

33. The changes resulting from implementation of the Order have brought the RPSGB’s procedures in line with those of the other healthcare regulators and overhauled pharmacist and pharmacy technician regulation (pharmacy technician regulation is voluntary at present).

57 http://www.rpsgb.org/acareerinpharmacy/undergraduateeducation/
58 http://www.rpsgb.org/pdfs/eddegnewreq.pdf
34. The changes have resulted in many benefits to the RPSGB’s regulatory machinery. For the first time, the RPSGB is able to take urgent action to impose Interim Orders suspending or placing conditions on the practice of pharmacists who present an immediate risk to themselves or the public. This is an important development in terms of safeguarding the public.

35. Pending legislation, the RPSGB’s Code of Ethics requires pharmacists to undertake continuing professional development (CPD) which is relevant to their area of practice. When pharmacists complete their annual retention form (to renew their registration) they make a declaration that they will undertake relevant CPD during the following year. Compliance with this undertaking is being checked through a pilot study during 2008 which is calling off a sample of pharmacists’ CPD records to look at their recording technique, to check if their CPD is relevant to their area of practice, and to provide feedback on both these areas.

36. The RPSGB is also now able to deal appropriately with pharmacists whose health problems (for example, but not restricted to, mental health problems or substance misuse) prevent them from practising to the required standards. Cases are referred to the Health Committee which, with the input of specialist advisors, can take appropriate action in such cases when necessary.

37. Implementation of the RPSGB’s new fitness to practise procedures in 2007/2008 has provided an excellent foundation for the future of pharmacy regulation and it is anticipated that the General Pharmaceutical Council will be able to continue to build on that foundation long into the future.59

38. As a result of the recommendations arising from the Shipman Inquiry, since 2007 the RPSGB Inspectorate has established arrangements with governments in England and Scotland for the inspection of systems in place to ensure effective management and use of controlled drugs within pharmacy premises. (Prior to this, the police were responsible for the monitoring of controlled drugs within community pharmacies.)

39. The RPSGB is also currently working with the National Clinical Assessment Service (NCAS) to establish a service which will help identify and support poorly performing pharmacists.

3. What the NHS should do next regarding patient safety

Pharmacovigilance

40. When drugs are being licensed they are tested on a relatively limited number of patients; it is usual for new adverse events to appear once the medicine is in routine use. Pharmacists, particularly in hospitals, have great potential to form a network to identify how the drugs are being used, and any adverse events. In UK hospitals pharmacists already visit wards, often daily, to monitor the prescribing and use of medicines. This is a tremendous resource which could be used to a far greater extent. A national pharmacovigilance network of hospital pharmacists could be established to document and report the early use and effects of new medicines.

— How to determine best practice and ensure it is spread throughout the whole NHS

41. There is currently no single source of information about improving medicines safety in the UK. For a pharmacist to find further information about a local concern they currently have to search the web and conduct their own literature search. It would be more difficult still for them to find information about interventions and initiatives that have been shown to be effective unless this was a topic of interest nationally. There is clearly a need for a repository of information and knowledge sharing about medicines safety and effective interventions and we recommend that this area is developed.

— What should be measured and assessed; and what data should be published

42. In order to track improvements in medicines safety there is a need for standard definitions and standard methods of measurement. The WHO is developing a classification system for patient safety incidents and the NPSA has developed a set of codes for analysing incidents reported through local risk management systems. Other methods such as the global trigger tool and case note review are now being recommended through campaigns and initiatives. We believe that in working towards making Britain a safer place to take medicines, a goal should be set in the UK for developing a standard set of measures for medicines safety and of commissioning work to establish a baseline from which to monitor improvements.

— What incentives there should be to improve patient safety

43. Medicines safety is an organisational issue and there should be incentives operating at the organisational level to encourage leadership across an organisation. NHS Trust boards should have a strong focus on patient safety, be aware of the Trust’s performance on safety and prioritise safety improvements in their medium to long-term planning. There should be greater use of commissioning and contracting levers at the local level to incentivise improvements in safety.

— How patients and the public can be involved in ensuring that services are safe

The Yellow Card Scheme (YCS)

44. Following the thalidomide tragedy the UK Yellow Card Scheme (YCS) was established in 1964. After a review of access to the YCS45 and a pilot program, a national scheme was introduced in October 2005 allowing patients to make direct reports to the MHRA if they thought a medicine or herbal remedy had caused an unwanted side effect.61 Patients can report suspected side effects by telephone, post, online, or at their local pharmacy. Community pharmacists have been involved in the MHRA scheme by promoting use of the Yellow Card Scheme to members of the public, in addition to making reports themselves.

45. The NHS Research and Development Methodology Programme, in partnership with the MHRA, have funded Professor Anthony Avery (University of Nottingham) to evaluate the patient reporting component of the Yellow Card Scheme.63 This research may highlight additional incentives for patient reporting, and the removal of any existing barriers to patient reporting which could improve patient safety.

Non-adherence

46. Whilst we can analyse and capture adverse events during the drug journey from development to dispensing, less is known about the safety of medicines at the point of administration by the patient at home. The true nature and extent of medicines safety issues in the home are not well understood or quantified and further research is required in this area particularly with the increasing complexity of care being delivered for patients at home.

47. Some would think it contentious to consider non-adherence an error—after all it can be a rational autonomous act. However non-adherence has the potential to cause patients harm and so we are considering it an error when the patient has not been sufficiently informed about the medicine to make a rational decision, or has decided to adhere but is thwarted by other factors.

48. We know that non-adherence levels are high—probably a third to a half of patients with chronic conditions are non-adherent to at least one medicine. This can cause real harm. It is sometimes assumed that these are “trivial” medicines, but we know it happens also in patients whose medicines are crucial, such as renal transplant patients, and those recovering from myocardial infarction. While counterintuitive, it is nonetheless real. Research is just beginning to deliver an understanding of what can make a difference, and investment is needed in this area. The recent pharmacy white paper suggests an innovative scheme to improve adherence to new medicines, which has been shown to be cost effective.64 The key to the scheme is the engagement with the patient once they have experienced the medicine. The exact effects of a drug (positive and negative) that a given patient will experience are unknown at the time of prescribing, so information given at this time is of limited effect; there is a need to engage with patients once they have begun to take the medicine to talk to them about their experience and to give them support and information.

49. Research published in 200665 highlighted the importance of tailoring advice to meet the needs of patients. Viewed from the patient’s perspective, non-adherence can represent “a logical response to the illness and treatment in terms of their own perceptions, experiences and priorities, including concerns about side effects and other unwelcome effects of medicines.”66 It also endorsed an approach to non-adherence that takes into account a patient’s own beliefs and preferences, and acknowledges the practical constraints (such as their capacity and resources) which may influence their intentional or unintentional non-adherence.

Other steps for improving medicines safety

The role of technology in improving medicines safety

50. Technologies such as those set out in Box 4 below have the potential to prevent medication errors, and are often widely advocated as such. However, the effectiveness of technology depends on context—the problems with different health systems vary, and so a technology shown to reduce errors in one system may have a very limited effect in another. For example there has been a tendency to assume technology that is effective in the USA will be similarly effective in the UK, but the two healthcare systems are very different. More work is needed to develop NHS-specific technologies, and to characterise the most error-prone parts of the system which technology can improve.

61 http://www.mhra.gov.uk/Safetyinformation/Reportingssafetyproblems/Medicines/Reportingssuspectedadversedrugreactions/Patientreporting/index.htm
63 Expected publication date is late 2010. (http://www.ncchta.org/project/1628.asp)
66 Ibid p. 14
Primary care
- Electronic patient records
- Electronic transmission of prescriptions
- Dispensing robots
- Electronic prescribing

Secondary care
- Dispensary-based dispensing robots
- Electronic prescribing
- Electronic medication administration records
- Barcode verification of medication administration
- Barcode verification of patient identity
- Ward-based automated dispensing systems
- Electronic transmission of discharge prescriptions between secondary and primary care
- Automated compounding machines

Box 4: Examples of technologies used in the medication process
51. There is now a large body of evidence showing that new types of error can be introduced with new technology—examples of these are set out in Box 5. Introducing new technologies usually requires changes in work processes, which can also introduce risks, particularly if staff develop “work-arounds” to save time or overcome parts of the technology which do not work reliably. Technologies demonstrated to have benefits in one healthcare system (such as in the USA) may not have the same benefits elsewhere due to differences in healthcare systems and work practices.

Box 5: Examples of new risks created by technologies
52. Evaluating technologies to assess their impact on medication safety is essential, to create an evidence base for their use, rather than assuming that errors will automatically be prevented. In this regard the Health Policy Forum (a joint venture funded by the RPSGB, CCA, NPA and PSNC) have commissioned an important piece of work on the impact of technology in community pharmacy over the next five to 10 years.

53. There is currently no central repository for the lessons from implementing new technology nor is there advice available from the early adopters of this technology for others following on to consider. In order to ensure that in implementing new technologies all those involved in medicines safety are aware of potential errors and how others have overcome them, we recommend that a national knowledge exchange system is established for new technology. Such a system would complement that run by NICE for assessing the risks of new interventional procedures.

Culture change—supporting pharmacists
54. For medicines safety to improve, pharmacists must be able to speak up about their concerns and to report safety incidents and near misses in an environment where this is encouraged and where action is taken to learn and improve. Not all organisations have a safety culture that is open and fair and pharmacists can find themselves in a very difficult position particularly when reporting concerns about another clinician (for example picking up persistent prescribing errors by a well-respected local doctor). In other circumstances the pharmacist themselves may have made an error and need help and advice in the aftermath.

55. The Community Pharmacy Research Consortium (a joint venture between the major national pharmacy bodies) commissioned research on errors in community pharmacy which highlighted concerns regarding “a prevailing blame culture” which deters pharmacists and support staff from reporting incidents and prevents organisational learning. Important factors to encourage voluntary incident reporting included “a non-punitive environment, simplicity in reporting, and timely and valuable feedback.”

56. Some advisory and counselling services are currently available to all pharmacists (eg the RPSGB’s Legal and Ethical Advisory Service,68 Pharmacist Support69) or to pharmacists who are members of particular organisations (eg the Pharmacists’ Defence Association,70 or the Guild of Healthcare Pharmacists71) but there is no single service or organisation which supports pharmacists in speaking up in their own organisations when things go wrong.

57. Further work is needed nationally to encourage local organisations to be open and fair in their approach to patient safety. In Denmark the law has been changed so that it is now an offence not to speak up when things go wrong, but measures to encourage whistleblowing need to be accompanied by strong measures to protect whistleblowers from dismissal and blacklisting. We recommend that the Committee considers whether the UK’s Public Interest Disclosure Act (1998)72 has been successful in encouraging and supporting whistleblowing, and whether additional measures are needed in this area.

Research into Medicines Safety

58. Research is fundamental to improving medicines safety from understanding the reasons why safety is compromised to finding new ways to improve safety in all areas of the drug journey. The DH-funded Patient Safety Policy Research Portfolio gave some unique insights into where and how medicine systems were hazardous, and some suggestions for improvements. It was disappointing that this policy stream was not continued to build on the knowledge it created, and we propose this funding stream is reinstated. We recommend that nationally a medication safety research strategy is developed and funded over the next 10 years. While the research councils notionally support this area, the best research stretches across disciplines in a way which, despite the rhetoric, combined research councils find challenging to deliver.

The changing nature of the workforce

59. The changing nature of the workforce is such that increasingly pharmacists are choosing to work flexibly. This means that locum pharmacists are being relied upon in many sectors. In order for medicines safety to prevail, locum pharmacists and those employing them need to be cognisant of the safety issues relating to temporary working. Again this is an area where there is insufficient knowledge to share, particularly about good practice and where more work is needed to understand the issues.

New pharmacy roles

60. The pharmacy profession is undergoing significant change in moving from a medicines supply function to more clinical roles involving medicines management. The introduction of pharmacist prescribing enables pharmacists to develop clinical roles that offer added value to patients and NHS commissioners. For example, additional training and registration as a pharmacist prescriber is a tool which enables pharmacists to extend their scope of practice (eg to work as Pharmacists with a Special Interest (PwSIs), who are commissioned by PCTs to supplement their core generalist role with expertise in a specialist area such as diabetes or asthma).

Influencing the pharmaceutical industry

61. The pharmaceutical industry has a central role in improving medicines safety through initiatives such as the design of the labelling and packaging of drugs, the naming of medicines and the information given to patients in the packs. These initiatives can help reduce dispensing errors, drug administration errors and non-adherence. Nationally and through the European Union, the government has tremendous opportunity to influence these vital areas for medicines safety. There may be merit in setting up a national working group bringing together experts in medicines safety to report to the government on what more can be done by the pharmaceutical industry to improve medicines safety in the next five years.

November 2008

68 http://www.rpsgb.org/informationresources/advisoryservices/legalandethicaladvisoryservice/
69 Pharmacist Support (formerly the Benevolent Fund) provides a number of services to pharmacists including the Listening Friends service which offers free listening services to pharmacists suffering from stress. The service provides the opportunity to talk to a pharmacist trained to offer support regarding the particular pressures that apply to the pharmacy profession; www.pharmacistsupport.org
70 http://www.the-pda.org/about_us/au_aims_and_objectives1.html?PHPSESSID=549b4adb4462f5b77fa5d1deb9fa8654
71 NHS-employed pharmacists can join the Guild of Healthcare Pharmacists which is part of the Unite trade union. Unite provides its members with free legal advice on work related problems (such as personal injury, unfair dismissal, discrimination and harassment) and a 24 hour legal hotline for advice on non-work related issues. See http://www.ghp.org.uk and http://www.unitewithus.org.uk/legal/
72 http://www.opsi.gov.uk/acts/acts1998/ukpga_19980023_en_1
MAKING BRITAIN A SAFER PLACE TO TAKE MEDICINES: PROJECT BRIEF

The scoping paper will cover the following:

1. Key stages of the “drug journey” including:
   — Prescribing
   — Dispensing
   — Administration of medicines
   — Medicine taking by patients
   — Pharmacovigilance
   — Storage and disposal of medicines.
   1.1 Since drug discovery, development and safety testing by the pharmaceutical industry are encapsulated in the drug licensing process, this area will not be covered in the paper. Similarly drug marketing and promotion will not be covered since little work has been done on this area related to patient safety.
   1.2 As pharmacovigilance is an enormous field in its own right, for the purposes of this paper we will limit this section to noting the major research findings on the contribution of pharmacovigilance to improving medicines safety including research findings on current weaknesses in the system eg the effectiveness or otherwise of the yellow card scheme and any changes required to improve the impact of current pharmacovigilance systems.

2. Relevant settings for medicines administration and medicine taking including:
   — Hospitals
   — Care homes
   — People taking medicines outside formal care settings without professional assistance
   — Domiciliary care.
   2.1 The team has recently completed a comprehensive study of medication safety in care homes which will be considered in this report. We are however aware that little research has been published on the subject of domiciliary care and it is likely that this will not form a major part of this section of the report other than to consider where further work is needed to enhance patient safety.
3. The role of Pharmacists in improving medicines safety:

3.1 In this section we will identify the roles that are needed to improve patient safety and consider which sector of pharmacy can deliver these, for example:

— Pharmacists working in the pharmaceutical industry
— Pharmacists as purchasers and suppliers of medicines
— Pharmacists as dispensers and prescribers
— Pharmacists working in multidisciplinary professional teams
— Pharmacists as trainers of (i) prescribers and (ii) those administering medicines or assisting people in taking their medicines.
— Pharmacists giving direct advice to patients

4. Improving medicines safety:

4.1 In this section we will consider strategies to improve medication safety at different levels from policy into practice. This will include a review of approaches from national guidance issued by the NPSA and NICE, the Safer Patient’s Initiative funded by the Health Foundation, the National Campaigns being run in England, Wales, Scotland and Northern Ireland and the work of the Regulators and the Pharmaceutical Industry and the influence of the RPSGB. We will consider the different levers for change open to the RPSGB and ways in which levers at different levels should be designed to work together. This will include:

— The process of commissioning or planning publicly-funded services by primary care organisations, and also by local authorities—who commission care-home places and personal care for people living in their own homes (consider levers here such as payment tariffs and contract specifications)
— Healthcare provider organisations (eg clinical governance systems, and national standards for care and regulation against those standards)
— Teams of healthcare practitioners
— Individual healthcare practitioners (eg education and training, clinical supervision, professional regulation, CPD and revalidation, and advice and support from professional bodies).

4.2 The role of benchmarking and performance management systems at all levels (eg for healthcare commissioning and planning organisations, provider organisations, teams and individuals) in improving medicines safety will be considered.

5. The role of technology in improving medicines safety.

5.1 This section will draw on the expertise of the team in eHealth from their work with Connecting for Health and the Department of Health giving a brief overview of evidence on how the major relevant technologies (eg robotic dispensing, electronic prescribing, electronic transfer of prescriptions, shared electronic patient records, screening and diagnostic tests, and therapeutic drug monitoring) can contribute to improving medicines safety. We note that the RPSGB, CCA, NPA and PSNC (via the Health Policy Forum) have commissioned a separate project on the impact of technology on community pharmacy over the next five to 10 years.

6. Safety and quality in healthcare are clearly related, but the paper will focus on the medicines safety agenda and not attempt to cover the whole field of the impact of medicines on health. For instance, the sub-optimal use of medicines (eg patients not taking their medicines as prescribed) is beyond the scope of this paper.

7. The geographical scope of the paper will be Great Britain, but where relevant comparisons with other countries will be included. Any models from other countries which are recommended will have clear applicability to the health systems of the three GB countries and the organisation and delivery of their health and social care services.

8. Major differences between health policies or services in England, Scotland and Wales which could have an important bearing on the type or incidence of medicines safety problems, or the interventions adopted to improve medicines safety, will be noted. We will not look in detail at the policy differences but rather look at where specific medication safety issues might arise.

9. Recommendations on next steps for wider implementation of the key safety improvements described, with a particular focus on how the future professional body for pharmacy can contribute to the implementation process.

12 June 2008

73 E.g. community pharmacists assessing the appropriateness of GPs’ prescribing, and hospital pharmacists checking patients’ drug charts
Additional memorandum by The Royal Pharmaceutical Society of Great Britain (PS 78A)

DISPENSING ERRORS

The Society welcomes the request to provide additional evidence to the House of Commons Health Committee’s inquiry into Patient Safety in regards to dispensing errors.

The Society’s policy since 2006 has been that dispensing errors should be decriminalised and that the Medicines Act 1968 is in need of modernisation.

The Society is currently seeking to have the law amended to remove the automatic criminalisation of dispensing errors and create a professional environment that encourages self-reporting of errors and a patient safety culture.

We believe that the current situation hampers patient safety and results in disproportionate regulation.

We believe that the automatic criminalisation of dispensing deters pharmacists from reporting dispensing errors. Initiatives to improve patient safety stress the need to obtain comprehensive information on adverse events so that it can be used as a source of learning and to prevent recurrences. Under reporting precludes the opportunity to use these incidents as learning opportunities to reduce the number of errors in the interest of patient safety.

The current provisions of the Medicines Act do not distinguish between different types of dispensing errors or their impact. We think that there needs to be greater consideration given to a risk based approach to errors in order to distinguish between those errors which are serious and call the pharmacist’s registration into question and those that are not.

The recent case of a pharmacist receiving a prison sentence for a dispensing error74 has created a climate of fear amongst the pharmacy profession that any dispensing error, no matter how minor could result in a custodial sentence. We believe that this will further deter pharmacists from reporting their own errors for fear of self incrimination. This situation is not in the interests of patients, the public or the pharmacy profession.

This memorandum outlines the Society’s policy, and a copy of the Society’s most recent press release on this issue is attached for the Committee’s information.75

The Society asks the Select Committee to consider a recommendation that the Government adopts an open and non-punitive system that improves patient safety by supporting the reporting of errors and supporting a change in the Medicines Act to remove the automatic criminalisation of dispensing errors.

We hope our submission will be of use to the Committee in its deliberations. We must all work together to find solutions to improve patient safety. We look forward to seeing the final report.

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN (RPSGB)

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession’s policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

1. What are dispensing errors?

1.1 Dispensing errors are errors made during the dispensing process from receipt of the prescription through to the supply of the dispensed medicine to the patient. Dispensing errors include incorrect labelling, dispensing an incorrect medication, incorrect strength and/or dosage, supplying an out of date medication, and clinical errors such as dispensing a drug to which the patient has a documented allergy or contraindication.

74 For coverage in the Pharmaceutical Journal see http://www.pjonline.com/news/former_locum_handed_suspended_jail_term_for_dispensing_error
75 http://www.rpsgb.org.uk/pdfs/pr090408.pdf
2. The issue

2.1 According to the NHS Information Centre 796 million prescription items were dispensed in 2007 in England alone. Whilst the vast majority of these would have been dispensed safely and effectively, most pharmacists will have made or will make a dispensing error at some point in their career.

2.2 Under current legislation, pharmacists commit a criminal offence each time they make a dispensing error—no matter how simple the error or what the affect of the error was.

2.3 The RPSGB is an enforcement authority under the Medicines Act 1968 (“the Act”) and it also has regulatory policies in place regarding dispensing errors. However, other organisations such as the police and the Medicines and Healthcare products Regulatory Agency (MHRA) also enforce certain provisions in the Act. The Crown Prosecution Service (CPS), who prosecute on behalf of the behalf of the police, may institute criminal proceedings for serious breaches of the Act for example, gross negligence manslaughter. There are therefore instances where police/CPS involvement is wholly appropriate.

2.4 However, it is submitted that there needs to be greater consideration given to a risk based approach to errors in order to distinguish between those errors which are serious and call the pharmacist’s registration into question and those that are not.

3. RPSGB Policy

3.1 The RPSGB Council considered the issue of dispensing errors in December 2006. The Council fully supported the decriminalisation of dispensing errors. It agreed that a change to the legislation which would have the effect of decriminalising such errors be sought.

3.2 The RPSGB Council agreed in March 2007 that subject to certain criteria (see Appendix 1) single dispensing errors which were not likely to amount to professional misconduct should not be referred to the Society’s Investigating Committee.

3.3 The Medicines Act 1968 is in need of modernisation. This has been recognised by the Department of Health and the MHRA. The MHRA are currently undertaking a project to consolidate and review the legislation. The RPSGB has submitted a concept paper to the MHRA as part of their review project which is publicly available on the website (http://www.rpsgb.org/pdfs/consdoc1754.pdf)

3.4 In this submission the RPSGB has urged the MHRA to specifically review section 64 of the Act with a view to exclude dispensing errors made by pharmacists.

Patient Safety

3.5 Research carried out in 2005 by the Community Pharmacy Research Consortium found that “underreporting of incidents either within the pharmacy or to the national incident reporting scheme is likely to be a significant problem.”

3.6 The research team estimated that within community pharmacies “26 incidents are detected during the dispensing process for every 10,000 prescription items dispensed, of which 22 incidents can be classified as a near-miss, whilst the remaining four are dispensing errors.”

3.7 Initiatives to improve patient safety stress the need to obtain comprehensive information on adverse events so that it can be used as a source of learning and to prevent recurrences. Under reporting precludes the opportunity to use these incidents as learning opportunities to reduce the number of errors in the interest of patient safety.

3.8 The 2005 research also indicates that “the development of a patient safety culture within community pharmacy is impeded by a pervading blame culture.” There is a need to diminish the blame culture which surrounds errors, encourage greater reporting of errors and thereby enhance patient safety.

Balanced and proportionate regulation

3.9 On rare and tragic occasions dispensing errors can cause serious damage to health or even death. For example, according to the National Patient Safety Agency (NPSA) between October 2007 and September 2008, 846,895 incidents from across the health service were reported in England. This includes reports of incidents from areas such as general practice, mental health services, community services (such as pharmacies and community hospitals) and ambulance services. Of these 66% were reported as causing “no
harm”, 27% were reported as “low harm”, 6% were reported as “moderate harm”. 1% of all incidents were reported as “severe harm.”82 The proportion of incidents reported to have resulted in death was rounded down to 0%.83 (A table of the NPSA’s incident grading is at Appendix 2).

3.1.1 The RPSGB understands the importance of regulating the pharmacy profession.

3.1.2 However, as outlined in the White Paper, Trust Assurance and Safety—the Regulation of Health Professionals in the 21st Century “professional regulation should not create unnecessary burdens, but be proportionate to the risk it addresses and the benefit it brings.”84

3.1.3 Currently this is not the case with dispensing errors automatically being categorised as criminal offences.

4. Causes of dispensing errors

4.1 A number of themes have emerged as to the causes of dispensing errors but further research is required.

4.2 The 2005 research mentioned a number of factors put forward as causes of dispensing errors; “distractions, similar looking and sounding drug names, inexperienced staff (including staff who work infrequently in the dispensary), stress and workload.”85

4.3 In the 2007 Fitness to Practice Annual Report reasons frequently given by pharmacists as mitigation for dispensing errors included “excessive workload in relation to numbers of staff; insufficient space to dispense safely; and poor lighting in pharmacy premises.”86

5. Current legal situation

5.1 The Medicines Act 196887 was introduced by the then Department of Health and Social Services following a review of legislation relating to medicines prompted by the thalidomide tragedy in the 1960s.88

5.2 It brought together most of the previous legislation on medicines and provided a system of licensing for the manufacture, sale, supply and importation of medicinal products into the UK.

5.3 It also introduced the three categories of medicines (prescription only, pharmacy only and over the counter) and sets out pharmacist’s legal obligations in relation to medicinal products, particularly their sale and supply.89

5.4 Sections 58, 64 and 85 of the Act are just some examples within medicines legislation which criminalise dispensing and labelling errors, however simple;

— Section 58 relates to supply otherwise than in accordance with a valid prescription.

— Section 64 relates to supply of a medicinal product not of the quality and nature demanded. It states that:

“No person shall, to the prejudice of the purchaser, sell (or supply) any medicinal product which is not of the nature or quality demanded by the purchaser…[or] specified in the prescription.”

— Section 85 specifically relates to selling or supplying a medicinal product where there is an error in the labelling and marking of containers/packaging.

5.5 If a controlled drug is involved then there may be other offences committed under the Misuse of Drugs Act 1971.90 The regulation of controlled drugs was reviewed and strengthened after the Shipman Inquiry. Section 67 of the Act states:

(2) “Any person who contravenes…section 52, 58, 64 and 65…shall be guilty of an offence…

(4) Any person guilty of an offence under subsection (2)…of this section shall be liable—

a) on summary conviction, to a fine not exceeding [the prescribed sum];

b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.”

86 RPSGB, 2007, Fitness to Practice Annual Report, p20 available at www.rpsgb.org
88 MHRA www.mhra.gov.uk
89 MHRA www.mhra.gov.uk
Section 91 (1) states:

“…any person who contravenes the provisions of section 85(5)...of this Act shall be guilty of an offence and liable—

a) on summary conviction, to a fine not exceeding [the prescribed sum];

b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.”

June 2009

Appendix 1

THRESHOLD CRITERIA

Cases are likely to be referred to the Investigation Committee if one or more of the following statements are true:

— There is potential for, or evidence that moderate or severe harm or death was caused as a result of the incident (the definitions of these are from the NPSA definitions for grading patient safety incidents).

— There is evidence that there was a deliberate attempt to cause harm to patients or the public.

— There is evidence that the individual departed from agreed safe protocols or standard operating procedures and in doing so took an unacceptable risk.

— There are no systems to record dispensing errors in the pharmacy (this should result in the Superintendent/Pharmacy owner being referred).

— There has been a failure to make a dispensing error log (if aware of the error).

— There are no systems to learn from the incident in the pharmacy (this may result in the Superintendent/Pharmacy owner being referred).

— No attempt has been made to learn from the incident.

— The Society has previously given advice that would have prevented the incident if it had been implemented.

— There has been an attempt to cover up.

— There has been a failure to co-operate with an investigation carried out by the Society’s Inspector or other investigatory body.

— There is evidence of other misconduct that would form the basis of a complaint.

— There is a failure to apologise/provide an explanation to the patient/representative (where appropriate).

Appendix 2

NPSA GRADING OF PATIENT SAFETY INCIDENTS*

<table>
<thead>
<tr>
<th>Grading of patient safety incident</th>
<th>Definition of degree of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harm</td>
<td>Impact prevented: any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm</td>
</tr>
<tr>
<td></td>
<td>Impact not prevented: any patient safety incident that ran to completion but no harm occurred</td>
</tr>
<tr>
<td>Low harm</td>
<td>Any patient safety incident that required extra observation or minor treatment and caused minimal harm</td>
</tr>
<tr>
<td>Moderate harm</td>
<td>Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm</td>
</tr>
<tr>
<td>Severe harm</td>
<td>Any patient safety incident that resulted in permanent harm</td>
</tr>
<tr>
<td>Death</td>
<td>Any patient safety incident that directly resulted in the death of the patient</td>
</tr>
</tbody>
</table>

Memorandum by Mrs Clare Bowen (PS 79)

PATIENT SAFETY

INTRODUCTION

Bethany Bowen had a hereditary blood condition (spherocytosis) that resulted in anaemia and significant swelling of the spleen. She was healthy and normal in every other way, and was able to attend school, interact with other children and engage in play. Visible symptoms were a slightly yellow skin, and the appearance of an enlarged stomach (due to the swelling of the spleen). Her condition required monitoring, but she was coping well with it at the time of the operation even with the complication of three small gallstones. The operation was necessary at some point in her childhood as existing alternatives are inadequate.

The operation is normally straightforward and comparatively risk free.

The procedure consented to by the parents:

Laparoscopic surgery would be employed to mobilise the spleen. The spleen would then be dropped into the pelvic area, where it would be removed via a bikini-line incision. Following splenic removal, the gall bladder would be opened and gall stones removed.

The procedure carried out:

Laparoscopic surgery was employed to mobilise the spleen. A morcellator was employed to break up the spleen inside an endoscopic bag, inside the body cavity. The morcellator blade was applied to the spleen via a small opening in the abdominal wall. Collapse occurred during this process and the rest of the operation had to be abandoned. Beth died in theatre never recovering from initial collapse.

KEY CRITICISMS

The following points are based on information gathered from letters, reports, and audio recordings of meetings held at the John Radcliffe Hospital and the inquest at Oxford Coroners Court.

— The proposed procedure for spleen removal was changed after the consent forms were signed by the parents.
— The parents were not informed of this change, or of any additional risks this entailed.
— No reason was given as to why the proposed procedure was changed at the last minute.
— The new procedure involved the use of a morcellator, which carried considerably more risk to the patient. The risks associated with the morcellator significantly outweighed the benefits.
— The new procedure was a training exercise.
— The doctor operating the morcellator was a trainee, and had never operated the tool before or heard of the procedure before that morning.
— The surgeon directly supervising him had never seen or operated the tool before.
— A third surgeon, believed to have some experience (but not in the UK and a number of years ago), was present in the room but not watching the tool in operation.
— This is considered by both the Trust and the surgeons as a perfectly acceptable definition of conducting an operation using trained staff.
— Evidence was destroyed: including the bag containing the spleen; the swabs; all the disposable parts of the morcellator including the blade; the bag applicator, and all the blood collected.
— Poor record keeping: an independent anesthetist examined some of the medical notes and found them to be completely inadequate, in terms of insufficient detail, and numerous omissions.
— Post mortem examination revealed Bethany’s Aorta to have two complete cuts, approximately 1cm apart. (It should be noted that the diameter of the morcellator blade is approximately 1cm.)
— With regard to the cuts, the testimony by the surgeons present in the operating theatre shifted from:
  (a) July 2006 (following Bethany’s death): blood vessel accidentally cut with morcellator resulting in major blood loss and death. To,
  (b) January 2007 (Recorded meeting): Aorta cut in two places, probably with the morcellator, but the resulting blood loss was not significant. Cause of death unclear. To,
  (c) November 2007 (Inquest): Aorta certainly not damaged by the morcellator, and the two cuts found have no explanation. Blood loss from the cuts insignificant, and cause of death unclear.
— Cuts were found to her large intestine and stomach, in addition to those found in the aorta. No explanation was given as to the cause of these cuts.
— The doctors have dismissed all suggestion they caused her death either through their actions or inaction, but have not presented any alternative explanation.
— The Trust failed to satisfactorily investigate the events surrounding Bethany’s death, and pursued a strategy of misinformation and obfuscation, including circulation of documents containing gross inaccuracies relating to the family. The only actions that could be seen as proactive on their behalf were failed attempts to find a pre-existing medical condition in the family.

— The family were forced to appoint a solicitor in an effort to overcome difficulties in dealing with the Trust and to fight for a full inquest.

— Sixteen months after Bethany’s death the Trust admitted liability for not gaining adequate consent, and for not having proper training procedures. However, a number of surgeons, when giving evidence at the coroners inquest, refuted the suggestion relating to inadequate consent, and stated that the training was sufficient.

— Instructions laid down by the manufacturer of the endo bag, which specifically state that a morcellator should not be used with this bag on the grounds of safety, were ignored by the surgeons operating on Beth. This was not acknowledged as an error of judgment. On the contrary, the need to comply with the manufacturers instructions was disputed in the coroner’s court.

— Training in the UK is offered and indeed recommended by the supplier of the morcellator (both at an external training centre, and on site at the hospital) but was not undertaken. The surgeons believe the morcellator is too simple a piece of equipment to require such training.

— Consultant surgeons are not required to log or record any of their training or experience. They are able to say to a hospital “I am trained on this piece of equipment” and that is usually considered sufficient. They do not have to prove it or show any records before carrying out the procedure.

— First indication from the anaesthetist of Bethany’s collapse occurred at 1615. The circulating nurse was told to leave at 1630. This instruction was unprecedented in his experience. A senior staff nurse took over as circulating nurse, and observed the doctors having a discussion about what to do next. They were not attempting CPR at that point. Attempts were made to release the other circulating nurse at 1645, but she resisted. She was relieved from duty at 1710.

— It has been stated that 1630 was the scheduled end of the nurses’ shift. This does not satisfactorily explain why a senior member of staff attempted to enforce a shift change during a medical emergency. Indeed, it is astonishing.

— A report into what happened to Bethany and what procedural changes would be made was promised by the JR Trust following her death. At the time of writing, two years, three and a half months have passed since Bethany’s death and the family have received plenty of excuses, but no report.

**Possible Conclusions**

1. Bethany’s death is a mystery. It occurred due to a symptomless pre-existing medical condition that was not diagnosed, not detected at post-mortem, and manifested itself simultaneously with cuts appearing in the aorta, leading to a stopping of the heart. The actions of the surgeons did not cause her death.

2. Bethany’s death has a scientific explanation. This would almost certainly have been established had
   (i) all the above-mentioned evidence been safeguarded,
   (ii) cameras been fitted to the walls of the operating theatre and their data verifiably protected.
   (iii) Data gathered by heart function and other vital organ monitoring equipment been recorded automatically, in real time, and protected with tamper seals.
   (iv) a national and independently appointed investigation team been brought in whenever an incident such as this takes place. This team should consist of people with an investigative background (eg former police officers), as well as medically trained members.

The verdict from the inquest stated that Bethany’s aorta was damaged by an unspecified surgical instrument. No attempt was made to hold any surgeon responsible for their actions, and no recommendations were made by the coroner.

**Recommendations:**

The time has to come to acknowledge that medical staff may not always be forthcoming with all the facts following the death of a patient that they were directly involved with. To do so could damage or even terminate their career, and implicate colleagues with whom they work closely.

It should also be recognised that it is not in the interests of the NHS Trust to publish information that reveals human error and serious shortcomings in procedure. They have a reputation to protect.

This may seem obvious, but the experience of the witness both in the 16 months prior to the inquest and during the inquest itself, is that the testimony of the doctors is *ultimately* decisive in determining the facts.
It is the key recommendation of this report that the only way to prevent a repeat of this accident, reduce the level of similar incidents, and safeguard against cover-up, is to introduce all the points listed in 2. i to iv above and to set up a regulatory body (either within or outside the NHS) that monitors and records all doctors training with new procedures, ensuring they are fully assessed and documented rather than the “let’s have a go” approach used in Beth’s case.

Also, it is common knowledge that clinicians close ranks, feeling they are under siege, when things go wrong. It would have taken a brave doctor or nurse to speak out after Bethany’s death.

The railway industry has a reporting system known as CIRAS. This stands for “Confidential Incident Reporting and Analysis System”.

“CIRAS is an alternative way for rail industry staff to report safety concerns that they feel unable to report through company safety channels. It is a completely independent and confidential way to report safety concerns without fear of recrimination.” [www.ciras.org.uk]

CIRAS has been in place for many years—the work has already been done—the government need only liaise and adopt this system for the NHS. We strongly recommend they do this.

**TREATMENT OF THE FAMILY BY THE HOSPITAL AFTER THE DEATH OF BETHANY—WRITTEN BY HER MOTHER CLARE**

We were informed of her death by the surgical team, whilst on the ward in front of other patients and visitors, and were not taken somewhere more private. Following disclosure of this devastating news, we were left to leave the ward and walk out of the hospital via the main entrance unaided and unaccompanied by any hospital staff. We were not asked as to our means of getting home, and we were not in a fit state to drive. By chance, other family members were available to drive us, but the hospital did not know this.

The hospital contacted us the following day, and arranged for a bereavement services appointment. However, the hospital later cancelled this visit, and offered no explanation.

No information was given to us unless we asked the right question, and even after we asked if all of the information had been given to us they produced new photos and slides at the inquest.

We spent a very long time talking to the hospital about Beth and what had happened, but all new information we received was because of questions we asked, they never volunteered information and they were always very closed and defensive towards us.

They never said sorry other than in a letter from their solicitors after the inquest when they admitted liability. [N.B. Liability admitted by the Trust; the surgeons remained in denial.]

None of them saw Beth as a little girl only a patient to practice on, another patient to wheel through the theatre.

If any of the operating team had stopped to question each other on what they were doing, or had been made, by procedure, to discuss options then I believe Beth would still be alive today, why did no one say,

— Is it not better to remove a broken bag than leave a child under anesthetic for an extra 45 minutes?
— Is it not better to get some retraining as you have not used this equipment for 3 to 4 years?
— Is it not better for the trained doctor to be hands on rather than outside the operational field watching a screen where the manufacturers [of the endo bag] believe you would not be able to see anything if it did go wrong?
— Is it not right to inform the parents we have altered the operation plan?
— This piece of equipment is not made specifically for paediatrics and had never been used in UK for splenectomy before. Do we not need more than a conversation on the morning of the operation before we go ahead and use it?

Why is it in the field of surgery that doctors training and experience allows them the right to make decisions without question and without fear of being held to account?

When I signed the consent form I believed a doctor who had relevant training was operating on Beth. This was not the case. Would you get onto an aeroplane with a pilot who did not know how to fly, with a copilot who had had it explained but never seen it done and a cabin crew who said they had done it three to four years ago, this is comparatively what situation they put Beth into.

**THE MORCELLATOR**

The Gynecare morcellator has a nose (or barrel) of approximately 20cm in length with a rotating blade protruding at the tip, in order to reach and cut tough material in parts of the body difficult to access by any other means. It has been specifically designed for use in gynaecology, where it is often used in hysterectomies.
It had not been used to break up a spleen inside an endo bag, laparoscopically, in paediatric surgery before, either at the JR, or anywhere else in the UK. The following are some of the risks associated with this new type of surgery:

1. The blade is capable of 1000rpm (although the surgeons who operated on Bethany state they used it on the lowest speed setting).
2. Located at the tip, the blade cannot be seen as it cuts into the spleen, which is inside an endoscopic bag within the abdomen.
3. The nose (or barrel) is too long for this type of operation. The surgeons stated at the inquest that they applied the tip no more than 2 or 3 centimetres into the abdomen. However, it is difficult to know precisely how far the device had been pushed in, without any gradations or marking to give an indication. An extra one or two centimeters could result in cutting through the bag and causing injury, and some point of reference is clearly essential—especially when the operator has no experience. To reiterate: they could not see the blade, and were relying on a best guess as to how deep it had penetrated.
4. A laparoscopic (or keyhole) camera was used, which gave a limited view of the bag inside the abdomen. During the inquest the court heard that the field of view was very restricted, showing only one side of the bag. Had the blade penetrated the other side, this would not be visible on the monitor screen.
5. The inquest heard of an incident which occurred in the USA in 2006, when a morcellator was used on a woman patient, to cut up the spleen inside an endo bag. The morcellator went through the bag, cut her aorta, and the patient died.
6. When used with inadequate training, (for whatever procedure) it is potentially dangerous. The representative from [Johnson and Johnson] stated, “I would not advise anyone to use the morcellator without first attending our training course, where the user practices on a cows tongue.”

Why would a Morcellator be used in this type of operation?

The lead surgeon cited the following advantages:

“You can remove the spleen piecemeal, not the total spleen, but partly remove it piecemeal to make it more softer [sic] and then remove it with the forceps.”

In addition, the morcellator will, in theory, speed up the process of spleen removal, which was of some relevance in Bethany’s operation because the surgeons had intended to proceed to remove gall stones, after the splenectomy. However, had time been a critical factor in this operation, it should be noted that the surgeons lost 45 minutes in the early stages in attempting to place the spleen into a damaged bag, before abandoning it and using a replacement bag. They cited the cost of wasting a disposable bag as the reason for their 45 minutes of perseverance. Safety to the patient, and time lost, was not a factor that seemed important during that part of the procedure.

It should also be noted that there are safer, proven, alternative techniques for breaking up the spleen inside a bag, which make use of blunt instruments.

Other Factors in Electing to Choose the Morcellator

As a new technique it is attractive to surgeons. As surgeons they are “hands on”, and there is clearly a degree of excitement about pioneering a new technique. Individual surgeons gain recognition within their profession and in the media for being the first to introduce new methods and embrace new technologies, that go on to become adopted by the profession at large.

Concerns

The difficulty is that there are no systems in place to hold them back. They are able to make spur-of-the-moment decisions that radically alter the risks to the patient. They are not compelled to comply with manufacturer’s safety instructions. A representative of the manufacturer of the endo bag, whilst giving evidence stated: “We’ve, in our experiments and in our research, discovered the bag is fantastic for keeping soft tissue and protecting wounds, wound edges, it’s not intended for use in conjunction with very sharp devices…”

“My experience is we’ve always said do not use the morcellator and I know that we have had experience either at the research stage, or early on in the use of the product which would suggest that the morcellator is not a good thing to do, in the bag, as you saw there it is very difficult to see what is going on in the structure when you can only see one face of it laparoscopically. The comment was ‘You can’t see either behind or below’”.

The instructions for use that accompany the retrieval bag specifically state that a morcellator should not be used in conjunction with it: “We stop people from doing it”, he said.
The surgeons do not have to attend training courses if they consider they have sufficient experience in the theatre. The point is—they decide. When things do go wrong, they are not held to account. This is evident from the outcome of the inquest, which stated that Bethany’s aorta was damaged by an unspecified surgical instrument. No attempt was made to hold any surgeon responsible for their actions, and no recommendations were made by the coroner.

**Record Keeping**

Blood loss was recorded as not significant, but no attempt made to quantify, where quantification was possible. Records were omitted; an independent anaesthetist at a meeting stated, “There are boxes to be filled in [she proceeds to list various categories] it’s just completely blank”.

The batch number and lot number of morcellator components was not logged. During a meeting with the Trust, Bethany’s father, Richard, noted, “Potentially you’ve got a box full of faulty parts in your hospital ready to use on somebody else.” This was in the context of a suggestion by the Trust that an electrical fault in the morcellator may have been the cause.

Her weight was incorrect on the notes, and this was not queried by the anaesthetist, who said that she had assumed figures had been transposed.

Given the magnitude of error that occurred on the day Bethany died, it is easy to lose sight of other, lesser systemic and procedural failings which, had the morcellator not been used, could have lead to other types of adverse event.

**Human Factors**

A great deal of the testimony of the doctors was in the third person, using phrases that repeatedly referred to how a given procedure would be carried out, should be carried out, or had to be carried out, but very rarely (if at all) said what they actually did on the day Bethany died.

Bethany’s father Richard, who tragically died from heart disease brought on by the stress of losing his daughter and the painful circumstances that followed, had this to say, “Until the NHS is called to account for taking these risks they will simply go on killing our children... We have little faith that lessons will be learned until there is an independent body that monitors surgical training in the NHS. The risks that were taken by the Trust during the operation on Bethany were simply incredible and the attitude of the Trust was truly appalling.”

November 2008

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**Memorandum by Professor Richard Thomson (PS 80)**

**PATIENT SAFETY**

**Executive Summary**

1. This paper summarises key elements of the evidence base for the frequency of harm related to patient safety incidents. Quoted figures vary, largely because of a variety of methods and sources for measurement. However, it is clear that such harm is an important problem throughout developed health care systems.

2. Up to 10% of patients admitted to hospitals may suffer some harm, of which just under half may be judged preventable. The great majority of harm is minor, but as much as 7% of all incidents may be associated with the death of the patient.

3. The figures on numbers of deaths in the NHS vary widely and a definitive study is needed to address the size of this problem and to identify priorities for action.91

4. Risk from health care cannot be eliminated, and overall the benefits of care far outweigh the risks. Nonetheless we should seek to minimise these risks.

5. Health care systems at all levels need to draw upon a range of data sources for surveillance and monitoring of safety incidents. They also need to have systems in place to prioritise areas for action.

**Brief Introduction**

6. I am Professor of Epidemiology and Public Health and Director of the Risk Communication and Decision Making research programme within in the Institute of Health and Society at Newcastle University. I am medically trained. My service and academic interests have predominantly been in quality and safety of healthcare. From 2004-07, I was on secondment at the National Patient Safety Agency as Director of Epidemiology and Research. I am a member of the WHO World Health Alliance Drafting Group developing an International Classification for Patient Safety (ICPS) and Associate Editor, since its inception, of the journal Quality and Safety in Healthcare.

91 Conflict of interest—I am seeking research funds to address this question
Health Committee: Evidence

Factual Information

Risk
7. The NHS remains one of the best healthcare systems in the world, if not the best. The population is extremely well served by a high quality health sector at relatively low cost compared to other healthcare systems, driven by the laudable public funding model in the UK. Modern healthcare is complex, bringing people with multiple problems into contact with clinical staff using increasingly complex technologies. Given the nature of complex systems and human error, incidents will occur and risks exist for patients coming into contact with services. The challenge of safety improvement is to minimise that risk without compromising the quality of care. For example, in the case of falls in hospitals, some level of falls is likely to exist in the presence of patient mobilisation and rehabilitation; there is a balance to be struck between providing patient autonomy and rehabilitation and in reducing the risk of injury from falls. However, other incident types are arguably “never events”, such as wrong site surgery, and here efforts should be made to develop systems that prevent these as completely as possible.

Size of the Problem
8. In order to reduce the impact of patient safety incidents, there is clearly a need to quantify and characterise the problem, and to understand the causes and hence prevent avoidable harm.

9. Estimates of the size of the problem come from a variety of sources, with a wide range of methods for identifying adverse events and patient safety incidents, each with its own strengths and weaknesses. The great majority of studies have been undertaken in acute general hospitals, with very few in mental health and primary care. Some methods are better at estimating the size of the problem; others are more valuable in helping to understand why things happen and what might be done to prevent incidents.

10. The studies most widely referred to as identifying the frequency of incidents and/or harm in healthcare are case note review (CNR) studies. The most frequently cited of these is the Harvard Medical Practice Study.62 This was the first major study to show that hospital-based health care may cause significant harm are case note review (CNR) studies. The most frequently cited of these is the Harvard Medical Practice Study.62 This was the first major study to show that hospital-based health care may cause significant harm. Partly this reflects variations in definitions, and partly in the sources and methods of extrapolation, constituting the majority.

11. CNR studies rely on incidents being reliably identified within the clinical record. However, they require a large sample of records to be reviewed, and are time consuming. They may be weak in identifying near misses or no harm events where the details may not be recorded in the notes. Their capacity to identify preventability, and especially how to prevent recurrence, is more limited.

12. A recent overview of eight case note review studies, covering over 75,000 patients, concluded there was an average overall incidence of harm events in 9.2% of hospital admissions, about 43.5% preventable.101 More than half of these patients experienced no or minor disability (56.3%), 19.1% temporary disability, 7% permanent disability and 7.4% were fatal. Operation—(39.6%) and medication-related (15.1%) events constituted the majority.

13. One area where there is considerable variation in widely quoted estimates is in the number of deaths caused. Partly this reflects variations in definitions, and partly in the sources and methods of extrapolation, especially from studies that have included small numbers of deaths.

14. Finally there is a considerable challenge in attribution and in assessing preventability. Thus deaths largely occur in older patients who are already very sick and suffering from multiple and complex problems, where risk of death from their underlying illness is high. The contribution of an incident to a death in such circumstances can be difficult to disentangle from the underlying illness.

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15. Extrapolating from data from the Harvard study, the 2001 US Institute of Medicine (IOM) report, “To Err is Human”, estimated 44-98,000 deaths each year in the US as a result of error. However, despite the passage of fifteen years since the publication of the original Harvard studies, the Public Accounts Committee in 2006 criticised the NHS for “the lack of accurate information on serious incidents and deaths.”

16. In CNR studies, overall 58% of hospital events occur in surgical specialities although many of these are due to ward care rather than operative procedures. Twenty four percent occur in medical specialties.

17. Another major source of incidents relates to medication. Medication error occurs in up to 11 in every 100 prescriptions. In the UK 6/100 patients report a wrong medication or dose in the last two years by doctor, hospital or pharmacist and 20/100 patients reporting a medication error stated that it caused them a serious health problem. In a systematic review 3.7% of hospital admissions were due to medication errors.

18. In primary care data is very limited. Sandars and Esmail concluded in 2003 that “medical error occurs between five and 80 times per 100,000 consultations, mainly related to the processes involved in diagnosis and treatment.”

Why do the figures for deaths vary?

19. The frequency of deaths from patient safety incidents is far from clear. For example, widely quoted figures, primarily derived from extrapolations of CNR studies, range from 25,000 to 40,000 per year or higher in the UK (Box 1). However, the source and methods of estimation vary.

**BOX 1: Widely quoted estimates of adverse events in UK settings**

<table>
<thead>
<tr>
<th>Estimated Deaths</th>
<th>Source</th>
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<tbody>
<tr>
<td>25,000 deaths</td>
<td>Cited in the Bristol Inquiry report (2001), and based on the upper range of the estimate of 44,000 to 98,000 deaths in the USA approximately adjusted to the size of the UK population by rounding the upper range to 100,000 and assuming the UK population is a quarter of the USA population. The US estimates were drawn from the Harvard study of events meeting the legal definition of clinical negligence.</td>
</tr>
<tr>
<td>34,000 deaths</td>
<td>Referred to in the National Audit Office report (2005), but not referenced. It is thought to derive originally from an unpublished extrapolation using rounded figures for hospital admissions and rounded percentages from a CNR study in the UK which included only nine deaths.</td>
</tr>
<tr>
<td>40,000 deaths</td>
<td>Cited by Aylin et al (2004) which referenced it to a web site including a conference presentation in Australia which referred to an article in the Sunday Times (1999), which was apparently derived from a journalist’s calculations.</td>
</tr>
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20. In contrast to these high estimates, a seminal study of 111 deaths in US hospitals sought to address the issues of preventability and patient prognosis. They found an estimate of 23–26 deaths per 10,000 admissions. However, after taking account of the probability that an event could have been preventable.
prevented, and the prognosis for the patient after three months had an error not occurred, the adjusted rate was 0.5–1.4/10,000. Applying these adjusted rates to acute hospital admissions in England would estimate 428 to 1,199 deaths as a result of preventable incidents.

21. An alternative method used analysis of deaths reported to the NPSA National Reporting and Learning System (2005).¹¹⁴ This estimate needs cautious interpretation, given known under-reporting; any estimate from this source will be an under-estimate. The NPSA analysis sought to address this by estimating only from consistently reporting hospitals and by systematically reviewing incident descriptions, and excluding those which did not indicate a preventable error contributing to death. This estimated a death rate of 77.4 per million hospital admissions, equivalent to 840 reported deaths per year in acute hospitals in England that could have resulted from patient safety incidents.

What is important?

22. Whilst it is clearly important to have an understanding of the size of the problem, arguably more important is an understanding of the preventability and the potential for reducing harm. Nonetheless, studies of the size and burden of the problem should be sufficiently robust to enable priority setting.

Role of Reporting and Surveillance

23. Incident reporting systems have an important role to play in safety improvement. Where they lack strength is in determining the absolute size of the problem, fundamentally because of issues of under reporting and bias in reporting. Nonetheless, they have been the mainstay of safety improvement in many other industries, including the airline industry. The NPSA National Reporting and Learning System has much to contribute to improving safety through the processes of reporting and analysis, aligned with priority setting and development of solutions which are subsequently disseminated and implemented locally. For example an NPSA review of deaths reported to the NRLS identified three priority areas namely failure to identify and act on patient deterioration, cardiac arrests and misdiagnosis.¹¹⁵

24. It is almost impossible to determine degree of under reporting, and this is likely to vary in terms of the setting, the type of incident, the people reporting etc. For example, it is likely that reporting of falls in hospitals is more complete than reporting of some other incidents, since there has been a long-standing emphasis on reporting of such incidents by nursing staff.

25. It is clear that whatever source of identification of patient safety incidents one uses, it is likely to provide a different profile of incidents.¹¹⁶ This emphasises the need for systems of surveillance and monitoring that recognise the strengths and weaknesses of different sources of data and brings them together to capture a fuller picture of safety. Thus, at hospital level for example, in order to understand the range and type of safety incidents, one would want to draw upon data from the hospital’s own risk management systems, from routine hospital information (including patient safety indicators and inpatient mortality data, for example), data from surveillance of hospital acquired infections, and data from case note review studies and other clinical audits.

26. Several studies have demonstrated that the overlap between different sources is relatively small. Such a system of bringing together data from a range of sources in an overarching surveillance and monitoring model would be a sensible approach to adopt at any level within the system.

27. It is also clear that the levels of incident reporting are rising within the NHS and it is likely that this reflects an improvement in the overall attitude towards reporting, the better implementation of reporting systems, and an overall change in safety culture. Recent work that I was involved in, due for publication shortly, shows that those hospitals that have higher reporting rates are also those that score better on other independent measures of safety culture and reporting including the Healthcare Commission staff surveys.¹¹⁷ It is important that we continue to support the development of an open and fair culture which will enhance reporting and the capacity to learn from incident reporting.

Priority Setting

28. Priority setting in the context of safety incidents and safety improvement is critically important, as in any other area of healthcare, such as the choices that need to be made about use of interventions driven by the evidence collated by the National Institute for Health and Clinical excellence (NICE). For safety improvement, arguably this is slightly more complicated (it is complicated enough for healthcare

¹¹⁴ NPSA. 2005, Building a memory: preventing harm, reducing risks and improving patient safety The first report of the National Reporting and Learning System and the Patient Safety Observatory
¹¹⁷ Hutchinson A, Young TA, Cooper KL, McIntosh A, Karnon JD, Scobie S, Thomson RG. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. QSHC In press
treatments), because of the many attributes that come to play in decision making. Thus, some of the most prominent and harmful incidents arising from healthcare, such as the death of patients inadvertently injected into the spine with vincristine, are widely deemed unacceptable and rightly so. However, they are extremely rare and the burden of ill health caused at an overall population level is relatively small, even though the impact at an individual or family level is severe.

29. On the other hand, falls in hospitals are very common, and reflect in part the high risk population that is treated in hospital settings. Overall, the number of falls occurring across the county is considerable and the overall harm caused is also high. An NPSA report which summarised the incidents reported to the NRLS (with the above riders on problems of underreporting) suggested that “In an average 800-bed acute hospital trust, there will be around 24 falls every week, and over 1,260 falls every year. Associated healthcare costs are estimated at a minimum of £92,000 per year for the average acute trust.”

30. Not only are there choices to be made between developing solutions and interventions in specific areas such as falls or preventing inadvertent spinal injection of vincristine, there are also choices to be made between developing specific solutions for particular types of incidents and events, and investing resources in wider initiatives to improve safety such as improving knowledge and understanding, enhancing safety culture, improving communication, and addressing generic issues such as patient handovers and transfers.

31. It is therefore important that any system has a robust and transparent approach to assessing and setting priorities for investment of resources and safety improvement. The criteria for determining priority should include the frequency of the incident, the degree of harm, the preventability and the availability of effective interventions.

Recommendations

— 32. Whilst there is a strong argument for investing more in development of solutions and interventions to improve safety, the challenge of continuing debate around the size of the problem, particularly with reference to harm/deaths caused by patient safety incidents, also supports calls for robust studies in the UK to address this issue, not only to understand the size of the problem, but more importantly to understand the range and types of incidents that cause death or severe harm in order to prioritise development of appropriate interventions.

— 33. Local and national systems should use a variety of sources and methods in an overarching surveillance and monitoring system of patient safety incidents and not rely unduly on one single source of data.

— 34. At each level within the system there should be approaches to prioritising investment in safety improvement based upon an understanding of the size and impact of the problem at the appropriate level and taking account of a range of attributes of safety including frequency, burden of harm, and potential to prevent incidents and harm.

— 35. Those involved in managing reporting systems and analysing data must increasingly feed back information to those reporting and demonstrate to all concerned how incident reports have been used to develop improvements and make changes leading to increased safety. This will further support appropriate and more complete incident reporting as well as enhancing the culture of safety.

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November 2008

Memorandum by Professor Alastair Gray (PS 81)

I am Professor of Health Economics and Director of the Health Economics Research Centre in the University of Oxford.

My main research interests are in the economic evaluation of health care and public health interventions, and in the economics of patient safety, medical negligence and compensation arrangements. With colleagues at the University of Nottingham (Professor Paul Fenn) and Surrey (Professor Neil Rickman) I have provided evidence to the Chief Medical Officer on current and future compensation arrangements (Making Amends). I have prepared extensive reviews of research evidence for the National Patient Safety Agency, and more recently have been exploring the workings of the current insurance arrangements provided by the NHS Litigation Authority, as part of the Economics and Social Research Council’s research programme on Quality in Public Services.

I would like to briefly touch on three topics:

1. the economic cost of errors in health care;
2. the cost-effectiveness of interventions to reduce errors; and
3. incentive mechanisms to improve patient safety.

1. **The Economic Cost of Errors in Health Care**

1.1 There is a sizeable literature on the costs associated with various types of harm; these use different methods and terminology, and it might be useful to think of these in relation to the Venn diagram shown in Figure 1, which is based on the terminology used by the Institute of Medicine in its 2000 report (Kohn et al. 2000). Errors occur in a proportion of all episodes of health care, and so do adverse events—that is, injury caused by medical management rather than by the underlying disease or medical condition of the patient. Some errors do not result in adverse events (so-called “near misses”), and not all adverse events arise from error. Adverse events which are attributable to error can be defined as preventable adverse events. Finally, there is a subset of preventable adverse events that satisfies or would satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected). Not all of these are pursued or settled, resulting in the final category of compensated negligent adverse events.

![Figure 1](image_url)

1.2 What do we know about the size and cost of these boxes? Professor Thomson is addressing the epidemiological evidence on the frequency of these events; much of the economic evidence builds on these epidemiological studies, and is subject to the same limitations and uncertainties.

We do know that in 2006–07 the NHSLA paid out a total of £579 million in connection with clinical negligence claims, including damages paid to patients and legal costs borne by the NHS. (This compares with £560 million in 2005–06.) These are likely to be the most serious and expensive cases, but are a very small proportion of all preventable adverse events.

1.3 Data from the Harvard Medical Practice Study and the Utah and Colorado studies—the most widely quoted studies of adverse events—have been used to estimate the cost consequences of adverse events (Thomas et al. 1999). An important point they make is the need to distinguish between the gross cost of adverse events, and the proportion of that total that can be attributed to the preventable event itself rather than the underlying illness. Typically they found that 20% of the total cost could be attributed to the preventable event.

1.4 They found that adverse events accounted for approximately 4.8% of all health expenditure, and preventable adverse events for about 2.2% of all health expenditures, in these States. Applying these results to the entire US suggested that around 4% of all health expenditure was related to preventable adverse events.
1.5 It should also be borne in mind that health expenditures are only part of the costs incurred by adverse events: in the Utah and Colorado studies, the average preventable adverse event had a total cost of $34,900, of which half was health care costs, and the remainder was accounted for by lost earnings and other costs incurred by the family, for example in providing informal care.

1.6 Studies in Australia (Rigby and Litt, 2000) have also found that between 2% and 3% of annual hospital expenditure can be attributed to preventable iatrogenic injuries.

1.7 A small pilot study in the UK (Vincent et al 2001), estimated a 10% adverse event rate, that 50% of these were preventable, and that each event added around 8.5 days to the hospital length of stay, suggesting that approximately 5% of all hospital admissions would experience a preventable adverse event, equivalent to an additional three million bed days and additional costs to the NHS of approximately £1 billion.

1.8 Another UK study (Plowman et al 2001) identified all hospital-acquired infections amongst 4000 adult patients admitted to an English general hospital over the period April 1994 to May 1995, and then collected information on daily resource use by both infected and uninfected patients in order to estimate cost. 8% of patients presented with one or more hospital-acquired infections during the study, and they incurred hospital costs almost three times greater than uninfected patients, equivalent to an additional UK£3,154. Extrapolated to all NHS hospitals in England, these results indicated that about 320,000 patients per annum acquire one or more infections which present during the in-patient period, at a total cost to the hospital sector of £931 million per annum.

1.9 These two studies have been widely quoted in subsequent reports. For example, the 2000 Department of Health report An organization with a memory: report of an expert group on learning from adverse events in the NHS,(Chief Medical Officer 2000) used the results of the pilot study by Vincent et al to estimate that the NHS in England as a whole might experience 850,000 inpatient episodes annually in which adverse events occurred, at a total cost of £2 billion in additional bed-days.

2. THE COST-EFFECTIVENESS OF INTERVENTIONS TO REDUCE ERRORS

2.1 Most of the studies documented above are descriptive, and tell us little about the effectiveness or the cost-effectiveness of interventions that might reduce medical errors or adverse events.

2.2 A small number of systematic reviews have tried to identify randomised trials of such interventions. For example, Ioannidis and Lau (2001) found 13 randomized studies of a variety of interventions ranging from nurse triage to identify bone fracture to better illuminated workplaces to reduce prescription error. 9 of these 13 studies found clear evidence of effectiveness in reducing error rates. Similarly, a US Agency for Health Care Research and Quality report identified 79 potential patient safety practices for detailed review, and then ranked them according to the strength of the evidence base for each. This approach illustrated how evidence-based methods could help identify practices likely to improve patient safety, but did not explicitly address the issue of the costs or cost-effectiveness of these practices.

2.3 Some interventions may be cost-saving—that is, the cost of the intervention may be exceeded by the savings that result, for example by avoiding excess lengths of stay. Alternatively, some adverse events may be preventable in principle, but only at such high cost that the intervention would not constitute an efficient or reasonable use of scarce health care resources—that is, the same resources could be used in some other way that would yield a greater health benefit. Consequently, even when effective interventions have been identified, there is a need to conduct rigorous cost-effectiveness studies of such interventions.

2.4 In practice, there are very few published cost-effectiveness studies of any patient safety interventions. A systematic review undertaken in 2003 found none that would meet the quality criteria used by the National Institute of Health and Clinical Excellence (NICE) or similar bodies when evaluating such studies.

3. OTHER INCENTIVE MECHANISMS TO IMPROVE PATIENT SAFETY

3.1 Where effective and cost-effective measures to improve patient safety are known to exist, it may be necessary to create incentives to ensure that these are provided.

3.2 My own research with colleagues has recently focused on the role of the NHS Litigation Authority, which in effects insures NHS providers against the risks of litigation and also seeks to improve standards of care. Insurers typically use mechanisms such as excesses (deductibles) to encourage the insured party to take due care. Until 2002 this was also the case with the NHSLA, but from that year all excesses were set to zero. In the absence of other measures this could have removed a useful patient safety incentive, but the NHSLA also introduced Risk Management Standards, which give Trusts discounts of 10%, 20% or 30% on their NHSLA contributions in return for meeting certain defined standards of care. These are designed to “contribute to the incentives for reducing the number of negligent or preventable incidents”. We have found limited evidence that variations in, for example, MRSA rates between hospitals and over time, can in part be explained by risk management standards.

3.3 The Committee has already heard some evidence concerning other financial incentives. For example, the Commissioning for Quality and Innovation (CQI) framework allows PCTs to withhold 0.5% of a contract with a provider if certain targets relating to patient safety were not met. Similarly, the Never Events
concept, whereby certain hospitals are deemed to be entirely liable for certain pre-defined clinical events that occur, and do not get payment for these from the PCT, is another interesting incentive mechanism that could help improve patient safety if well designed.

**Summary**

1. Evidence on the economic impact of adverse events and preventable adverse events on the NHS and also on those affected is very limited, but may amount to 2–3% of total NHS expenditure.

2. There is a pressing need to identify potential interventions to reduce preventable adverse events, and subject them to rigorous evaluation to assess their effectiveness and cost-effectiveness.

3. There have been some interesting experiments in using financial incentives to encourage NHS providers to adopt and fully implement patient safety interventions and standards of care. These should be encouraged, but should also be evaluated to ensure they are having the intended effects.

**References**


November 2008

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**Memorandum by Josephine Ocloo (PS 82)**

**PATIENT SAFETY**


The submission should be read in conjunction with three appendices:

— Appendix One—*The Guardian* article on my personal story.119

— Appendix Two—The article “The Patient’s Tale”.120

— Appendix Three—The Break Through Programme Newsletter.121

1. **THE PATIENT SAFETY CONTEXT**

   In the patient safety context, a number of the inquiries into serious failings of clinical care since the late 90s, have focused on the issue of governance as central to addressing issues of safety and quality of patient care in NHS organisations. Yet whilst some progress has been made in developing a patient safety culture, there are a number of areas where considerable problems remain.

   This submission suggests that a culture of denial is still firmly in place within the NHS and a lack of appropriate systems of governance which can hold individuals and organisations to account when negligence and wrongdoing takes place. This situation is seen to cause considerable harm and distress to

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patients and also to prevent the learning that needs to take place from adverse incidents that will prevent them occurring over and over again in healthcare. The issues associated with the failings of the justice, complaints and systems of professional regulation (outlined below), to provide victims of harm with accountability and the consequences of this situation are rarely discussed in the mainstream patient safety movement. This submission identifies what some of the key issues are in this area and then highlights the issue of the lack of progress made in involving patients and the public in patient safety despite the development of this agenda in other parts of healthcare. The general conclusion from my evidence is that victims of harm have been relegated the lowest priority in the attempts to build a new patient safety culture and yet bring to the table issues that are very different to the dominant perspectives shaping the current patient safety reforms. These issues are important in representing the voices of people who have been disenfranchised by health services, who are seeking changes to the ways those services are provided and which also raise issues about more democratic governance, citizenship and human rights.

In general it is agreed that about 10% of hospital admissions result in an adverse incident, about half of which are preventable (DOH 2000; NAO 2005). Whilst no actual data is available on the numbers of negligent PSIs occurring in the UK, respected international studies such as The Harvard Medical Practice Study (HMPS) (Brennan, Leape et al 1991; Leape, Brennan et al 1991) and The Quality in Australian Health Care Study (QAHCs) (Wilson, Runciman et al 1995) suggest these make up somewhere between 27–51% of all adverse incidents. Yet despite these numbers, only a tiny proportion of those affected by PSIs are able to bring a legal claim each year. In 2006–07 the total figure for negligence claims was 5,426 which was roughly the same for the preceding two years.

2. Governance and Accountability

The situation described above suggests that many people are being denied justice and much needed compensation, when affected by the most serious PSIs. There has also been a failure to implement no-fault Compensation or redress Scheme cited as vital to building a safety culture in Making Amends, five years after this report was published. Lack of access to justice is also aggravated by the culture of denial within the NHS acknowledged within Safety First (2006) and the evidence that patients are not being told when a PSI has occurred, particularly about the most serious incidents (House of commons public accounts committee 2006). Questions remain as to whether this situation has improved and what is being done to address the lack of incident reporting in Primary Care, of which little evidence exists in the National Reporting and Learning System (NRLS).

The Complaints System

Patients attempting to resolve their concerns through the complaints system have long faced considerable barriers in trying to resolve their concerns. These issues have been well documented by numerous reports and reviews over the last 20 years (DOH 1994, 2001; 2003; Parliamentary and Health Service Ombudsman 2005; HCC 2007), which have found the NHS complaints procedures to be seriously failing complainants and widely viewed as biased and lacking in independence. In recent years these reviews have led to a myriad of changes in order to make these procedures more responsive to patient concerns. This led to further proposals to reform complaints handling set out in the White Paper, Our Health, our care, our say (2006), proposing the establishment of a new comprehensive single complaints system across health and social care by 2009 and more comprehensive complaints handling at a local level. Since then the consultation document Making Experiences Count (2007) has recognised continuing failings in the existing complaints system and made proposals as to how a single system might work in practice.

The recent NAO report Feeding Back? Learning from complaints handling in health and social care (2008) also makes a number of points in this area. In reviewing complaints handling their survey found generally, that around 14% of those using NHS and social care services in the past three years were dissatisfied with their experience. Of these, only 5% dissatisfied with NHS services went on to make a formal complaint compared to one-third who made a complaint about adult social care services. The main reason cited for not complaining formally was that individuals did not feel anything would be done as a result. The NAO report noted that only 59% of survey respondents felt that their complaint had been received in an open and constructive manner. Drawing upon research carried out by the consumer watchdog Which on hospital complaints it was also noted that whilst most people were happy they had made a formal complaint, only 27% were happy with the way their concerns were dealt with. The report makes a number of recommendations on specific issues that currently need to be addressed both by the Department of Health and at a local level if the new complaints system is to be effective.

Professional Regulation

Dame Janet Smith, Chairperson of the Shipman Inquiry, noted in her conclusions on past conduct within the GMC:

Having examined the evidence, I have been driven to the conclusion that the GMC has not, in the past, succeeded in its primary purpose of protecting patients. Instead it has, to a very significant degree, acted in the interests of doctors. Of course, I accept that the GMC also has a duty towards doctors; it must be fair in all its dealings with them. But, in the past, the balance has been wrong
and, in my view, the imbalance was due to a culture within the GMC, a set of attitudes and an approach that put what was seen as being “fair to doctors” ahead of protecting patients’ (Shipman Inquiry Fifth Report 2004: 4570).

Clearly the proposals in the White Paper “Trust Assurance” and the wide-ranging reforms to professional regulation in health, are an attempt to address the above situation, but I believe a number of gaps still exist as outlined below:

— There is no mechanism in which patients can challenge the GMC if they refuse to investigate their case, apart from through the costly procedure of a Judicial Review that is beyond the means of most people. This meant that even when the Chief Medical Officer suggested that the GMC investigate the serious allegations in my case, there was nothing he could do when they refused to do this.

— The Council for Healthcare Regulatory Excellence (CHRE) does not have the powers to review and intervene on individual cases despite the suggestion in the White Paper that this might become the case. Neither does the Parliamentary Ombudsman.

— The lack of a body that can review miscarriages of justice or intervene when a complainant falls outside of the timescales or remit of an organisation with powers to investigate a complaint is greatly lacking. At the moment there is widespread evidence that victims of harm can go round and round in circles trying to navigate systems which can properly and independently investigate their complaint.

— Despite the publication of the White Paper, on 13 June 2008, the CHRE issued a press release entitled: “Performance Review Makes Strong Recommendations For Improvements To The Nursing and MidWifery Council”. This not only highlighted serious concerns about the inadequate operation of the NMC’s fitness to practise processes, but also noted allegations about racism and bullying. The latter is seen as an issue, given serious concerns acknowledged by the Healthcare Commission about the disproportionate numbers of Black and Minority Ethnic (BME) staff who in one study were found to be 69% more likely to face disciplinary measures than white staff in relation to misconduct issues in health. The GMC also disciplines more BME doctors, but refused to investigate serious allegations of discrimination in my case against a white doctor. This raises questions about racism in the NHS and how it affects care and also raises questions about the application of a blame culture in health, that appears to be more likely to be directed at Black and minority ethnic staff.

— This evidence about racism should also be seen in the light of reports by the HealthCare Commission (HCC) that BME patients and other groups such as those with learning disabilities receive worse healthcare and treatment. In 2006, this led the HCC to issue a press release entitled: “Healthcare Watchdog puts NHS Trusts on notice over compliance with race relations law”. It is my submission that NHS trusts are still widely failing to comply with the Race Relations (Amendment) Act 2000, which has implications for staff and patients connected to patient safety. The Healthcare Commission is currently conducting a national review of race equality across the NHS.

In concluding this section it is my view that issues to do with having appropriate governance and accountability systems and procedures in place in NHS in organisations are fundamental to creating a patient safety culture. However evidence suggests that these procedures still do not operate properly in many NHS organisations. This can result not only in harm occurring to patients from PSIs, but patients being doubly harmed through being unable to get explanations, justice and accountability once the original adverse incident has taken place (see Church and Vincent 1996; DOH 2003).

Charles Vincent in writing about how this situation impacts upon patients has noted that:

“Many people harmed by their treatment suffer further trauma through the incident being insensitively and inadequately handled. Conversely, when staff come forward, acknowledge the damage and take the necessary action, the support offered can ameliorate the impact both in the short and long term” (Vincent 2006:124).

Sir Liam Donaldson also notes in Safety First that:

“Consumers of healthcare are at the heart of patient safety. When things go wrong, they and their families suffer from the harm caused. Such harm is often made worse by the defensive and secretive way that many healthcare organisations respond in the aftermath of a serious event” (DOH 2006:30).

3. PATIENT AND PUBLIC INVOLVEMENT IN PATIENT SAFETY

Central to the recommendations in the Bristol Report was the view that increasing the participation of patients or parents and the public was important in developing a new safety culture and that this involvement might help to prevent the occurrence of errors and ameliorate the effects of harm (Secretary of State for Health 2001). Sir Ian Kennedy subsequently expanded upon the view about the importance of involvement after Bristol and as shadow chair of the predecessor organisation to the current Healthcare Commission. The point made in advocating the need for PPI in healthcare, was that patients should no
longer be treated as passive and uninvolved individuals in their own care, but as partners with healthcare professionals. This he argued was because doctor and patient were both experts in their own fields, “the doctor in clinical matters, and the patient in his or her experience, feelings, fears, hopes and desires” (Kennedy 2003:1276).

This issue about addressing paternalism, as part of creating a safety culture in which patients and the public can be involved, was recently reinforced by Sir Liam Donaldson, the Chief Medical Officer, writing in the Journal of the Royal Society of medicine. He argued that addressing patient safety concerns still required further cultural change, and that one of the challenges was in relation to how patients were involved in their own care. He pointed out that whilst the NHS in the past was characterised by paternalism, “Tomorrow’s patients will not be willing to accept the role of grateful and passive recipient of care. Recognizing and acting on the part that they and the public can play in shaping the NHS is vital. The quality and safety of care in the future depends on it” (Donaldson 2008:341).

Whilst there is little in the literature on the experiences and views of harmed patients on patient safety concerns, what evidence that does exist suggests that these patients have strong opinions about the medical profession and safety issues and changing the system and see the issues differently from other patients. Allsop (2004) has pointed to what she calls protest groups who have formed as a result of adverse clinical events. She found that these groups were more likely than other health consumer groups to “view medical practices as paternalistic and oppressive and to see health professionals as people who withheld information and close ranks against patients when questioned” (Allsop et al, 2004: 751). Other evidence suggests that in developing a patient safety culture, issues to do with justice and accountability are seen as vitally important concerns (Davies and Shields 1999; Ocloo 2007). The demands from these groups therefore bring to the table issues that are very different to dominant perspectives shaping the current patient safety reforms.

Post-Bristol, a number of important inquiry reports such as “Learning from Tragedy” (2007), part of the Governments response to the Shipman Inquiry report, have emphasized the importance of involving patients and the public in new organisational arrangements. The importance of involving and working in partnership with patients, carers and their families in all aspects of the patient safety agenda and after the occurrence of a patient safety incident has also been given a strong emphasis in “Safety First” (2006). Recommendation 8 of the report in particular states:

“Accountability for patient safety rests with the Chair and Board of each NHS organisation. Each Board should therefore be expected to outline how it intends to discharge this responsibility. Importantly, each Board should also make clear how it intends to ensure that patients and carers play an integral part in all initiatives to introduce a patient safety culture change within the NHS” (Safety First 2006: 27).

Yet eight years after the publication of the Bristol report (2000), growing evidence about practice on the ground suggests a lack of progress in involving patients and the public in the patient safety agenda. In 1999, the document “Clinical Governance: in the new NHS” set out clear expectations for NHS Trusts in developing PPI in this area. However evidence from two National Audit Office reports published in 2003 and 2007 looking at the progress achieved in implementing clinical governance arrangements in the NHS in both the primary care and hospital sector found that progress in developing PPI in this area was limited. Findings from a two-year pilot initiative, the Patients for Patient Safety (PiPS) project funded by the National Patient Safety Agency (NPSA) and run by Action against Medical Accidents (AvMA) also found a number of problems in this area. In particular a key finding from their project work was that whilst patients and the public were willing to work in partnership with NHS organizations they faced substantial barriers to real involvement (Ocloo, 2008).

The Picker Institute (2006) has carried out the most systematic review of the literature looking at evidence for involvement in patient safety. A key point made with the review was that, “The UK has had a major programme to improve patient safety since 2001, but with little recognition of patients potential to take an active role” (Picker Institute 2007:6). It was also noted that historically the patient safety movement has overlooked the role of the patient and tended to view patients in a passive way as simply the victim of errors. In practice this had meant disregarding the various ways in which patients already contribute to their care (Coulter and Ellins 2006).

This situation has meant in practice that harmed patients have struggled not only to highlight their concerns when affected by a patient safety incident, but also then found it virtually impossible to get involved in the mainstream patient safety movement in order to raise issues about change from their own perspectives. In mainstream patient safety conferences, patients and the public are rarely represented. The agenda does not include them, apart from as objects to be discussed and the harmed patient who wishes to raise issues about accountability will routinely be denied a voice, screened out and censored by most healthcare organisations.

November 2008
Memorandum by Professor Brian Toft (PS 83)

PATIENT SAFETY

1. INTRODUCTION

1.1 I am Professor of Patient Safety at Coventry University and Principal, Risk Partnerships, a consultancy specialising in patient safety issues and Root Cause Analysis.

1.2 I was a specialist advisor to the internal inquiry team investigating the Ladboke Grove Rail Collision 5 October 1999 and a member of the “Management of Change”, seminar at Lord Cullen’s—Ladboke Grove Rail Inquiry Part 2, Seminar 7, Central Hall, Westminster, London.

1.3 I was the Specialist advisor to Taylor Joyson Garrett, instructing solicitors for Michael Mansfield QC legal Council for the Marchioness Contact Group at the Thames Safety Inquiry.

1.4 I was the independent external risk advisor to the Big Lottery Funds Audit and Risk Committee until 2008.

1.5 I was a member of the expert group which produced the document An organisation with a memory... chaired by the Chief Medical Officer in 2000.

1.6 I was the first “lay” person to be the Chairman of an investigation into the death of patient in the National Health Service following the death of Wayne Jowett from the inadvertent intrathecal administration of Vincristine in 2001.

1.7 I was Chairman of the investigation into the circumstances surrounding how the female partner of a Caucasian couple gave birth to mixed race twins 2002–04.


1.9 I have carried out a number of investigations for NHS Trust’s in England. Two of which resulted in the National Patient safety Agency issuing “Alerts” to the healthcare community. The first Alert was to those who work in the field of radiotherapy and the second to the wide healthcare community on the dangers of “heparin flushes”.

1.9.1 I was presented with The Glyn Evans Memorial Medal, by the Royal College of Radiologists for my work on involuntary automaticity in 2006.

1.9.2 I am currently a lay independent external member of the following bodies:

1.9.3 Joint Commission International European Regional Advisory Council on healthcare and patient safety, a World Health Organisation collaborating centre for patient safety.

1.9.4 United Kingdom Intrathecal Chemotherapy Advisory group.

1.9.5 Royal College of Radiology and National Patient Safety Agency joint project: Patient Safety in Radiotherapy.

1.9.6 Royal College of Anaesthetists and National Patient Safety Agency joint project: Anaesthesia: Improvement through partnership.

1.9.7 Safety Committee, Association of Anaesthetists of Great Britain and Ireland.

1.9.8 My evidence concerns the following areas in the Committee’s Terms of Reference: “what the risks to patient safety are and to what extent they are avoidable”, “safety culture” and “what the NHS should do next regarding patient safety”.

2. EXECUTIVE SUMMARY

2.1 It is impossible for anyone to prespecify all the risks to which patients are exposed thus proactive techniques like “Failure Modes and Effects Analysis” while helpful are not a panacea. It is however possible to learn from a patient safety incident (PSI) and to take remedial measures that will prevent a recurrence. Consequently the role of the National Patient Safety Agency (NPSA) in collecting adverse incident data and learning from such events is crucial to patient safety. However the evidence does suggest that the National Reporting and Learning System (NRLS) should be redesigned to make it become more effective.

2.2 The NHS is a complex socio-technical system in which both people and the technology used must perform well together if patients are to receive safe, high quality medical care. It is therefore important for all those involved in the healthcare system, particularly management, to recognise that dysfunctional working environments can force healthcare professionals to make inadvertent errors, even when verbal double checking safety protocols or other forms of Standard Operating Procedures (SOP) are being used. Thus the whole system of work, ie the individual, group, organisational, cultural and technological factors must be addressed in such a way that they are congruent with each other and not antagonistic if patient safety is to be substantially improved. Thus training should be provided to clinical and non-clinical healthcare professionals to ensure that a common understanding exists of how this might be achieved.
2.3 There is also evidence to suggest that the safety culture of some healthcare professionals who work in the NHS is not all that it might be and as a consequence patient safety is undoubtedly compromised on occasions as a result. Thus there is a need to find ways to engage all healthcare professionals so that they embrace the concept of “safety first” and realise that it is not a fashionable slogan.

2.4 The evidence also suggests that all those who review or investigate PSI’s should have a formal grounding in the wealth of factors that can lead to adverse events occurring and the techniques for learning from them. This would enable a more complete analysis of PSI’s to be undertaken and assist in producing recommendations of greater utility than at the present time. In an attempt to address this issue an E-learning Post Graduate Course in Root Cause Analysis is currently being developed at Coventry University by the author of this evidence.

2.5 The present regime for introducing new medical devices designed to significantly improve patient safety does not appear able to act in a timely manner. Thus the regulatory framework currently in place should be modified so as to provide a “fast track” route for the introduction of such medical devices.

3. Risks to Patients

3.1 The National Health Service (NHS) can be categorised as an open socio-technical system in which both social and technical processes interact to produce medical services for patients. One of the properties of an open system is that of “equifinality” which means the organisation can arrive at a given end state, for example, success or failure, from different starting conditions, via different routes and following disturbances to their processes. Therefore the same final system end state can be reached equifinally. It can thus be argued, that there are an infinite number of equally likely ways by which an organisation (or a person) can arrive at or be responsible for a PSI. It logically follows therefore that the risks to patient safety are also infinite.

3.2 One of the inferences that can be drawn from this hypothesis is that when one finite set of failure scenarios has been evaluated for risk analysis purposes, there is another equally likely set waiting to be calculated and so on, ad infinitum. Therefore, when the risks to patients are proactively evaluated using techniques such as FEMA these are in one sense, meaningless as there are always other, equally likely, ways in which a Trust can meet with a patient safety incident that has not been considered. Hence, while techniques like FEMA are useful they are not the universal remedy sometimes portrayed by their adherents. In short it is impossible for anyone to explicitly know or state the totality of risks to patients using the NHS or in any open socio-technical system. Hence the ideal of risk free medical practice cannot be achieved.

3.3 However, while it is not feasible to explicitly know what all the risks to patients in the NHS my work has demonstrated that it is possible to avoid repeating those that the medical profession already know about providing there is a will to do so (see Case Study one below).

4. National Patient Safety Agency

4.1 The National Patient Safety Agency was created to collect and analyse data on PSI’s then disseminate the lessons learned to prevent their reoccurrence. Unfortunately those entrusted with the NPSA’s construction, while dedicated healthcare professionals, appear to have known little about why or how organisational failures or PSI’s occur. Nor what techniques might be used to learn from such events. Moreover when specialist help was offered by myself, I had been a member of the expert group that had produced the report “An organisation with a memory...”, it was refused. Thus it was not surprising to see the critique of its performance by the Public Accounts Committee in 2006.

4.2 However that said, I disagree with the inference in the evidence submitted to this Committee by Stuart Emslie and John Step. They suggest that the NPSA should have procured either the Australian Patient Safety Foundation “AIMS” or the Safecode computer incident reporting systems. However on its foundation the NPSA had the opportunity to design and develop a NRLS which could have produced results far superior to those systems already in use. Thus the NPSA decided to take that route and they are to be applauded for it. The fact that the end result was not as they would have wished does not make the decision they took at that time wrong. Hindsight is a wonderful predictor of what has occurred.

4.3 It should also be noted that it is my understanding that Stuart Emslie when Head of Controls Assurance for the NHS at the Department of Health was involved in the procurement process for the AIMS system. And that he was also involved in the actual production of the Safecode system while working at Strathclyde University. To have had both reporting systems with which he had been personally involved rejected by the NPSA may therefore have coloured his views on the subject.

4.4 There is evidence however from the RCA of four PSI’s I carried out that the current NRLS system is not as effective as it needs to be. Thus the NRLS does need to be redesigned as recommended by the authors of “Safety First A report for patients, clinician and healthcare managers”. However it is important that the redesign team recognise that they must create an agreed detailed specification of all the NRLS’s required outputs, including any training that might be required before work commences. Otherwise the redesign process is highly likely not to deliver the improvements sought and patient safety will be adversely affected.

5. Case Study One: A Failure of Hindsight

5.1 Provided Vincristine is administered intravenously (IV), it is a powerful and useful medicine in the fight against a variety of cancerous conditions. However, if the medicine is administered, in error, through an intrathecal (spinal) injection (IT) the result is usually the death of the patient or if the patient does survive, then they typically suffer from severe neurological and physical trauma.

5.2 The first record death of a patient from the inadvertent intrathecal administration of Vincristine occurred in the United States of America in 1968. Seven years later, on 17 December 1975, Lee Duggins aged 8, died in Doncaster Royal Infirmary as a result of a doctor inadvertently administering Vincristine intrathecally. The tragedy occurred even though the dangers of Vincristine were known and the instruction on the label of the syringe containing the Vincristine stated that it was to be administered IV. It should however also be noted that neither of the doctors involved in these two serious PSI’s had been warned of the consequences of inadvertently administering Vincristine intrathecally. Lee Duggins was the first recorded patient safety incident in the United Kingdom (UK) where a patient had died under such circumstances.

5.3 On 2 February 2001, Wayne Jowett aged 18, died in the Queens Medical Centre, Nottingham as a result of two doctors inadvertently administering him “Vincristine” intrathecally. Subsequently, I was commissioned by Professor Sir Liam Donaldson, Chief Medical Officer (CMO) for England to hold an External Investigation into the circumstances surrounding the inadvertent intrathecal administration of Vincristine that lead to the death of Wayne Jowett.

5.4 The immediate underlying physical cause of this tragic event was the ability of the doctors who were administering the medicine to connect the syringe containing the Vincristine to the spinal needle used for administering medicines intended for intrathecal administration. There were a number of procedural systems in place to try to prevent such an error from occurring, because the dangers were known, but these had been unintentionally defeated with the best of intentions by some the healthcare professionals working at the hospital.

5.5 The doctors who made the error had, as in the two cases noted above, never been warned that Vincristine must only be administered to a patient IV and never IT. The doctors involved with the administration of the medicine, as noted earlier, also failed to follow the instructions printed on the label attached to the syringe by Pharmacy at QMC that the Vincristine was to be administered IV. Thus, it can be argued, this disastrous PSI was due to inadvertent human error and systems failure. However, Wayne Jowett was now the 14th patient to have died in the UK from the inadvertent intrathecal administration of Vincristine since the death of Lee Duggins at Doncaster Royal Infirmary 26 years earlier.

5.6 The investigation into Wayne Jowett’s death produced 55 recommendations designed to stop such a catastrophe from ever occurring again in the UK. However, in the first instance, the working party set up to produce guidance on how the operational recommendations should be implemented by Trusts only produced guidance to put half of them into practice. This was even though all the recommendations had been accepted by the Government as being relevant. The reluctance of the working party to implement all the operational recommendations that had been made was because it would mean significant changes to the current working practices of healthcare professionals in that particular field of medicine and this was deemed to be undesirable. This was even though 14 patients had now been inadvertently killed by their colleagues making the same errors on each occasion.

110 Toft, B Independent review of the circumstances surrounding four serious adverse incidents that occurred in the Oncology Day Beds Unit, Bristol Royal Hospital for Children on Wednesday, 3 January 2007, published at http://www.who.int/patientsafety/information_centre/reports/Toft_report_Heparin.pdf
111 Carruthers, I and P Philip, Safety First—A report for patients, clinicians and healthcare managers, Department of Health, December 2006.
5.7 Only following a forthright meeting between myself and Chairman of the working party, Professor Mike Richards, was the implementation guidance on the reports operational recommendations changed to include all those which had been made. Without the support of Professor Richards those changes may never have occurred.

5.8 I am therefore pleased to report that, in so as far as I am aware, to date no patient, in the UK, has suffered death or injury from the inadvertent intrathecal administration of Vincristine since Wayne Jowett’s tragic death. Thus, it can be argued, that an investigation in to a serious PSI can produce the information required to prevent a recurrence of that adverse event. This is however contingent on the fact that the person or persons undertaking the Root Cause Analysis (RCA) have the necessary qualifications and experience. Unfortunately the current literature in the field suggests this is frequently not the case. Wallace et al235 concluding in the UK that there was a “Lack of skill in developing in depth causal analysis and actionable recommendations [and a] need for Master classes . . .” A study in New South Wales, Australia by Braithwaite et al236 also came to similar conclusions.

5.9 It is for these reasons that the author of this evidence is currently producing an E-learning Postgraduate Certificate course on RCA at Coventry University. The course however will not simply teach the processes to be followed when a healthcare professional is undertaking an RCA. It will also develop the student’s critical thinking with regard to the investigation of a PSI and the application of domain knowledge based upon practical experience gained in the field.

5.9.1 It is also apposite to note that the most critical recommendation made in my report following the death of Wayne Jowett’s death is still outstanding seven years later. The recommendation was that:

“A new spinal needle with a connection that cannot fit Luer mount intravenous syringes should be introduced, in conjunction with a new syringe which can only be fitted to that specific spinal needle. Or, incorporating within this concept, a pre-filled syringe and spinal needle system for all drugs that are administered intrathecally should be developed and implemented.”237

5.9.2 Work has and still is being carried out by the Department of Health on this particular recommendation, however, progress has been painfully slow for reasons, I have been given to understand, that are outside their control.

5.9.3 However if, as noted above, the recommendation regarding the spinal needle had been implemented universally by the manufactures of medical devices then the death that occurred in the USA in 2002238 and those reported more recently by the World Health Organisation239 (WHO) which have occurred in Hong Kong, 2007; USA, 2005; Spain, 2005 and Australia 2004, could have been prevented. It is interesting to note that of the two proposals made by the WHO to prevent a repetition of this type of patient safety incident one is by:

“Making it physically impossible to attach an intravenous syringe containing vincristine to a spinal needle (‘lock and key design’).”240

5.9.4 Given the length of time that has passed since the recommendation regarding the spinal needle was made and the additional deaths that have occurred, although not in the UK, the Committee may wish to ascertain what has caused such a monumental delay.

6. CASE STUDY TWO: A FAILURE TO DOUBLE CHECK

6.1 Besides being used as a prophylactic heparin’s anticoagulant properties are also used in an effort to keep intravenous catheters and cannulas unobstructed by blood clots or “patent”. The reason that these medical devices need to be kept free of blood clots is because if they should become blocked then they must be changed as the patient can no longer receive the treatment or have the diagnostic tests that they require.

6.2 Thus changing an intravenous catheter in a patient, particularly one that has been implanted in a child, is a task to be avoided if at all possible. Therefore conventional wisdom dictates that intravenous catheters and cannulas should be “flushed” with a weak solution of heparin in an effort to ensure they remain patent for as long as possible. However this practice can lead to patients being inadvertently harmed.

6.3 The investigation of the four PSI’s discussed below was undertaken by the author of this evidence.241 Four young patients were admitted to undergo diagnostic tests in an Acute Trust’s Day Beds Unit. As young children do not tolerate invasive procedures very well when awake the tests were to be carried out under

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141 Toft, B, Independent review of the circumstances surrounding four serious adverse incidents that occurred in the Oncology Day Beds Unit, Bristol Royal Hospital for Children on Wednesday, 3 January 2007, published at http://www.who.int/patientsafety/information_centre/reports/Toft_report_Heparin.pdf
general anaesthesia. One of the drugs to be administered by a Consultant Paediatric Anaesthetist (CPA) was heparin, at a concentration of 50 International Units in 5ml. However, due to inadvertent human error and systems failures, heparin at a concentration of 25,000 International Units in 5ml was administered to each patient by mistake. Thus each child received a dose of heparin 500 times greater than that which had been intended. All the children recovered quickly from their experience and none of them appear to suffer from any long term problems. However, the seriousness of these PSI’s cannot be overstated. As there have been numerous occasions when patients have been injured or killed as a result of being inadvertently administered an overdose of heparin instead of the flush that was prescribed.142

6.4 Included in the list of direct causes of these incidents was the fact that the CPA had inadvertently misread the labels on the ampoules of heparin. However if the CPA had carried out an explicit verbal double-checking safety protocol and another member of staff was able to ensure that the medicine he had selected was the correct one it is highly likely the incidents would not have occurred. As a consequence a recommendation was made that verbal double checking safety protocols should be employed, subject to a clinician’s judgement, when patients were to be administered an injectable medicine at the Trust.

6.5 However while the majority of the anaesthetists’ at the Trust where the PSI’s took place could see the value in such a check, but had reservations about its practical implementation, there was a sizable minority absolutely opposed to any such safety measure. Currently there is a pilot project being undertaken at a number of Trust’s by the Royal College of Anaesthetists and the National Patient Safety Agency to ascertain the viability of introducing a verbal double checking safety protocol as part of their professional practice. Once again however there has been opposition expressed at some of the pilot sites and else where regarding the introduction of such a safety protocol.

7. Standard Operating Procedures are not failsafe

7.1 Explicit double checking safety protocols or Standard Operating Procedures (SOP) however are not the panacea some authorities believe in preventing harm to patients. Such as for example, the recent PSI that occurred at St. Mary’s hospital in London this year (October 2008) illustrates.143 On this occasion a surgeon removed a gall bladder from the wrong patient. The skills of the healthcare professionals at St Mary’s hospital are recognised internationally and Lord Darzi, the Health Minister, is Professor of Surgery. Moreover, such is the professional regard in which the surgical teams at St Mary’s are held that they were recently chosen to pioneer a new World Health Organisation SOP designed to promote surgical safety. Yet an inadvertent error still occurred despite the qualifications, experience, skills and explicit safety checks carried out by the surgical team.

7.2 Another example of explicit verbal double checking safety protocols failing is to be found in an RCA carried out by the author of this evidence.144 Part of the treatment regime prescribed for a patient about to undergo radiotherapy was that a radiation attenuation device known as a “wedge” be placed in one of the treatment beams. However, this parameter was not entered into the computer database that controls the Linear Accelerator (Linac) which delivers the treatment beams. As a result the patient was administered an overdose of radiation on 14 of the 15 individual treatments prescribed by the Consultant before the error was discovered. It was calculated that the patient had been inadvertently administered 2.5 times the total dose of radiotherapy that had been prescribed.

7.3 The erroneous treatment was inadvertently administered by 12 different dedicated radiographers working in assorted pairs using a verbal double checking safety protocol. However on each occasion that the participating radiographers, treating the patient failed to perceive that the wedge field of the Linac console displayed the word “OUT” instead of the word “IN”. The research undertaken by the author of this evidence during the investigation of that PSI led to the identification of a newly articulated error forcing phenomenon called “Involuntary Automaticity”. The phenomenon was thought to be sufficiently important to be debated in the House of Commons through a written question (51905) put to the Health Minister Jane Kennedy MP by Steve Webb MP (Hansard, 2 Mar 2006: Column 920W).

8. Resistance to Change

8.1 In Case Study One I noted the reluctance of some clinicians to embrace all the operational recommendations that had been made in the wake of Wayne Jowett’s death. While in Case Study two I observed that there has been resistance to the idea of using verbal double checking safety protocols by a number of anaesthetists.

142 Toft, B, Independent review of the circumstances surrounding four serious adverse incidents that occurred in the Oncology Day Beds Unit, Bristol Royal Hospital for Children on Wednesday, 3 January 2007, p 17 published at http://www.who.int/patientsafety/information_centre/reports/Toft_report_Heparin.pdf


8.2 Additionally, in a letter to the *British Journal of Obstetrics and Gynaecology* the author of this evidence noted that following an RCA into a number of still births at a Trust in 2004 I found that my findings replicated those of a paper published in the same journal 13 years earlier.\(^{146}\) Thus given that the same errors continue to be made it is perhaps not surprising that *The Times* (17/11/08) reported that there were “Doubts about safety of NHS maternity care after £1 billion negligence payments”. Particularly, since when discussing the Trusts maternity services following a supervisory audit the report stated that it was “...like taking a step back in time...”

8.3 In a similar vein the Chief Medical Officer, Sir Liam Donaldson, in his 2004 Annual Report wrote that an audit of 19 of the Trust’s who should have implemented the intrathecal chemotherapy guidance to prevent a recurrence of the circumstances which lead to Wayne Jowett’s death revealed that:

“NHS Trusts took 19 months to comply with the original guidance and 18 months to comply with revised guidance and, worse still, after a first round of peer review visits, 47% of NHS Trusts were still not fully compliant with the latest up-to-date guidance...This case study reveals much about the safety culture of the NHS, which is clearly not yet focused or organised enough to reduce a potentially fatal risk to patients rapidly enough.”\(^{447}\)

9. **Reluctance to Criticise Colleagues**

9.1 Having undertaken a RCA of four PSI’s one of which was where the female partner of a Caucasian couple, who had undergone In vitro fertilisation (IVF) gave birth to mixed race twins, one of the conclusion that I drew from the evidence was, “...that in general clinicians can be disinclined to criticise their peers publicly”.\(^{148}\)

9.2 Moreover, I recently experienced such a situation again. I found it impossible to attract any full time practicing clinicians of sufficient experience and professional standing to be member of a Review Panel that was being assembled. The reason given by one eminent clinician was that he did not wish to prejudice his professional career by being a member. The Review Panel of which he had been requested to be a member was to review medical work that had already been undertaken by the clinician’s professional association. It was thought by the clinician that if the Review he had been asked to join cast doubts upon the findings of the Review undertaken by his professional association this would have a detrimental effect on his livelihood.

10. **Groupthink**

10.1 The author of this evidence, following a review of the Human Fertilisation and Embryology Authority in connection with the IVF PSI's noted above, found evidence that both clinicians and the “lay” persons working with them can become the unconscious victims of a socially created dysfunctional mindset called “Groupthink”.\(^{149}\) When a group of people are captured by this phenomenon group norms are bolstered at the expense of critical thinking and rationalisations are created to support their position even when they are wrong. Additionally, they will brook no interference from anyone outside the group and if a member of the group has reservations about the course of actions they are taking they generally engage in self-censorship. Or they are told to rethink their position if they wish to remain a member of that group.

10.2 A tragic example, of the dysfunctional affects of Groupthink, but by no means the only one in healthcare, comes from “The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984–1995”. Although not using the term Groupthink Sir Ian Kennedy identified its symptoms when he observed that:

“There was an insular ‘club’ culture, in which it was difficult for anyone to stand out, to press for change or to raise questions and concerns.”\(^{150}\)

10.3 As the committee will, no doubt be aware, in his report Sir Ian Kennedy stated that 30–35 more children under the age of one died than might have been expected in the period 1991–95. Thus if patient safety is to be improved the negative aspects of Groupthink must be avoid at all costs within the NHS. This is because Groupthink can prevent a good safety culture from being established or undermine one that is.

November 2008

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149 Toft, B. “Independent review of the circumstances surrounding four adverse events that occurred in the Medical Reproduction Units at The Leeds Teaching Hospitals NHS Trust, West Yorkshire.” *Department of Health, June 2004*, p 79.

Supplementary memorandum by Professor Brian Toft (PS 83A)
COMMITTEE PARLIAMENTARY INQUIRY: PATIENT SAFETY

1. INTRODUCTION

1.1 This additional evidence has been submitted by Professor Brian Toft, Professor of Patient Safety, Coventry University and Principal, Risk Partnerships, a consultancy specialising in patient safety issues and Root Cause Analysis.

1.2 My evidence concerns the following area in the Committees Terms of Reference: “National Policy”.

2. EXECUTIVE SUMMARY

2.1 There is evidence which suggests that the implementation of the surgical safety checklist developed by the World Health Organisation has reduced the incident of patient deaths and complication rates in the eight cities in which it was piloted.

2.2 There is evidence from the aviation industry that the universal mandatory adoption of safety checklist have made aviation significantly safer than before they were introduced.

2.3 There is evidence that there are those within the medical profession who do not wish to adopt the WHO surgical safety checklist into their operational practices.

2.4 In my previous submission to the Committee I also noted that there was evidence to demonstrate that some members of the medical profession did not want to implement operational changes designed to improve patient safety.

2.5 There is evidence to suggest that the Medical Act 1858 should be reviewed by Parliament and evidence taken as to whether or not the medical profession should be allowed the privilege of regulating itself in future as it has in the past.

3.0 WORLD HEALTH ORGANISATION PATIENT SAFETY STUDY

3.1 On the same day as the Parliamentary Select Committee Health took evidence on “Patient Safety” (15/01/2009) a paper on that topic was published in The New England Journal of Medicine. The paper described a study where a surgical safety checklist developed by the World Health Organisation to improve patient safety in Operating Theatres had been implemented in eight cities around the world. In the results section of the paper it was reported that that:

“The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward (p = 0.003). Inpatient complications occurred in 11% of patients at baseline and 7% after introduction of the checklist (P < 0.001)”.

3.2 As a consequence it was concluded that:

“In this study, a checklist based program was associated with a significant decline in the rate of complications and death from surgery in a diverse group of institutions around the world”.

3.3 Thus the study would appear to provide evidence that the use of a surgical safety checklist in the Operating Theatre does reduce the risk of harm to patients.

4.0 WORLD HEALTH ORGANISATION EUROPEAN REGIONAL WORKSHOP

4.1 Following the presentation of my evidence to the Parliamentary Select Committee Health on the 15 January 2009 I attended the joint World Health Organisation and National Patient Safety Agency “Safe Surgery Saves Lives, European Region Workshop” held at the British Library where the results of the paper were presented. However in the question and answer section of the “Dissemination” seminar led by Sir Liam Donaldson, Chief Medical Officer for England, there were negative comments regarding the implementation of surgical safety checklist from healthcare professionals from several different European countries including the UK.

4.2 Moreover there appeared to a number of representatives from the UK who, for a variety of reasons, did not want to see the WHO surgical safety checklist implemented. However given the evidence provided by the WHO study how anyone in the healthcare profession could adopt such a position is beyond comprehension.


5.0 Previous Evidence

Moreover in the evidence which I have already presented to the Committee I stated in item 8 that there was evidence to demonstrate some members of the medical profession did not want to implement operational changes designed to improve patient safety.

6.0 Aviation Safety and the Medical Profession

6.1 Frequently analogies are drawn between the medical profession and the commercial aviation industry. However, one major difference between the two professions, in terms of their operating procedures, is that while all aircrews must perform safety checklists members of the medical profession do not. It should be noted therefore that the safety record of the aviation industry has come about, in no small part, through the universal adoption of mandatory safety checklists.153

6.2 For example, the UK commercial aviation industry has an excellent record for safety. For example, the UK Civil Aviation Authority has recently stated that:

“Provisional figures for 2007 show that UK large public transport aeroplanes carried approximately 128 million passengers...During this time, UK large public transport aeroplanes were involved in seven accidents, none of which were fatal and none involved injuries to passengers or to crew on board the aircraft”.154

6.3 This safety record stands in stark contrast to the NPSA report that between January 2005 and June 2006 the National Reporting and Learning System received approximately 800 reports each month of errors relating to injectable medicines alone. During this period 25 patients lost their lives and there were 28 incidents of serious harm.155

7.0 Review of Medical Act 1858

It is paradoxical to note that it is the medical profession who have rightly issued warnings to the British public of the risks to their health that they run by over eating, drinking, smoking and so forth. Yet it would seem that some of those very same healthcare professionals are quite willing to have surgical patients run a higher risk of dying or face serious complications than voluntarily change their working practices. Thus, in the light of such recalcitrance to improve patient safety it is time that Parliament reviewed the Medical Act of 1858 and took a fresh look at whether or not the medical profession should be allowed the privilege of regulating itself in future as it has in the past.

January 2009

Supplementary memorandum by Professor Brian Toft (PS 83B)

PATIENT SAFETY

1. Introduction

1.1 This additional evidence has been submitted by Professor Brian Toft, Professor of Patient Safety, Coventry University and Principal, Risk Partnerships, a consultancy specialising in patient safety issues and Root Cause Analysis.

1.2 My additional evidence concerns the following area in the Committees Terms of Reference: “National Policy”.

2. Potential Design Solution for a Non-Luer Connector

2.1 In my evidence to the Committee 15 January 2009, at question 219 I stated that the work undertaken so far by the Department of Health to find an engineering solution to the problem of intravenous medicines, such as Vincristine, being inadvertently administered intrathecal to a patient had yet to be found. My answer to the Committee’s query was reported in the media and as a result I received an E-mail (27 January 2009) from a Mr Matthew Root stating:

“My company is a UK needle & syringe manufacturer and we have just successfully launched a female luer lock enteral syringe to avoid maladministration of enteral medication (www.enteralok.com). We are also about to commence production of a retractable hypodermic safety needle.

“I was reading a recent press release on the astonishing story of Wayne Jowett, and the subsequent report you made.”


“I would be very happy to fund a project to develop a unique type of intrathecal needle/syringe in an attempt to prevent this appalling tragedy ever happening again. Having successfully launched Enterok®, which is now on contract with NHS, I feel we have the resources and experience to produce a product specifically for intrathecal medication. We are a small, privately-owned operation which gives us the commercial agility to embark upon such a project.”

“If you are interested in exploring this possibility further please do not hesitate to contact me.”

2.2 I subsequently telephoned Mr Root and offered to help his company on condition that he allowed me to provide my assistance without any financial consideration. I insisted upon this condition as I do not wish to be accused of having a vested interest in the commercial success of such a product produced by his company.

2.3 Mr Root and his company have also worked in collaboration with the National Patient Safety Agency (NPSA) and at a meeting held at the NPSA (15 April 2009) the Chief Executive, Mr Martin Fletcher; Head of Safe Medication Practice, Professor David Cousins and myself were shown a prototype device by Mr Root and his Technical Director, Dr Shams, that appears to hold great promise. Moreover, it is also envisaged, that “clinical trials” could start at the end of June or the beginning of August and if all goes well, the product could be on sale as early as this November.

2.4 I therefore thought that the Members of the Committee would like to be aware that it is solely as a result of their enquiry into patient safety that a solution to prevent another tragedy like that of Wayne Jowett now appears to be near at hand. Additionally, it is also thought that the engineering solution that has been devised can also be used to provide similar fail-safe connections to prevent the maladministration of medicines in a range of other medical devices.

April 2009

Memorandum by the Confidential Reporting System in Surgery (CORESS) (PS 84)

EXECUTIVE SUMMARY AND CONCLUSIONS

i. The Association of Surgeons of Great Britain and Ireland (ASGBI) submits this memorandum to the Parliamentary Select Committee on Health for their enquiry into Patient Safety and specifically in relation to the use of incident reporting systems and risk management.

ii. The Association is clear that there is great potential for safer medical and surgical practice if an effective incident reporting system is in place.

iii. Such systems work only if they operate in a blame free environment and reporters can have absolute trust in the confidentiality and impartiality of the system.

iv. The under-reporting by surgeons of important near-miss and minor adverse events reflects a profound lack of trust by surgeons and their teams on all the above counts, and has confounded the effectiveness of national schemes set up during recent years under the direct control of local and national management.

v. CORESS, a national incident reporting system, was started three years ago by the specialty surgical associations with the material support of the Royal Colleges of Surgeons. It has demonstrated a method by which this problem can be overcome and a successful incident reporting system operated within a large group of professionals working both within and outside the NHS.

vi. CORESS follows these key principles:

a. It is managed and led by the profession with all other input, including lay and management representation, held at arm’s length.

b. It operates using a unique and now well-proven method for reporting, which provides absolute protection for the confidentiality of reporters. These reports are analysed and form the basis of the recommendations that are fed back to the wider surgical community.

c. The recommendations are published and circulated widely as “feedback” using a format that has been shown to be highly readable and effective.

d. It is highly economical in its use of resources.

vii. The system is gaining widespread support throughout the surgical community as evidenced by the take up of its feedback reports and the increasing supply of near-miss and minor incident reports from surgeons and their teams.

viii. This experience exactly mirrors the development from start-up of similar systems in aviation and marine transport, upon which it is based.

ix. The Association commends this model to the Select Committee and would be pleased to provide further details if required.
One characteristic of all systems operated by humans is the inevitability that mistakes and accidents will occur. There is clear scientific evidence that major mishaps are usually preceded by clues in the form of more minor mishaps and/or near-misses. Mature, well led and managed organisations have in place effective feedback systems, which rapidly assimilate and use such incidents to “learn” and improve the safety of their operations.

Confidentiality is fundamental to the concept of the CORESS service. On receipt of a report, identifying data are removed and it is transferred to a standalone computer with no wired or wireless connections to any network. Identifying data is available to the Programme Director and System Manager only. The anonymised report is reviewed by a pan-specialist Advisory Committee to determine what lessons can be learned from the incident. The reporter is provided with personal feedback and informed of the proposed outcome of the report. The original report is returned to the reporter and all identifying data securely deleted from the CORESS system before any publication of feedback for the surgical community at large.

x. Incident reporting systems are accepted as one of the most powerful learning tools for professionals and the systems within which they operate. On account of the potential for improvements in patient safety, great efforts have been made to introduce such systems into NHS medical practice through the NPSA and local management initiatives.

xi. These systems do not appear to be achieving the impact on surgical practice for which all hoped. The root cause of this is the reluctance of surgeons and their team members to submit reports that detail such incidents and near-misses. This is a great loss to the evolution of safer surgery in the NHS since the leaders of the surgical teams, ie consultant surgeons, are best placed to report, receive feedback and where necessary bring about changes in practice.

xii. It appears that this reluctance is not due to sloth or lack of belief in the worth of such endeavours but rather for the following reasons:

a. Such reports, *per se*, will include details of errors and omissions, which have led to a problem or potential problem. It is clear that there is a fundamental mistrust of any system that may expose those involved to disciplinary, medico-legal or media attention.

b. However well-intentioned local reporting systems may be, they often contain a clause to the effect that “only under exceptional circumstances” will action be taken by management against those involved in a reported adverse event. Such clauses, the rationale for which is perfectly understood, do little to encourage trust among reporters.

c. Data security is an issue as any breach of confidentiality through leaks to the local media could easily be traced back to those involved. Leaks of confidential material from Trust sources have occurred in the past and any such disclosure of this type of material would be likely to generate substantial negative publicity for the Trust and have a major adverse impact on all those concerned.

xiii. Since the surgical community remained keen to see an effective surgical incident system established, the surgical Specialty Associations of Great Britain and Ireland, with the support of the Royal Colleges of Surgeons of England and Scotland, started a national surgical incident reporting system (CORESS) in February 2005.

xiv. The purpose of the system is to alert surgeons and their teams across the UK to the factors causing such incidents and from these to suggest measures by which practice can be improved and similar problems occurring in the future and elsewhere.

xv. It is based on the successful system operating in aviation and maritime (Confidential Human Factors Incident Reporting Programme: “CHIRP”—see http://www.chirp.co.uk/). The features which make these systems attractive to professionals are:

a. They are managed and operated by the professionals (surgeons, pilots, mariners), for the professionals and their teams. Employers and regulators are involved but “at arm’s length”.

b. They operate a secure, confidential, but not anonymous system for receiving and ‘processing reports of mishaps and near misses. This enables verification and checking of detail.

c. Reporting is straightforward and involves a minimum of bureaucracy.

d. The material (feedback) that is produced is highly relevant to the practices of those concerned.

e. The style of the feedback reports, in the form of short, personalised accounts, has proved attractive to readers.

xvi. During the three years for which it has been in existence, and in contrast to many other more expensive initiatives, CORESS has proved successful in stimulating a steady and increasing supply of reports. From these, useful feedback has been derived, published and in this way fed back at regular intervals to the surgical community. The feedback is also freely available to the public and all health care professionals via the website on http://www.coress.org.uk/

xvii. Resourcing: The CORESS project is resourced and managed by the profession through the Association of Surgeons, with contributions from other specialist societies. Encouraged by its success and the support of surgeons, the project will endeavour to continue developing its work further across the surgical specialties. Independent charitable status is being sought for early 2008 and will help to ensure that
independence, impartiality and hence the trust of all concerned is maintained. This is in keeping with its sister organisations in aviation and marine transport. For a nationwide system, it has proved remarkably economical to operate. During the year 2007–08 the budget was £34,000.

December 2008

Further memorandum by CORESS (PS 84A)

TIMES FOR A MEDICAL ACCIDENTS INVESTIGATION AUTHORITY (MAIA)?

I. The key to improving safety is the proper, effective and objective investigation of accidents which cause injury and death. Surprisingly, no such system exists in the NHS.

II. In 1915, through Act of Parliament, this country instituted an Air Accidents Investigation Branch (AAIB) to provide independent investigations into military flying accidents; the scope of AAIB investigations were later extended to the commercial and leisure aviation sectors. The Marine Accident Investigation Branch (MAIB) was formed in 1989 following the Public Inquiry into the Herald of Free Enterprise. Again one of the principal objectives was to provide an independent accident investigation agency. The AAIB and the MAIB have been instrumental in transforming the standards of safety in their respective operating environments, are now widely regarded as benchmark organisations in safety investigations and have been widely copied by other countries.

III. It is our belief that there should be a Medical Accidents Investigation Authority (MAIA), set up to operate along similar lines in the United Kingdom.

IV. This Authority would be completely independent of the NHS, although ultimately responsible to the Secretary of State and it should have full powers to investigate the causal and circumstantial factors associated with fatal and serious medical incidents, publish reports and make recommendations. The Authority would not apportion blame or provide evidence for criminal investigation and/or disciplinary action.

V. Given the enormous number of patients injured or whose deaths are materially contributed to by unacceptable levels of care, the MAIA could not investigate every case. Nevertheless it should have the power to investigate any case referred to it by Coroners or other competent agents and incidents identified by the MAIA as warranting an investigation.

VI. No one could argue that serious accidents do not require full and fearless independent investigation. Only from detailed reports of such investigations can lessons be learned to reduce the number of similar accidents. The MAIA would fill an important gap in the NHS Redress Act 2006 and its cost would be offset by improvements in the quality of care within the health service and reduced expenditure on lawyers and compensation payouts.

THE CASE

The Cost: Financial and Human

VII. With a budget of £76.4 billion, inevitably much of the focus in the NHS is on cost but central to this focus should be patient safety. The suffering and despair associated with injuries and death caused by inadequate care is inestimable. Substantial improvements in safety will lead not only to reduced morbidity and mortality, but to a reduced demand on NHS services to treat what used to be termed “iatrogenic” conditions.

VIII. Each year hundreds of thousands of patients are harmed by the NHS. Thousands more die because of poor care and errors in medical treatment yet most of these deaths attract no attention. Far too little is being done to address this appalling loss of life. What has happened to the Hippocratic doctrine of *first do no harm*. What lessons are being learned? Has anyone stopped to ask the financial cost to the NHS and society of this intolerable human attrition?

IX. Openness in Improving Safety

X. Notwithstanding repeated attempts to persuade health care workers to be open about mistakes and failures, little progress has been made. In September 2005, the NHS National Patient Safety Agency (NPSA) issued a “Safer Practice Notice”. It was entitled “Being Open when Patients are Harmed”. An Australian project on openness was cited which showed patients were fully supportive of healthcare workers being open!

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156 Received the Royal Assent on 8 November 2006
157 Year 2005–06: more than the GDP of 155 nations
158 No accurate figures exist; on the basis of hospital diagnostic codes some put the figure at about 850,000/yr but adverse events may be under-recorded within hospital episode statistics
159 Epidemics. Bk.I. Sect. XI: “As to diseases, make a habit of two things: to help, or at least to do no harm”
160 eg: DOH June 2003 “Making Amends”
XI. It is neither patient sensitivity nor a “blame culture” which is responsible for this lack of openness. At best it is because of ignorance of the occurrence or cause of the harm suffered; at worst it is because of a determination to cover up individual and systemic failings. Why should anyone expose themselves to possible criticism, ridicule and censure by being open and truthful if loss of pride and humility could be avoided?

XII. The Safer Practice Notice offers help for those struggling with this openness concept but we have yet to find anyone working in the NHS who has even heard of the notice. The NPSA has developed a “Being Open” e-learning tool. One has to assume that this is some cyber device to encourage health workers to tell the truth.

XIII. It is frequently said by the opponents of clinical negligence actions that the fear of litigation leads to a lack of openness and that without a “blame culture” health care workers would be more forthcoming about the circumstances in which patients are injured or die. But there is no evidence to support this contention. Would health care workers really be more forthcoming about their failures? We doubt it.

XIV. Greatly to the credit of the Association of Surgeons of Great Britain and Ireland and the Royal Colleges of Surgeons, a confidential reporting system in surgery (CORESS) mirrored on the effective CHIRP in the aviation and maritime industries has been established. These systems enable lessons to be learned from incidents and near misses, which might not otherwise come to light but reliance cannot be placed only upon encouraging openness about serious medical untoward incidents or accidents. A statutory, demonstrably independent accident investigation authority is required.

The Role of Litigation

XV. Litigation has exposed many poor practices and brought about improved safety standards in health care. Before the 1980s, when there was no “litigation threat”, the medical profession enjoyed and fostered a culture of secrecy. Such accountability as there was existed only through an entirely self-regulated GMC.

XVI. Even now a patient injured by potentially negligent medical treatment still has no means of compelling those responsible to be called to account. Apart from a public inquiry, coroner’s inquest or a fully contested criminal or civil trial, there is no means of effectively exploring the facts and issues relating to medical accidents. Neither the GMC nor the NHS Complaints system fulfils this function. Patients injured by medical treatment are far more numerous than the civil claims made for damages. Medical Audit is poorly co-ordinated at a multidisciplinary and national level with little learning benefit. It is still in its childhood and, like Peter Pan, likely to remain there.

XVII. No one in the field of risk management can fail to appreciate that litigation, notwithstanding its deficiencies, still remains the only way in which patients can compel a proper investigation of the circumstances of their injuries. So would those opposed to clinical negligence litigation in the NHS be in favour of a MAIA which would not attribute “blame”? We would hope so, but we remain pessimistic. Who would want an effective investigation of the facts of a medical accident by a powerful independent body when the full facts are likely to speak for themselves, regardless of the absence of attribution of blame?

XVIII. Statutory powers of investigation and protection of information provided to an MAIA in the course of an investigation would be essential. Reliance cannot be placed upon obtaining the consent of those involved or a voluntary waiver of claimed professional and legal privileges. Since factual investigation and not blame or criticism would be the function of the MAIA there neither should be nor could be any objection to full compliance with an investigation conducted by the Authority.

XIX. The Role of the Coroner

XX. It could be argued that much of the foregoing lies within the remit of the coroner. When a death results there is the prospect of an independent coroner’s inquiry into the factual circumstances. There are no national figures but anecdotal evidence suggests between 7,000 and 13,000 of the 25,000 inquests each year relate to deaths in hospitals. Nevertheless, thousands of deaths caused through incompetent care are never investigated at all. This particularly affects those most disadvantaged in our society who do not have the means to ensure that the deaths of their relatives are effectively investigated.

161 Confidential Human Factors Incident Reporting
162 Consciousness of patient safety really began to develop at the beginning of the 1980s with the publication of the first CEPOD and AVMA was formed to provide assistance to solicitors seeking to bring claims against Health Authorities and doctors. Hitherto, advancing medical negligence actions was enormously difficult. Solicitors did not have the experience to advance claims which were considered simply to be a variant of personal injury claims. Experts were difficult to find and inexperienced in giving evidence.
163 BRI Inquiry July 2001—Brief history of audit paras 23 & 29
164 National Audit Office: A Safer Place for Patients 31 October 2005
165 Some put the figure of deaths caused by poor medical care at 40,000/year: Dr Foster BMJ 14 Aug 2004; 329
XXI. Of those deaths which are investigated, the quality of the investigation is variable. Coroners are under financial pressures from their local authorities and complain that they simply do not have the resources properly to carry out full investigations. The present system is totally unsatisfactory.166 The anticipated “urgent official attention”167 to the problem has finally resulted in the Government’s Draft Bill on Coroner Reform.168 Although the proposed legislation would increase coroners’ powers of investigation there is little new money available and neither the quality nor the number of investigations into deaths caused by poor clinical care is likely to increase.

XXII. The work of the MAIA would not need to be duplicated by a coroner in fatal accident cases. One would expect the coroner and the family in most cases to be content to admit, as evidence, the MAIA’s report without the need for witnesses to be called. The coroner should have the power to adjourn an inquest in order for a medical death to be investigated by the MAIA. Under the present legislation a simple amendment to S.17A of the Coroners Act 1988 (Adjournment of Inquest in the Event of Judicial Inquiry)169 would be required. Unless there was an exceptional reason for doing so the coroner could have the discretion not to resume an inquest after a full MAIA investigation.

Conclusion

XXIII. The Medical Accidents Authority proposed would provide an effective means of investigating the facts surrounding medical accidents without the need for litigation or the attribution of blame. Similar authorities such as the AAIB and MAIB have proved this concept to be effective in improving safety.

XXIV. Effective, independent investigation provides the key to ensuring that lessons from medical accidents really are learned. All involved in patient safety should welcome such an authority: it is essential to ensure high standards and improve morale in the NHS.

Dr Michael J Powers QC
Mr. Denis Wilkins FRCS
Association of Surgeons of Great Britain and Ireland
Mr Peter Tait
Chief Executive, CHIRP
December 2008

Memorandum by the National Association of Laryngectomees Clubs (PS 85)

PATIENT SAFETY

Terms of reference

The Committee has decided it will undertake an inquiry into patient safety. The inquiry will focus on:

1. What the risks to patient safety are and to what extent they are avoidable, including:
   — Role of human error and poor clinical judgement

In NALC’s judgement many of the risks created by human error or poor clinical judgement are due to lack of training of staff, since working with some Trusts, and more especially with the professionals whose aim is to improve patient care it has become increasingly clear that improved awareness of the needs of neck breathers should be included from the beginning of professional development pathway.

In the case of specialised services, clinicians should be asked to support their colleagues in primary care—including those practitioners working out of hours—who may lack the specialised skills required to support patients with very specific care needs, by sharing with them in detail how to access any additional support those patients may need, especially where that support may continue to be needed over years rather than months

   — Systems failures would appear in some cases be routed in a lack of clarity of text which leads to variations in practice both nationally and locally. NALC feels however that as specialist services become centralised it is essential that minimum standards of support are maintained in localities, if only to ensure that for transport and distance reasons patients are not put at risk. It is clear that failure to retain a local support network, who would be able inform other professionals locally is detrimental to patient care, as well as increasing the time lag in getting effective specialist care.

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168 June 2006
169 Inquest into the death of the government scientist, Dr David Kelly, not resumed after Lord Hutton’s Inquiry (January 2004)
— How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare—whilst NALC is aware that no practice can be risk free we would maintain that good training and awareness raising can reduce if not remove avoidable risk. Risk due to excessive travel requirements should not be ignored in this context however.

— The role of public perceptions of risk in determining NHS policy—this may be an element but NALC would perhaps argue that greater awareness by the public of some risk factors could be beneficial for those at greatest risk.

2. What the current effectiveness is of the following in ensuring patient safety:

a. local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services) NALC would argue that only by the active involvement of all related services in joint working will the safety and well being of our members be safeguarded. NALC is aware that at present even in areas where enlightened provision is made, most if not all of the needs of Laryngectomees are ignored—“there are no care needs for Laryngectomees” “there are no established care needs of those with speech impairments”—even where the local authority itself commissioned a report to establish those needs [Newcastle Joint Advisory Group Physical & Sensory Disability “Breaking the Silence” April 03 http://www.newcastle.gov.uk/condiary.nsf/diary/3DCC5E2BA5A4BFE18025712B0042FFA7?opendocument. NALC will be interested to observe the provision made for young people following the transition stages following the interventions planned as the result of the Bercow review.

— How far the Boards of NHS bodies have established a safety culture SHA Our Vision, “Our Future” proposals should include proposals to improve safety for all patients

b. systems for incident reporting, risk management and safety improvement

NALC feels that where serious incidents occur robust mechanisms are in place but lack confidence of minor incidents being reviewed adequately if at all

— Whether adequate measurement and assessment is undertaken and acted upon

NALC is aware of concerns over inadequate information sharing practice which impacts on any such intervention

— The impact of the changing public-private mix in provision

NALC does not have confidence that those establishing the new provision mix have addressed the needs of Laryngectomees

c. national policy

— The appropriateness of the objectives set out in national policy statements, including Safety First and High Quality Care for All, and what progress has been made in meeting them

NALC is unaware of Laryngectomy proposals

— Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be

NALC is clear that there is a need to extend training programme to ensure Laryngectomy patient safety across all Health and Social Care provision

— The appropriateness of national targets

d. the National Patient Safety Agency and other bodies, including:

NPSA have been extremely supportive in ensuring that advice was issued nationally, however NALC recognises that the NPSA lacks regulatory role to ensure implementation of guidance

— Healthcare Commission/Care Quality Commission

NALC lacks confidence that either commission has addressed all the varied needs of Laryngectomees adequately, in particular NALC is concerned to learn from its members that centralisation of cancer services would appear to be resulting in higher risks for post discharge Laryngectomees requiring ongoing care.

Whilst ambulance services have recognised the very specialised care and support required by Laryngectomees living in the community, this does not appear to have been considered when the centralisation of cancer services was being planned, nor has the guidance contained in the NICE Head & Head guidance been given precedence over restructuring. NALC members nationally and locally have certainly not been consulted on the changes, which would appear to be on contradiction of NHS protocols resulting in the wellbeing and health of this particular group of vulnerable patients being ignored

— NHS Litigation Authority

NALC lacks information on this issue and for that reason would not wish to comment.
e. education for health professionals

NALC has with the support of Macmillan piloted and more recently mainstreamed training for nursing professionals and emergency ambulance professionals, this joint enterprise has been recognised by a number of national and international bodies. NALC would welcome support in ensuring that similar initiatives are mainstreamed to all health professionals throughout the UK where due to centralisation it could be argued that the skill base is reducing outside specialist centres. Whilst at the same time due to the additional travel requirements for very vulnerable patients, new configurations of provision are seen as increasing risk by delayed support being available at a time of urgent or emergency need.

We note that there is no mention of the role of the local PPI Forum—or its successor body in this role, and have had reason to regret the withdrawal of the support provide by the various CHCs to our local groups.

NALC also notes that there is no mention of the role of the local authority Health scrutiny panels in reviewing proposed changes, we feel they may have an important role in ensuring recognition that “even where the patients who are affected form a small group (as in this case patients accessing specialised services) any changes to provision may still be regarded as substantial, particularly if patients need to continue accessing that service for many years”.

NALC feels that there could be a role for the Healthcare Commission/Care Quality Commission allied to the National Patient Safety Agency in arbitrating where patients, carers or their national body identify practices which they feel are unsafe or not in the best interest of the patients.

3. What the NHS should do next regarding patient safety

— Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness

This could of course be determined by the Litigation Authority but NALC feels this would produce at top slice answer for public consumption, whereas a group of patients and their families together with informed but independent professionals/academics could be the best judge of what is actually happening.

— How to determine best practice and ensure it is spread throughout the whole NHS

Joint working by the MDT group of health and social care professionals, patients and families, together with support group representatives where equal waiting is given to all the views expressed could be used to identify best practice, however this would require guidance and direction to ensure its implementation

— How to ensure that learning is implemented

perhaps this will be achieved by greater recognition by Trusts and individuals that implementation guidance is mandatory and that failure to implement will reduce ratings and remuneration as reported in the media recently.

— What should be measured and assessed; and what data should be published

accredited training for all professionals should be recorded by individual Trusts
crime incident reporting made to independent adjudicators, with full inclusion of patients, and families to ensure all those supporting the patient are aware of the importance given to achieving improvement rather apportioning blame

— What incentives there should be to improve patient safety

Public recognition ie innovations awards which should include recognition of staff who draw attention to training gaps, together with regulation which ensures that patient safety is given higher recognition in the overall Health economy

— How patients and the public can be involved in ensuring that services are safe

Independence of the reporting mechanism where the risk of future treatment problems are reduced for all when it is felt, they can report both concerns and praise. In addition public recognition is given to all achievements not just those in high tech/high profile cases.

NALC would welcome the Select Committees view on how best to ensure that these vulnerable patients, and their carers, recognised as having specialised needs can be assured that they can be supported in the community by staff specifically trained to provide care to meet their needs, whilst allowing them to maintain their independence. The Committee may wish to consider the distances to be travelled to the new centralised cancer services, together with the lack of arterial roads to be found in some rural areas in which Laryngectomees live, as part of this submission.

March 2009
Memorandum by Professor Bryony Dean Franklin and Professor Nick Barber (PS 86)

MEDICATION SAFETY: IS TECHNOLOGY THE SOLUTION OR THE PROBLEM?

1 EXECUTIVE SUMMARY

1.1 This submission summarises current knowledge in relation to medication safety in the UK, and considers the role of technology in both preventing and causing medication errors. The submission focuses on medication errors; safety issues in relation to drug development, side effects and patients’ adherence to medication in their own homes are not addressed in detail.

1.2 Technology has great potential to improve medicines safety. Its ability to handle large amounts of information, to support decisions, and to repeatedly do the same act, has many potential benefits. Examples of technologies advocated for use in relation to medication management include electronic prescribing systems, automated dispensing systems, barcoded verification of patients and medications and electronic transmission of prescriptions. However, introducing new systems can also lead to new types of error occurring and there is little evidence to date for the effectiveness of many of these technologies in the UK setting, nor for their economic viability.

1.3 More work is needed to develop NHS specific technologies, rather than importing those from the USA. Evaluating technologies to assess their impact on medication safety is essential to create an evidence base for their use, rather than assuming that errors will automatically be prevented. We therefore need a toolkit of standard methods and definitions to allow organisations to assess the impact of technological changes on patient safety. There is also a need for a repository for information and knowledge sharing in relation to the lessons learned from implementing new technology. We need a greater educational focus on the correct way to achieve safe adoption and implementation of technology. Finally, we recommend that nationally a medication safety research strategy is developed and funded, and that this should include funding for the robust evaluation of technologies to create an evidence base for their use.

2 INTRODUCTION

2.1 This submission summarises current knowledge in relation to medication safety in the UK, and considers the role of technology in both preventing and causing medication errors. Medication can cause harm in one or more of three ways. First, the medication may interact with the patient at the molecular level and cause an Adverse Drug Reaction (ADR). Second, medication errors can be made by those prescribing, dispensing, administering or monitoring the patient. Third, the patient might not take the medication as prescribed, usually called nonadherence or noncompliance. The submission focuses on medication errors; safety issues in relation to drug development, side effects arising from appropriate medication use and patients’ adherence to medication in their own homes are not addressed in detail but briefly described to add context.

2.2 Professor Bryony Dean Franklin is Director, Centre for Medication Safety and Service Quality, Imperial College Healthcare NHS Trust and The School of Pharmacy, University of London; Acting Director of the Centre for Patient Safety and Service Quality and Executive Lead Pharmacist for Research at Imperial College Healthcare NHS Trust; she is also Professor of Medication Safety at The School of Pharmacy, University of London. Nick Barber is Professor of the Practice of Pharmacy at The School of Pharmacy, University of London, and Visiting Professor in Patient Safety at Harvard Medical School.

2.3 Throughout this report, the terms “medication”, “medicine” and “drug” are used interchangeably. References are available from the authors on request.
3 What the Risks are to Patient Safety from Medication and to what Extent they are Avoidable

3.1 Box 1 summarises the evidence on medication-related harm in the UK.

- 9 (1%) of 840 inpatients suffered preventable harm due to medication in two UK hospitals.
- 265 (6.5%) of 4093 patient admissions were judged to be drug related and 178 (67%) of these were judged to be preventable in a UK hospital. The drugs most commonly implicated were non-steroidal anti-inflammatory drugs, antiplatelets, antiepileptics, hypoglycaemics, diuretics, inhaled corticosteroids, cardiac glycosides, and beta-blockers.
- 6.5% of 18,820 admissions were due to an adverse drug reaction in two large hospitals, with the reaction directly leading to the admission in 80% of these cases. Most reactions were either definitely or possibly avoidable. Drugs most commonly implicated in causing these admissions were low dose aspirin, diuretics, warfarin, and non-steroidal anti-inflammatory drugs, the most common reaction being gastrointestinal bleeding.
- 30 (2.7%) of 1,101 emergency admissions to a Scottish hospital were related to an adverse drug reaction. Three (9.7%) of the 30 were associated with non-prescription medicines. The adverse drug reaction was the dominant reason for admission in 17 cases (56.7%) and only four (13.3%) were considered to be unavoidable.

Box 1: Key studies of the incidence of medication-related harm in the UK

3.2 As above, harm from medicines results from ADRs, errors and nonadherence. ADRs are to some extent a necessary risk of therapy (although they are more likely to occur following errors); little can be done about them until we have made more progress in mapping pharmacogenomic issues. However, medication errors and nonadherence are both based on behaviours and can be changed. In the next paragraph we briefly consider nonadherence and then the rest of this section focuses on medication errors.

3.3 Nonadherence occurs in about 30–50% of patients taking chronic medication. Some nonadherence is rational and appropriate, for example making an informed decision, or stopping medicines causing unacceptable side effects, however this represents a small proportion of chronic patients. About half the remaining nonadherent patients will be have decided to be nonadherent (intentional nonadherence) and about half will wish to be adherent but have some barrier to adherence (confusion, supply problems, cannot effectively manage the formulation prescribed etc). Most of this latter group could be changed by improving prescribing, dispensing (such as daily dispensing services), systems of support and so on. Although not classically termed medication errors, the solutions require the same sort of approaches. Intentional nonadherence is strongly influenced by beliefs (often false ones) about their medicines; these beliefs are tractable. Pharmacists talking to patients already on medicines has been shown to be a cost effective way of shifting beliefs and improving adherence.

3.4 The process of medication use generally follows the route of prescribing, dispensing, sometimes making up the medication, then administration (whether self administration or by others), for some medication there is also an additional need for formal monitoring and review to ensure the medicine is effective and not causing potentially dangerous side effects. All these stages need to be communicated clearly and recorded accurately. The process may vary according to the drug and the setting.

3.5 Types of medication error include omitting to prescribe or administer a drug that is required, giving the wrong drug, giving too much or too little, giving the right drug but in the wrong pharmaceutical form, failing to order the drug, preparing it incorrectly and giving it by the wrong route or the wrong rate of administration.

3.6 Medication errors are typically subdivided into prescribing errors, dispensing errors, administration errors, and monitoring errors; however many are multi-factorial and involve errors at more than one of these four stages.

3.7 About 80% of drug use takes place in primary care, where 530,000,000 prescription items are dispensed each year; Box 2 shows what we know about error rates at each stage of the process.

3.8 Box 3 summarises the data relating to secondary care, where 1,000 medication orders are written each day in a typical hospital.
3.9 On any day seven of ten patients in care homes are subject to a medication error. Box 4 shows the frequency of each type of error in care homes, based on recent work commissioned by the DH Policy research initiative: the Patient Safety Research Portfolio.

1) Patient is prescribed medication.
   — Prescribing error rate: 7.5% of prescription items written.
2) Medication dispensed.
   — Dispensing error rate: 3.3% of all items dispensed.
3) Patient takes medication.
   — Drug related admissions to hospital: 2.7–6.5% of all admissions, 67% of which are preventable
4) Prescribing reviewed at least every 6th request
   — Medication not reviewed in 15 months: 72% of medications
5) For patients seen in hospital outpatients:
   — Prescribing error rate unknown
   — Medication details not added to GP records: 5% of prescribed items
   — Dose taken not added to GP records: 13% of consultations
6) For patients admitted to hospital:
   — Unintentional discrepancies in medication prescribed on admission: 58% of patients/18–60% of prescribed medicines.
   — Inpatient prescribing error rate: 1.5–9.2%.
   — Unintentional discrepancies in discharge medication: 11% items.
   — Unintentional discrepancies in discharge medication subsequently received from GP: 46–60% items; 57% patients.

Box 2: Error rates at each stage of the medicines use process based on UK studies, Based on work by Garfield, Barber, Walley and Willson, commissioned by the National Leadership and Innovation Agency of NHS Wales

   — Inpatient prescribing error rate: 1.5–9.2% of medication orders written
   — Dispensing errors: dispensing errors identified at the final-check stage in 0.6–2.7% of dispensed items, and outside of the pharmacy department in 0.02%
   — Medication administration errors in non-intravenous doses: 3.0–8.0% of all doses
   — Medication administration errors in intravenous doses: 49–94% of all doses
   — Monitoring errors: currently unknown

Box 3: Summary of error rates identified in secondary care, based on published UK studies.

   — Prescribing errors: 8.3% of prescribed items
   — Dispensing errors: 9.8% of dispensed items
   — Administration errors: 8.4% of doses observed
   — Monitoring errors: 14.7% of relevant medicines

Box 4: Summary of error rates identified in UK care homes

3.10 Technology has great potential to improve medicines safety. Its ability to handle large amounts of information, to support decisions, and to repeatedly do the same act, gives the potential for many benefits. For example, a cytotoxic reconstitution robot has the potential to reduce operator error, and to reduce repetitive strain injury in the operators; computerised decision support can be useful in guiding treatment choices. However, introducing new systems can also lead to new types of error occurring.

3.11 The relative benefits and disadvantages of technology depend on many factors, such as how it is used and how the human and technological systems interact. The effectiveness of technology also depends on context; the problems with different health systems vary, and so a technology shown to reduce errors in one system may have a very limited effect in another. For example there has been a tendency to assume that technology that is effective in the USA will be similarly effective in the UK; however the healthcare systems are very different and the benefits (both health and financial) do not necessarily transfer.
3.12 Box 5 gives examples of technologies that have the potential to prevent medication errors, and are often widely advocated as such. However there is little evidence to date for their effectiveness in the UK setting, nor for their economic viability.

<table>
<thead>
<tr>
<th>Primary care</th>
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<tr>
<td>— Electronic patient records</td>
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<tr>
<td>— Computerised dispensing</td>
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<td>— Electronic transmission of prescriptions</td>
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<tr>
<td>— Dispensing robots</td>
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<tr>
<td>Authentication at the point of dispensing using barcodes or radiofrequency identification (RFID)</td>
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<table>
<thead>
<tr>
<th>Secondary care</th>
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<tbody>
<tr>
<td>— Dispensary-based dispensing robots</td>
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<td>— Electronic prescribing</td>
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<td>— Electronic medication administration records</td>
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<tr>
<td>— Barcode verification of medication administration</td>
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<td>— Barcode verification of patient identity</td>
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<tr>
<td>— Ward-based automated dispensing systems</td>
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<tr>
<td>— Electronic transmission of discharge prescriptions between secondary and primary care</td>
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<td>— Automated compounding machines</td>
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Box 5: Examples of technologies being developed for use in the medication process

3.13 In primary care, work is in progress to evaluate the impact of electronic transmission of prescriptions; there is no published evidence on the effectiveness of dispensing robots in UK community pharmacies. It has been estimated that authentication at the point of dispensing (using barcodes or radiofrequency identification (RFID) tags) could reduce dispensing error rates in community pharmacy to nearly a half, as well as identifying counterfeits, but this has not yet been tested in a controlled trial in the UK.

3.14 In secondary care, several research papers report modest reductions in dispensing errors from the use of dispensing robots in hospital pharmacy, as well as other benefits. Studies also show modest reductions in prescribing errors from the use of electronic prescribing, with the benefits varying depending on how the system is configured and used in practice. The implementation of a closed-loop system comprising electronic prescribing, automated ward-based dispensing, electronic medication administration records and barcoded patient identification led to a substantial reduction in medication administration errors on one UK hospital ward. We are not aware of any published UK data on barcoded verification of medication administration or electronic transmission of discharge prescriptions. Work is in progress to assess the impact of a robot for compounding intravenous cancer chemotherapy.

3.15 There is a growing body of evidence showing that new types of error can be introduced with new technology, examples of these are set out in Box 6. Introducing new technologies usually requires changes in work processes, which can also introduce risks, particularly if staff develop work-arounds to save time or to overcome parts of the technology which they consider slow, overly constraining, or unreliable.

| — Over-reliance on the technology to check for errors, and assuming that the technology is more effective than it actually is, and so decreasing personal vigilance |
| — Development by staff of work-arounds to avoid safety features |
| — New types of error introduced, eg errors when selecting from pull-down menus |
| — Introduction of additional steps into work processes |
| — Failure of the computer system |
| — Deskilling |
| — Assumption that the technology is more advanced than it is—eg assuming that a computer system includes decision support where none exists |

Box 6: Examples of new risks created by technologies

4 What the current effectiveness is of incident reporting and education in ensuring medication safety

4.1 While most healthcare organisations have systems for incident reporting, risk management and safety improvement, incident reports identify only a small proportion of the events that actually occur. Reporting an error as an incident requires someone to be aware of the error, aware of the system for incident reporting and having the time and motivation to report it. Evidence suggests that only one in 100 prescribing errors and one in 1,000 administration errors are reported as incident reports. In addition, a safe organisation is likely to report more errors as it is alert to them, and staff are motivated to report. Consequently absolute numbers of incidents reported are difficult to interpret. However it is necessary to report incidents to provide local awareness and intelligence as to some of the types of errors that occur, so changes can be made to avoid
them in the future. This means that incident reporting systems cannot be relied upon to gauge the efficacy or otherwise of system change; more formal evaluation is required. Unfortunately such evaluations can be time consuming.

4.2 While most health care professionals are highly educated, there has historically been a lack of education about risk and how it can be reduced. This issue is now being met in part by developments in medical education, however it is somewhat patchy and nursing education lags behind. Pharmacists have a culture of dealing with poisons, safe manufacturing practices and risk which has put them ahead in understanding safe systems, but more is needed on the theories of risk and how to manage these risks in practice. There is also an urgent need for such education to include the developing technologies and how to work with them.

5 WHAT THE NHS SHOULD DO NEXT REGARDING MEDICINES SAFETY

5.1 More work is needed to develop NHS specific technologies, rather than importing those from the USA or elsewhere, and to characterise the most error-prone parts of current systems that technology can improve.

5.2 Evaluating technologies to assess their impact on medication safety is essential to create an evidence base for their use, rather than assuming that errors will automatically be prevented. We therefore need a toolkit of standard methods and definitions to allow organisations to assess the impact of technological changes on patient safety and to proactively identify any new risks that may arise. Developing this toolkit will require careful consideration of the time required to collect data, balanced against the validity and utility of that data.

5.3 There is currently no single source of information about improving medicines safety and the role of technology in the UK. The published evidence base for many technological interventions is very limited. There may well be additional evidence available as in-house reports from sites where technologies have been introduced and evaluated, but unless this is made publicly available, the evidence and any lessons learned are not available to be shared. There is clearly a need for a central repository for information and knowledge sharing, including advice from the early adopters of each technology for others to consider, as well as potential errors and how others have overcome them.

5.4 As discussed above, there is a need for education for all health care professionals in the correct way to achieve safe adoption and implementation of technology.

5.5 A greater understanding is needed of the relationship between error and harm. We know that a great many errors occur, but fortunately, few result in harm. This area is complex as the occurrence of harm depends on whether or not the error is intercepted and the vulnerability of the patient concerned, as well as the nature of the error itself and whether it is a recurring error or a one-off. A reduction in the overall number of errors is somewhat meaningless if an increase in serious errors occurs. While there has been some work in this area, additional research is needed to better characterise those errors with the greatest potential for harm, so that interventions can be targeted appropriately.

5.6 Research is fundamental to improving medicines safety, from understanding the reasons why safety is compromised to finding new ways to improve safety in all areas of the drug journey. The Department of Health funded Patient Safety Policy Research Portfolio previously gave some unique insights into where and how the medicine systems were hazardous, and some suggestions for improvements. It was disappointing that this policy stream was not continued to build on the knowledge it created. We recommend that nationally a medication safety research strategy is developed and funded over the next 10 years, and that this should include funding for the robust evaluation of technologies to create an evidence base for their use. While the research councils notionally support these areas, the best research stretches across disciplines in a way which, despite the rhetoric, combined research councils find challenging to deliver.

Bryony Dean Franklin and Nick Barber
January 2009

Supplementary memorandum by Professor Mike Murphy (PS 87)

PATIENT SAFETY

I would like to add additional information to my oral evidence given on 15 January.

1. The research money I referred to as being so helpful to get our work started was provided by NHS Blood & Transplant.

2. In the discussion on wider, even national, roll-out of our electronic transfusion system and its slow progress in the NHS, it would be worth adding that Ireland have recently announced that they have funded a national implementation and I believe that Norway will be doing the same; both are based entirely on the system we developed in Oxford.
3. I hope that the committee won’t exercise itself too much about the labels on blood bags. The only time that the label is important in clinical areas is for the bedside checking before transfusion to ensure it is the right blood for the patient. This should be done BEFORE the blood unit is hung up… the checking is done with the unit either being held by the nurse or doctor or laying flat on a convenient surface close to the patient.

Once the blood is hung up (upside down!) and the blood is running, it is TOO LATE to be carrying out checks on whether it is the right blood for that patient.

I hope this is clear. Please come back to me if there are any queries.

Professor M F Murphy
Professor of Blood Transfusion Medicine, University of Oxford
Consultant Haematologist, National Blood Service and Oxford Radcliffe Hospitals

17 January 2009

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Memorandum by Dr Susannah Long (PS 88)

PATIENT SAFETY

1. I am a junior doctor, training in Geriatric and General Medicine. I am currently working as a clinical research fellow at Imperial College London, looking at safety and quality issues in elderly medical inpatients. This evidence is based on my own clinical experiences since qualification in 2000, together with the knowledge that I have gained since commencing this research in 2007. I do not have the expertise to give evidence pertaining to all of the terms of reference in this inquiry, so have elected to write only about a selection of them. I have done this from the point of view of a hospital junior doctor, although clearly all healthcare professionals play equally important roles in patient safety.

What are the risks to patient safety and to what extent are they avoidable?

Role of human error and poor clinical judgement.

Human error and the junior doctor.

2. Junior doctors are at the “front line” of patient care and are therefore play a crucial role in reducing harm to patients. They are involved in the hour-by-hour and day-to-day monitoring, treatment and decision making for patients, based on a constant flow of information, which has to be assimilated and prioritised appropriately. Although junior doctors strive to make decisions and carry out tasks as safely as possible, there is always the possibility that they will make errors. There are many factors that may contribute to these errors, including cognitive biases, inexperience, lack of supervision, adverse working conditions, time pressures, communication failures and team factors. Although junior doctors may feel that they can do little to prevent errors caused by “systems” problems, they are part of the buffer between patients and the system—the final line of defence against harm. There are several ways in which junior doctors can enhance patient safety; these should perhaps be made more explicit and emphasised in medical training.

Poor clinical judgement and the junior doctor.

3. When a hospital inpatient acutely deteriorates, it may well be the most junior member of the medical team who is called to attend first, and it is they who must use their clinical judgement to make swift and effective assessments and produce and carry out appropriate management plans to the best of their ability. Obviously this ability improves with clinical experience, training and learning from situations where things may have been done better. Whilst these skills are developing, it is vital that junior doctors feel adequately supported, so that they do not hesitate to ask for senior help as soon as they recognise that it is needed. It is also therefore crucial that they have good situational awareness and awareness of their own strengths and limitations, from their very first day, in order to swiftly recognise dangerous or worrying situations that they may not be adequately equipped to cope with alone. It also follows that they should work in an environment where the development of these attitudes and attributes is encouraged and where there is a strong emphasis on teamwork and learning.

Systems failures.

4. In many patient safety incidents, even where it may appear that the immediate cause was an error made by an individual, there are likely to be several underlying systems factors that provoke or worsen the error. Conversely there are various ways in which healthcare systems can reduce or minimise patient harm. As mentioned above, a crucial aspect of this is the overarching ethos and attitude within the institution. In addition, numerous practical system changes, which affect the way junior doctors work, have been shown to reduce errors and subsequent harm. These include simplification and standardisation of clinical processes, the use of checklists and aide-mémoires, the use of information technology, team training, and mechanisms to improve the uptake of evidence based treatment patterns. Trainees are likely to become involved in adverse events whilst still trying to familiarise themselves with the hospital system, and individual hospitals
vary in their protocols and systems. It is therefore vital that local guidelines and methods of working are made as clear as possible as part of an effective induction process and that they are subsequently easily accessible at all times of day or night.

What should be measured and assessed; and what data should be published?

Patient Safety and the Elderly

5. When choosing measures to assess patient safety, it is important to remember that the majority of hospital inpatients are elderly. This has unique ramifications for patient safety. There is substantial evidence that the elderly are significantly more likely to experience adverse events in hospital than younger patients. This is likely to be related to comorbidity, complexity and frailty rather than age alone. Other patient-related contributory factors include cognitive impairment, sensory impairment and polypharmacy. These are complicated by the fact that illness presents in different, often more non-specific, ways in older people than younger people.

6. The attitudes and skills of staff play a vital role here; in order to maximise safety in the elderly, staff require a holistic approach, with excellent clinical reasoning and communications skills. These skills are essential for accurate and thorough initial assessment and if lacking may lead to diagnostic errors and subsequent mismanagement, as well as poor quality care overall. The same communication and clinical reasoning skills required for initial assessment are also required to detect and manage adverse events in older people once they have occurred during the hospital admission. One of the cornerstones of geriatric medicine is multidisciplinary team working, which although is hugely beneficial, may also bring its own hazards that we should be aware of. In addition, there are numerous systems factors which may contribute to adverse events in the elderly.

7. The elderly experience different types of adverse events than younger patients, for example being more prone to preventable “geriatric syndromes” in hospital such as delirium, falls, undernutrition and functional decline. Their limited physiological, functional and cognitive reserve means that they may also experience more severe consequences of adverse events, such as more severe injuries, prolonged lengths of hospital stay or unnecessary readmissions. By their very nature, frail elderly patients are complex, and there are usually multiple causes for any problems they may have. There are blurred boundaries between adverse outcomes of hospitalisation that are not preventable, preventable adverse events and providing a high quality service for the elderly. Patient dignity is of course of paramount importance in all of this.

Dr Susannah Long
Clinical Research Fellow/SpR Geriatric and General Medicine
Clinical Safety Research Unit
Imperial College London
January 2009

Memorandum by Professor David Webb (PS 89)

PATIENT SAFETY

Professor Webb trained as a cardiovascular physician and clinical pharmacologist in London, before moving to Edinburgh where he was appointed to the Christison Chair of Therapeutics and Clinical Pharmacology in 1995. He subsequently led Edinburgh’s Department of Medical Sciences (1998–2001), Wellcome Trust Cardiovascular Research Initiative (1998–2001), and Centre for Cardiovascular Science (2000–04). He currently runs a Wellcome Trust-funded Scottish Translational Medicine & Therapeutics Initiative.

He was Clinical Vice-President to the British Pharmacological Society (BPS: 1996–98), Chair of the Royal College of Physicians Committee on Clinical Pharmacology (1998–99), Chair of the BPS Committee of Heads and Professors of Clinical Pharmacology (2004–07) and Chairman of the Scottish Medicines Consortium (2004–08). He is currently a member of the Executive Committee of the International Union for Pharmacology (IUPHAR: 2004–), and Vice-President of the Royal College of Physicians of Edinburgh (2006–).

FOCUS: PRESCRIBING OF MEDICINES

1. What are the risks to patient safety in relation to use of medicines and to what extent are they avoidable?

It is perhaps not surprising that medication errors occur. Prescribing is a high-level task integrating complex diagnostic skills, clinical judgement and an understanding of therapeutics. It is a skill practiced by virtually every doctor in their routine work, and yet is a task that carries significant risks as well as benefits. Matters are complicated because, year on year, there are more medicines available, with an increasing evidence base for their use. With an ageing population there are more patients to treat, requiring more complicated drug regimens that increase the risk of drug interactions, in potentially vulnerable patients.
Standardised protocols now exist for the routine treatment of many conditions, but many patients either do not meet the criteria for these protocols, or have a number of conditions that may produce conflicting requirements. In this situation clinical judgement is crucial.

Prescribing errors are common in UK hospitals. One study from a London teaching hospital detected 135 errors each week, one-quarter of which were potentially serious, with most made by junior doctors [Dean et al., 2002a]. The National Patient Safety Agency database receives >50,000 reports annually of medication incidents from acute and general hospitals [2007]—very likely a small fraction of all events. An Audit Commission report [2001] has suggested that adverse medication events were responsible for the death of 1100 hospital patients in 2001 in the UK, a 5-fold increase over the previous 10 years. Approximately 6.5% of admissions to hospital are related to adverse drug reactions, with an associated mortality of 0.15%; this costs the NHS £466m annually [Pirmohamed 2004]. Most reactions were judged to be “definitely” or “probably” avoidable.

Some errors are “system” based whereas others relate to the knowledge or skills of prescribers. System errors include the risk of receiving the wrong medicine when different medicines have similar names, the risk of receiving the wrong medicine when different medicines are presented with similar packaging, and the risk of giving a medicine by an inappropriate or dangerous route when they are presented in ways that allow such mistakes (such as the potentially fatal risk of intra-thecal administration of anti-cancer drugs designed for intravenous use). These issues need to be addressed through systems approaches. In particular, a blame-free approach to reporting of critical incidents, a robust means of responding to system failures, and electronic support for prescribing may assist in reducing some of these system-based errors. The clinical pharmacist has a key role in this area of work.

In this evidence, I will focus on those errors related to lack of knowledge or skills. There is evidence that inadequate training is often a contributory factor in prescribing errors [Dean 2002b; Leape 1995]. An analysis of 88 serious medication errors in a UK hospital has suggested that a deficit in “skills and knowledge” was a factor in 60% of cases [Dean, 2002b].

In 2008, Heaton [Heaton 2008] reported the results of a web-based survey which sought the opinions of 2,413 students graduating in 2006–08 from the 25 UK medical schools (mean 96.5 per school) about their undergraduate training to prescribe and their confidence about meeting the relevant competencies identified by the GMC. Distinct courses and assessments in “clinical pharmacology & therapeutics (or equivalent)” were identified by only 17% and 13%, respectively, with mode of learning described most commonly as “opportunistic learning during clinical attachments” (41%). Only 38% felt “confident” about prescription writing and only a minority (35%) had filled in a hospital prescription chart more than three times during training. The majority (74%) felt that the amount of teaching in this area was “too little” or “far too little”, and most tended to disagree or disagreed that their assessment “thoroughly tested knowledge and skills” (56%). When asked if they were confident that they would be able to achieve the prescribing competencies set out by the GMC, 42% disagreed or tended to disagree, whereas only 29% agreed or tended to agree.

Subsequently, the GMC Education Committee has undertaken its own study on preparedness to practice. This involved three diverse medical schools (Glasgow, Newcastle and Warwick) with different approaches to undergraduate teaching (problem-based learning, systems-based integrated curriculum, and graduate entry respectively). The study was multi-method, cross-sectional and prospective, involving in-depth interviews and questionnaires. Newcastle and Warwick Foundation year 1 doctors also completed a safe prescribing assessment. Qualitative triangulating data were collected from nearly 100 clinicians (undergraduate tutors, educational supervisors, key managers and members of clinical teams). Illing and colleagues [GMC website Dec 2008] have now “published” the report of the study on how prepared medical graduates are to begin practice. This document clearly shows that a crucial concern is prescribing ability, as follows:

“There was a consistent thread, from primary sample data throughout the year, and from triangulation data, of under-preparedness for prescribing. Weaknesses were identified both in the pharmacological knowledge underpinning prescribing, and the practical elements of calculating dosage, writing up scripts, drug sheets, etc. While there was some feeling from triangulating data that F1s were prepared for prescribing, pharmacists did identify severe gaps. Prescribing was also the main area of practice in which errors were reported by respondents, indicating a significant potential risk. Risks were reduced, but not removed, by support from colleagues, with F1s speaking particularly highly about the help received from pharmacists.”

The key significance of this report, part from confirming the earlier work from Heaton is that it compared the full range of competencies expected of newly qualified doctors and identified prescribing as the most significant weakness, and one that has the potential to put patients at serious risk. Of 10 competencies that were scored under 3 (out of 5), 4 of these were in the area of prescribing.

The GMC report concludes that the priorities are to:

“… address particular weaknesses in prescribing by supporting the development of teaching of prescribing as a skilled procedure which is subject to the time pressures and contingencies of all clinical skills. Such teaching should place greater emphasis on prescribing as an instance of applied pharmacology, and the need for new doctors to engage with prescribing and develop their own expertise rather than relying on others.”
The report also showed problems in a safe prescribing assessment administered to Foundation doctors within two of the schools. Indeed, over 80% of foundation doctors failed the assessment in the first round. Whilst it may be that this assessment had problems, it does highlight the need for continuing reinforcement and reassessment of prescribing skills in the early years after qualification.

The particular needs for education described by the GMC—in pharmacokinetics (how the body handles medicines), interactions between medicines, and common prescribing skills—are all met by the core curriculum in clinical pharmacology and therapeutics produced by the British Pharmacological Society [Maxwell 2003]. As a result of Tomorrow’s Doctors (1993, 2003), time spent on undergraduate teaching in this area has reduced substantially and this now needs to be corrected.

2. What is the effectiveness of current approaches to patient safety in relation to use of medicines?

It is widely recognised that newly qualified doctors are at the sharp end of prescribing, and that this work is largely unsupervised. Although junior doctors are protected from undertaking many high-risk practical procedures, they are able to prescribe powerful medicines from their first day of clinical work. Here, clinical pharmacists are well recognised to play a very important support and educational role. Nevertheless, there is a critical need to provide medical students with an undergraduate education and training in therapeutics and prescribing that prepares them effectively to fulfil this role, and to be able to develop as an effective prescriber thereafter. Essential support in prescribing can be provided, and several studies have suggested that the delivery of targeted education can improve prescribing performance and reduce prescription errors [Scobie 2003; Garbutt 2006; Langford 2001; Vollebregt 2006]. However, some of the changes in recent years have served to reduce the preparedness of doctors for prescribing (see below).

The GMC’s recommendations on undergraduate medical training published in Tomorrow’s Doctors (1993) heralded a major change in medical training. The focus was on a reduction in the burden of factual learning, a slimming down of the science base taught to medical students and the development of an integrated medical undergraduate curriculum in an organ based structure. There were many potential benefits to this approach, but one of non-organ based areas of teaching that lost out was the vertical theme of pharmacology, clinical pharmacology and therapeutics, which in most medical schools became a much less visible area of teaching. Again, in many medical schools, the assessment of teaching in therapeutics was no longer identifiable and this diminished the demand on students to focus on this area of learning. Another important driver for loss of teaching in this area was the national round of Research Assessment Exercises, which meant that universities placed a higher value on research than teaching and, as a largely academic specialists, clinical pharmacologists were encouraged to focus on this aspect of their work. In some medical schools therapeutics disappeared as a teaching discipline and it has been noted that many nursing schools provide more hours of education in this area than most medical schools [Aronson 2006]. These concerns about teaching in therapeutics and prescribing within in the UK [Maxwell 2006], have been mirrored in Europe [Maxwell 2007] and Australia [Hilmer 2009].

In the past, medical students were encouraged to prescribe, under supervision, and to have their prescriptions signed off by a more senior member of staff. This is no longer considered an acceptable practice but it has not generally been replaced in medical schools by other means to give students an understanding of the complexity of prescribing, and to thereby ensure that they give this area of learning the time and effort it justifies.

Interestingly, there have been recent moves by the pharmaceutical industry to fill the void and take on this role [Coombes 2009]. However, there are well-recognised concerns about the ability of industry to provide such information in an unbiased way [House of Commons Health Committee 2005], and in a recent poll in the British Medical Journal around 80% of respondents thought that drug companies should not teach therapeutics to medical undergraduates [This Week 2009]. Indeed, one could argue more broadly, for the same reasons, that the pharmaceutical industry should not be involved in the education of doctors but should focus their efforts on the development of powerful and innovative new medicines.

Importantly, following a public debate on the preparedness of newly qualified doctors for prescribing [Aronson 2006, Rubin 2006a], the GMC assisted in creating a Safe Prescribing Working Group (SPWG) [Rubin 2006b] established by the Medical Schools Council under the chairmanship of Professor Robert Lechler. The work of SPWG [Lechler 2007] had two important outcomes: first, a description of the prescribing competencies required of a newly qualified doctor; and second, the generation of a major Department of Health E-Learning project on Prescribing.

The prescribing competencies defined by SPWG, which now provide a yardstick against which undergraduate education in this area can be judged, are that all medical graduates should be able to:

- Establish an accurate drug history.
- Plan appropriate therapy for common indications.
- Write a safe and legal prescription.
- Appraise critically the prescribing of others.
- Calculate appropriate doses.
- Provide patients with appropriate information about their medicines.
— Access reliable information about medicines.
— Detect and report adverse drug reactions.

The Department of Health e-Learning for Healthcare project, led by Dr Simon Maxwell and undertaken in collaboration with the British Pharmacological Society, will provide funds to develop a national e-Learning solution in clinical pharmacology and prescribing for students of medicine and allied professions. The project will be known as Prescribe and is intended to provide e-learning materials that will enable students to develop a firm grounding in the principles of basic and clinical pharmacology, which underpin safe and effective prescribing in the NHS. Prescribe will contain both interactive learning sessions and information covering the pharmacology, clinical pharmacology and therapeutics that a student might expect to encounter within a standard medical curriculum. Also in development is an interactive student formulary, the opportunity to practice skills relevant to prescribing, self-assessment exercises, a library of important publications, a glossary and links to other resources. Prescribe will be available free of charge to students registered with UK universities and NHS-affiliated organisations. Further details are available at www.cpt-prescribe.org.uk.

3. What should the NHS do next regarding patient safety in relation to use of medicines?

Together with gathering evidence by taking a history from the patient, undertaking a medical examination, and interpreting the results of laboratory investigations, prescribing of treatments is one of the defining activities of the doctor. Prescribing is not an exact science, as it requires the weighing of evidence and the use of clinical judgement about harms and benefits of intervention, but safe, effective and cost-effective prescribing requires training in the principles of pharmacology and its application in therapeutics. In the absence of incontrovertible evidence (which would be hard to obtain) that poor prescribing leads to harm to patients, all of the evidence we have to date would support the risks of poor prescribing skills and the precautionary principle would justify a greater emphasis on improving prescribing quality.

Addressing this problem requires collaboration between the medical schools, GMC and NHS. The following are important ways in which patient safety in relation to prescribing could be improved.

1. Undergraduate medical students need to receive a sound grounding in the principles of pharmacology and therapeutics, supported by training in the practical skills of prescribing, and a professional attitude to its performance. The required competencies in prescribing are defined by the Medical Schools Council Safe Prescribing Working Group [Lechler 2007]. Research is needed to define the best way to deliver these competencies.

2. The next iteration of Tomorrow’s Doctors (2009; the last was in 2003), currently in draft form, addresses many of the previous omissions, and is an important development in undergraduate medical training. Nevertheless, it should identify the report from the Medical Schools Council Safe Prescribing Working Group, and include the full list of prescribing competencies required of a newly qualified (Foundation) doctor. In addition, it should identify prescribing as one of the key therapeutic procedures. The opportunity to make an unequivocal statement on this issue should not be missed.

3. Teaching and training need to be backed up by rigorous methods of assessment of knowledge, skills and attitudes around the time of graduation so that these competencies can be assured. If necessary, these should be undertaken on a national basis.

4. It should be anticipated that undergraduate teaching and training will be very usefully supplemented by the Department of Health e-Learning for Healthcare package, Prescribe, currently under construction.

5. In addition, there is a need for continuing medical education in this area, backed up by assessment of prescribing in the foundation period of training, and beyond. Benefits would be gained by having prescribing “champions” in training environments where foundation doctors are placed. The creation of a “prescribing skills test” to be undertaken early in the early postgraduate period might be a helpful step.

6. Additional benefits might well accrue from introducing a standardised prescribing form across routine UK hospitals so that there is less risk of error associated with doctors moving between centres.

7. The creation of effective electronic prescribing systems would assist in ensuring that patients received the right medicine at the right dose, would serve to encourage use of the most effective medicines, and would assist in providing alerts to potential contraindications and drug interactions. It should also serve to ensure clarity about current treatment in the movement of patients between primary care and the hospital setting.

8. Patients need to receive unbiased evidence about the benefits and harms of licensed medicines. In the US, direct-to-patient advertising by the pharmaceutical industry can serve to distort this advice [Berndt 2005], especially in relation to the relative benefits and harms of medicines. Direct-to-patient advertising should be resisted within the EU.
9. Clinical pharmacologists, and other clinicians with skills, knowledge and a focus on teaching of prescribing skills are required to assist junior clinicians in integrating prescribing into clinical care. Clinical pharmacists have complementary roles in education to ensure safe prescribing, and there are substantial benefits from pharmacists working closely with clinicians in this important area.

10. The discipline of clinical pharmacology and therapeutics is the only medical specialty within the NHS that is declining in numbers, as other specialties grow. Given that clinical pharmacology is the key medical specialty with a focus on safe and effective prescribing, and its numbers are at a critically low state, urgent work is needed within the Department of Health to increase the numbers of doctors training in clinical pharmacology and therapeutics in the UK.

Professor David Webb MD DSc FRCP FRSE
January 2009

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Memorandum by the Patient Safety Education Study Group (PS 90)

PATIENT SAFETY IN HEALTH CARE PROFESSIONAL EDUCATIONAL CURRICULA: EXAMINING THE LEARNING EXPERIENCE

Background: The formal stages of pre—and post-registration training for health professionals together make up the biggest systemic intervention designed to assure patient safety in health care practice in the U.K. This intervention is complex and multifaceted, including multiple components, which vary across sites and disciplines, and also between tutors and learners. Whilst formal curricula are being encouraged to change in order to highlight patient safety alongside evidence-based practice, and educational frameworks for learning and teaching about patient safety are advocated, it has not been clear how far behaviour is driven by the informal or hidden curriculum, nor which educational strategies are most effective in creating change.

Aims: This study has investigated the formal and informal ways pre-registration students from four healthcare professions learn about patient safety in order to become safe practitioners. The study aims to understand some of the issues which impact upon teaching, learning and practising patient safety in academic, organisational and practice “knowledge” contexts.

Methods: A two stage, phased design using multiple qualitative methods was employed. The overall approach drew on “illuminative evaluation” (Parlett and Hamilton (1977) which is concerned with exploring, describing and interpreting rather than measuring and predicting.

In Phase 1 we used a convenience sample of 13 educational providers across England and Scotland linked with five universities running traditional and innovative courses for doctors, nurses, pharmacists and physiotherapists. We gathered examples of existing curriculum documents for detailed analysis, and interviewed course directors and similar informants.

In Phase 2 we undertook eight case studies to develop an in-depth investigation of learning and practice by students and newly qualified practitioners in universities and practice settings in relation to patient safety. Data were gathered to explore the planning and implementation of patient safety curricula, the safety culture of the places where learning and working take place, the student teacher interface and the influence of role models and organisational culture on practice.

Data from observation, focus groups and interviews were transcribed and coded independently by more than one of the research team. Analysis was iterative and ongoing throughout the study.

Results: NHS policy is being taken seriously by course leaders, and Patient Safety material is being incorporated into both formal and informal curricula. Patient safety in the curriculum is largely implicit rather than explicit. All students very much value the practice context for learning about patient safety. However, resource issues, peer pressure and client factors can influence the development of safe practice. Variations exist in students’ experience, in approach between university tutors, different placement locations—the experience each offers—and the quality of the supervision available. Relationships with the mentor or clinical educator are critical to student learning. The role model offered and the relationship established affects how confident students feel to challenge unsafe practice in others. Clinicians are conscious of the tension between their responsibilities as clinicians (keeping patients safe), and as educators (allowing students to learn under supervision). There are some apparent gaps in curricular content where relevant evidence already exists—these include the epidemiology of adverse events and error, root cause analysis and quality assessment. Reference to the organisational context is often absent from course content and exposure limited. For example, incident reporting is not being incorporated to any great extent in undergraduate curricula. Newly qualified staff were aware of the need to be seen to practice in an evidence based way, and, for some at least, the need to modify “the standard” way of doing things to do “what’s best for the patient”.

Rubin P. A prescription for better prescribing: medical education is a continuum. BMJ 2006a;333:601
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Conclusions: We found that there were considerable similarities in the story told about formal and informal patient safety education by staff and students from all four disciplines. Our observations in general confirmed their impressions. Patient safety is rather more implicit than explicit in curriculum documentation, and for most students it is experienced as integrated throughout their studies. Assessment (unsurprisingly) tends to drive learning, and most students report learning more in practice than from university based activities. Role models are important in demonstrating appropriate attitudes and safe practice. Engagement with patients (whether in the classroom or in practice) also seems to facilitate learning. There was no support for patient safety to be separated out in a silo, but academic staff did feel that content and outcomes should be made more explicit.

Although this has been a very substantial piece of work, there are many areas which require further investigation. For example, the broad nature of this study meant that we made only slight inroads into understanding something of the culture of practice in each profession and its influence upon students and newly qualified staff. Understanding more about the factors which shape the attitudes of clinical educators and mentors will be important in devising appropriate education for them. There was some indication of the importance of interprofessional learning in this area, but again more work is required. We have also become aware during the course of this study that there is a need for greater understanding of the ways in which patient safety education is delivered across Europe.

Since this study was commissioned, patient safety has risen up the policy agenda. Recent initiatives seek to change the culture of the NHS to one which in the words of NHS North East (2008), look for “no avoidable deaths, injury or illness and no avoidable suffering or pain”. There is an increased focus across NHS on safety and quality and on the use of commissioning and contracting to ensure this. However, whilst significant investment has been made in campaigns to promote infection control, and technology to ensure that the right patient gets the right treatment, education remains essential in developing and sustaining appropriate attitudes and behaviour amongst staff—now and for the future.

Recommendations: A number of recommendations have been made, some generic and others specific to individual professions.

Generic recommendations

1. Clinical or placement educators in all disciplines need to be effective role models who are clear about how to help students to learn about patient safety: attention is needed to development of training for this group
2. In identifying placements, assessment should include relevant aspects of patient safety, and whether or how staff explain non-standard practice.
3. Curricula should include developing students’ capacity to constructively challenge unsafe or non-standard practice
4. Learning activities about patient safety should be designed appropriately to the students involved: The balance between lectures, small group and “hands on” experiential learning should be considered.
5. All courses should be readily able to identify a vertical integrated thread of teaching and learning related to patient safety in their curricula. This should be clear to staff and students. Assessment for this element should also be identifiable.
6. Students find encounters with patients and learning about their experiences and concerns helpful: Opportunities of this sort focusing on patient safety should be incorporated into all courses.
7. There is a need for courses to find ways to increase students’ awareness of the current knowledge base on patient safety, so that they have an appropriate grounding from which to reflect on their experiences.
8. Further innovative approaches should be developed to make patient safety issues “real” for students—examples may include the use of role plays and simulation, interprofessional learning events, service improvement activities or significant event enquiries.
9. Closer links should be developed between academic staff in HEIs and NHS Trust managers in each SHA to ensure clarity about policy trends, desired areas of competence for students at qualification and to work towards an appropriate balance of learning between university and practice settings. Opportunities for interprofessional dialogue would be likely to enhance this.
10. Courses should be encouraged to appoint a patient safety champion to facilitate the topic’s profile and drive content development.
11. Professional regulators’ expectations of courses in relation to patient safety education should be explicit and regularly reviewed.
Recommendations for medicine

There are some ways in which courses might enhance their outputs, at the same time bridging some of the cultural divide between the academic/clinical alignment and the organisational/systems approach:

1. It is crucial to have excellent clinical placements led by good role models who are clear about how to help students to learn about patient safety.

2. All learning activities about patient safety need to be appropriately designed: this may need careful consideration of student numbers on placement, and ensuring that the workload of supervising lead tutors does not interfere with core educational process and feedback.

3. Make every opportunity to involve students in meeting with patients and learning about their experiences and concerns—this can be done in placements, but also by the use of “expert patients” who can offer specific teaching on safety issues and managing the experience of medical errors.

4. Pay more attention to the current knowledge base on patient safety, so students have some theoretical and conceptual build to use when analysing their experiences and trying to practise safely—this is NOT recommending a separate theory course, but making more explicit some more complex issues like missed diagnoses (abuse, red flags), handover challenges (transfer of information, clinical priorities) and epidemiology (common errors in different settings).

5. Utilise the educational expertise available to make all patient safety issues “live” for students—through case and problem based discussions, consultation skills role plays, interprofessional learning events, significant event enquiries.

6. Ensure that all medical schools can map their patient safety curriculum across all five years, so that this is explicit to both students and staff (without necessarily increasing the volume of curricular activity): assessment of this curriculum should also be mappable.

7. Link managers into undergraduate education, as a source of “cases”, as advisers on core systems which NQPs need to be competent in, and in order to encourage interprofessional understanding and respect between doctors and management.

8. There is a need to look more explicitly at why practice breaks down and the circumstances in which it does so: doing this repeatedly in different settings including in the NHS might help with the anxiety about litigation and whistleblowing, as it would show how active learning from errors and adverse events allows early detection and remediation of problems in many instances, as well as enhancing quality over time. This could be done by including senior students in team-based learning activities (mortality enquiries, child protection cases, medication reviews etc) and consider using them as part of the enquiry both so their skills are developed and to give active engagement.

9. Both the GMC’s expectations of medical schools, and the creation of senior patient safety leads for each medical course, would assist the profile and likelihood of patient safety competencies becoming more stable and effective over time.

Recommendations for pharmacy

1. Curricula should be revised to include topics including the epidemiology of adverse events and error, root cause analysis and quality assessment. These have been described as core domains in medication error education.

2. Courses should seek to incorporate teaching and learning about factors affecting the organisational context. This might involve input from NHS based staff or completion of reflection concerning formal planned visits and tutorials.

3. Curricula should be developed to provide meaningful clinical experience in relation to patient safety throughout the undergraduate programme (as recently recommended): this could build upon examples of good practice identified in this study.

Recommendations for physiotherapy

1. Curricula should clearly address developing students to deliver safe and effective professional practice. Course directors should consider the balance between classroom based and practice based learning about patient safety at each stage.

2. Assessment in relation to competence and safe practice should be incorporated into curricula at all levels as it drives and consolidates learning about patient safety.

3. Course directors should consider building in opportunities for interprofessional work related to patient safety and particularly focusing on service improvement as these generate reflection on the issues involved.

4. Student placements should be assessed for their suitability in relation to the attitude of educators to patient safety and the relative density of staff.
5. In practice situations, students should be encouraged to build up a portfolio of reflections on safe practice to draw from in future work.

6. In practice based learning educators should seek to provide opportunities for repetition of activities and skills in order to build confidence.

7. Students need to be empowered to question and “challenge” unsafe practice, procedures and processes without fear of being penalised.

Recommendations for nursing

1. Curricula should enable students to understand patient safety issues for real patients (to enhance motivation), and to contrast evidence based “safe” or “correct” performance with variations which may be seen in practice.

2. Patient safety education should seek to promote positive behaviour rather than defensive practice.

3. Curricula should enable students to develop skills to challenge unsafe practice in other staff.

4. Selection of placements should examine staffing and resources, staff attitudes to patient safety and client factors (for example levels of dependency) in relation to learning safe practice.

5. Courses should consider “patient safety debrief” sessions after each placement, both as an educational tool and for review of placements.

6. Staff selected as mentors should provide evidence of positive attitudes towards patient safety, regular ring-fenced availability to students, active readiness to teach and positive attitude to questioning.

7. Practice placement facilitators should be encouraged to support mentors in clinical areas, particularly in developing appropriate patient safety learning activities.

8. Students should be made more aware of Trusts’ approaches to risk assessment, perhaps through greater use of visiting lecturers from Trusts.

Pauline Pearson, Amanda Howe, Aziz Sheikh, Darren Ashcroft, Pam Smith, Alison Steven on behalf of The Patient Safety Education Study Group

January 2009

Memorandum by the Medicines and Healthcare products Regulatory Agency (PS 91)

PATIENT SAFETY

PURPOSE OF THE MHRA

1. The principal aim of the Medicines and Healthcare products Regulatory Agency (MHRA) is to safeguard public health. It plays a significant and statutory role in the broader patient safety agenda by ensuring that medicines and medical devices on the UK market work properly and as intended and are acceptably safe. The MHRA also works with relevant organisations to improve quality and safety of blood and blood components.

2. The MHRA is the competent authority for the regulation of medicines across the UK and assists Ministers in the discharge of their responsibilities as the Licensing Authority responsible for the safety of medicines as set out in the Medicines Act 1968 and relevant European Community legislation. For medical devices, powers derive from relevant European legislation as set out in the Medical Device Regulations 2002.

REGULATION OF MEDICINES

3. All medicinal products have to be licensed—given a marketing authorisation (MA)—before they can be put on the market in the UK. The MHRA will only grant a MA if it is satisfied that a medicinal product meets these provisions. The decision to grant a MA is based on an overall risk/benefit analysis which recognises that all drugs have some risk attached. The MHRA and its advisory committees will decide whether the benefits justify the risks for a medicine and its intended use. The Agency also approves applications for clinical trials that are to take place in the UK, ensures risk management plans are in place for new medicines and pre-approves the advertising of certain medicines. The Agency has a statutory role in relation to product information for health care professionals and the public, including the approval of user tested patient information, now required for all medicines on the UK market. The Agency also works closely with the NPSA on improving design of information to enhance patient safety. Decisions are always based on good science and robust methodology and judgments on safety, quality and performance will be informed by all available, relevant and reliable evidence. A similar risk to benefit analysis is undertaken for imported medicines that are urgently needed but do not hold a marketing authorisation.
4. The MHRA regulates the medicines distribution supply chain by a system of inspection and licensing of manufacturers, importers and wholesale distributors. Agency Inspectors review the compliance of Marketing Authorisation Holders to ensure they are meeting their obligations in reviewing the ongoing safety of medications they market. It monitors the market place providing advice and guidance as to what is a medicine and what is not considered a medicine. It also, through the British Pharmacopoeia, publishes standards on ingredients and expected quality for medicines. The Agency also manages the General Practice Research Database (GPRD), information from which is used to detect healthcare trends and monitor the safety and risk benefit of licensed medicines.

5. Once a medicine has been given a licence, the MHRA continuously monitors and takes appropriate action to safeguard public health within its regulatory remit. The Yellow Card Scheme is the national scheme for the reporting of adverse drug reactions (ADRs) and is run by the Agency and the Commission on Human Medicines (CHM). The Agency reviews all ADRs to identify new benefit/risk signals that require action. For over 40 years, this scheme has proved highly effective in the early identification of patient safety issues, receiving around 25,000 reports of possible side effects each year. Subsequent regulatory action is based on the available evidence of the risk and benefit if it is considered that action is necessary to address safety concerns. Such action can include updating the product information with new side effects; changing the legal status of a medicine in light of new benefit/risk information or suspending or cancelling the licence of a medicine.

6. The Agency is committed to continually strengthening the Scheme and recently introduced patient reporting following a successful pilot period. Some 9,000 reports have been received from patients/parents/carers since that pilot began in 2005. Facilitating reporting is key to the success of the Scheme and the Agency introduced a new online reporting system in February 2008 to make reporting easier and more accessible. The launch of the new system coincided with the formal extension of the scheme to patients and a national awareness campaign was run through community pharmacies. Further initiatives are underway including working with NHS system providers and Connecting for Health to investigate how to maximise IT to further improve reporting of ADRs.

REGULATION OF MEDICAL DEVICES

7. A medical device cannot be marketed in the UK without carrying a CE marking. A CE marking is applied by the manufacturer and means that the device meets the relevant regulatory requirements. But generally a manufacturer is required to conduct a risk benefit analysis, have clinical data to show the device claims can be achieved, provide the information required to use it safely and have post market surveillance systems in place to ensure that faults identified in use are picked up and acted upon. For all but the lowest risk devices a CE mark must be verified by an independent certification Notified Body before it can be affixed to the product. The MHRA is responsible for appointing UK Notified Bodies and regularly audits them to ensure they perform to high standards.

8. The MHRA undertakes a proactive and reactive inspection programme to help ensure that only compliant devices are placed on the market. The Agency also approves protocols for medical device clinical investigations. It has the power to prosecute where regulations have been breached, and to ensure medical devices meet the requirements of the Regulations. The Agency can also remove unsafe products from the supply chain.

9. In 2008, MHRA’s Adverse Incident Centre received over 8,900 adverse incident reports relating to medical devices. Around 37% of these reports were from healthcare professionals and other medical device users and 47% were from manufacturers. Of these, 212 concerned patient deaths and 1193 concerned serious injuries. It is important to note, however, that not all of these were caused by faulty devices. In many instances, adverse incidents with a device are caused by user errors, indicating a lack of training or awareness in the safe and proper use of device. In 2008, as a result of investigation of adverse incident reports; MHRA issued 88 Medical Device Alerts and notified other European health authorities. MHRA also supervised over 560 manufacturer field actions (recalls etc) more than 360 of which required the provision of advice on safer device use or improved staff training. Additionally MHRA obtained about 800 undertakings from manufacturers to improve medical device designs, manufacturing processes or quality systems.

10. MHRA continues to encourage the reporting of medical device adverse incidents by healthcare professionals by maintaining a network of Medical Device Liaison Officers in all acute and primary care trusts in England and by working in close collaboration with Royal Colleges, professional bodies and the Healthcare Commission.

REGULATION OF BLOOD AND BLOOD PRODUCTS

11. The MHRA has since 2005 acted as the UK Competent Authority for the EC Directive governing quality and safety of blood and blood components (EC2002/98). The Agency receives reports of serious adverse reactions (ie a patient reaction after receiving blood) and serious adverse events (ie which include labelling issues); and undertakes inspections on a risk basis, informed by compliance reports—of blood banks and blood establishments. In 2008, 449 serious adverse reactions and 817 serious adverse events involving blood and blood components for transfusion were reported to the MHRA via the SABRE online
reporting system. MHRA also reviewed 388 compliance reports from relevant hospital blood banks during the 2007–08 reporting period. 195 of these required further consideration, resulting in 73 further inspections, with one suspension of activities.

THE AGENCY’S ROLE IN PROVIDING INFORMATION

12. The MHRA enables the safe use of medicines and medical devices through effective information to patients and healthcare professionals and by responding promptly on new patient safety concerns. The MHRA has developed robust reporting systems for incident reporting and risk management. When a product is reported as faulty the MHRA works immediately with manufacturers and wholesalers on the most appropriate and timely action to take. By law, manufacturers must report to the MHRA any important defects in both medicines and medical devices. Warnings are sent out to healthcare professionals and organisations and are publicised widely in print and on line, and where appropriate by working with the media.

13. The MHRA alerts healthcare professionals about safety issues relating to medical devices by publishing Medical Device Alerts, Device Bulletins, posters and a variety of other educational materials.

14. The Agency has recently set out an Agency Communication Strategy which will better target information to healthcare professionals and the public and seeks to both improve understanding of the benefit/risk balance of medicines and medical devices and increase patient and public engagement with the Agency’s work. The Agency has also taken forward a range of initiatives to improve communications, including into the NHS, to enable messages about the safe use of medicines and devices to have maximum impact.

COUNTERFEIT PRODUCTS

15. The MHRA is also responsible for enforcement action, including tackling the growing threat of counterfeit medicines and medical devices and the risks they pose to patient safety. The supply of counterfeit medicines and medical devices is a growing problem worldwide and one the Agency is taking very seriously.

16. Evidence suggests that whilst counterfeit medicines are not typically manufactured here, the UK is an intended destination for them. Counterfeit medicines found in the UK can contain a reduced amount of the active pharmaceutical ingredient, too much, or, none at all. They can contain contaminants or a different active pharmaceutical ingredient entirely. The combination of high prices for medicines, a complex supply chain and high levels of parallel imports makes the UK an attractive destination. Counterfeit medicines are also commonly available in the UK through Internet websites traditionally in the area of “lifestyle” products such as erectile dysfunction and weight loss medicines. However, the risk is not exclusively to “lifestyle” products, and seizures in recent years have involved anti-psychotics, anti platelets, statins and cancer medicines.

17. The UK has had nine known cases of counterfeit prescription only medicines reaching patients through the legal supply chain since 2004, resulting in the batches being recalled. A further four counterfeit batches were intercepted at wholesale level and one incident in which the counterfeits were intended for use as comparator medicines in a clinical trial. During one incident 32,000 packs of counterfeit heart and cancer medicines reached pharmacies and patients. Fortunately no fatalities have been attributed to counterfeit medicines in the UK.

18. It is worth noting that each year over 800 million prescriptions for medicines are written in the UK. MHRA Investigators have seized £6 million of counterfeit medicine since 2006 and the MHRA has successfully conducted five prosecutions for distributing counterfeit medicines in the past 12 months with sentences up to six years’ imprisonment. A further four cases are awaiting prosecution. Confiscation of assets proceedings are pending.

19. In November 2007 Health Minister Dawn Primarolo launched the MHRA’s Anti-Counterfeiting Strategy which features on a multi-agency, multi-stakeholder sustained programme of communication, collaboration and improved regulation. A key feature of this strategy is the thorough review of UK supply chain arrangements involving all stakeholders from the point of importation of medicines to the point of sale to the patient. The Agency is conducting a public consultation on a set of far reaching proposals. A 24 hour Counterfeit–reporting hotline has been launched and an awareness programme for the public and healthcare professionals and a market surveillance programme is underway. The MHRA also works with international initiatives to combat counterfeiting, and takes a leading role in work led by the World Health Organisation in this area.

KEY REGULATORY DEVELOPMENTS

20. The MHRA has taken a range of initiatives across its responsibilities to enhance patient safety, such as leading a strategy to enhance the safe use of medicines in children. The Agency has been a leading player in the development of a European risk management strategy to enhance the safe use of medicines across the Community and in leading the development of European legislation, research networks and information to support safe use of medicines in children.
21. As a science based organisation it is essential for the MHRA to have close links at all levels with science, research and innovation. The Agency will ensure that the regulatory framework can respond effectively to emerging new technologies to ensure that patient safety is properly addressed and secured. For example, the MHRA played an active role for the UK in the negotiations leading to agreement on the recent European Regulation on Advanced Therapy Medicinal Products, which will regulate medicinal products within the categories of gene therapy, somatic cell therapy and tissue engineered products.

22. MHRA works closely with other Agencies to ensure a joined up approach across Government, for example with DH, NICE and NPSA on the safe use of particular medicines and devices and effective reporting mechanisms.

THE MHRA IN A GLOBAL CONTEXT

23. The MHRA also has an important international role in ensuring UK public health and patient safety are protected. The MHRA has a strong history of influence within the EU and plays a leading role to help bring high UK regulatory standards to EU level and ensure that EC legislation has a positive impact on patient safety in the UK. Recently this has meant taking a leading role in the development of the European legislative proposals on counterfeiting and drug safety monitoring published on 10th December 2008.

24. The Agency plays a leading role beyond the EU and has developed a strategy for improving international cooperation. This will facilitate the exchange of information and knowledge between key regulators worldwide which has a direct effect on patient safety. And the Agency is actively working bilaterally with strategically important countries such as China and India which are home to an increasing amount of pharmaceuticals, their active ingredients and medical devices which are then imported into the UK. We aim to ensure that products developed or manufactured in those countries meet the same high standards taken for granted in the UK and that the arrangements for checking the quality and integrity of such products are sufficiently strong to protect UK patients. The MHRA also supports the introduction of harmonised standards for global pharmaceutical and device industries by contributing to the work of the International Conference on Harmonisation and the Global Harmonisation Task Force on medicines and devices respectively.

February 2009

Memorandum by the General Medical Council (PS 92)

PATIENT SAFETY

1. The General Medical Council is the independent regulator of doctors in the UK. We are independent of Government as the dominant provider of healthcare in the UK, and independent of dominance by any particular interest.

2. Our statutory purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.


OUR APPROACH TO REGULATION

4. The GMC aims to help doctors by creating a regulatory environment within which professionalism can flourish. Regulation must therefore be about more than just taking disciplinary action. As the Report of the Bristol Inquiry (2001) stated, medical regulation “involves all matters affecting the performance of the individual . . . and covers initial education, training, appraisal, continuing professional development and, where relevant, disciplinary action.”

5. We have promoted a four layer model of regulation:
   (a) Personal regulation.
   (b) Team based regulation.
   (c) Workplace regulation.
   (d) National regulation.

Personal regulation

6. Doctors must:
   (a) Regulate their own practice, which includes practising within the limits of their knowledge and skills.
   (b) Show commitment to a common set of values, conduct and relationships that underpin the trust the public has in doctors.
(c) Put patients first.
(d) Use knowledge, clinical skills and judgement to protect and restore human well-being.

**Team based regulation**

7. Team members must:
(a) Accept responsibility for the team as a whole.
(b) Accept responsibility for others in the team.
(c) Work in partnership with members of the wider healthcare team.
(d) Act when a colleague’s conduct, performance or health puts patients at risk.

**Workplace regulation**

8. The NHS and other healthcare providers must:
(a) Ensure that doctors are fit for their roles.
(b) Operate effective clinical governance.
(c) Create an organisational infrastructure to support doctors in the exercise of their professional responsibilities.
(d) Take prompt and effective action if actual or emerging impairment puts patients at risk.

**National regulation**

9. The GMC must:
(a) Control entry to the medical register; and ensure that doctors on the register are up to date and fit to practise.
(b) Set educational standards for medical schools; and coordinate all stages of medical education.
(c) Determine and promote the principles and values that underpin good practice.
(d) Take firm, fair, action to protect patients and the public interest when fitness to practise is impaired.
(e) Reinforce, promote and facilitate personal, team based and workplace based regulation.

**How the GMC exercises its role**

**Controlling entry to the medical register**

10. Doctors applying for registration in the UK are assessed against the requirements laid out in the Medical Act 1983. As part of the registration process we carry out a number of checks to validate the doctor’s identity, qualifications, fitness to practise and, where permitted under EU law, knowledge of English. This is effected through identity checks, verification of original documentation, primary source verification with universities and other regulators.

11. We have information sharing agreements in place with other regulators to obtain information about doctors who have been subject to disciplinary action. This alerts us to doctors whose applications may need to receive additional investigation or consideration before their registration is granted. The GMC also conducts the PLAB test (Professional and Linguistics Assessment Board) which demonstrates that an International Medical Graduate has reached the required standard to practise safely in the UK.

**Licensing and revalidation**

12. In autumn 2009, we will introduce licences to practise. This will represent a major step toward the introduction of revalidation.

13. Doctors will need registration with a licence:
(a) If they want to hold a position as a doctor in the NHS or independent sector, on a permanent or locum basis.
(b) If they want to write prescriptions, sign death certificates or exercise any of the other legal privileges currently reserved for registered medical practitioners.
(c) Or if their employer, those who contract their services or another party require them to hold a licence.

14. All doctors holding registration with a licence will be required to participate in revalidation, normally every five years. Revalidation will be a single process with two potential outcomes: relicensing for all licensed doctors; and recertification for doctors on the GP Register or Specialist Register.
15. The aims of revalidation are:

(a) To confirm that licensed doctors practise in accordance with the GMC’s generic standards.

(b) To confirm that doctors on the GMC’s specialist register or GP register continue to meet the standards appropriate for their specialty.

(c) As a backstop to identify for further investigation and remediation where appropriate doctors whose practice is impaired or may be impaired.

16. Revalidation will require doctors to demonstrate to the GMC, normally every five years, that they continue to practise in accordance with the standards set by the GMC and, for those on the Specialist or GP Registers, by the relevant Royal College or Faculty.

17. Revalidation will give patients a regular assurance that licensed doctors are up to date and fit to practise. It is not primarily designed to find doctors whose fitness to practise is impaired but to promote excellence in clinical practice and, through supporting the professional development of doctors, enhance patient safety.

18. In order for revalidation to succeed local clinical governance must be demonstrably effective and the lines of accountability for patient safety, particularly within primary care, need to be clear.

**Education and training**

19. The GMC works to promote patient safety by maintaining standards in education and training. The GMC’s role is to set the standards and outcomes for basic medical education at the undergraduate level, the first year of the foundation programme of post graduate training and in continuing professional development (CPD). The GMC also runs a quality assurance programme for basic medical education and with the Postgraduate Medical Education and Training Board PMETB is developing a quality assurance programme for the foundation programme.

20. Our guidance, *Tomorrow’s Doctors*, sets out the GMC’s standards for the knowledge, skills and behaviours that undergraduate medical students in the UK should learn. This includes expected competencies relating to prescribing—further information about this subject can be found in Annex 1. These standards then provide the framework that UK medical schools use to design their own detailed curricula and schemes of assessment. A revised draft version of *Tomorrow’s Doctors* was published for consultation in December 2008.

21. As endorsed by the Health Select Committee in its report on *Modernising Medical Careers*, PMETB will merge with the GMC in 2010. For the first time, the GMC will be the regulator for all stages of medical education and training.

**Determining and promoting good practice**

22. In addition to our core guidance, *Good Medical Practice*, we publish and regularly updates a range of ethical guidance for doctors. Those publications provide a benchmark for evaluating a doctor’s performance and help doctors to deal with the challenges of daily practice. Examples include guidance on consent for treatments and explaining risk to patients (revised in 2008); guidance on confidentiality and the disclosure of personal patient information which is currently being revised following extensive consultation and is due to be published in Autumn 2009; and draft guidance on end of life care which will be published for consultation in Spring 2009.

23. Patient experience and feedback is an important part of improving the quality of healthcare and improving awareness of risks to patient safety. Although our guidance is addressed to doctors, it is also intended to demonstrate to the public what standards they can expect from their doctor. We recently launched an online, interactive version of *Good Medical Practice* on our website to make our standards more accessible to patients and the public. We also aim to raise awareness of all new guidance as widely as possible once it is published.

**Taking firm, fair action to protect patients**

24. Our fitness to practise procedures make a significant contribution to safeguarding patient safety. The most serious complaints against doctors are referred to fitness to practise hearing.

25. Our interim orders powers allow us to act quickly to suspend or restrict a doctor’s right to practise while our investigations continue.

26. Fitness to practise panels can erase a doctor from the register, suspend registration or impose conditions on registration.
27. The purpose of our fitness to practise procedures is to consider whether action needs to be taken to protect the public interest for the future, by removal or restriction of a doctor’s right to practise. The purpose is not in order to punish doctors or to provide redress for complainants. Where appropriate, in cases that do not require GMC action on registration, we redirect the complaint or enquiry to the NHS or other healthcare provider.

28. In 2008 we launched Patient’s Help, an online information resource aimed at educating the public and advice organisations. It shows the public how and where to lodge a complaint about a doctor and includes an interactive map for local advice centres across the UK. Typically, we receive around 5,000 complaints a year, most of which are suitable for local resolution. The aim of the online information resource is to help the public direct their complaint to the correct place so it can be dealt with more quickly and effectively.

Reinforcing, promoting and facilitating personal, team based and workplace based regulation

29. The Government’s proposals for the establishment of a network of ‘Responsible Officers’ were incorporated in the Health and Social Care Act 2008. Responsible Officers will be a senior doctor within a healthcare organisation with specific and personal responsibility for those aspects of clinical governance linking to medical revalidation and to the conduct and performance of doctors working in or for the organisation.

30. The four layer model highlights the importance of effective local clinical governance. The Government’s White Paper Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century set out proposals for a network of local GMC Affiliates. Last autumn the GMC launched two year-long pilots, in London and West Yorkshire to study the role of GMC Affiliates. The pilots aim to establish whether the appointment of medical and lay Affiliates at regional level will help to link up national and local regulation and provide faster, more effective resolution of complaints and concerns about doctors in England.

31. The GMC has signed a Memorandum of understanding, information sharing agreement, with a wide range of organisations to help us work together effectively and efficiently to protect, promote, and maintain the health and safety of the public. Typically they commit the GMC and the partner body to the sharing of information and cross-referral of concerns. Organisations with whom we work in this way include the Crown Prosecution Service, Nursing and Midwifery Council, Healthcare Commission, Health and Safety Executive, National Clinical Assessment Service and NHS Quality Improvement Scotland.

Conclusion

32. We approach to regulation is based on the fostering of professionalism and the support of doctors at every stage of their careers. We believe that greater professionalism will encourage support high quality healthcare and contribute to continuous improvement in patient safety.

33. We will continue to work with the health departments in all four countries of the UK, with the NHS and other healthcare providers, with medical schools and medical Royal Colleges, with system regulators, and with the medical profession to enhance patient safety.

February 2009

Annex 1

PRESCRIBING AND TOMORROW’S DOCTORS

1. In his oral evidence to the Committee on 22 January 2009 Professor David Webb suggested that UK graduates are not well prepared for prescribing, due to a perceived decline in the teaching of pharmacology in medical schools.

2. To ensure that concerns about prescribing are understood and addressed by medical schools, the GMC supported the establishment by the Medical Schools Council of the Safe Prescribing Working Group, chaired by Professor Robert Lechler, which included Professor Webb. The Working Group produced a Statement of competencies in relation to prescribing required by all Foundation doctors.

3. The GMC is consulting on the draft of a third edition of Tomorrow’s Doctors, our standards for undergraduate medical education. As Professor Webb told the Committee, this consultation draft “enshrines” the competencies drawn up by the Safe Prescribing Working Group. It also reflects the conclusions of research commissioned by the GMC into the skills of UK medical graduates.

4. The Tomorrow’s Doctors consultation draft states that graduates must be able to:

   “Prescribe drugs safely, effectively and economically.
   (a) Establish an accurate drug history, covering both prescribed and other medication.
   (b) Plan appropriate drug therapy for common indications, including pain and distress.
   (c) Provide a safe and legal prescription.
   (d) Calculate appropriate drug doses and record the outcome accurately.
   (e) Provide patients with appropriate information about their medicines.
(f) Access reliable information about medicines.

(g) Detect and report adverse drug reactions.

(h) Demonstrate awareness that many patients use complementary and alternative therapies, and awareness of the existence and range of these therapies, why patients use them, and how this might affect other types of treatment that patients are receiving.”

5. The draft also addresses the issue of therapeutics, specifically that graduates must:

“Demonstrate knowledge of drug actions and pharmacokinetics, drug side effects and interactions including effects on the population, such as the spread of antibiotic resistance.”

6. The standards enshrined in Tomorrow’s Doctors are those required at a key transition in the continuum of medical education and training. It sets outcomes required for graduation and for a doctor to begin the two year Foundation Programme. The Foundation Programme curriculum states:

“The Foundation Programme is designed to bridge the gap between undergraduate and specialist medical training. It builds on undergraduate training to allow foundation doctors to demonstrate performance in the workplace rather than competence in isolated test situations”.

7. All Foundation Programme doctors must work in approved practice settings that include a framework of clinical governance and provision for appropriate supervision and appraisal arrangements. This management context allows graduates to develop their clinical skills without compromising patient safety.

Supplementary memorandum by the General Medical Council (PS 92A)

PATIENT SAFETY INQUIRY ORAL EVIDENCE SESSION 5 MARCH 2009

I thought it might be helpful to provide some additional information following the GMC’s oral evidence session on 5 March.

Medical education

We contacted Dr Olga Kostopoulou following her evidence to the Select Committee to ensure we fully understood her concerns relating to formal medical education in diagnosis. She has provided a most helpful response and we will bring this to the attention to the Medical Schools Council. We are also considering how her comments can be reflected in the new version of Tomorrow’s Doctors, the GMC’s guidance for undergraduate medical education.

Stream 2 complaints procedures

In response to Q697 from Mrs Sandra Gidley and Q702 and Q703 from Dr Naysmith I referred to the GMC’s follow-up to Stream 2 cases. I thought I would provide the following statistics and explanation regarding the triaging of inquiries to the GMC.

The GMC received a total of 5,212 inquiries last year. Of these 1,485 raised potential questions about a doctor’s fitness to practise and as a result were investigated under our Stream 1 procedures. 1,673 were unlikely to require us to take formal action against the doctor and therefore were dealt with under Stream 2 procedures. The remaining 2,054 cases were not investigated because they are beyond the GMC’s remit and did not raise patient safety concerns. For example they could relate to a doctor’s immigration status, a minor motoring offence or systemic failures. In such cases we would recommend to the complainant that they contact the relevant body to deal with their concerns.

While we do not actively investigate cases under Stream 2 procedures ourselves, and do not have the authority to compel an employer to investigate a complaint the purpose of Stream 2 is to seek reassurance from a doctor’s employer to ensure that there are no wider concerns about the doctor’s fitness to practise. We only conclude a Stream 2 enquiry once we have assurance from the employer that there are no matters which the GMC should be made aware of or should investigate.

In cases where a doctor is employed as a locum or entirely in a private capacity we will contact each of the doctor’s employers for details of any previous complaints, before we decide whether we should carry out any further investigation.

Consensual disposal

I would also like to add to the points I made in response to Q697 from Mrs Gidley regarding a “fair blame” culture.
The White Paper *Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century* acknowledged that regulatory processes should not only protect patients but also have built-in mechanisms to help health professionals retain or regain their fitness to practise status when that is an appropriate and proportionate course of action. Rather than refer a doctor to a fitness to practice hearing, the GMC may, in appropriate cases, accept undertakings from the doctor if they believe that those undertakings will protect the public interest. This is known as consensual disposal. Undertakings may involve restrictions on scope of practice or require the doctor to undergo remediation or training.

The GMC is confident that it can extend consensual disposal without risk to patient safety and we believe it could contribute towards creating an environment where doctors are encouraged to recognise, accept and address deficiencies in their own practice or that of a team member. The GMC is currently consulting on expanding the category of cases which can be concluded at the Investigation Stage by consensual disposal. The consultation closes on 19 August 2009.

Finlay Scott TD  
Chief Executive and Registrar  
11 June 2009

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**Memorandum by Dr Peter Greengross (PS 93)**

**PATIENT SAFETY**

**EXECUTIVE SUMMARY**

1. This submission focuses on a major and relatively hidden patient safety issue: the care of deteriorating hospital patients. Very large numbers of inpatients die or suffer harm each year because clinicians fail to recognise that their condition is deteriorating, leading to avoidable delays in resuscitation: 40,000 deaths, 23,000 preventable cardiac arrests and 20,000 admissions to intensive care each year are thought to be preventable.\(^{170, 171}\)

2. The problem and underlying reasons are well reported in the medical literature although the issue has not grabbed the attention of the general media as much as other less significant safety issues.

3. Current “track and trigger” systems intended to improve the care of deteriorating patients (as promoted by the National Confidential Enquiry into Patient Outcomes and Death, the National Patient Safety Agency and the National Institute for Health and Clinical Excellence) are important mechanisms for improving standards but do not address the underlying system failures. These include:
   
   (a) failure to accurately and completely monitor patients in a timely fashion;  
   (b) errors in calculating Early Warning Scores (EWS) that quantify risk of death;  
   (c) insensitive and non-specific EWS systems that fail to identify who is actually sick;  
   (d) failure by nurses to escalate care; and  
   (e) failure by doctors to respond when called.

4. The National Programme for IT, irrespective of other problems with its implementation, does not include provision for real-time, point-of-care data capture, analytics and decision support to address these issues.

5. We believe that the NHS should address the lack of real-time data available in healthcare settings. It should ensure that there are proper systems in place to identify and escalate the care of acutely ill patients. Such systems should be universal and independent of personal decision making. They should be monitored on a regular and ongoing basis to allow comparison within and between hospitals. The data generated should be used as a key quality and safety indicator and as triggers for quality-related payments under the Commissioning for Quality and Innovation (CQUIN) scheme.

**INTRODUCTION**

6. We are pleased to submit this response for consideration by the Health Select Committee as part of its inquiry into patient safety. This response addresses, in particular, the following areas that the Committee is focusing on:

   1. Risks to patient safety, particularly the role of human error and poor clinical judgement and systems failure.

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2. The adequacy of current measurement and assessment.

3. What the NHS should do next—especially how to ensure learning is implemented, what should be measured and assessed and what data should be published.

**RISKS TO PATIENT SAFETY**

7. The evidence presented here relates to the management of the deteriorating hospital patient. This is an area of clinical practice that, although being addressed by a growing number of bodies including the National Institute for Health and Clinical Excellence (NICE), the National Confidential Enquiry into Patient Outcomes and Death (NCEPOD), the National Patient Safety Agency (NPSA) and the Royal College of Physicians (RCP), has yet to gain the same public profile as other widely reported safety concerns such as Hospital-Acquired Infection, Safe Side Surgery or blood transfusion. However, the problem is arguably much larger and relates directly to fundamental aspects of patient care.

8. The scale of the problem is huge: 40,000 people are estimated to die for avoidable reasons every year, 23,000 people each year suffer potentially preventable cardiac arrests and 20,000 admissions to intensive care are thought to be unnecessary\(^{172, 173}\). Over half of patients on ICU are estimated to have received sub-optimal care prior to admission and two-thirds of such patients are consequently admitted later than they should have been.\(^{174}\)

9. Abnormalities in key vital signs occur before 79% of in-hospital cardiac arrests, and before 54% of in-hospital deaths and emergency ICU admissions\(^{172}\) suggesting that it is eminently feasible to recognise these patients earlier and institute suitable resuscitation measures to prevent further deterioration and/or death. Overall, patients with abnormal vital signs have 90-day mortality rates of 20% compared with 1.6% for all hospital patients.\(^{175}\)

10. However, it is well known that there are systematic problems with the routine monitoring and management of acutely ill patients. In summary, these are as follows:

   (a) Vital sign observations, the key to assessing how sick someone is, are often done as a batch process (ie: the interval between observations does not reflect how sick the patient is).

   (b) They are often delegated to the most junior and inexperienced staff (Health Care Assistants—HCAs). The National Patient Safety Agency has reported that, in 31% of 119 cases where patients died or had poor outcomes, staff failed to take a complete set of observations or did not record them.\(^{176}\) For example, the best predictor of risk is respiratory rate but this is the sign most commonly not recorded. In our experience, the proportion of observations that are complete is somewhat lower, particularly if examining observation charts for a fully documented, dated and signed set of observations along with a correctly calculated risk assessment.

   (c) HCAs and nurses make many errors when calculating Early Warning Scores (EWS). These algorithms provide a measure of risk of deterioration and are used to trigger more aggressive care. They are based on allocating scores to a number of key vital signs, higher scores reflecting greater variations from normal values. Studies have shown overall error rates of 25—50% when calculating EWS manually,\(^{177, 178}\) increasing to 80% for the sickest patients. Of particular concern is that the errors tend to score individuals as less sick than they actually are, delaying escalation of appropriate care.

   (d) In 46% of cases with poor outcomes that have been studied, ward staff failed to recognise the importance of worsening vital signs\(^{176}\) or to escalate care promptly to senior colleagues through ignorance\(^{179}\) or lack of confidence.\(^{180}\)

   (e) Doctors and others failed to respond promptly in 20% of studied cases.\(^{176}\)


The Adequacy of Current Measurement and Assessment

11. Guidance published by the National Institute for Health and Clinical Excellence in 2007 requires hospitals to have effective “track and trigger” systems in place, or provide an explanation for non-compliance.\(^{181}\)

12. In particular, NICE requires that:

   (a) Adult patients should have vital signs recorded on admission or first assessment.
   
   (b) Observations should be repeated regularly, at least 12 hourly for the least sick patients and more frequently for others.
   
   (c) Track and trigger systems should be used to monitor progress and escalate care, and should be dynamic so that the frequency of observations reflects each patient’s level of sickness.
   
   (d) The track and trigger system should generate graded responses of escalated care so that patients receive care from staff with appropriate levels of training, experience and skills.

13. Track and trigger systems have been introduced into many hospitals but, as described earlier, there is evidence that compliance with the systems is poor. If such systems are not delivered to a consistently high standard throughout a patient’s admission (and indeed prior to admission and after discharge), the skills and experience of the wider clinical team, and the tools they employ for diagnosis and treatment, are severely compromised. Indeed, this may be why there is only minimal evidence that Emergency Medical and Critical Care Outreach teams improve outcomes for sick patients.\(^{182, 183, 184}\)

14. A particular issue is a lack of accurate, reliable and real-time information to enable clinical teams to provide excellent care and to review cases where care has been sub-standard. In many high-risk industries, it is taken for granted that there are real-time feedback loops so that if a system is moving out of control, operators can adjust the system and return it to normal. This requires mechanisms for accurate data capture, instant submission and review, and a control system to make changes.

15. Hospitals rely largely on coded hospital discharge records to analyse healthcare processes and outcomes. These records are primarily used as “pay records” to determine hospital income and are available for analysis at best three months after the patient is discharged. However the quality of coding is poor and it is extremely difficult if not impossible to drill-down from the high-level data captured to examine individual episodes of patient care.

16. A further issue is the discriminatory power of the Early Warning Scores used in hospitals to identify deteriorating and high risk patients. There are about 30 similar Early Warning Score systems in use across the UK but little consistency regarding which physiological components are included nor how these are weighted. The performance of most is poor when used to discriminate between patients. Clearly this means that, even if other system errors in caring for deteriorating patients were rectified, there would remain a fundamental problem with initial identification.

17. The Royal College of Physicians has proposed developing a National EWS but the driver has mostly been to ensure that doctors and nurses moving between hospitals are familiar with a single system rather than addressing its validity per se.

What the NHS Should Do Next

18. Routine monitoring and timely escalation of care for hospital patients is such a basic, fundamental element of care that it is rather overlooked. As an indicator of high quality and safe care, it ranks alongside basic standards such as privacy, dignity, cleanliness and hygiene that should be guaranteed whenever a patient encounters a health professional. Indeed, its very ubiquity across all health care settings, medical specialties, procedures and diagnoses means that it is a potentially powerful means of comparing quality and safety across institutions, wards and clinical teams.

19. Furthermore, we would suggest that the concept of routinely measuring how well these aspects of care are delivered is easily understood (if not demanded) by and resonates with the public and patients and would form a suitable set of indicators for the newly proposed Quality Accounts and to trigger hospital payments under the Commissioning for Quality and Innovation scheme.

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20. However, such developments require that hospitals and other organisations have an effective and reliable means of capturing data on their performance as well as providing better and more timely care. Over the past four years The Learning Clinic has developed such a system, VitalPAC, that uses handheld personal computers (Personal Digital Assistants—PDAs) to capture vital signs data and upload it wirelessly to the patient’s record. VitalPAC supports best clinical practice and improves standards of care because it:

(a) Guides nurses through a series of easy to use data entry screens so ensuring that a complete set of observations are recorded.
(b) Generates alerts to highlight a deterioration in patient condition, risk of infection, oxygen dependency and when the next set of observations are due.
(c) Automatically and immediately calculates the patient’s Early Warning Score (EWS) in accordance with hospital protocol.
(d) Provides advice to the nurse on whether to ask for senior colleagues’ support and how soon to repeat the observations.
(e) Ensures that colleagues respond in a timely fashion, and generates calls for more senior support if this doesn’t occur.
(f) Maintains a comprehensive, real-time audit trail of system usage, data entry, patient condition and staff usage so providing a detailed picture of compliance for operational management and performance improvement.

21. VitalPAC allows hospitals to remove paper charts and other documents by capturing and displaying information electronically, clearly and accurately. Clinical staff can review observation charts and other reports including patient lists and bed locations, Early Warning Scores, alerts and test results on the PDA itself, on tablet PCs and on the hospital intranet.

22. Doctors and nursing teams that work hospital-wide have access to patient information anywhere in the hospital. Outreach and pain teams, for example, carry their own PDAs so that they can pro-actively identify and monitor higher risk patients without depending on ward staff to initiate their input.

23. VitalPAC is localised for each Trust to ensure that practice conforms with local protocols. For example, we adopt the hospital’s local EWS system and alert thresholds. However, we have worked with research partners to develop a much more powerful and discriminating EWS algorithm. This is currently being validated using VitalPAC’s database of more than 2 million sets of observations. Compared with existing Early Warning Scores the discriminatory power is significantly better (C-statistic greater than 0.9 compared with average 0.7).

24. VitalPAC is largely intuitive. That means that it takes only 10 minutes or so for nursing and other staff to learn how to operate and use the system. This confers considerable safety benefits for hospitals that employ large numbers of Agency Nurses. Such nurses may not understand the hospital’s protocols, nor who to escalate care to, if a patient’s condition worsens, however technically competent they may be. VitalPAC allows such staff to get up to speed rapidly, with the assurance that they will operate to the hospital’s standards and protocols.

25. In addition, VitalPAC’s continuous and ongoing reinforcement of hospital protocol means that it is a learning tool in its own right. It has been described by one Critical Care Outreach Nurse as being like “an outreach nurse on the shoulder of every ward nurse”, providing general staff with prompts and guidance on best practice, routinely, as part of their everyday job.

26. VitalPAC improves care significantly. Key benefits include:

(a) Complete, accurate, timely and fully auditable observations, 24 hours per day.
(b) Observations tailored to patient need.
(c) Prompt and appropriate escalation of care in accordance with local hospital protocol.
(d) Almost complete compliance with screening protocols for MRSA and C Diff and achievement of very high levels of prophylaxis of venous thromboembolism (blood clots in the legs that can dislodge and severely affect breathing).
(e) Pro-active monitoring and intervention by medical and other ambulatory staff (outreach, pain teams etc).
(f) Based on extrapolation from published studies, and according to anecdotal reports from sites that are using VitalPAC, likely reductions in length of stay, cardiac arrest rates and Intensive Care Unit burden (eg: volume or acuity of admissions).
(g) Improved communications, better use of (and possible cost savings from) nursing time, high levels of staff satisfaction.
(h) More sophisticated performance management and improvement, generation of reliable and innovative datasets for Quality Accounts, Commissioning for Quality and Innovation (CQUIN) payments and claims management (CNST premiums).
27. We believe that the VitalPAC system has huge potential to improve patient care and reduce risk. We are exploring the potential to develop the system to work in pre-hospital, community and mental health settings. The unique database of vital signs that we have collected provides extensive opportunities for research which we are discussing with academic partners. For example, we are interested in developing more dynamic Early Warning Score systems that are case-mix adjusted or reflect trends and rate of change of vital signs. We also wish to investigate the potential for admission avoidance or earlier discharge of patients based on profiling their physiological, biochemical and haematological status. We believe that such investigations offer the prospect of significantly furthering understanding of risk and how to apply those findings in real world situations.

Dr Peter Greengross MA MSc MBA FRCS FPH
Medical Director
The Learning Clinic
March 2009

Memorandum by the Joint Epilepsy Council (PS 94)

PATIENT SAFETY

1. The Joint Epilepsy Council (JEC) is the umbrella body for 26 epilepsy organisations operating in the UK and Ireland. The JEC also provide the secretariat to the APPG on Epilepsy.

2. Epilepsy is a common serious neurological condition characterised by recurrent, unprovoked epileptic seizures, controlled for many, but not cured, with anti-epileptic drugs (AEDs). Surgery works in some cases but is rarely available. Epilepsy affects almost half a million people in the UK, that is one in every 131 or 705 in an average constituency.

WHAT THE RISKS TO PATIENT SAFETY ARE AND TO WHAT EXTENT THEY ARE AVOIDABLE, INCLUDING

Role of human error and poor clinical judgement

3. People with epilepsy experience the effects of poor clinical judgement in a shockingly high level of misdiagnosis. Incorrect diagnosis leads to ongoing seizures and incorrect treatment, often lasting for many years. NICE quotes misdiagnosis rates of between 20 and 31%. The medical cost alone of misdiagnosis and mistreatment is estimated at around £22 million. The full economic cost is about £134 million a year.

4. There are a serious lack of epilepsy specialists and no sign of their numbers increasing significantly. Commissioners need to create services that enable clinicians to follow the NICE clinical guideline of 2004. Widespread evidence of the failure to implement the NICE guidelines was published by Epilepsy Action (EA) in January 2009. It is available in full at www.epilepsy.org.uk/timeforchange

5. 990 people in England die every year of epilepsy related causes. About 365 of those deaths are young adults and children. Of the total number of deaths about 400 per year are avoidable. A shameful 59% of childhood deaths are considered avoidable.

6. These avoidable deaths are often as a result of the poor clinical judgement of non-specialists. The failure to implement the NICE guidelines has resulted in a continued shortfall of epilepsy specialists and the consequent difficulties of access by patients to specialists.

7. The JEC believes that in view of the numbers affected, the seriousness of the effects and the cost savings achievable, there is a strong case for a specific review of epilepsy services.

SYSTEMS FAILURES

8. The provision of services for people with epilepsy fails at all levels. In primary care, only basic care is measured in the QOF. There are far too few epilepsy specialist nurses (ESNs). Many are qualified but few posts exist. In secondary care, access delays to the too few specialists exceed targets by far. In tertiary care, patients who should be referred are often not. For a full discussion of the issues see Wasted Money, Wasted Lives published by the APPG on Epilepsy in June 2007. The Report contained 30 recommendations and is available in full at www.jointepilepsycouncil.org.uk/inquiry.asp

9. The NICE clinical guideline requires preconception counselling (PCC) for women of child-bearing age. The guideline is widely ignored. The level of PCC is estimated by the EA Ideal World Survey at 21% of women with epilepsy aged 16-44. This figure was 25% in 2002. The Organisation for Anti-Convulsant Syndrome (OACS) reports that only 20% of women in their organisation received PCC.

10. OACS estimate that the total number of children with Foetal Anti-Convulsant Syndrome (FACS) born in the UK could be as high as 38,000. OACS further reports that the risk of malformations stood at 9% in 1995 for children of mothers taking anti-epileptic drugs (AEDs) and that this risk went up to 11% in 2000 and again to 17% in 2007.
11. The term Sudden Unexpected Death in Epilepsy (SUDEP) is used when there is no clear explanation for the death. The group most at risk are young people between 20 and 40 years who are not seizure-free. SUDEP accounts for at least 500 deaths per year, greater than the total of cot deaths and Aids related deaths together. These 500 deaths equate to 22,500 lost years annually.

12. Patients and their families commonly receive no information at all about the possibility of SUDEP or the management of its risk. NICE Guidelines recommend that health professionals tailor discussions about risk and SUDEP with their patients, but clinicians appear to remain reluctant to tell patients about SUDEP.

13. Although the failure to provide PCC or information about SUDEP are more examples of the failure to implement the NICE clinical guideline, we submit that these failures go further than that. Does it need a guideline for clinicians to know that they need to advise women of the extremely serious effects their AEDs can have on their unborn child and to advise patients about the risk of SUDEP and its management? As a matter of urgency, PCC should be made available to all relevant women and all relevant patients should be advised of the risk of SUDEP.

14. Only paramedics or more qualified staff are able to give emergency medication to stop status epilepticus, a condition that can result in long term brain damage or death. Often the key drug (diazepam) is not carried on the ambulance. Treatment is then reliant on the patient having medication at hand and a carer present to direct staff to it. Ambulance staff able to administer emergency epilepsy drugs are not present on all ambulance calls.

**How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare**

15. The consistency of supply of anti-epileptic drugs (AEDs) is a major issue where application of the precautionary principle would have significant benefits. The regular switching to and from different versions of AEDs may cause breakthrough seizures, increases in seizure frequency and severity and different or worse side-effects. These effects can be caused by small differences at the manufacturing stage. There appears to be a reluctance and even a refusal to recognise the issue owing to the economic pressure to impose generic prescribing without recognising epilepsy as an exception. NICE guidelines are not being followed. The NHS should recognise epilepsy as an exception to general guidelines for drug switching and generic prescribing, encourage greater use of the patient yellow card system and apply NICE guidelines.

**The role of public perceptions of risk in determining NHS policy**

16. Certainly the political, media and public profile of different conditions appears to have an effect on decisions. Government appears to say it’s all down to local decision-making—except when they decide to intervene on behalf of autism, dementia, diabetes, etc. Epilepsy kills about three people a day and one of these deaths is considered “avoidable”. The poor level of services is also responsible for much morbidity and other challenges. The case is laid out in full in Wasted Money, Wasted Lives and elsewhere. Relevant Minister Ann Keen agrees “that much more needs to be done”.

**Current Effectiveness in Ensuring Patient Safety**

17. We do not believe that any provider of NHS services for patients with epilepsy currently offers a safe service for people with epilepsy with the exception of a very few centres of excellence. At the very least, a reasonable minimum standard needs to apply across the country. The thrust towards more local commissioning does not assist conditions such as epilepsy, where low volume on a local scale leads to a low priority.

18. In the case of epilepsy, adequate measurement and assessment is not undertaken and acted upon. It has taken the action of voluntary bodies not, for instance, the Healthcare Commission, to expose failures including the failure to implement NICE clinical guidelines.

19. According to the Department of Health Workforce Issues Discussion paper of 2006, there is a shortage of medical care staff with training and expertise in epilepsy. The National Statement of Good Practice recommends that epilepsy care staff should have a recognised qualification in epilepsy.

20. A survey of geriatricians, carried out by EA in 2005, found that 84% of geriatricians that see between one and 20 patients aged 60 and over with epilepsy each month, have never been on an epilepsy-related course.

21. To improve education for healthcare professionals, the JEC recommends that Government fund or set up relevant Continuing Professional Development (CPD) modules for health professionals validated by the Royal Colleges, that there should be a register of primary care CPD within each PCT to ensure coverage of all key conditions and that Government should ensure that key information about epilepsy—and other conditions—including the pertinent points from the NICE guidelines, is available to all health professionals at the click of a button.
22. NICE clinical guidelines are in effect a determination of best practice. They do not need to be made mandatory in order to encourage their implementation. The argument that NICE should not interfere with the freedom of clinicians to use their best judgement is largely a red herring. It is not problems with clinical judgement that has led to non-implementation, it is problems with the failure to commission appropriate services. Currently, clinicians are unable to choose to follow the guidelines because the service is simply not available. There should be a duty upon commissioners to provide resources to enable clinicians to implement, the NICE guidelines.

**WHAT THE NHS SHOULD DO**

The NHS should encourage the spread of best practice by imposing a duty on commissioners to provide the services that would enable clinicians to follow NICE guidelines.

- The NHS should take steps to ensure that provision for low volume conditions is not adversely affected by local commissioning of services.
- The NHS should take immediate steps to ensure the provision of appropriate advice re SUDEP and PCC. The NHS should take urgent steps to increase the numbers of ESNs and epilepsy specialists.
- The NHS should take urgent steps to ensure that all those responsible for the care of people with epilepsy should at minimum attend an appropriate CPD course.
- The NHS should take immediate steps to recognise epilepsy as a condition not suitable for drug brand switching.
- The NHS should ensure that diazepam and staff qualified to administer it to those in status epilepticus are available for all relevant journeys.

*March 2009*

**Appendix**

Extracts from the speech by Minister Ann Keen MP in reply to the Adjournment Debate obtained by Chris McCafferty MP on 17 July 2007, the month following publication of *Wasted Money, Wasted Lives*:

> “I want to mention the importance of the all-party group’s report. I have read it in detail and have been astonished by some of the findings . . . I will give . . . a commitment to seriously consider the recommendations and I accept the invitation to attend the all-party group, with which I look forward to working… Clearly, people with epilepsy need and deserve better services . . .

. . . Undoubtedly, we will have to look at different levels of training and monitor what happens to patients who present to their GP and how we follow up those cases.

. . . I know of the often-voiced concern that without targets or dedicated funding there is neither the power nor the incentive to force through improvements. National standards will always be necessary to protect people against inequalities in service provision . . .

. . . although to devolve responsibility might be a comfortable solution, we cannot walk away. Leadership should come at a national and local level, and I give my assurances that I shall monitor that leadership to ensure that we make that progress.

. . . Specialist nurses must be brought to the forefront . . . we support maximising the use of the specialised skills of specialist nurses. Indeed, we are proud that the UK leads the world in the development of specialist nursing roles . . . we want to ensure that local health economies are encouraged to utilise fully the skills and experience of specialist nurses.

. . . Having enough staff with the right skills and experience . . . is key to implementing the national service framework for long-term conditions. The national service framework is now our key delivery mechanism for improving services for people with neurological conditions . . . Successful implementation of the national service framework is of vital importance to us.

. . . I believe that the (number of neurologists) is 437. So we have areas to look at concerning the number of neurologists.

. . . Yes, there are problems and yes, the case for improving the quality of services overall is compelling . . .

. . . Through the national service framework, NICE guidance and the epilepsy action plan we have set out very clearly what the expectations are for the pattern of services for people with epilepsy.
. . . We take the findings of the APPG’s report seriously. . . We share the desire . . . for people living with epilepsy to receive the services that they need and deserve. I assure her that the Government will continue to provide support and leadership to the health service to ensure that that happens. Leadership locally, which my hon. Friend has shown, can perhaps encourage us all to deliver leadership throughout the health service.”

Memorandum by Astellas Pharma Ltd (PS 95)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. This submission addresses patient safety specifically in relation to Prograf® and Advagraf®, two immunosuppressant therapies used in post-transplant care, developed by Astellas Pharma.

2. Astellas is a leading pharmaceutical company focused on four key therapy areas: Transplantation, Urology, Dermatology, and Anti-Infectives. In transplantation we have two immunosuppressants products, Prograf (tacrolimus) and Advagraf (tacrolimus prolonged release) used to prevent organ rejection.

3. Prograf and Advagraf both contain the active ingredient tacrolimus and both have a narrow therapeutic index, they are not freely interchangeable. In transplantation, changes in the exposure of immunosuppressant drugs such as Prograf and ADV AGRAF can increase the chances of adverse clinical consequences such as graft rejection or nephrotoxicity. This instability of dosing can lead to reduced survival of the transplanted organ.

4. This issue needs to be brought to the attention of healthcare professionals, pharmacists and patients through national guidelines to ensure these errors do not continue to occur.

QUESTION 1

What the risks are to patient safety are and to what extent they are avoidable

As of 10 December there have been 55 medication errors, largely in the UK, in prescribing, dispensing and administering Prograf and Advagraf. These errors have in some cases resulted in patients being dosed incorrectly, and have led to serious adverse reactions, including biopsy-confirmed acute rejection of transplanted organs, or other side-effects which could be a consequence of either under exposure or over exposure to tacrolimus. Four serious cases have been reported to the manufacturer.185

Decreasing the risk of unplanned switching requires clear communications to prescribing clinicians, pharmacists and patients, through government and/or government agency endorsed guidelines.

The cost to patients’ quality of life and the financial costs are significant if the immunosuppressant regime is not accurate. A successful kidney transplant allows for near-normal quality of life, with the cost of immunosuppressants approximately £5,000 per year. A rejected kidney impacts severely on the quality of a patient’s life. The patient may face re-hospitalisation, the loss of the organ, a return to dialysis at a cost of around £30,000 per year, and the need for re-transplantation. The implications in liver, heart and lung transplantation are potentially even more serious with no alternative treatments available.

QUESTION 2

What is the current effectiveness of local and regional NHS bodies in ensuring patient safety

Astellas are not able to comment on the majority of local and regional NHS bodies systems for ensuring patient safety, however we can give two excellent examples of Trusts leading the way in their guidelines for the care of post-transplant patients.

Greater Manchester Interface Prescribing Group, include the following statement in their Shared Care Guidelines for Immunosuppression after Kidney Transplantation:186

PARAGRAPH 4.2 OF THE SHARED CARE GUIDELINES FOR IMMUNOSUPPRESSION AFTER KIDNEY TRANSPLANTATION

Treatment Regimen

Even where available, patients should never be prescribed generic formulations of any of the above*. This is because of varying bioavailability and pharmacokinetics that may compromise their transplant. In the primary care setting prescribing should be by brand name to reduce the risk of generic substitution. (Greater Manchester Interface Prescribing Group)

* included immunosuppressant tacrolimus (Prograf®)

185 MHRA Drug Safety Update, Volume 2, Issue 6, January 2009
Brighton and Hove City NHS Teaching Primary Care Trust noted in their January 2009 edition of City Scripts\textsuperscript{187} the following:

Action: In order to reduce the risk of serious ADRs such as graft rejections, Prescribers are reminded to prescribe tacrolimus by brand name (by reference to hospital letters) and ensure that the frequency is written on the prescriptions as a double check for the dispensing Pharmacist.

**QUESTION 3**

*What the NHS should do next regarding patient safety*

A national guideline is required for prescription and dispensing of narrow therapeutic index immunosuppressant therapy in post-transplant care from the Department of Health or an appropriate Government Agency, in this case the lead agency is the MHRA, which strongly encourages prescription by product name rather than by the generic/ingredient name in this case. This would minimise this unnecessary risk to patient safety, which is currently resulting in prescribing and dispensing errors with serious implications for patient outcomes.

The precedent to ensure careful prescribing by brand has already been set in transplantation with Neoral\textsuperscript{®} (ciclosporin) which has the following stated in the British National Formulary (BNF):

*Because of differences in bioavailability, the brand of oral ciclosporin to be dispensed should be specified by the prescriber*\textsuperscript{188}

In order to minimise the risk of prescribing and dispensing errors with Prograf and Advagraf the following insertion into the BNF and also importantly prescribing and dispensing computer systems is suggested:

*Because of differences in bioavailability, the brand of tacrolimus immediate release (Prograf\textsuperscript{®}) or tacrolimus prolonged release (Advagraf\textsuperscript{®}) to be dispensed should be specified by the prescriber*

The current issue of inadvertent switching between Prograf and Advagraf, and the narrow therapeutic indexes of some immunosuppressant therapies, is a problem likely to be compounded following the expected introduction of the implementation of the prescription pricing regulatory scheme (PPRS) generic substitution in Primary Care from January 2010. The Royal Pharmaceutical Society of Great Britain commented in November 2008 that there needs to be clear guidance for prescribers and pharmacists on when it is appropriate to have generic substitution and patients must be provided with relevant advice and reassurance from their pharmacist.\textsuperscript{189} In this case we would suggest that both Prograf and Advagraf are exempt from this substitution.

**SUMMARY OF SUGGESTIONS FOR RISK MINIMISATION FOR PROGRAF AND ADVAGRAF**

1. Statement inserted into BNF, Dictionary of Medicines and Devices, prescribing and dispensing computer systems as follows:

   *Because of differences in bioavailability, the brand of tacrolimus immediate release (Prograf\textsuperscript{®}) or tacrolimus prolonged release (Advagraf\textsuperscript{®}) to be dispensed should be specified by the prescriber*

2. Prograf and Advagraf exemption from PPRS generic substitution in Primary Care from 2010

March 2009

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**Memorandum by Dr Helen Hogan (PS 96)**

**PATIENT SAFETY**

1. *What are the risks to patient safety and to what extent are they avoidable?*

   1.1 Patient safety is a broad topic with many facets but a particularly contentious issue has been the number of deaths associated with adverse events. Incidents such as the death of 18 year old Wayne Jowett in Nottingham following the inadvertent intrathecal injection of a chemotherapy agent and concerns about healthcare acquired infections such as MRSA and C. difficile have highlighted the issue in the public eye.

   1.2 The Institute of Medicine Report “To Err is Human”\textsuperscript{190} estimated, from extrapolation of retrospective case note review studies, that 44,000–98,000 people die annually in the US due to medical errors, but controversy surrounds this estimate.

   1.3 Currently, within the NHS, there are limited data on the scope and scale of harm occurring in patients as a result of adverse events occurring during healthcare.

\textsuperscript{187} Brighton and Hove City NHS Teaching Primary Care Trust, City Scripts, January 2009  
\textsuperscript{188} British National Formulary 56. September 2008  
1.4 Estimates of the number of patients dying each year as a result of unsafe practices are mainly based on extrapolation of findings from international studies which examined samples of patient case records. This practice has led to widely quoted estimates of 25,000–40,000 UK deaths in adults per year caused by adverse events. The validity of these figures has been questioned.

1.5 The case note review studies have often had only a small number of deaths in their samples resulting in uncertainty about the estimates.

1.6 Around 25,000 serious untoward incidents are reported annually to the NPSA National Reporting and Learning System (NRLS). Levels of information accompanying these reports is often too limited to identify the process failures that lie behind and to what degree these events are avoidable.

1.7 In 2006, the Public Accounts Committee concluded that “lack of accurate information on serious incidents and deaths makes it difficult for the NHS to evaluate risk or get a grip on reducing high-risk incidents”.191 One preventable death is one too many, and every death is a tragedy for the patient and the family, and for the staff involved. Nonetheless, it is important that we have a reliable measure of preventable deaths occurring as a result of safety incidents within the NHS.

2. How effective are current measures in ensuring patient safety?

2.1 The lack of knowledge in this area hampers the development of appropriate solutions to tackle serious events and leaves the public, politicians and healthcare staff feeling uncertain as to what level of risk patients face each time they are admitted to hospital.

3. What should the NHS do next regarding patient safety?

3.1 The National Institute for Health Research’s Research for Patient Benefit Programme has agreed to fund a research project that I am leading, supported by: Professor Richard Thomson—formerly Director of Epidemiology and Research, National Patient Safety Agency and now Professor of Epidemiology and Public Health at Newcastle University, Professor Charles Vincent, Director NIHR Centre for Patient Safety and Service Quality and Professor of Psychology and Director, Clinical Risk Unit, Imperial College London, Professor Nick Black—Professor of Health Services Research, London School of Hygiene and Tropical Medicine, Ms Sarah Scobie—Head of the Analysis and Feedback and Lead for Patient Safety Observatory, National Patient Safety Agency, Dr Graham Neale, Clinical Research Fellow, Clinical Risk Unit, Imperial College London, Ms Amanda Cale and Mr Jeremy Laurance, Health Editor, The Independent Newspaper (patient and public representatives)

3.2 The Preventable Incidents, Survival and Mortality Study (PRISM) has the following aims:

— To provide a baseline estimate of the number of deaths in adult patients who die during or soon after hospital admission associated with adverse events.
— To make judgments as to the contribution of the adverse event to the death of the patient and to determine how many of these events were preventable.
— To identify factors contributing to adverse events associated with patient deaths.
— To estimate the length of life lost due to deaths caused by preventable adverse events.
— To support priority setting for national and local actions to substantially reduce harm from patient safety incidents and improve the quality and efficiency of NHS care.
— To disseminate findings to the widest possible audience.

3.3 A sample of 10 acute NHS hospitals in England will be selected. In each hospital a random sample of 100 case records related to adult patients who have died during hospital admission or within 30 days of discharge will be reviewed to identify adverse events.

3.4 The review will use methods developed for one of the largest UK studies of adverse events to date conducted by Charles Vincent, Graham Neale and Maria Woloshynowych.192 Case record reviews will be conducted by trained doctors who have recently retired from clinical practice using a structured form.

3.5 Reviewers will be asked to judge which adverse events were preventable and by how much a patient’s life was shortened by the event.

3.6 This study’s findings will fill a hole in our knowledge and understanding of deaths related to safety incidents within hospitals. A robust estimate of the level of fatal and preventable harm will support the identification of priorities for action to reduce preventable mortality and morbidity (locally, nationally and internationally), and support the development of solutions aimed at reducing high impact incidents.

3.7 Outcome from the study have the potential to achieve major benefits for patients in terms of reduced harm, as well as increased confidence in, and financial savings for, the NHS.

3.8 A better estimate will also provide a baseline against which the completeness of reporting to the NPSA can be gauged and help rebalance public and political debate around risks of death and severe harm.

Dr Helen Hogan
Clinical Lecturer in UK Public Health
London School of Hygiene and Tropical Medicine
March 2009

Memorandum by Isabel Healthcare Ltd (PS 97)
PATIENT SAFETY

EXECUTIVE SUMMARY

— Diagnosis, as the first decision in the patient’s journey that determines subsequent treatment and medication, should be considered as a key element of patient safety. So far it has received scant attention.

— Research shows that missed and delayed diagnosis far outweighs medication error as a source of error. The Healthcare Commission recently revealed that the main cause of complaints in primary care is diagnosis at 25% of complaints and is also a significant issue in the acute sector where it reaches 10%. A study of adverse events at a large NHS hospital published in 2007 showed that misdiagnosis accounted for 5% of all adverse events yet 14% of preventable adverse events. Diagnosis had the highest level of preventability. A YouGov survey carried out in November 2005 showed that one in five of the UK adult population say they have experienced a misdiagnosis either directly or indirectly within the previous five years.

— The reasons for misdiagnosis are many split between system errors and cognitive errors. Within cognitive errors the single major cause of misdiagnosis is called premature closure or the failure to consider other reasonable possibilities after the initial diagnosis has been reached. Researchers have suggested that the way to avoid this tendency is for clinicians to use a hypothesis, or list of likely diagnoses, routinely for each case.

— Technology has now made it possible for clinicians to access a checklist of diagnoses within their clinical workflow. The recent research around surgical checklists has shown that their routine use can significantly reduce morbidity and mortality. It is likely that the introduction and routine use of diagnosis checklists will also lead to similar reductions in morbidity and mortality due to missed and delayed diagnosis.

— We recommended to the committee that the routine use of diagnosis checklists should be mandated and there should be a requirement for a differential list of diagnoses to be included in all medical notes. Further research should also be carried out on the impact of missed and delayed diagnosis.

SUBMITTER

Jason Maude serves as Chief Executive Officer and Co-founder of Isabel Healthcare Ltd. Prior to co-founding Isabel Healthcare Ltd, Maude spent 12 years working in the finance and investment banking industry in Europe. Throughout his career, Maude served as an equity analyst at Kleinwort Benson Securities, Smith Barney and Dillon Read. While at Dillon Read, a U.S. investment bank, Maude served as partner and managing director of the company’s UK office. This position led Maude to AXA Investment Managers where he lead equity research and managed $500 billion global investment initiatives.

In 1999, Maude’s three-year-old daughter, Isabel fell seriously ill, as a result of a misdiagnosis. Isabel’s illness and experience inspired Maude to create Isabel Healthcare.

SUBMISSION

1. Diagnosis is the first and most important decision in the patient’s journey. It determines all subsequent treatment and medication. Appropriate treatment cannot begin until the correct diagnosis has been determined.

2. There cannot be any proper understanding of patient safety without a study and understanding of diagnosis error. To try and address patient safety without addressing diagnosis error would be like aviation safety looking at every aspect of flying except takeoff. So far scant attention has been paid to diagnosis error within the NHS patient safety initiatives.

3. Missed and delayed diagnoses have a significant impact not only on patient safety and quality of care but also the appropriateness of testing, admissions, referrals, length of stay and patient satisfaction. Many patients, for example, are subject to unnecessary and invasive testing because the clinician has not specified a diagnosis suspected and has, instead, requested a battery of tests in the hope that one will reveal the answer. Anecdotally, clinicians agree that around 80% of tests ordered comeback with a normal result and many agree that this figure should be more like 30–40%.
4. Published research has shown that misdiagnosis far outweighs other issues such as medication error that is normally the main topic of patient safety campaigns. A literature review study published in 2004 by the US AHRQ showed that misdiagnosis accounted for between 10 and 30% of all medical error.

5. A recent article entitled “Diagnostic Errors-The Next Frontier for Patient Safety” by David Newman–Toker and Peter Pronovost stated that an estimated 40,000 to 80,000 US Hospital deaths result from misdiagnosis annually. Adjusted for the UK, this would mean 8,000–16,000 hospitals deaths annually due to misdiagnosis.

6. A study of autopsy results published by the Journal of American Medicine in 1998 showed a discordance of approximately 40% between what clinicians thought was the cause of death ante mortem and the actual post mortem diagnosis.

7. The Healthcare Commission, in its regular publication entitled “Spotlight on Complaints”, has revealed that misdiagnosis is the leading cause of complaints in primary care, accounting for 25% of the total, and is an important cause of complaints in the acute sector accounting for 9–10% of the total. Professor Ian Kennedy, in a recent press conference, referred to the “black hole” of missed and delayed diagnosis.

8. A study of adverse events in a large NHS hospital published in 2007 entitled “Extent, nature and consequences of adverse events: results of a retrospective case note review in a large NHS hospital” showed that misdiagnosis accounted for 5% of all adverse events but 14% of preventable adverse events. Misdiagnosis had the highest level of prevent ability.

9. Diagnosis errors fall into two categories, system errors and cognitive errors. System errors would generally be communication issues such as test results being lost etc whereas cognitive errors are to do with the judgement of clinicians. Within cognitive errors the most significant single cause of error is referred to as premature closure or failure to consider other reasonable diagnostic possibilities after the initial diagnosis has been reached.

10. There is a large body of research about clinical reasoning describing over 30 different mental biases that clinicians are subject to as human beings that affects their judgement. These biases are well described in a popular book called “How Doctors Think” by Jerome Groopman.

11. Most academics agree that the most practical solution to the problem of cognitive misdiagnosis is for clinicians to work through a comprehensive list of likely diagnoses for each patient. A comprehensive list is, by nature, an objective list that would counterbalance the naturally biased thinking of clinicians. This is also how many clinicians were trained at medical school. The classic training being to take a thorough history, examine the patient and then produce a list of likely diagnoses, referred to as a differential diagnosis. The problem is that this process is not followed when clinicians deliver service; there is no requirement for a differential diagnoses to be produced for a patient. We believe that the main reason for this is the lack of time. The production of a comprehensive list of diagnostic possibilities for a patient could take many hours or days while the clinician goes through his textbooks, refers to his colleagues, or goes online. Since this is not a practical option in most clinical settings, the production of a differential diagnosis is not required and, instead, clinicians rely on the many shortcuts and heuristics that have been developed with experience. This works to a large degree but research has shown that about 15% of all diagnoses are wrong. This level of error should not acceptable today.

12. The recent work by the WHO on surgical checklists has shown that the use of a checklist can be a very effective tool for patient safety. The advances in technology have now made it possible for clinicians to have access to a diagnosis checklist within their clinical workflow. There is, therefore, now no reason why the use of a checklist for diagnosis should be mandated within NHS hospitals.

13. Isabel Healthcare Ltd produces one such diagnosis checklist called Isabel. This is web based, covers 10,000 diseases, 4,500 drugs and several hundred bio terrorism conditions. For a given set of signs and symptoms entered in free text the system provides back to the clinician, almost instantly, a list of likely diagnoses to consider. Each diagnosis is linked to knowledge from textbooks, journals and other web based resources to aid further consideration. The system can be used on a stand alone based or interfaced with an electronic medical record. Isabel has been thoroughly validated with over 20 articles in peer-reviewed journals. Some studies were funded by the Department of Health. The Isabel system is currently being used by several highly rated hospitals in the USA.

RECOMMENDATIONS FOR ACTION

14. Further research is commissioned on the extent of missed and delayed misdiagnosis in the NHS and, in particular, its impact on the appropriateness of admissions, referrals, testing and length of stay.

15. A benchmark should be established for the average time to diagnosis within the NHS for a sentinel group of diagnoses so that variations can be monitored.

16. That clinicians, in all settings where a diagnosis is contemplated are provided with access to a diagnosis checklist. This should include settings where a quasi diagnosis such as referral, decision to admit etc is contemplated.
17. That the medical notes should contain a differential diagnosis for the patient. The notes currently contain the patients working diagnosis and the discharge notes will contain their final diagnosis however there is currently no requirement for a list of the diagnoses that were considered for this patient to be documented and form part of the medical record. A clinician cannot be considered as practising safely unless he has considered the important diagnoses for each particular case and this list of diagnoses that were considered should be documented and be included as part of the medical record.

18. That medical education and validation or assessment of doctors should include a specific measurement of their diagnostic and clinical reasoning skills.

19. Patients should be provided with tools such as symptom checkers to help them make sense of medical information and become more informed about their own diagnosis. They should be encouraged to ask their doctor the question “doctor, you think I have disease x, what else do you think it could be?”

Jason Maude
March 2009

Memorandum by Dr Tony Wright MP (PS 98)

STAFFORD HOSPITAL

This short note identifies issues which arise out of events at Stafford Hospital and which seem to me to require further attention. I am glad that the Select Committee is including this in its own inquiry.

I am doubtful about the utility of a formal public inquiry, when we already have the substantial Healthcare Commission report and when the urgent priority is to bring about improvement at the Hospital, but I do think we need to learn the lessons for the NHS from what happened at Stafford. I have asked the Secretary of State for Health to consider a further inquiry with this focus, unless the Select Committee would itself take this on.

All the reports so far identify the failings in basic patient care, and the fact that the quality of patient care was not the primary focus of the Trust. Lack of staff contributed to this, but there was not a culture of high standards. Complaints were made, and upheld, but not translated into learning, action and improvement. Staff recognised the deficiencies in care, but did not blow the whistle. The elaborate regulatory machinery of the NHS, both local and national, failed to pick up the problem over an extended period.

This suggests some of the issues that the Committee could usefully give attention to:

— How can we ensure that the quality of patient care is at the top of the agenda for all Trusts?
— How can patient views and experience be built into every Trust and contribute to all inspection and assessment?
— How can we ensure that complaints are dealt with properly and are learnt from in terms of the culture of the organisation?
— How can we ensure that the several bodies involved in NHS management, monitoring and regulation act in a co-ordinated way to identify problems quickly and tackle them?
— How can general guidance on whistleblowing be converted into local practices in every Trust so that staff can have confidence in raising concerns without the fear of recrimination?

If the Select Committee can help with these issues, it will have helped us to learn some of the lessons for the NHS from what happened at Stafford.

Dr Tony Wright MP
(Cannock Chase)

20 May 2009

Memorandum by David Kidney MP (PS 99)

PATIENT SAFETY: MID STAFFORDSHIRE NHS FOUNDATION TRUST

When I last corresponded with you I said that I wished to refer the Committee members to my speech in the Westminster Hall debate that I led on 1 April.193 This remains my wish.

As regards patient safety, I believe that the following issues are relevant in the wake of the Healthcare Commission’s report into Mid Staffordshire NHS Foundation Trust.

193 HC Debates 1 Apr 2009: Column 270WH
REGULATION

I said in my speech it was odd that the Healthcare Commission gave the Trust rising assessments during the three years in which we later learn there were services (A&E and emergency care) and some nursing care that ought to have been condemned. I believe that there was at least one physical inspection during those three years but perhaps there was room for failings to be missed because of an over-reliance on self-assessment.

I have spoken to Baroness Young about how the Care Quality Commission will do its work as regulator and I believe that there will be a better, more balanced and eclectic approach to surveillance, monitoring and direct regulation. This is reassuring but surely an area of questioning.

Regulation becomes more problematic when there are two regulators involved, as there are when Monitor is also engaged because the provider is a Foundation Trust. Again, the danger of each regulator saying “But I thought you were taking care of that” means that this is surely an area of questioning. Locally in Staffordshire there are angry demands for an explanation why Monitor accepted Mid Staffordshire for FT status when some of its services were sub-standard.

NHS

The SHA should have been performance managing, and the PCT should have been commissioning services in a way that enabled them both to pick up warning signals, including what David Colin-Thomé calls “soft” intelligence. Their defence appears in part to be that they relied on the Healthcare Commission’s annual assessments. There ought to be questioning about their respective approaches to discharging their responsibilities.

The PCT, like all PCTs, is now engaged in World Class Commissioning and this should raise the game of all PCTs in future.

Lord Darzi’s report “High Quality Care for All” is now focusing all SHAs and all PCTs on the care quality that was sadly not the top priority of the hospital trust’s management during the years investigated.

HSMRs

The Commission’s report contains no figures for avoidable deaths at Cannock and Stafford hospitals. Despite this a newspaper reported “400 to 1,200 deaths” and thereafter all the media always state that “it has been reported that…” followed by the same figures. David Colin-Thomé calls this ill-informed speculation but there is no evidence available to prove or disprove the figures quoted. I believe that around 90 requests have been received for an independent review of case notes in cases where patients died. The Coroner Mr. Haigh has told the Secretary of State for Justice that he gave the Commission’s investigation team an estimate of 120 inquests arising out of deaths at the two hospitals during the three years investigated.

To my mind, one of the useful purposes of holding an independent inquiry is to try to come to some conclusion as to the number of avoidable deaths that occurred at the two hospitals.

WITNESSES

The Chair and Chief Executive in post during the three year period investigated have both left their posts now and they are not witnesses before your Committee. The Trust requested a report from Peter Garland about the responsibility of the former Chief Executive for the failings identified so clearly in the Commission’s report. Peter Garland’s report has not been made public. The former Chief Executive has resigned. There will therefore be no disciplinary proceedings. This means there appears to be no prospect of any public airing of the senior management’s responsibility for what went wrong. This again supports the call for an inquiry.

You are due to take evidence from the interim Chief Executive but obviously his ability to help you to understand what went wrong is extremely limited. You might consider hearing from a near-top management official who was in post during the period investigated if you want to hear first-hand evidence of what went wrong.

PATIENT & PUBLIC INVOLVEMENT

Our experience in Mid Staffordshire has been that a reasonably effective Community Health Council was abolished and replaced by a well-intentioned but less effective PPI Forum, which in turn has been abolished and replaced by a LINK which is, a year after the start date, still not doing anything useful.

There are some great examples of best practice in David Colin-Thomé’s report and I want us locally to look at those and implement some of them in order to get effective patient and public involvement.

AN INQUIRY

As I said during the Commons debate, there is strong and widespread support locally for an inquiry to answer some of the questions that remain unanswered despite the three reports that have been published so far. I think the Government should heed this support and grant an inquiry. I would appreciate your Committee giving its support to the calls for an inquiry if this is possible.
Finally

Stafford hospital is in a precarious position. On the one hand there are hard-working, loyal staff doing everything possible to make a success of all the services provided by the hospital. On the other, the media reporting remains negative, staff are demoralised and it is possible that recruitment of the much-needed additional staff will be more difficult as a result. I wish to make representation to your Committee as strongly as I can that the focus right now needs to be firmly fixed on making the changes that are required to ensure the excellence of the hospital trust’s services in the future. If this is the case, Professor Alberti is optimistic that this Trust can become a model of its kind. This is the outcome that I am working for and the one that overwhelmingly local people want.

David Kidney MP
29 May 2009

Memorandum by the Mid Staffordshire NHS Foundation Trust (PS 100)

PATIENT SAFETY

1. Trust Profile

Mid Staffordshire NHS Foundation Trust was authorised as a Foundation Trust on 1 February 2008. The Trust is a medium sized district general hospital, providing a comprehensive range of services from two modern hospitals, Cannock Chase Hospital and Stafford Hospital. Details of the services provided are included in Appendix 1 of the report.

Stafford Hospital has a 24-hour Accident and Emergency department, an Outpatient Department and 360 beds for inpatients.

Cannock Chase Hospital has a nurse-led minor injury unit (open daily 8am to midnight), an Outpatient Department, 77 inpatient beds and comprehensive rehabilitation facilities.

The Trust has a number of outreach services in the community and has a specialist centre for Rheumatology serving a wider geographical area that includes Sutton Coldfield and North Birmingham.

The Trust is one of the largest employers in the region, with over 3,000 staff and its main commissioner is South Staffordshire Primary Care Trust.

1.1 Trust Overview

During the last twelve months (April 2008 to March 2009) the Trust has:

— Significantly reduced its mortality rate which at 31 March 2009 was better than the national average.
— Considerably reduced the number of hospital acquired infections:
  — MRSA by 59% and C Difficile by 25% within the last 12 months.
— Invested over £750,000 in Accident & Emergency (A&E) and transformed the Emergency Care service to the extent that the Healthcare Commission (HCC) was very positive about the service provided after an unannounced visit in February 2009. This was confirmed by Professor Sir George Alberti on an independent visit to the Trust.
— Signed up to the National Patient Safety campaign and started to use new tools to evaluate any harm to patients.
— Become one of only a few trusts in the country to be fully compliant with the Government’s Hygiene Code.
— Increased the number of nurses by over 100 and appointed nine additional matrons.
— Implemented a number of training programmes for nurses, matron and leaders.
— Invested over £200,000 in additional housekeepers.
— Improved governance arrangements, including the process for responding to complaints.
— Actively sought views from relatives of bereaved patients with regard to the standards of care provided.
— Invested over £6 million in refurbishment and equipment.
— Established Divisional Patient and Carer Councils with the aim of proactively seeking the views of our patients.
— Improved performance against the 98% target for transfer or discharged within a maximum waiting time of four hours in A&E. The Trust just failed to meet the target achieving 97.8%.
— Exceeded the milestones for the 18 week referral to treatment target, providing a high quality of access to the services provided for patients. Trust results were 99% against a target of 95% for outpatients and 95% against the target of 90% for inpatients.

Over the coming year the recommendations made in the HCC Professor Alberti and Dr Colin-Thomé reports will be addressed through the Trust’s Transformation Programme to ensure:
— There is a systematic means of monitoring rates of mortality and other outcomes for patients.
— There are arrangements for overseeing the quality and safety of clinical care within the Trust.
— The recent improvements to the emergency department are sustained and extended to ensure that the service is safe, that it meets the needs of patients, and that the department is adequately staffed and equipped at all times.
— Continue the work already started to recruit additional nursing and medical staff, to ensure that care provided to patients throughout the Trust, including at night and at weekends, is safe and meets accepted standards.
— Review training and supervision of nursing staff and junior doctors, to ensure they are undertaking appropriate roles, are confident and clear about the expectations placed on them, and are receiving all necessary support.

2. PATIENT SAFETY

To support the drive to improve patient safety the Trust has signed up to the National Patient Safety Agency’s Patient Safety Campaign and has also enrolled on the National Institute for Innovation’s Leading Improvement in Patient Safety Programme (LIPS).

Executive Directors and senior staff have attended the LIPS training programme and have already begun to implement some of the suggested actions including reviews of clinical notes utilising a systematic process.

The following areas will be the main focus for patient safety for 2009–10 and stretching goals will be applied:
— Reduction of harm from drug administration.
— Care of the deteriorating patient.

The Medical Director has been nominated by the Trust Board as the champion for Patient Safety to ensure that this continues one of our top priorities.

2.1 Health Governance

In order that the Board of Directors has assurance on all issues relating to clinical quality, a Healthcare Governance Committee has been formed and held its first meeting in April 2009.

This Committee is a formal sub-committee of the Board of Directors and will hold the organisation to account on all issues relating to quality of care. The Committee is chaired by Sir Stephen Moss, Non-Executive Director who has an extensive nursing career and is highly respected within the NHS.

The Committee has four main priorities for 2009–10 which are aligned to the recommendations from HCC report:
— Mortality.
— Patient feedback, including complaints.
— Patient Safety.
— Clinical Audit.

Clinical Audit

There is a Trust-wide audit programme to review compliance with local and national initiatives. This will also quality assure service provision and identify areas of concern.

2.2 National Patient Safety Agency (NPSA)

The NPSA visited the Trust in January 2009 to discuss the reporting of patient safety incidents via the National Reporting and Learning System (NRLS). All incidents marked as patient safety incidents are reported to the NPSA via the NRLS system.

Feedback highlighted that the Trust was categorising the potential impact of incidents rather than the actual impact. The issue of correctly grading incidents is being addressed through training.

Positive feedback was received regarding the timescales between incidents occurring and reporting, and the relatively high number of prescription errors reported, preventing potential harm to patients.
2.3 Prevention and Control of Infection

The HCC inspected the Trust against the Hygiene Code in October 2008. Assessors inspected wards, interviewed staff of all levels and examined the infection prevention and control policies and processes. The inspection team also checked the Trust’s cleanliness, isolation facilities and antibiotic prescribing policies.

The HCC report dated November 2008 the Trust was highlighted as being completely compliant. At the time, the Trust was one of only five trusts out of 51 inspected to achieve this standard.

During the year, all Trust staff, with the support of patients and the public have worked hard to reduce the number of infections. The campaign “Cleanest Place in Town” has continued and many new practices implemented to help reduce the incidence and spread of infection including:

— improved audits of practice;
— better root cause analysis when infections occur;
— increased training of all staff; the introduction of a new prescription chart; and
— increased staffing in the infection prevention and control and in the housekeeping teams.

Performance against Infection Control Targets—2008–09

MRSA

There was a 59% reduction in MRSA bacteraemia in 2008–09 compared with the previous year. The reduction in cases is particularly evident in relation to hospital acquired bacteraemia. In 12 months there have been three MRSA bacteraemia acquired in the Trust in comparison to six patients who were admitted with the infection. Two cases during the year were removed from the Trust’s numbers as these were attributable to other Trusts.

<table>
<thead>
<tr>
<th>Period</th>
<th>Target 111111111111</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre 48 Hours</td>
<td>000110001201</td>
<td>6</td>
</tr>
<tr>
<td>Post 48 Hours</td>
<td>010100000001</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>010210001202</td>
<td>9</td>
</tr>
</tbody>
</table>

The Trust has implemented MRSA screening for elective admissions in line with the Department of Health recommendations and is implementing screening of non-elective admissions ahead of the recommended timeframe of March 2010.

C. Difficile

There was a 25% reduction in the number of *C. difficile* cases in 2008–09 compared to the previous year. The Trust did come in under trajectory, however there were two periods in the year in which there were increased numbers of cases. As can be seen from the graph there was a rise in cases in July and another rise between January and March. Both these peaks were treated seriously and during the outbreak in March the Health Protection Agency supported the Trust in establishing a database so that all cases could be tracked appropriately. The Trust also opened a cohort ward in March.

<table>
<thead>
<tr>
<th>Period</th>
<th>PCT Target</th>
<th>Actual positive samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>May</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>June</td>
<td>14</td>
<td>19</td>
</tr>
<tr>
<td>July</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>August</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>Sept</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td>Oct</td>
<td>13</td>
<td>7</td>
</tr>
<tr>
<td>Nov</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Dec</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>Jan</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Feb</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Mar</td>
<td>163</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>138</td>
<td>7</td>
</tr>
</tbody>
</table>

Number of Positive C.diff Samples for MSGH patients only

![Graph showing number of positive C.diff samples for MSGH patients over time]

- PCT Target
- Actual positive samples
All Trusts have been set an upper limit target and by 2011 the Trust should not have more than 81 *C. difficile* cases. In order that the 2011 requirement is achieved the 2009–10 target has been set at no more than 100 cases. This approach allows for incremental improvement.

The performance demonstrates a significant improvement when compared to previous years however: the Trust is by no means complacent. During the coming year the Trust will be concentrating on ensuring performance continues to improve. The Trust's infection rates are published monthly on its website www.midstaffs.nhs.uk.

2.4 *Hospital Standardised Mortality Ratio (HSMR)*

Against the national baseline HSMR of 100 the Trust’s performance during 2005–06 was 127. By December 2008 the HSMR was 88 and is currently 90.9.

<table>
<thead>
<tr>
<th>Year</th>
<th>2006–07</th>
<th>2007–08</th>
<th>2008–09</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSMR</td>
<td>127</td>
<td>116</td>
<td>90.9</td>
</tr>
</tbody>
</table>

The Trust’s HSMR began to significantly improve following Q1 2008 and has remained below the national average since Q2 2008. This improvement coincides with a number of factors including the appointment of new Emergency Care and A&E Consultants, enhanced nurse recruitment and improvements in the depth of coding to capture co-morbidities to reflect the acuity of the patients that we treat.

Mortality Comparisons

For comparative purposes, the Trust used the Dr Foster system to identify Trusts with similar % volume activity to act as a “peer” group. The figure below shows the crude mortality for all activity by this Trust compared to its peers from 2006 to 2009. (Crude mortality = percentage of people who died in hospital compared to the number of patients discharged each month).
The following figure shows the crude mortality for emergency admissions to the Trust in comparison to its peers from 2006 to 2009.

### 2.5 Adverse incidents

The Trust reports to the National Patient Safety Agency (NPSA) weekly and the data is reported on their website.

#### Overview of Adverse Incidents

During the 4th quarter of 2008–09 there were a total of 1,157 adverse incidents reported. This is an increase in the amount reported in the previous quarter (1,014) and an increase in the number reported in the same quarter last year (973). This increase is seen as a positive indicator, reflecting a changing culture of staff awareness of risk issues resulting from the publication of the HCC report and increasing staff training.
Actions are taken for each of the areas and plans are in place to reduce the risk of incidents occurring.

2.6 Serious Untoward Incidents

During Quarter 4, 2008–09, eight incidents were reported (not including those reported as infection prevention and control) compared with six the previous quarter. The investigation reports and subsequent actions are presented to the Healthcare Governance Committee and shared with the Primary Care Trust.

The Trust has established a Serious Untoward Incident Review Panel. Its role will be to look at all reported incidents to review patient care and ensure lessons are learned and changes implemented.

2.7 Safeguarding Children

The Trust has submitted Safeguarding data to the Care Quality Commission safeguarding review, the outcome is awaited.

The results of the Staffordshire Safeguarding Children’s Board (SSCB) annual health check on safeguarding arrangements by the Trust have been received for 2007–08. The Trust is fully compliant with 82% and partially compliant with the remaining 18% of standards. This is an improvement on the previous period. The current shortfalls centred on:

— Information-sharing policies: the SSCB policy on information sharing was presented to the Information Governance Group in April 2009.
— HR procedures, in particular the Trust’s inability to provide assurance that the SSCB standard on criminal records bureau checks was being adhered to. A plan is now in place to address this.

The Trust was commended by the SSCB for good practice.

3. Patient Care

In response to the 2007–08 patient survey a comprehensive plan was put in place to support the continuing progress being made in improving the quality of care delivered to patients. The plan “Confidence in Caring” ensured there was a co-ordinated and systematic approach applied to all actions.

Key measurables from the Plan included:

— a reduction in the number of complaints and PALS contacts relating to nursing care;
— an increase in the uptake of training by registered nurses and healthcare support workers;
— improvement in performance in relation to key nursing duties that relate to patient safety and increased staffing levels across the Trust.

Whilst improvements were made during 2008–09 it was recognised that there was still a significant amount of work to do and therefore the Plan has been updated for 2009–10.

The Trust is committed to working with its patients, Governors and the public to ensure it is responsive to the needs of those who use its services.

To ensure accurate feedback that the Trust can act upon, the Trust has through the year:

— Continued to implement our Public and Patient Engagement strategy.
— Undertaken two independent patient surveys.
— Held focus groups with our Members.
— Established Patient and Carer Councils.
— Held regular meetings of our Patient Experience group.
— Implemented Patient Experience Trackers.
— Engaged with the local LiNks.
— Introduced unannounced inspections to our clinical areas.
— Worked closely with our Governors and Membership.
— Continued to work closely with Age Concern.

3.1 The Transformation Programme

A Transformation Programme has been developed by the Trust in response to the recommendations of the Healthcare Commission, the Alberti and Colin-Thomé reports. It has also been influenced by Monitor and the Care Quality Commission.

The Programme will ensure that patients receive the quality of care they are entitled to. Top priorities are Patient Safety; Patient Experience and Effectiveness of the Care delivered.

The Programme focuses on seven areas and sets 107 goals for improvement. Most will be achieved in the next eight months, however this is a living, developing programme and the number of goals might increase as the programme is shared.
Each goal is the responsibility of a named Executive Director, who will report progress to the Trust Board.

1. Improving care—Developing comprehensive guidelines for clinical and non-clinical staff to ensure a high standard of care is delivered for patients.
2. Clinical staffing—Reviewing staffing levels and development and training requirements to ensure the correct numbers of appropriately trained clinical and non-clinical staff are in place to deliver a high standard of care.
3. Involving people—Increasing the involvement of patients and the public in the Transformation of Mid Staffordshire NHS Foundation Trust.
4. Voicing concerns—Two-way dialogue with all concerned to identify any problems and promote change.
5. Control of systems and procedures—Establishing procedures to make sure the Trust is meeting high expectations and is accountable through regular reviews.
6. Equipment and Facilities—Ensuring the Trust has the right equipment, train staff to use it and relocates clinical services to improve patient experience.
7. Vision for care—Changes in the short and longer term which will have an immediate impact on patient care from admission to discharge.

A Transformation Programme Board has been set up, led by the Deputy Chief Executive and includes Clinical and Professional Leads, the Primary Care Trust and Trust Governor representatives.

3.2 National Adult Inpatient Survey Results

Nationally 72,000 patients responded to the survey which was 54% of patients eligible. 437 patients responded to the Trust survey giving a response rate of 51.8%. (2007 survey response rate of 59.1%).

Key Findings

Benchmarked against Trusts, Mid Staffordshire is identified in the lowest 20% in the following six of the 61 questions.
— How much information did you get whilst in the emergency department?
— Did you have confidence and trust in the doctors treating you?
— As far as you know, did doctors wash or clean their hands between touching patients?
— In your opinion were there enough nurses on duty?
— Did your family or someone close to you have enough opportunity to talk to a doctor?
— How would you rate how well the doctors and nurses worked together?

The Trust performed in the best 20% in one area:
— Were you offered a choice of hospital for your first hospital appointment.

For the remaining 54 questions the Trust received average scores in line with 60% of all Trusts.

Trust comparisons 2007 and 2008

The comparative data demonstrates that out of the 61 questions used in both the 2007 and 2008 surveys, that despite the ongoing pressures, the Trust’s performance was:
— Significantly better on 25 questions.
— Significantly worse on 0 questions.

During 2009 the Trust, in conjunction with the PCT and SHA will commence a round of postal patient surveys, over a three month period. These results, once collated, will be reported to the Healthcare Governance Committee.

Comments from Reports supporting improvements in Care

When HCC expressed concerns, it noted that the Trust “responded positively and began to take action”. In their report, they noted “significant progress has been made.”

The HCC also found improvements to the emergency department during an unannounced visit in February 2009. A four-bedded surgical assessment unit had been opened; a clinical outcomes group set up; the Trust was reviewing the provision of emergency theatre lists at weekends and ensuring that changes happen following complaints. Training was taking place in “Modified Early Warning Scores” and with cardiac monitors.

The HCC commented that the Trust “deserves credit for the improvement in the prevention and control of infection and it was recently found to comply with the hygiene code”.

Professor Sir George Alberti found much improvement since HCC began investigating the Trust, including major improvements in A&E, which he said was now providing safe, good quality care.
Staff improvements noted by Professor Alberti included the addition of four consultants, three acute physicians and eight middle-grade doctors together with the improved training of junior doctors. He found that A&E consultants provide excellent shop-floor presence. A new way of working will accelerate care and provide early consultant-delivered decisions and there is now nurse triage every day and eight emergency nurse practitioners with a matron in charge. He noted a strong primary care presence from 25 local GPs working on rotation. Major illness patients were seen within 30 minutes.

He found that the interim Chair, interim Chief Executive and new Medical Director were having an impact.

Professor Albert commented on the highly committed, acute surgeons working for the Trust and excellent collaboration with clinical staff. There is now a review within 24 hours of any case where the patient dies, with consequent benefit to learning.

The appointment of three physicians has resulted in greatly improved care and an excellent daytime service. He also noted a well-developed endoscopy service and very committed staff.

4. Voicing Concerns

The HCC report raised concerns about the culture of the organisation and its openness and transparency. A number of actions have already been taken to start the change in culture including:

— Quarterly Board meeting held in public.
— Council of Governor meetings held in public.
— Regular reports presented to local Overview and Scrutiny Committees.
— Executive Director walk-rounds of the hospital.
— Creation of Divisional Patient and Carer Councils.
— Recruitment of patient experience facilitator.
— Revision of Whistle Blowing Policy which has been distributed to staff and promoted throughout the hospital.
— More open reporting including greater use of the Trust’s website to impart information to public/patients.
— Working with Governors to get feedback including unannounced inspections.
— Implementation of Fair Blame Policy with letter from Chief Executive to all staff attached to Pay Slips of all staff in May.

4.1 Complaints Handling

The Trust takes all complaints seriously and acts on all issues that are raised, ensuring problems are resolved quickly. The responsibility for managing complaints has recently transferred directly to the Chief Executive from 1 June 2009.

During 2008–09 changes were made to ensure that improvements in the Trust’s services resulted from issues raised via complaints. Changes include:

— making earlier verbal contact with those that raise concerns;
— face to face meetings to discuss concerns;
— setting up complaints review panels.
— Reviewing the Trust’s Complaints Policy in-line with the Department of Health Complaints Handling requirements.

Over the next few months the Complaints handling process will be reviewed to ensure that the systems are “patient friendly”.

The total number of formal complaints raised in 2008–09 was 368 in comparison to 339 in 2007–08. The rise in complaints reflects the Trust actively encouraging people to give feedback on services and the impact of the publicity surrounding the publication of the HCC report. The breakdown of these complaints into themes/issues is included as Appendix 2.

Throughout the year the Trust has continued to receive support from patients who have used the service and from members of the public. During 2008–09 the Trust received 2,818 compliments in the form of letters, cards, donations and small gifts. In comparison, 2,012 were received during 2007–08.

Review Panels

Following the publication of the HCC report the Trust offered relatives the opportunity for a case note review for patients that had died in hospital. The review panels are being led by Dr Mike Laker, formerly a Medical Director in Newcastle Upon Tyne who currently holds a position with the North East Strategic Health Authority.
The review panels are multidisciplinary and comprise individuals from medical and nursing backgrounds appropriate to the nature of the case being reviewed. Panels have been drawn from clinical staff with no connection to Stafford Hospital.

Review panels are asked to review notes for:

- Timeliness of treatment.
- Did care follow good evidence based practice (at that time).
- Appropriate investigations offered/acted upon.
- Nursing care.
- Evidence of errors/complications of surgery.
- Judgement as to whether the outcome was expected.
- Was appropriate specialty doctor involvement evident.
- Was the level of senior doctor input adequate.
- Was death certification appropriate and reflective of the cause of death.
- Any issues the relatives wish exploring.

This list is not exhaustive and will vary depending on the discussions the reviewers have with the relatives.

It is proposed that each review will be completed within 20 working days of agreement to proceed. The final report from each review will be shared with the Trust, following agreement from the relatives, so that lessons can be learnt. From the reviews that are shared with the Trust a final report will be developed, that highlights the themes from the Reviews thereby ensuring that lessons are learnt and that all appropriate actions have or are being taken to address all issues identified. It is proposed that on completion the report is presented at a public Board of Directors meeting and the Council of Governors.

To date the Trust has had 110 requests for case note reviews.

To ensure that all members of the public who wish to have a case note review carried out have the opportunity to do so, the offer will remain open till the end of June 2009. If people make a request after this date their cases will still be considered for review.

On completion of the review individuals will have the opportunity to discuss the findings with Trust staff should this be requested.

The Trust does not currently offer a counselling service to bereaved relatives however, should this be necessary the Trust will ensure that relatives have access to these services and are signposted accordingly.

26 May 2009

Appendix 1

SERVICES PROVIDED BY MID STAFFORDSHIRE NHS FOUNDATION TRUST

The Trust provides services in a range of specialties, which form our principal activities. The services are organised into three clinical Divisions, each led by a partnership between a Head of Division, who is a medical consultant and a Divisional Manager.

Divisions consist of the following clinical specialties:

<table>
<thead>
<tr>
<th>Clinical Support Services</th>
<th>Medical</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audiology</td>
<td>Cardiology, Acute Coronary Unit</td>
<td>Anaesthetics</td>
</tr>
<tr>
<td>Bereavement Services</td>
<td>Dermatology</td>
<td>Cannock Eye Centre</td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>Elderly Care—Bradbury House Day Unit, Diabetic Centre, Davy Unit</td>
<td>Community Midwifery</td>
</tr>
<tr>
<td>Bone Densitometry</td>
<td>Gastroenterology</td>
<td>Critical Care</td>
</tr>
<tr>
<td>Breast Screening</td>
<td>General Medicine</td>
<td>Day Ward</td>
</tr>
<tr>
<td>Chaplaincy</td>
<td>Genito Urinary Medicine</td>
<td>Diagnostic Unit</td>
</tr>
<tr>
<td>Chemotherapy Treatment Unit</td>
<td>Lung Function</td>
<td>Ear, Nose &amp; Throat</td>
</tr>
<tr>
<td>Clinical Chemistry</td>
<td>Metabolic</td>
<td>General Surgery</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>Neurology</td>
<td>Gynaecology</td>
</tr>
<tr>
<td>Haematology</td>
<td>Neurophysiology</td>
<td>Obstetrics</td>
</tr>
<tr>
<td>Health Records</td>
<td>Paediatrics, Special Care Baby Unit</td>
<td>Ophthalmology</td>
</tr>
</tbody>
</table>
Outpatient services are provided for all specialities at both Stafford and Cannock Hospitals. Our staff also run “outreach clinics” at locations outside the hospital, such as in GP surgeries or health centres. The Trust is planning to increase the number of these clinics to support the delivery of services nearer to patients’ homes.

Current Outreach clinics:

— Rheumatology in Lichfield, Tamworth and Sutton Coldfield.
— Gynaecology in Stone, Gnosall and Newport.
— Orthopaedics in Lichfield.
— Ultrasound in Gnosall and Newport.

### Appendix 2

#### COMPLAINTS STATISTICS 2007–09

<table>
<thead>
<tr>
<th>Complaint Issue/Themes issues raised, a complaint can have more than one theme</th>
<th>2007–08</th>
<th>2008–09</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admissions, Discharge and Transfer</td>
<td>48</td>
<td>43</td>
</tr>
<tr>
<td>Aids, Appliances, Equipment and Premises etc.</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Appointments, delay/cancellation (OP)</td>
<td>6</td>
<td>31</td>
</tr>
<tr>
<td>Appointments, delay/cancellation (IP)</td>
<td>35</td>
<td>12</td>
</tr>
<tr>
<td>Staff Attitude</td>
<td>50</td>
<td>68</td>
</tr>
<tr>
<td>All Aspects of Clinical Care</td>
<td>257</td>
<td>373</td>
</tr>
<tr>
<td>Communication/Information to Patients</td>
<td>67</td>
<td>77</td>
</tr>
<tr>
<td>Consent to Treatment</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Complaints Handling</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Patients’ property and expenses</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Patient privacy and dignity</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Personal records</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Policy and decisions of the Trust</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Failure to follow agreed procedures</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Patient status (discrimination)</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Mortuary and Post Mortem arrangements</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Transport</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>Hotel Services (including food)</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>541</strong>*</td>
<td><strong>675</strong>*</td>
</tr>
</tbody>
</table>

* Every complaint is categorised by issues/theme. One complaint will often have more than one issue/theme raised which explains why the numbers above do not equal the numbers detailed in 4.1

During 2008–09 of the 368 complaints received there were five complainants who were not satisfied with the response the Trust gave to their complaint and they therefore approached the Healthcare Commission for a second stage review. Of these complaints four have been upheld, and one was not upheld. The Parliamentary Ombudsman is currently considering a complaint that relates to a patient that received care in 2001.
Memorandum by Cure the NHS (PS 101)

PATIENT SAFETY: THE LESSONS OF MID-STAFFORDSHIRE

EXECUTIVE SUMMARY

In October 2007, I spent eight weeks caring for my mother and others on Ward 11 in Stafford Hospital. What I witnessed was the most dreadful thing I have ever experienced and I am now left with many unanswered questions and so too is this community. In December 2007 I launched Cure the NHS so that I could campaign with other relatives in a similar position. We are still campaigning.

The Healthcare Commission’s report of March 2009 has provided some explanations of what went wrong but signally failed to answer the question WHY? Every day since the publication of the report more relatives bring continuing accounts of the dreadful standards of care at Stafford Hospital and harrowing stories of the deaths of their loved ones.

We do not believe that people outside this community understand the actual extent of the problem here in Stafford. We believe that extends to the Health Secretary, himself, his ministers, the chief Executive of the NHS, and the Executive Chairman of Monitor. The Health Secretary has noted the lack of “whistleblowing”; but the reality is that “whistleblowers” have been, and continue to be vigorously suppressed by the hospital.

The “culture” within the hospital was distorted and non executive directors and governors far from challenging the chairman and chief executive over the poor standards of treatment and care praised them to the sky. Even the chief executive of the Royal College of Nursing, after a visit soon after the start of the Healthcare Commission’s investigation, wrote to a local newspaper in glowing terms about the chairman, chief executive, and director of nursing, all subsequently heavily criticised by the Healthcare Commission.

We believe it was a systemic failure across the West Midlands NHS which caused the failures at Stafford. The NHS even today has no modern patient safety and quality “system” to preclude such failures so the responsibility for them must extend to the Department of Health, the Health Secretary, his ministers, and the executive of the NHS and Monitor.

Only a systematic inquiry, that is a full public inquiry under the 2005 Act can answer these questions. Please tell the Health Secretary that he must order such an inquiry now.

1. OUR EVIDENCE

1.1 Cure the NHS welcomes the opportunity to make submissions to the Health Committee’s inquiry on patient safety at Mid Staffordshire NHS Foundation Trust.

1.2 Because of the Committee’s limit on the length of this submission, and because we have not been invited to give oral evidence, we ask you to understand that this document represents a very short summary of our views on this vital subject.

1.3 A full Public Inquiry under the 2005 Act is essential to answer the very many questions that remain unanswered by those already carried out.

1.4 In October 2007, I spent eight weeks caring for my mother and others on Ward 11 in Stafford hospital. What I witnessed was the most dreadful thing I have ever experienced and I am now left with many unanswered questions and so too is this community.

1.5 Today and everyday since the Healthcare Commission (HC) report was published, I sit and listen to another relative who has lost a loved one, another tragic death. We all seem to have lost under similar circumstances, where we are now left thinking either they shouldn’t have died, or they shouldn’t have died the way they did. When you lose someone in this way it is something that you never get over, because you feel it was avoidable. We all seem to have tried to alert the people who could have helped us but it seemed no one wanted to listen.

1.6 I do not believe that people outside this community understand the actual extent of the problem here in Stafford. We have lost so many people under dreadful circumstances, some have lived but are still suffering, failed by the very people we put our trust in to care.

1.7 The amount of people who have made contact with the group has been absolutely overwhelming. I am sure that there are many more but the only way of contacting these people is through the media, some do not have contact with the media.

1.8 The independent casenote review will not be a true reflection of the extent of the problem. I myself and I know many others would not want contact ever again with the hospital. Although it is claimed to be independent we firstly have to contact the hospital or the Primary Care Trust to register. Then we will be invited to meet with an independent doctor to discuss the case notes. Many people from this community want nothing more to do with the hospital, we have dreadful memories of the sufferings of our loved ones. What about those who have died who have no one to request a review there must be many? Other relatives, elderly themselves are in no position to request a review. Again the only way of knowing about the reviews is through the media, many people will not even notice they are on offer.
1.9 Cure the NHS has tried to stop further deaths and improve patient care but it has proved to be very difficult. We first tried to expose the horrors we witnessed and our loved ones suffered to those in the system that should be there to listen and scrutinise.

1.10 In January 2008, we contacted the Secretary of State, Alan Johnson, David Kidney MP, Tony Wright MP, Bill Cash MP. We wrote and told them, that patients were being denied their basic human rights. Their advice was to talk to the hospital management and the board of Governors.

1.11 We did, by this time we had around 50 grieving relatives who addressed a Council of Governors meeting. We told them how our relatives had died, suffering with a total lack of dignity, some screaming out in pain as they died. They listened, but did nothing in fact our accounts of our loved ones dreadful deaths were not even included in the minutes from that meeting.

1.12 In the same month we told the Stafford Overview and Scrutiny Committee of our concerns, despite receiving a letter from their solicitor’s department, warning us not to contact them with individual concerns. We persisted and told them we felt it was systemic failings within the hospital with vulnerable and elderly members of this community suffering. During the eight weeks I cared for my mother I had to feed vulnerable patients as there was no one else to feed them. I saw confused patients, physically and verbally abused daily. Patients continually fell and no one was around to help them, staff didn’t seem to understand risk and how to manage it. The Overview and Scrutiny Committee spoke to the hospital management who told them everything was fine, they believed them and did no more.

1.13 We contacted the Healthcare Commission in February 2008, we alerted them to the third world conditions within the hospital. We set out 69 points that we had all witnessed and our loved ones had suffered. Although we believe the Healthcare Commission provided the evidence to expose many of the hospitals failing we feel somewhat let down by their intervention to date. We question why, when they inspected the A & E department of the hospital in May 2008 and found it in such an unsafe condition, no immediate intervention was taken. I know that during the HC intervention from March to October 2008, we lost many more members of this community unnecessarily, as their family have since contacted me.

1.14 Furthermore it seems that the Healthcare Commission recommendations for the hospital over the last year have not been implemented in full and in October 2008 they still had concerns when they had finished their investigation. Even after Professor George Alberti had reviewed the hospital there remained a lack of suitable numbers of staff and vital equipment still hadn’t been purchased. Why wasn’t something more done when the hospital appeared to be dragging its feet over improvements? Why were they allowed to delay putting safe systems in place when they had been told to do so?.

1.15 Ironically too in February 2008, the hospital was awarded foundation trust status by Monitor. This community wants to know how this status was awarded while patients inside were being denied their basic human rights. How could such a status be awarded whilst conditions inside were appalling?

1.16 Cure the NHS continued to hear from more grieving relatives and in May 2008, we contacted the Primary Care Trust with our concerns. They said they wanted to help but like others didn’t, their advice was for us to speak to the hospital management. We told them we had but they told us to speak to them again. We contacted the Local Management Committee who also advised us to speak to the hospital management. We contacted the Local Involvement Network, they too could offer us nothing to stop the abuse we had witnessed. In fact they were hostile toward us telling us to bring evidence to support our claims of neglect.

1.17 It seems everyone we spoke to wanted us to speak to the management of the hospital, they all seemed to hold the management in high regards and told us what a good job they were doing. They tried to tell us that things had improved a new action plan had been put in place and the hospital was meeting the targets. What we had witnessed would never happen again, we tried to tell them it still was, but no one wanted to hear and no one would listen.

1.18 We began to feel that we were getting nowhere, people were still contacting me telling us of the same dreadful conditions we had seen and yet those that could help stop the abuse were telling us that things had improved. At this point it seemed that everyone who could do something didn’t, it appeared they did the very opposite.

1.19 Our MP David Kidney, spent time in the hospital doing a work experience, telling the local press that everything was fine at the hospital. His only recommendation was to promote more recycling within the Hospital.

1.20 Peter Carter, Chief Executive of the Royal College of Nursing spent a day at the hospital and applauded the staff and management, he even made a point of writing to our local paper informing the community that we should be proud of the hospital.

1.21 The chair of the Local Management Committee and the RCN local representative did the same, they went as far as saying that the hospital had adequate staffing levels and the right skill mix, all nonsense but why? It may have led to us losing even more members of this community which we have over the last year. More deaths where questions are left unanswered, some relatives still don’t know where their relatives died. Suspiciously the files have gone missing, others have died covered in bruises, with no explanation. We are all left with something that concerns us and the complaints procedure hasn’t helped to tell us what has happened.
1.22 The complaints procedure appears to of worked against us too, we suspect the tactic has been to wear us all down and hope we will go away.

1.23 We cannot because this hospital has destroyed many proud members of this community under cruel circumstances and we want to know why. We have been told that a Public Inquiry under the 2005 Act would hamper the hospital moving forward. Simple changes to improve care can and should be introduced very quickly, but we do not feel that the hospital can truly move forward with so many questions left unanswered. The very staff who have been part of this appalling standard of care are still employed within the hospital. The staff themselves, want a public inquiry, they want the truth to be exposed themselves. Only recently the managers have hidden more deaths from Clostridium Difficile, they appear to be incapable of moving forward. Families continue to contact us and tell us that their relatives are still not having their basic needs met. Patients are still suffering harm and South Staffordshire Primary Care Trust remain concerned as complaints have increased and serious untoward incidents remains high.

1.24 Another reason we have been given is the cost, we do not find this reason acceptable. We believe unless the truth is told and bad practice exposed it will resurface once again and in fact the hospital will never have the opportunity to move forward. In the long term the cost would be higher because the hospital will always be plagued with problems, as it has. The cost would be reduced as a public inquiry could build on the work done by the Healthcare Commission report.

1.25 As members of society we should all want to know what has happened, how could so many people die in such awful circumstances? We don’t even know how many people died which we believe as a community we have a right to know. Most of these people were elderly or vulnerable with many not having anyone to speak up for them.

1.26 We want to know why so many people stood by and let this happen. Within the hospital we found some fantastic staff, but we also found some dreadful ones. We want to know why, why were some so cruel towards our loved ones? We want the bad practice exposed.

1.27 We want to know why those who should have been scrutinising the hospital didn’t, despite us telling them there were serious problems. Why did they appear to conspire against us and tell this community that everything at the hospital was fine, in fact it was excellent. Why did some local press support them and try to discredit our accounts?

1.28 Everything was pointing to problems over a number of years, Healthcare Commission inspections, patient surveys, staff surveys and yet nothing was done. Surely this in itself deserves further investigation, why did no one do nothing apart from supporting the management?

1.29 We are still being approached by families who have relatives in the hospital now, still suffering. This is wrong and we are asking you to help to expose the systemic failings by recommending a full public inquiry where people are compelled to give evidence. We believe only then can this community move forward and help to build a hospital to be proud of.

1.30 The Health Secretary claimed the failings at Stafford Hospital were attributable just to the failings of local management. The Chief Executive and Chair have been allowed to resign, no other senior executives and managers have been held to account in any way? Does the massive array of criticism in the Healthcare Commission report mean nothing for those continuing to run Stafford Hospital every day?

1.31 We believe the Health Secretary is wrong, Stafford Hospital is not an isolated case. We now have contact with other groups experiencing similar problems; Warrington, Tameside, Norwich and Birmingham, all with high mortality figures.

2. Some Further Issues for your Attention

2.1 Cure the NHS—Our Analysis—We will be shortly be publishing an extended version of the views above and commentary on the following:

2.2 Review by Professor Sir George Alberti—The remit clearly excluded any analysis of the “why”. Professor Alberti was later interviewed on BBC Radio Stoke and asked if he would feel safe being admitted to the hospital, he said he would for something minor like a broken leg, but for more serious conditions would want to go to regional centres; so are patients for these more serious conditions being treated at Stafford Hospital now?

2.3 Review by Dr David Colin-Thomeé—We believe that his investigation was sketchy, covered much of the ground already covered by the Healthcare Commission, but in no greater depth, and was in no way systematic and reached no significant conclusions.

2.4 Independent Casenote Review—Set up by the hospital. It is not independent. The hospital’s own board papers demonstrate very clearly that they are managing the process; they should not be involved at all in any part of it.

2.5 Patient and Public Involvement—It was this Government which twice closed down channels for patient and public involvement, the short history of the Local Involvement Networks in Staffordshire is little short of farcical.

2.6 The Role Of The Coroner—Was is correct that he would not assist the Healthcare Commission? If not, why not?
2.7 *The Royal Colleges and Unions*—Did none of them receive any alerts from their members? Did they not spot the alerts from Dr Foster?

2.8 *The Regulators*—Were none of the regulatory bodies contacted by members of the public complaining about registered professionals?

2.9 *Tony Wright MP’s Inquiry*—Dr Tony Wright, MP for Cannock Chase has suggested an inquiry in public, a lesson to be learnt from Stafford inquiry which does not replicate what the Healthcare Commission inquiry has done, but pulls all the lessons together for the NHS. Since it would have no statutory powers, key witnesses would simply not appear and it would not and could not produce any meaningful results.

2.10 *Royal College of Nursing*—Dr Peter Carter has suggested a public inquiry but in camera. This would be equally meaningless. The truth needs to be heard in public.

2.10.1 Claims at the recent RCN conference that the RCN representatives raised concerns are in direct contradiction to their chief executive’s letter to the Stafford press in May 2008 and should be questioned carefully by the members of your Committee.

2.11 *Culture Of Challenge*—Why did so many people not challenge the hospital on its poor standards of care? Non-executive directors of all NHS bodies, councillors, GPs, governors of the foundation trust, members of the PPI Forum and the Local Involvement Network?

2.12 *Ideas for Change*—Cure the NHS put four key suggestions to the Health Secretary’s team in early April:

2.12.1 a simple mechanism to ensure that all other hospitals are “safe”;

2.12.2 the outline of a modern system of patient safety and quality of care based on the fundamental principle for all the NHS that there should be “zero untoward incidents” and “excess” deaths. Currently there seems to be an acceptance of errors and excess deaths as inevitable; they are not;

2.12.3 “turning the NHS the right way up again” so that the enormous burden of managerialism is lifted from front line carers so that they, once again, can lead the delivery of high quality care;

2.12.4 bringing all the standards-setting, licensing, and regulatory bodies under one roof with just the investigatory arm separate. The model of civil aviation is instructive; and

2.12.5 turning the National Quality Board from its search for early warning signs of failure to eliminating failures in the first place. This latter concept has been common in many sectors for very many years.

2.13 *Targets do More Harm Than Good*—The Stafford Hospital failure should destroy for ever anyone’s belief that “targets” are the way to give the best to patients. The fact that the government still clings to them demonstrates that they do not understand what organisations need to do to deliver consistent levels of quality. They must be replaced by measures of treatment and care quality derived from the treatment and care derived themselves. This is so straightforward.

2.14 *Annual Healthcheck Declaration*—Has this method of “self-assessment” not been seriously discredited by the failures at Stafford Hospital?

2.15 *Stafford Hospital’s ‘Transformation Plan’*—Stafford Hospital’s transformation plan was recently published. We asked to be involved in its development but we were not given that opportunity. The plan is written completely in “management speak” has far too initiatives. It is anyway a rehash of similar programmes which the hospital itself and others have produced over time. What happened to the action plan drawn up in 2008 by South Staffordshire Primary Care Trust?

2.16 *Chaos in the West Midlands NHS*—In the year between Summer 2005 and Summer 2006 there was chaos in the West Midlands NHS as the primary care trusts and strategic health authorities were reorganised under the leadership of the current Chief Executive of NHS. The board minutes of the time demonstrate it very clearly.

2.17 *Financial Chaos Too*—That same period was accompanied by a rapidly growing deficit in many parts of the NHS. Stafford Hospital had a deficit and cut staff numbers to reduce it.

2.18 *The Care Quality Commission*—The chairman of the new Care Quality Commission is reported as saying that the Healthcare Commission’s investigation into Stafford Hospital was a blunt instrument and would not be used again, is that correct? What approach would be taken now?

2.19 *Whistleblowing*—There has been a great deal of talk of “whistleblowers” or rather the lack of them at Stafford Hospital. The reality is that they have been and continue to be firmly suppressed by the hospital management.
2.20 Does This Extend Across The NHS?—Of course it does. Look at the serious investigations carried out by the Healthcare Commission in its short life. As this is written we read of major chaos in A and E departments across the country. Cure the NHS has been contacted by people from a number of other places. Performance will be like most other things in human affairs, “distributed” roughly in the shape of the “bell” curve, the “normal” or “Gauss” distribution. Stafford Hospital is probably at the very end of the tail of the poor performers but the big question is, how many more poor performers have been missed?

2.20.1 The difficulty and the challenge for the Department of Health and the NHS is that they have no mechanism for finding out; they have not developed and implemented modern patient safety and quality systems to guarantee high quality care for all for every minute of every day of every patient’s stay; systems designed and implemented by frontline hospital carers with the help of patients. We are all patients and potential patients.

2.21 Excess Deaths—Why do we tolerate “excess” deaths?

1 June 2009

Memorandum by the Oxford Radcliffe Hospitals NHS Trust (PS 102)

PATIENT SAFETY

1. Summary

1.1 This memorandum is submitted by the Oxford Radcliffe Hospitals [“the ORH”] NHS Trust, with the intention of assisting the Committee in its inquiry into patient safety, and specifically in its consideration of evidence relating to the case of Bethany Bowen, as laid before the Committee in PS24, PS79, and in oral testimony heard on 20 November 2008.

1.2 The ORH is very sorry that it failed to prevent Bethany’s death, and for the grief and distress caused to the Bowen family.

1.3 In submitting this memorandum, the ORH emphasises that it values greatly Mrs Bowen’s personal account of her experience, and commends her evidence to the Committee. Indeed, we have taken careful note of Mrs Bowen’s account (and that of Mr Bromiley) and are grateful for the time that Mrs Bowen spent with senior members of the trust, articulating her perceptions of the issues first hand.

1.4 If required, in relation to specific points raised in evidence laid before the Committee, the ORH would be happy to provide further detail to clarify factual accuracy.

1.5 Based on the investigation into the specific details of the case and Mrs Bowen’s contribution, the ORH identified several key lessons, which have led directly to specific changes in clinical practice and procedures, and in the processes of clinical governance across the Trust which the Committee may consider could be applied more generally within the NHS. Further detail of these changes is given below.

1.6 In analysing all of the key issues arising, the ORH also identified principles for broader application, including the importance of developing an effective protocol to foster responsible innovation, while safeguarding the interests of patients and practitioners. The ORH Board is setting up an externally-chaired working party, to examine the future management of surgical risk, and would be happy to share its conclusions across the NHS.

2. Investigation

2.1 It is understood that details of Bethany’s medical condition, and the surgery performed, have been provided to the Committee by Mrs Bowen.

2.2 The circumstances surrounding Bethany’s tragic death during surgery in July 2006 have been subjected to lengthy and detailed investigation. There has been an internal Serious Untoward Incident [“SUI”] investigation, a three-day Coroner’s Inquest, investigation of and response to the family’s complaints and settlement of a clinical negligence claim. The ORH also obtained independent expert opinion194 on the care that Bethany received. The Bowen family put their own questions to the independent expert, through their solicitor, and his report was shared with them, and with the Coroner.

2.3 The conclusion drawn from all investigations undertaken was that Bethany suddenly deteriorated and was found to have sustained damage to her aorta, causing some blood loss and that despite repair of the aortic damage and initial stabilisation, Bethany deteriorated again and all attempts to resuscitate were unsuccessful and that she died. On the evidence provided to the coroner over three days, the Coroner’s conclusion was that the damage to Bethany’s aorta was caused by unspecified surgical instrumentation. Although Bethany’s collapse coincided with the use of a mechanical morcellator, it was thought by the Coroner and the independent expert that it was unlikely that this had caused the damage to her aorta, but more likely that the damage had been inflicted by the surgical graspers routinely used in laparoscopic surgery.

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194 From Mr Gordon MacKinlay, Consultant Paediatric Surgeon at The Royal Hospital for Sick Children, Edinburgh, and Senior Lecturer in Paediatric Surgery at the University of Edinburgh.
surgery. This conclusion was based on the nature of the injuries sustained, and the absence of significant injury to other intervening and surrounding structures. [It is of great regret to all who have been involved in examining this tragic case that a more definitive cause has not been established.]

2.4 It is worthy of comment that, shortly after Bethany’s death, the surgeon in charge met with her parents and explained (what the surgeon at the time thought to be the case) that the morcellator had caused the damage and that the bleeding from the damage to the aorta had caused the death. However, over the forthcoming days and weeks, and then extending to the inquest, surgeons and investigators and our external expert reviewer questioned whether this explanation made sense. We recognize that giving an initial explanation which is later questioned as different facts emerge can be perceived as becoming defensive. We hold firm, however, to the principle that we must be as honest as possible at all points throughout the process, even if conclusions are altered by the findings.

3. LESSONS LEARNED

Use of new surgical techniques

3.1 The ORH has identified key lessons with regard to regulating the introduction of any new surgical technique, including adaptation of an existing technique. Even if the morcellator was not the cause of the damage sustained in this case, very careful consideration needs to be given to the introduction of any such new approach, carrying significant potential risk. Without wishing to inhibit responsible innovation, any proposal to introduce a new (or newly adapted) surgical technique must now obtain formal approval from the Trust’s Technologies Advisory Group [“TAG”], on the basis of its proven clinical effectiveness, and conditional upon the demonstration of appropriate training, an assurance of competencies and ongoing audit of the clinical outcomes.

3.2 The technique of mechanical morcellation has not been used again in paediatric splenectomy at the ORH nor, so far as we are aware, has it been used anywhere in the UK.

Explaining risk and obtaining consent from patients, parents or guardians

3.3 We have identified key lessons with regard to the information that should be given to a patient (or parent) when obtaining consent. Although the surgeon’s use of the morcellator was based on consideration of its benefits (avoiding the need to extend the incision to remove Bethany’s enlarged spleen), weighed against the potential risk, it was judged that the selection of equipment was regarded as a technical detail, which as such was not explained to Bethany’s parents. Even if the morcellator was not the cause of the damage sustained in this case, any significant potential risk associated with the equipment selected should be explained. The ORH has therefore produced supplementary guidance for clinical staff, to emphasize this point, and to ensure that information offered should disclose whenever the equipment or technique to be used represents a different approach.

Documenting blood loss

3.4 A key lesson has been learned with regard to the importance of documenting a reasonably accurate estimate of blood loss, corroborated so far as possible by all available data. In Bethany’s case, it was not possible to provide an estimate of blood loss with any great degree of accuracy, as swabs had been disposed of at the change of nursing shifts, at a time when it was thought that Bethany’s condition had stabilised. While there is no validated way of measuring the exact volume of blood loss in paediatric patients undergoing surgery, in all cases where the assessment of blood loss might be important (including all cases where blood has been cross-matched, in the expectation that there may be a need to replace blood lost), it is now expressly required that swabs be weighed, and suction contents measured. Where appropriate, the estimate might be further refined by the anaesthetist applying specialist formulae and equations.

Disposal of equipment

3.5 The disposal of swabs, and of the morcellator blade, and the bag within which the spleen had been contained within the abdomen, significantly hindered the investigation undertaken, and meant that Bethany’s family were denied some information, eg whether the intra-abdominal bag remained intact, indicating whether it could have been breached by the morcellator. The responsibility of the theatre teams to retain equipment and consumables which may be implicated in any incident is stipulated within the Trust’s Medical Devices Management Policy, and its Incident Reporting Policy. This has been further under-scored by cascading the Medical Devices Alert to that effect, issued by the Medicines and Healthcare products Regulatory Agency [“MHRA”] in January 2008.

Clinical documentation

3.6 Following the investigation of Bethany’s case, the Clinical Lead for Paediatric Surgery initiated a Review of Surgical Process, to review the entire care pathway for paediatric surgical episodes from referral to discharge. Noting deficiencies in written operation notes, this emphasized the importance of including all relevant detail (including an estimate of blood loss, where appropriate), and recommended that the written record be supplemented by digital recording where possible, with relevant images to be placed in the patient’s record.
Paediatric Weighing

3.7 There had been an error in transcribing Bethany’s weight, which was then used as the basis for calculating her pre-medication. Although the dosage given was still within the parameters of the British National Formulary for Children, it was recognized that such a transcription error could—in other circumstances—have caused harm. A Paediatric Weighing Protocol, requiring a second independent confirmation of a child’s weight, has therefore been developed and introduced.

Investigation of Serious Untoward Incidents

3.8 Overall, we recognize that Bethany’s family was not satisfied with the process of the investigation undertaken. Key lessons have been identified with regard to the investigation of serious untoward incidents, within the broader context of clinical governance arrangements across the Trust. Specific changes instituted include the clear designation of an appropriate individual who will have prime responsibility for ongoing family liaison following any SUI. In general terms, efforts are now better concentrated on undertaking a more comprehensive and detailed investigation of any SUI from the outset; ensuring clearer communication of the progress being made throughout the process. The Final Report of an SUI Investigation now details the root cause analysis undertaken, and organisational learning points are clearly identified, for dissemination. The ORH is committed to the ongoing process of keeping policies, procedure and practice under review, to make any changes necessary; and to ensure that these are clearly communicated and embedded throughout the organisation.

Clinical Governance at ORH

3.9 We note Mr. Bromiley’s evidence that this tragic outcome represents a total failure of clinical governance. The principles of clinical governance require staff to be well trained and competent, to consider the risks and to follow evidenced guidelines. These principles reduce but can not completely eliminate clinical risk. At the time it was considered acceptable medical practice to be supervised in a new technique by an experienced practitioner.

We do not believe that the actions of the clinicians involved represented reckless or arrogant behaviour, although do believe with the benefit of hindsight, that tighter controls could and should be introduced to better safeguard patients. We are also trying to consider the challenge of enabling clinicians truly to see risk through the eyes of the patient and their parents and still have the courage and necessary focus to pick up and use the scalpel.

4. Conclusion

4.1 Bethany’s death was a tragic event. Although this will be of little consolation to the Bowen family, the subsequent investigation raised a number of issues for us, which have resulted in changes in practice and procedure. We have submitted this memorandum in the hope that those changes may be of use to other NHS Trusts.

May 2009

Memorandum by William Cash MP (PS 103)

MID STAFFS NHS TRUST

As the Member of Parliament for Stone, my constituents are directly affected because they are within the immediate vicinity of the Stafford Hospital. Indeed, the organisers of what became the Cure the NHS campaign came to see me because one of them was a constituent of mine, Debby Haseldine, and they were in despair. I had several meetings with them and I advised them to organise themselves into a campaign and presented the Healthcare Commission with a detailed list of matters which we insisted that the hospital Trust addressed before the Commission completed their report.

The day this report was leaked by the *Daily Mail*, I called immediately for a public inquiry under the Inquiries Act 2005 because it was clear that although the Healthcare Commission had done the preliminary work there were other matters before and since their report which required a full inquiry with evidence on oath, calling of witnesses and the production of papers, etc . . . There are other inquiries, such as that in Wales of which the Committee will be aware, which will serve as precedents. Indeed in 1985, I called for an inquiry under the then Tribunals and Inquiries Act in the same hospital where there had been an outbreak of Legionnaires’ disease and where there had been a tragic number of deaths.

Because I have worked so closely with the Cure the NHS campaign and have helped to campaign using a significant amount of evidence with them on a mutual basis, including minutes of the Strategic Health Authority in the course of reorganisation and subsequently the South Staffs PCT etc . . ., I am glad to endorse the views of the Cure the NHS campaign and thereby save the Committee time. However, I do strongly believe that an inquiry under the Inquiries Act 2005 is necessary because it has the powers necessary to get to the bottom of what has gone so tragically wrong and also to protect whistleblowers and where justified to exonerate those who need exoneration.
I enclose my contributions to the various statements and debates in chronological order because I have concentrated on each occasion on the reasons why I believe a 2005 Act inquiry is needed and these are all on the record in Hansard.

In the context of whistleblowing, as I have stated on a number of occasions, although the Public Disclosure Act has many good features, it can be bypassed and in my opinion, has been bypassed. Consequently, even the Secretary of State stated that there have been no whistleblowers from Stafford Hospital so far and I would refer the Committee to the recording of the programme produced by the BBC produced by Simon Cox on 16 April 2009. I have however been approached by, in the context of concerns for my own constituents had exchanges with, certain whistleblowers whose evidence I now enclose as Annex A.

I have indications from as many as 20 Consultants that they are deeply concerned in the public interest but that from their communications to me directly and indirectly, they are exceedingly apprehensive of revealing their names. This demonstrates the need for greater disclosure under the Public Disclosure Act. The only really effective legal protection for whistleblowers would seem to be evidence on oath where they are totally protected by legal privilege.

In the case of Mr Ahmed, you will notice that although he is currently suspended from the University Hospital of North Staffordshire he has conducted work in relation to Stafford and I understand that either of them may be prepared to give evidence and my office can supply their e-mail addresses and telephone numbers if required.

For all the reasons I have set out. I strongly believe that the Committee will wish to take oral evidence perhaps more extensive than at first thought and I would strongly urge them to conclude from my close examination of what has happened and the dreadful impact on the victims and the bereaved and my constituents and in order to restore confidence in the future of Mid Staffs NHS Trust that a public inquiry under the Inquiries Act 2005 should be recommended, where all these matters can be dealt with in the manner they deserve. I also believe as I have said in the debate that this is not only a local issue but has profound national implications given the role of the Chief Executive of the NHS, David Nicholson, and the Chief Executive of the Care Quality Commission, Cynthia Bower, both of whose evolving careers parallel closely the course of this tragedy from about 2005.

I also believe that the minutes of the meeting in December 2007 demonstrate the fact that Bill Moyes, the Chairman of Monitor pursued a line of questioning prior to the giving of Trust status, which was largely inappropriate and contributed to the failures in due course. Of the 46 questions, only relatively few related to patient care and quality—the rest were about finance and governance. The same appears to be true of Strategic Health Authority as they were reorganised and turned into the West Midlands SHA. The reports of Professor Alberti and Colin-Thomé are also critical of the performance of the Trust and the Committee will no doubt form its own judgements about these which have no doubt gone some way but do not get to the bottom of this problem.

May 2009

Annex A

WHY WE NEED A PUBLIC INQUIRY INTO THE MID STAFFS NHS TRUST TRAGEDY

Bill Cash, MP

Many of you will have heard the Radio 4 show “Any Questions?”, broadcast on Sunday from Stafford Gatehouse Theatre, followed by “Any Answers?”, about the call for a public inquiry into the Mid Staffs NHS Trust tragedy. As you will know, I was the first MP to call for a public inquiry and at the right time. In parliamentary terms, it was absolutely essential to call for one as the Prime Minister and Secretary of State were in the House of Commons to give their own statements and explanations, which they did on the same day on 18 March, one immediately after the other. I had already called for an inquiry on national radio and television. The reason for my pre-emptive action was to give them the opportunity to give a public inquiry before they locked themselves into a Governmental refusal which involves a U-turn. This is where we are now. This is what I did in 1984 when I won the case for our public inquiry on Legionnaires’ disease at Stafford Hospital.

I believe that with the right kind of public inquiry, under the Inquiries Act 2005, we will be able to sort matters out for the future but in order to do so we must establish what went wrong and why. On the day of the statement, Wednesday 18 March, I told the Prime Minister “What we need is a full public inquiry to get to the bottom of the matter. It is not enough simply to deal with the issue in the way that he described.” This kind of inquiry involves evidence on oath and compulsion of witnesses and papers, which is absolutely essential and would protect whistleblowers.

I then told the Secretary of State, Alan Johnson, that instead of holding several scattergun reviews, the Government should be “bringing all those matters together in one public inquiry, as we did in different circumstances back in 1984, with Legionnaires’ disease in the same hospital . . .”. A series of mini-reviews commissioned by the Government itself will not deal with the matters adequately and nor will it restore public confidence in the hospital for the future.
The devastating Healthcare Commission report fulfilled a useful preliminary purpose but it is a mere stepping stone. Its investigation would undoubtedly shorten and reduce the cost of an independent inquiry. In Parliament, Shadow Health Secretary, Andrew Lansley, at my suggestion, tabled an Early Day Motion calling for a public inquiry and it has now been signed by over 150 Members of Parliament. The Commission’s investigation has achieved a considerable objective, but I call for an independent inquiry because it would be truly “independent”. Moreover, it would restore confidence and trust and get to the bottom of the failures of governance and culture as well as specific medical issues and give justice to the bereaved, to the victims and the patients and provide a basis for compensation. It would also, where appropriate, exonerate those who should be exonerated.

The disaster marks a systemic failure internally and externally at every point on the compass by a wide variety of bodies charged with investigating and providing analysis, statutorily or otherwise. For the reasons that I have given, no confidence can be placed in the arrangements that the Secretary of State has put in place in relation to the Trust, because they lack the fundamental elements of real independence. There is also the problem of conflict of interest because when the Prime Minister said that the Care Quality Commission would review the matter, I pointed out that the Chairman of the Strategic Health Authority at the time is now Executive Director of the Care Quality Commission.

As I said in a debate in the Westminster Hall in the House of Commons on 1 April, “That is a travesty, given that in the minutes of a meeting of the strategic health authority board on Tuesday 18 March 2008, which I have with me, Cynthia Bower said that ‘there appeared to be nothing to indicate anything out of the ordinary was taking place on mortality.’” I have also called attention to the methods of self-assessment which the Healthcare Commission report criticises and which the new Care Quality Commission, under the new Act of Parliament, is not going to improve.

As I further explained in the debate, the Government’s reviews of the Trust are not truly independent in the most important sense—“They are scattergun reviews, with different terms of reference and timelines for reporting, and they do not allow the compulsion of witnesses and papers. That is a vital ingredient to get to the bottom of this tragedy. If the Government refuse to have an independent inquiry under the 2005 Act, that will be a local and national disgrace.”

Furthermore, I went on to say “There is no answer to this question other than an independent inquiry—the people of my constituency insist on one, the people of neighbouring constituencies insist on one and every national, regional and local newspaper insists on one. I can think of no reason why the Secretary of State and the Minister should not agree to such an inquiry. If they do not, the Government’s integrity will be at stake.”

I could not believe the Health Minister, Ben Bradshaw’s response to our calls for a public inquiry in the Westminster Hall debate. I was appalled at his assertion that the Healthcare Commission report was the end of the matter as it was an inquiry of sorts—in other words, this was our justice. And so I will continue to press for a public inquiry.

To put that in context, now that Local Government Secretary, Hazel Blears, has come to Stafford and seen the full extent and rage of local people, and has even promised to relay the strength of feeling about the Stafford Hospital scandal to Alan Johnson, I am now writing to the Secretary of State again pressing for a public inquiry.

I was glad to see that Cure the NHS campaign leader, Julie Bailey, who all of us in our area are indebted to, not only vowed to continue pressing for a public inquiry to be held on Stafford Hospital, but gave Hazel Blears a piece of her mind on her visit.

Memorandum by Dr Peter Daggett (PS 104)

BACKGROUND

There are presently 15 Consultant General Physicians in Stafford, who are on duty approximately one in 13. When on duty, we are supported during the day by a team of five junior doctors led by a specialist registrar and during the night by a team of three, led by another registrar. Emergency patients are usually seen by different staff in the Accident and Emergency Department, who refer patients to the admitting physicians or surgeons.

Patients are then transferred to the Emergency Assessment Unit (EAU) or the Clinical Decisions Unit (CDU). Sick patients are seen within a short time by a Consultant Physician and all are reviewed within about 12 hours. Subsequently they are either discharged from one of the assessment areas, or moved to a speciality ward.

There is a Clinical Director (CD) for Medicine, supported by a team of middle grade managers. There is a separate hierarchy for nurses, reporting ultimately to the Director of Nursing. She sits on the Trust Board, while the CD has access to the board through the Hospital Management Board (HMB). The appropriate line for medical and related matters is through the medical directorate and for nursing matters, through the matrons. The Consultants do have direct access to the Director of Nursing and have made use of that option.
**Concerns Expressed by Consultant Physicians**

It has been clear to the Consultant Physicians for a considerable period of time that there were not enough nurses or junior doctors. Our concerns have been raised with a number of managers since 2001 and there is abundant written evidence of that. Individual Physicians have raised concerns about the staffing of their own wards and that of the EAU. In general, the response from management has been that all is well and that although there may have been occasional shortages, the overall situation was not as bad as the Physicians had suggested. The first documented expression of concern was in 2001, at which time the then CD for medicine sent round a questionnaire asking for views on how the hospital was being run. I indicated that I had anxieties about lack of staff. The Clinical Risk Management committee was however told in March 2001 that staff shortage should no longer trigger an incident report. Over the next three years, many verbal and written expressions of concern were made by several Consultant Physicians, addressed to the Clinical Directors, the Director of Nursing and the Chief Executive. In May 2004 there was a meeting of the Hospital management Board (HMB), one minute of which (04/62) indicates that the PCT were aware of the difficulties under which the hospital was working. This was even before the PCT withdrew about £10 million pounds from the hospital budget. This was around the time that Mr Martin Yeates took over from Mr David O’Neill as Chief Executive. Between 2005 and 2008, numerous letters were sent to various managers expressing concern that wards were understaffed and that the care being given to patients was unsatisfactory. The recipients of warnings included:

- Clinical Directors in Medicine and Surgery
- Middle managers within these directorates
- Matrons and other nurse managers
- The Director of Nursing
- The Medical Director
- The Chief Executive directly

On 21 May 2008 (well before the HCC report), there was a meeting of a body called the Clinical Forum, at which were present 25 General practitioners, 25 Consultants from different specialities, the Medical Director and the Director of Nursing. The minutes indicate that the PCT was aware that the meeting was taking place. Considerable concern was expressed by several senior GPs about the standards of nursing care. The CD for medicine said at that meeting that he recognised the need for more nursing staff in Accident and Emergency and the Director of Nursing explained how this was being addressed.

**Other Expressions of Concern**

Incident forms drawing attention to inadequate staffing were completed by members of the nursing staff on many occasions between 2005 and 2008, well before the HCC investigation.

**The Consultants’ Impression of How the Crisis Occurred**

The PCT has reduced further the hospital’s budget by a considerable amount every year since the initial £10 million cut. This has made it very difficult to maintain services and this difficulty has been compounded by the changes in the GP contract which has increased the number of emergency admissions coming to the hospital. In the last three years, there has been an increasing emphasis on meeting targets. Within the Accident and Emergency department, one colleague died in a mountaineering accident and another colleague became ill. That resulted in a single Consultant trying to run a busy department at a time when the decision had been taken completely to refurbish this area of the hospital. The working conditions for the nurses and doctors working there were very difficult for nearly twelve months and the patients passing through at this time would have had a poor view of the facilities available in our hospital.

**The Response from Hospital Management**

All departments of the hospital were required to reduce expenditure considerably and this requirement appears not to have been negotiable. Within the Medical Directorate, the decision was taken to reduce the proportion of qualified nurses to 40%, the rest of the ward staff being Health Care Support Workers (HCSWs). In the Surgical Directorate, this was not accepted and the ratio was reversed. Since that time, there have been more qualified nurses on surgical wards than medical, but it is the medical wards that bear the brunt of emergency admission. This has been acknowledged as being unsatisfactory by the present Director of Nursing.

It was made clear to the Consultant Physicians by their Clinical Director that financial pressures were very considerable and that funding by commissioners was fixed.
AVENUES AVAILABLE TO EXPRESS CONCERNS

Many Consultant Physicians wrote letters to express their concern about the consequences of lack of staff and spoke personally to managers at all levels. The directorate structure is used to convey concerns to the Clinical Director, who passed these on to the Chief Executive, either in person, or through the Hospital Management Board, which usually meets monthly. Concerns expressed to nurse managers reached the Director of Nursing, who sits on the Trust Board.

HOW MIGHT THE PROBLEMS HAVE BEEN AVOIDED?

The Chief Executive became increasingly isolated and after the first few months of his tenure, was rarely seen visiting the wards. He seems to have lost touch with feelings on the ground and knowledge of the opinions of senior doctors was mainly information given by CDs at the Hospital Management Board. One option might have been for him to attend directorate meetings, where he would have got a flavour directly of just how worried we all were. These meetings are held every month and would only have involved two hours of his time. It would have been perfectly reasonable to attend each directorate in turn, so that every four months he would have had a clearer idea of concerns within his hospital.

This resume has been prepared on behalf of the Consultant General Physicians of Stafford Hospital by Dr Peter Daggett. I have been a consultant in this hospital since 1982 and a Fellow of the Royal College of Physicians of London since 1990.

26 May 2009

Memorandum by Andrew Lansley CBE MP (PS 105)

INTRODUCTION

I am pleased to hear that you will soon be conducting an inquiry into the failures in care at Mid Staffordshire NHS Foundation Trust.

As I am sure you agree, the key to learning lessons for the future is understanding thoroughly what went wrong in the past. I am concerned that reports to date have not sufficiently scrutinised what went wrong in Mid Staffordshire. There remain a number of unanswered questions.

To that end, I enclose a paper setting out the areas that I believe have not yet been thoroughly investigated. I would be grateful if you would circulate my submission to other members of the committee, and consider these points as part of your inquiry.

MID STAFFORDSHIRE NHS FOUNDATION TRUST: UNANSWERED QUESTIONS

1. Role of the Department of Health

Dr Colin Thomé made three recommendations for the Department of Health, relating to complaints procedures, oversight of performance management and assessment bodies, and organisational change:

The Department of Health should review whether the new complaints procedure has improved the complaints process with particular consideration of its independence to act if local systems are not sufficient.

The Department of Health should describe how the roles of PCTs, SHAs and the regulators are different and how they interrelate.

The Department of Health should set out clear expectations on all health organisations that effective “business continuity planning” is the norm, and work in co-production with the NHS to develop guidance for organisational transition, including effective formal record keeping.

If it is in the Department’s power to implement three of the solutions, Colin Thomé must have identified three areas where the Department of Health failed in the past to discharge its responsibilities, in a manner which contributed to the failures at Stafford Hospital. Yet in the body of his review, the Department of Health is not mentioned once. I believe that it would be beneficial to investigate these failures, in order to give us full confidence that the Department of Health has learnt all possible lessons for the future.

2. Foundation Trust approval process

The Healthcare Commission report criticised Mid Staffordshire NHS Foundation Trust, saying “The evidence suggests that the top priority for the trust was the achievement of foundation trust status” (p 9). Mid Staffordshire NHS Foundation Trust was granted Foundation Trust status on 1 February 2008.
A presentation on the NHS Confederation website, given by the Department of Health’s Foundation Trust team describes the role of the Department of Health applications committee and the Secretary of State as follows:

“The Apps Committee tests the assurance obtained by the SHA”. There are seven of these assurances: “Legally constituted and representative, Good business strategy, financially viable, well-governed, capable board to deliver, good service performance, local health economy and external relations” (slide 6).

It would be beneficial to investigate the advice formulated by the Applications Committee in this instance, in order to ensure public confidence in the process for awarding foundation trust status.

3. Failure of SHA/PCTs

The Colin-Thomé report raises serious concerns over the failures of the West Midlands Strategic Health Authority and South Staffordshire Primary Care Trust:

“In the case of Mid Staffordshire hospital, the trust, PCTs past and present and SHAs past and present do not appear to have taken notice of signs that were present in the survey data and in complaints that indicated poor patient care.”

“Evidence of poor care has emerged that was not collated or challenged by the PCTs or SHAs at the time.”

“It seems that during the period 2002 to 2006, likely in common with many other PCTs and SHAs, the focus of the local PCTs and SHAs was on finance. In the case of South Staffordshire, this was potentially at the expense of quality of care.”

“There was over reliance by the PCTs and the SHAs on Monitor and the Healthcare Commission to ensure quality of care at Mid Staffordshire hospital trust. As discussed in the previous section on data, triangulation of data sources gives the most accurate picture, the PCTs and SHAs relied on too few sources.”

These findings are confirmed by analysis of West Midlands SHA board minutes, which show that the CEO (Cynthia Bower) only raised mortality rates once in her routine briefings to the Board. This was only in relation to the Healthcare Commission’s announcement of their intention to investigate MSFT in March 2008. On that occasion, she stated that “there appeared to be nothing to indicate that anything out of the ordinary was taking place on mortality”.195

Professor Sir Ian Kennedy stated:

“In February 2008, the Trust was granted Foundation Trust status. The investigation team at the Commission . . . was not asked whether there were concerns about the performance of the Trust . . . We understand that Monitor asked the SHA for its views; the SHA was aware of our work on mortality outliers and ‘alerts’ by then.”196

It is clear that the West Midlands SHA failed in its duty of performance management. Board minutes indicate that they focused their energies on Department of Health initiatives, finance and reconfigurations, relying on performance assessment bodies to consider the quality of patient care.

In particular, Dr Colin-Thomé repeatedly criticises the “focus” of West Midlands SHA during the periods when both David Nicholson and Cynthia Bowers were Chief Executive. Given that these individuals now lead the NHS and CQC respectively, their role in the failures of the organisation that they led previously should be investigated, to provide public assurance that both individuals are now capable of ensuring that the organisations they lead have the correct focus.

4. Complaints system

The Healthcare Commission wrote to Martin Yeates in July 2008, warning him that they were seriously concerned about:

“problems with communication with relatives, and with the complaints process and difficulties in getting a response. Over a third of stakeholders mentioned these issues.”

Colin-Thomé recommended that the Government address this failing:

“The Department of Health should review whether the new complaints procedure has improved the complaints process with particular consideration of its independence to act if local systems are not sufficient.”

“There were failures in Staffordshire, at the hospital and the PCT, to hear messages from patients about poor quality of care. This was in part a failure of the local health system but my recommendations also challenge the current policy and processes to go further faster.”

195 Unconfirmed Minutes of the Meeting of the Board. 18 March 2008. 03/08/06.7.
196 Letter from Professor Sir Ian Kennedy to Rt Hon Kevin Barron MP. 31 March 2009.
But these conclusions are not based on any investigation of the failures of the complaints procedure. There is no investigation of the reasons why only a small proportion of the complaints against the Trust from 2002 to 2007 actually reached the Healthcare Commission. It is clear that if all second-stage complaints had routinely gone to the Healthcare Commission, the regulator could have had the information to intervene and address the poor standards of care at an earlier stage.

There is no investigation of the ad-hoc complaints process uncovered by the Healthcare Commission—where some were directed to the SHA and some directed to the NPSA. There is no analysis of the mechanisms that failed to compel the Trust to respond in an adequate or timely way to complaints. I have received evidence that even where one family’s claim was pursued by the Healthcare Commission, and a conclusion of gross professional negligence was reached, the Trust’s response and action plan never came.

5. Local commissioners

None of the reports commissioned so far get to the bottom of local commissioning failures.

In his report, Colin-Thomé notes:

“The PCT Chief Executive began a programme of visits to GP practices in the area. The transition board, PEC board, nor GPs raised any issues about patient care in the hospital trust.”

However, the Healthcare Commission report makes clear that local GPs did have significant concerns:

“The PCT . . . contacted its two local commissioning groups to ascertain the views of GPs on standards of care. The responses were highly critical.”

There is no explanation for this discrepancy.

Colin Thomé acknowledges that practice based commissioning did not empower GPs to act upon their concerns upon patients behalf:

“Since 2006, local practice based commissioning arrangements have been strengthened. However, these did not translate into escalation of concerns about the care at Mid Staffordshire hospital trust.”

However, he simply accepts this failure, rather than exploring further why practice based commissioning did not fulfil its purpose in this situation. The failure of local commissioning procedures must be investigated thoroughly in order to provide assurance that local services will improve in the future.

6. Targets

All of the reviews acknowledge that process targets were a central theme of the failure. Dr Colin-Thomé acknowledges their centrality in the failures at Stafford Hospital in the evidence section:

“A central theme of the failures at Mid Staffordshire hospital trust appears to be an over reliance on process measures, targets and striving for Foundation Trust status at the expense of an overarching focus on providing quality services for patients.”

Alberti acknowledges that one of the central problems was targets prioritised over clinical care in his introduction:

“It is also unfortunate that the main PCT commissioning services (South Staffordshire Primary Care Trust) did not pay more attention to standards and quality of clinical care and comments from patients but focused more on throughput and targets.”

Neither review goes on to address or mention the problem again. I can find no evidence that this central theme has been addressed. The Chief Executive of the PCT informed me that their only quality metric in commissioning A&E services until 2007 was the four hour target. The correlation with the “over-reliance” on this target is clear.

This failure must be investigated to ensure that all lessons are learnt, and to inform and assist commissioners in developing other quality metrics for A&E.

7. Whistleblowing/closed culture

In his statement to the House on 18 March, the SoS said that the lack of whistleblowers was “one of the great mysteries of Stafford”:

“The Healthcare Commission has said that clinicians and staff gave up registering complaints at the hospital because they felt that they were wasting their time, but I cannot answer the question of why those complaints did not come up through a different route . . . there is no answer to it in the Healthcare Commission’s report. Perhaps one will emerge from the other reviews.” 18 Mar 2009: Column 922

Colin-Thomé reported that:

“The Mid Staffordshire hospital trust demonstrated a closed culture with a lack of sharing of data and information that allowed poor care to continue undetected.”
He recommended that:

“All clinicians must speak up for patients when they witness poor quality care. It is our overarching duty.”

But none of the reviews provide any answers on whistleblowing. There are no mentions of the inadequacy of whistleblowing procedures, or questions raised about why staff inside Stafford Hospital did not feel that they could speak out and stop what was going on. I have received evidence that potential whistleblowers at Stafford have received intimidating rebuttals from the hospital’s legal team. It is vital to get to the bottom of this mystery through an investigation of whistleblowing procedures, and the manner in which staff who attempted to raise their concerns have been treated.

8. NPSA

The National Patient Safety Agency’s website states that they exist to identify and reduce risks to patients receiving NHS care, and to feed any concerns back to healthcare organisations through their National Reporting and Learning System.

The Healthcare Commission found that serious incidents in the Trust were sometimes reported to the SHA, and sometimes to the NPSA. There has been no further investigation of whether the body tasked with alerting NHS organisations of risks to patient safety fed these complaints back to the SHA, the DH or the Healthcare Commission. If not, do you not consider it important to investigate why the NPSA failed in its duty in Stafford, in order to ensure public confidence in the capability of the National Reporting and Learning System to safeguard patients elsewhere.

Andrew Lansley CBE MP
Shadow Secretary of State for Health
28 May 2009

Note by the Academy of Medical Royal Colleges (PS 106)

Ben Bradshaw’s Evidence to the Health Select Committee 3 June 2009

Further to Neil’s discussion with you in his College this morning, we write to record our concern that a Minister of Health should try to implicate the Royal Colleges in the Mid-Staffordshire quality of care issue (Q 1069 and Q 1087). As you know the Colleges are deeply concerned about quality of care, but have no direct responsibility for this at a local level.

Further our right to inspect hospitals for the quality of training, during which we often identified quality of care issues, ceased in September 2005 with the establishment of the PMETB.

We would be grateful for reassurance that the Health Select Committee’s report will acknowledge this, and regard this particular piece of evidence as inaccurate and misleading, and will therefore not apportion any blame to the Medical Royal Colleges.

Professor Dame Carol Black
Chairman

Professor Sir Neil Douglas
Chairman Elect

Academy of Medical Royal Colleges
11 June 2009

Memorandum by Dr Pradip Singh (PS 107)

Mid Staffordshire Hospitals NHS Trust

Thank you for asking me to present my written evidence for submission to the Health Committee meeting next week about matters relating to the Mid Staffordshire Hospitals NHS Trust. I would have preferred to present the evidence in person at the meeting but unfortunately I have to be away next week.

Firstly, despite my anxiety about victimisation as a result of this submission, I consider it my moral and ethical obligation to raise matters of concern relating to patient care at my hospital.

I was appointed a Consultant Gastroenterologist at the Mid Staffordshire Hospitals NHS Trust in September 1995. Over the years, many clinicians had noticed deterioration in the standards of patient care which had became particularly acute approximately three years ago when major cut backs were made in staffing numbers. This included a savage reduction in the number of nursing staff and a cut back in the level of secretarial support to consultants. These changes caused major destabilisation, led to undesirable and long term changes in the culture in the organisation, and ultimately compromised patient care.
Many of us (including me personally) have on numerous occasions raised concerns at various fora, and with senior managers such as the Head of the Division of Medicine, about poor patient care as a result of reduction in staffing levels and also the much more serious insidious and long lasting impact of that on the culture in the Trust. It appeared from the attitude of the management that not only they never took our concerns seriously, but clinicians who raised such issues were made to feel as trouble makers who were not “team players”.

I personally reported dozens of serious adverse clinical incidents resulting from abysmal secretarial support in my department. Letters were not being typed for months. Grossly abnormal results (eg CT scan showing possible pancreatic cancer) were not shown to the consultant for weeks or months. These adverse incidents were only acknowledged reluctantly after many remainders. It was clear that concerns were not taken seriously, nothing other than platitude was offered as a solution, and specifically in my department, a discriminatory approach to secretarial support continued. This discriminatory practice ceased only recently after several years of unpleasant battle (risking my personal career) and only when I raised the issue of the appearance of blatant racial discrimination.

Over the last three years, as a result of cut backs in nursing numbers, it has become a routine practice for no support to be available on consultant ward rounds including the scheduled post take ward rounds. Indeed, as the culture in the Trust has changed it has now become the accepted practice not to expect nurse presence as a matter of course on the ward rounds. This situation puts the consultants in an unacceptable, invidious, and extremely frustrating position. They are denied the basic tools they need to do their job properly. Nurses are the only staff who can provide a modicum of continuity of care as the junior doctors who attend the ward rounds and the consultant who lead them, are not usually the doctors who would be responsible for the ongoing care of the patient after the initial admission. Nurses are the key element in the two way communication process without which it is not possible to deliver effective and safe patient care.

The problem is particularly acute in the Emergency assessment Unit (EAU). The EAU has four bays. If a consultant wants nursing input on his/her post take ward round, he/she will have to beg or grovel for that eight times (four bays on two occasions -once for the night time admissions and then for the day time admissions with a different set of junior doctors). Most consultants will simply somehow try to manage as it is extremely frustrating to do this routine on a regular basis and is also likely to attract the wrath of the nursing hierarchy who have now got used to ward rounds without nursing input and who resent consultants who insist on nurse presence. In my view, the post take ward round is the most important event of the day on the ward, but is not seen like that by the management as is obvious from the numerous discussions that have taken place about this matter even after the Healthcare Commission report. This is what I meant by the long lasting cultural shift which has occurred in the Trust and which has put patient safety at risk, and demoralized consultants who put patient care at the centre of their work. Such consultants are disliked by the management, treated as awkward trouble makers, and they are at risk of jeopardising their personal positions. In such a climate most clinicians quietly accept the changes and fall in line. It is clear that the prevailing culture in the Trust is not likely to promote clinical excellence.

Sadly, despite the recent talk of transformation, and the damning Healthcare Commission report, the ground realities have not changed much. Consultant ward rounds are still not supported by nurses and the Trust management are still dragging their feet on this crucial matter.

Many clinicians have felt frustrated for a long time. In my own personal case, as you can see from the email I circulated to my consultant colleagues, I was suspended from work on flimsy grounds without even following the elementary rules of natural justice because I had dared to stand my ground and repeatedly raised the issue of adverse impact on patient safety of routine non availability of nurses on consultant ward rounds, and because I had been outspoken in my criticism of the culture of a palpable atmosphere of intimidation in the Trust which is why more clinicians have not openly voiced their concerns about standards of patient care.

With this letter, I attach the following documents as evidence of the poor culture that has operated in this Trust:

1. My email dated 15 April 2009 to consultant colleagues explaining events around my suspension. (Annex A)
2. Adverse incident report about non availability of nurse support on post take ward round on EAU on 16 April 2009 and the abysmal care of a patient with acute renal failure. (Annex B)
3. A recent chain of emails about widespread concern about the impact on patient safety of routine non availability of nursing staff support on consultant ward rounds. (Annex C)
4. My email dated 27 January 2006 to Dr Elizabeth, then Clinical Director of Medicine, requesting feedback on the stream of adverse incidents resulting from poor secretarial support. (Annex D)

Annexes A–F available for inspection in the Parliamentary Archives.
5. Letter from Mr David Durrans, then Deputy Medical Director, dated 23 November 2005, documenting the fact that concerns raised by myself and other clinicians of the impact of A & C review (major cut back) on patient care having been presented at the HMB and the then Chief Executive’s resolve to press ahead regardless. (Annex E)

6. Email exchange in June 2008 between Dr Hearing, Lead Clinician for Gastroenterology and Dr Pradip Singh about substandard care as a result of nonavailability of nursing staff for ward rounds. (Annex F)

Dr Pradip Singh MD, DM, FRCP
Consultant Gastroenterologist
Mid Staffordshire Hospitals NHS Trust
29 May 2009

Memorandum by Richard Stein (PS 108)

PATIENT SAFETY: THE LESSONS OF MID-STAFFORDSHIRE

Cure the NHS welcomes the opportunity to make submissions to the Health Select Committee’s inquiry on patient safety at Mid Staffordshire NHS Foundation Trust.

EXECUTIVE SUMMARY

1.1 Since April 2005, Mid Staffordshire NHS Foundation Trust has had a consistently high mortality rate for patients admitted as emergencies. The Trust has been the subject of severe criticism as to the standards of care it has provided over the same period.

1.2 It is estimated that 400 patients are likely to have lost their lives unnecessarily as a result of these failings, though the figure may be as high as 1,200. A far larger number have received grossly inadequate standards of basic care over the same period.

1.3 Concern as to the mortality rate gave rise to an investigation by the Healthcare Commission in 2008, whose findings were published on 17 March 2009. These findings and subsequent reviews commissioned by the Department of Health identify a range of serious failures on the part of the Trust.

1.4 The government has adopted such recommendations as were made in these documents, but key questions of serious public concern remain unanswered: chiefly how the situation at Mid Staffordshire NHS Foundation Trust was allowed to develop and continue undetected for so long and how such failures may be addressed in the future.

1.5 In the circumstances, a public inquiry is necessary. This is because:

(a) There has been an inadequate level of public participation and scrutiny.

(b) Serious matters of public concern remain outstanding that have not been addressed.

(c) The ongoing nature of the failings strongly suggests patient safety will continue to be compromised until such time as responsibility for these failings has been considered in full.

1.6 While the Secretary of State for Health has resisted demands for a public inquiry, a definitive decision has yet to be taken. Cure the NHS requests the support of the Health Select Committee in recommending a public inquiry on terms of reference allowing for the timely and efficient review of outstanding issues of public concern.

2. ABOUT CURE THE NHS

2.1 Cure the NHS was set up by and for individuals who have lost relatives or were victims of poor care provided by Mid Staffordshire NHS Foundation Trust (the Trust). As such it represents the views of a significant proportion of those affected.

2.2 The organisation was founded in 2007 by Julie Bailey after her mother, Bella, died in Stafford Hospital. Ms Bailey was angered by the poor quality of care received by her mother and many other patients and has since campaigned to improve patient safety.

2.3 The campaign has a broad base of support from patients and relatives whose loved ones experienced appalling standards of care at Stafford Hospital.

2.4 Its objectives are to ensure adequate scrutiny of the failings has been carried out and to change the management and ethos of the Trust so people can feel safe and secure if they are admitted to hospital.
3. BACKGROUND

3.1 The Trust was awarded Foundation Trust (FT) status in February 2008 on meeting the criteria of the Department of Health and Monitor.

3.2 FT status was awarded despite independent evidence, published in 2007, that the Trust’s hospitals had the fourth highest rate of unexpected deaths in England between 2003 and 2006. With a standardised mortality ratio (HSMR) of 127, 27% more deaths than would ordinarily be expected occurred in the period in question.198

3.3 The Trust (then Mid Staffordshire General Hospitals NHS Trust) had received performance ratings by a variety of organisations, disclosing an inconsistent pattern:

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<tr>
<th>Period</th>
<th>Organisation</th>
<th>Rating</th>
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<tbody>
<tr>
<td>2002–03</td>
<td>Commission for Health Improvement</td>
<td>3 stars199</td>
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<tr>
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<td>Healthcare Commission</td>
<td>0 stars200</td>
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<tr>
<td>2007–08</td>
<td>Healthcare Commission (annual health check)</td>
<td>Provisionally “Good”/“Good”, subsequently downgraded to “Weak”/“Weak”204</td>
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3.4 However, the Healthcare Commission’s formal investigation in March 2008 into the Trust’s unusually high HSMRs since April 2005 identified “systemic problems across the Trust’s system of emergency care”.205

3.5 In March 2009 the Secretary of State announced measures in response to the Healthcare Commission report. These included reviews by Professor Sir George Alberti (National Clinical Director for Emergency Care) and Dr David Colin-Thomé (National Clinical Director for Primary Care), completed in April 2009.

3.6 To date the Secretary of State has resisted calls for a public inquiry. His responses to questions from Liberal Democrat health spokesman Norman Lamb on 18 March 2009206 and Conservative MP William Cash on 18 March 2008207 indicate he considers the Healthcare Commission report and subsequent reviews to be sufficient.

3.7 Cure the NHS considers any decision not to hold a public inquiry would be flawed and irrational. The reasons why this is the case are detailed in section 7 below.

4. THE HEALTHCARE COMMISSION’S FINDINGS

4.1 The Commission’s investigation prompted responses from 103 patients and relatives, 99 of whom were critical of the Trust’s hospitals, or had had a poor experience of them. Many criticised poor standards of nursing care.205 These responses represent the only public involvement to date in the investigations into the [Trust’s] failings.

4.2 Among other matters, the Healthcare Commission found:

(a) The abnormally high mortality rates related to emergency admissions at the Trust’s hospitals.205 A visit to the A&E department in May 2008 fuelled “serious” concerns.

(b) The hospital was under-staffed and under equipped. Receptionists were left to carry out initial assessments of patients as there were too few nurses. Patients faced delays for medication and pain relief and there were too few consultants and middle grade doctors.208

(c) Standards of care were extremely poor: some patients were left “for hours in wet or soiled sheets”, call bells for patients who were in pain or needed the toilet were “often not answered, or not answered in time” and families claimed that doses of medication were not given on time, if at all.209

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198 The Hospital Guide 2007 Dr Foster Intelligence
199 Commission for Health Improvement NHS Performance Ratings (2002–03)
200 Healthcare Commission NHS Performance Ratings (2003–04)
201 Healthcare Commission NHS Performance Ratings (2004–05)
202 Healthcare Commission Annual Health Check Ratings (2005–06)
203 Healthcare Commission Annual Health Check Ratings (2006–07)
204 Healthcare Commission Annual Health Check Ratings (2007–08)
205 Investigation into Mid Staffordshire NHS Foundation Trust, Healthcare Commission, March 2009, pg 4
206 House of Commons, Hansard, c917, 18 March 2009
207 House of Commons, Hansard, c919, 18 March 2009
208 Investigation into Mid Staffordshire NHS Foundation Trust, Healthcare Commission, March 2009, pg5
209 Investigation into Mid Staffordshire NHS Foundation Trust, Healthcare Commission, March 2009, pg 6
(d) There were “deficiencies at virtually every stage of the pathway of emergency care”. There were no clear protocols for the management of patients. Factors contributing to a poor patient outcome included missing or faulty equipment, delays in assessment and treatment, insufficient and poorly trained/supervised staff and a lack of beds.

(e) The Trust’s investigations of its mortality rates were not sufficiently objective or robust. There were failures to report serious untoward incidents. Senior leaders and the Trust’s board were criticised for not developing an “open learning culture” and for failing to inform themselves about the quality of care.

4.3 While the Healthcare Commission report catalogued these failures, it did not address the systemic causes of the failures identified and why they remained undetected. Areas of inquiry that remain outstanding are discussed below.

5. REVIEW BY PROFESSOR SIR GEORGE ALBERTI

5.1 Professor Sir George Alberti considered the standard of emergency care being provided by the Trust since publication of the Healthcare Commission report and submitted his findings to the Secretary of State on 29 April 2009. The government published his report the following day, along with a response accepting all of his recommendations.

5.2 The review found some improvements since the start of the Healthcare Commission investigation including raised staffing levels and a new medical director.

5.3 However, it also found that there is “still too much focus on business and finance to the detriment of the real needs of the local population” and that “safety, quality and day-to-day care of patients could be further improved in some areas”.

5.4 This review was limited in scope, being confined to current service provision.

6. DR DAVID COLIN-THOMÉ’S REVIEW

6.1 Dr David Colin-Thomé was commissioned by the Secretary of State to consider how the PCT and SHA failed to expose what was happening at Stafford Hospital. Again the government’s response has been to accept Dr Colin—Thomé’s recommendations.

6.2 Dr Colin-Thomé agreed with the Healthcare Commission that there had been “appalling standards of care and chaotic systems for looking after patients”.

6.3 He described failures to detect the poor standards as “disturbing” and expressed disappointment at the failure of individual clinicians to raise concerns.

6.4 Dr Colin-Thomé identified “an over-reliance on process measures, targets and striving for Foundation Trust status at the expense of an overarching focus on providing quality services for patients” as a core theme. He also highlighted a “lack of good patient engagement” which he considered “essential for a responsive service”.

6.5 His review concluded that primary responsibility for these failings rests with the Trust’s board and the staff, though lessons should also be learnt by the PCT and the SHA. While the Trust had a “closed culture” that allowed poor care to continue, the PCT and SHA failed to seek out data that would have triggered concerns.
7. **Case for a Public Inquiry**

7.1 A public inquiry is required because:

(a) There has been an inadequate level of public participation and scrutiny.

(b) Serious matters of public concern remain outstanding that have not been addressed by the report and reviews.

(c) The ongoing nature of the failings strongly suggests patient safety will continue to be compromised until such time as responsibility for these failings has been considered in full.

**The need for a public hearing**

7.2 At a conservative estimate 400 “excess” deaths occurred over the period in question, based on mortality at 27% in excess of expected standards. Mortality rates in fact reached highs of 45% in excess of expected standards, so it is possible that up to 1,200 unnecessary deaths have been caused.\(^\text{221}\)

7.3 The state is obliged under Article 2 of the European Convention on Human Rights (ECHR) to provide an effective investigation with a degree of public scrutiny in these circumstances. The serious lapses in care standards identified in the reports and widespread allegations of degrading and inhuman treatment received by patients in the care of the Trust engage a parallel obligation to investigate under Article 3 ECHR.

7.4 The reviews conducted to date fall far short of the necessary standard of scrutiny. The responses received by the Healthcare Commission represent the only involvement of the public in the investigation of what went wrong at the Trust’s hospitals.

7.5 While there have been a limited number of inquests, these represent only a minority of the individual cases brought to the attention of Cure the NHS. The HM Coroner for [check] declined to provide the Healthcare Commission with information about inquests involving the Trust.\(^\text{222}\) Such findings as there have been in individual cases have not been considered in any broader review.

7.6 The Secretary of State has made a process of external review of individual patient files available to those requesting it.\(^\text{223}\) However, these will be private reviews confined to information available in individual patient files.

7.7 An inquiry held in public is therefore necessary to:

(a) Satisfy the obligations to conduct an effective public investigation into breaches of Articles 2 and 3 ECHR.

(b) Identify culpable and discreditable conduct.

(c) Enable dangerous practices and procedures to be rectified.

(d) Confirm or allay suspicions of any deliberate wrongdoing.

(e) Provide those who have lost loved ones with the satisfaction of knowing that lessons learnt from his/her death may save the lives of others.

7.8 In addition, in a public inquiry:

(a) witnesses are less likely to exaggerate or attempt to pass on responsibility;

(b) information becomes available as a result of others reading or hearing what witnesses have said;

(c) there is a perception of open dealing which helps to restore confidence; and

(d) there is no significant risk of leaks leading to distorted reporting.

7.9 As many as 4,000 individuals have signed a petition organised by Cure the NHS and the Patients Association calling for a public inquiry into the failures at the Trust. The events in question have seriously undermined public confidence in the regulation of care standards and the process by which FT status is acquired.

7.10 The publication of a report resulting from a public inquiry would command greater public confidence and help to restore trust in Stafford Hospital.

**Matters not addressed by the reviews**

7.11 The Healthcare Commission, Alberti and Colin-Thomé reports have not addressed a range of issues of serious public concern.

\(^\text{221}\) The Trust’s Standardised Mortality Ratio in fact varied between 127 and 145 between 2005–06 and 2007–08 for patients admitted as emergencies aged 18 and over: Investigation into Mid Staffordshire NHS Foundation Trust, Healthcare Commission, March 2009, pg 4

\(^\text{222}\) Investigation into Mid Staffordshire NHS Foundation Trust, Healthcare Commission, March 2009, pg 11

\(^\text{223}\) Government response to Alberti and Colin-Thomé reports, 30 April 2009, page 3
7.12 Cure the NHS recommends that these form the scope of any public inquiry and they are set out in detail in Section 8 below. Broadly, the report and reviews failed to establish:

(a) The complete picture of the scope of the problem including the number of deaths caused and cases of inadequate treatment and the standards of care delivered in both emergency and non-emergency wards.

(b) The systemic failures that allowed these problems to persist, including whether the responsibilities of external bodies, including Monitor, were properly discharged and the effectiveness of complaints procedures available to patients and relatives.

(c) The effect of the Trust’s drive for FT status in 2007–08 and the role of other targets to which the Trust was subject.

7.13 Cure the NHS has justifiable concerns about the scope of the reviews conducted by Professor Alberti and Professor Colin-Thome´. The Professor Alberti review was brief and limited in scope, being a current audit of emergency care.

7.14 The review by Dr Colin-Thome´ was far from systematic or exhaustive. Dr Colin-Thome´ states that “much of my analysis was gathered verbally due to a lack of formally documented paperwork”224 and concedes he encountered a “lack of organisational memory” about the events in question.225

7.15 It is submitted that a large body of documentation, including board minutes of the SHA and PCT, was freely available and appears not to have been considered. In the absence of assurances as to the reliability of verbal accounts gathered, only limited weight can be given to information received in private from those closely connected to the subject matter of the investigation.

Ongoing nature of the concerns

7.16 A public inquiry is also necessary in view of evidence that the circumstances giving rise to the failures identified in the reviews still persist and poor standards of care continue to be provided.

7.17 Without adequate public scrutiny of the concerns identified, Cure the NHS has justifiable concerns patient safety will continue to be compromised.

7.18 The evidence for these concerns includes:

(a) A marked increase in the number of complaints about standards of care. This has included a 100% rise in complaints concerning A&E admissions and a 75% rise in complaints concerning AEU. [VERIFY and footnote source]

(b) With the exception of the Chief Executive of the Trust, most of the senior operational and clinical management of the Trust remains in place despite criticism of senior management in the Healthcare Commission report.

(c) Complaints Cure the NHS continues to receive demonstrate inadequate care is still being provided to elderly and otherwise vulnerable patients at Stafford Hospital. Since [date], Cure the NHS has received details of [number] cases where there have been failures to provide basic care needs, including adequate nourishment.

8. KEYS AIMs OF A PUBLIC INQUIRY

8.1 Accordingly, a public inquiry is required to cover the following concerns:

(a) Establish the extent of the impact of failures at Stafford Hospital, including the number of deaths and the number of cases of neglect/inadequate treatment.

(b) Explore how Mid Staffordshire NHS Foundation Trust managed to achieve both a 3 star performance rating226 from the Commission for Health Improvement (CHI) for 2002–03 and FT status in February 2008.

(c) Determine whether the pursuit of 3 star and FT status contributed to the Trust’s failures. If so, consider how these processes could be changed to avoid repetition.

(d) Consider whether the existence of NHS targets contributed to the Trust’s failures. If so, consider how these processes could be changed to avoid repetition.

(e) Explore what factors should have alerted regulators and others to the serious crisis at Stafford Hospital. Which bodies should have been alerted and what action should have been taken? Did the bodies have the relevant powers to enable them to take timely and effective action to limit/avert the crisis?

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224 Mid Staffordshire NHS Foundation Trust: A review of lessons learnt for commissioners and performance managers following the Healthcare Commission investigation, Dr David Colin-Thome´, 29 April 2009, p.10

225 Mid Staffordshire NHS Foundation Trust: A review of lessons learnt for commissioners and performance managers following the Healthcare Commission investigation, Dr David Colin-Thome´, 29 April 2009, p23

226 Commission for Health Improvement NHS Performance Ratings (2002–03)
(f) Explore whether the NHS Complaints procedure was able to deal with patients’ complaints adequately and whether recent changes have remedied any deficiencies.

(g) Find out why none of the clinicians at Stafford Hospital raised concerns about the Trust’s failures and whether measures can now be taken to ensure this valuable safeguard is in place.

9. SUMMARY: CURE THE NHS RECOMMENDS

9.1 That the Secretary of State should hold a public inquiry into the questions of public concern that remain unanswered. Cure the NHS requests that the Committee supports that recommendation.

9.2 Such an inquiry need not require significant financial outlay or be unduly lengthy: a six to eight-week inquiry should be sufficient. This would not delay attempts to improve standards of care, as recommended by the Healthcare Commission, Professor Alberti and Dr Colin-Thomé.

9.3 Patient participation should be encouraged to allow a full and proper investigation of the mistakes of the past and to inform lessons for the future so that such an appalling failure of services is never allowed to occur again.

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