



House of Commons
Health Committee

Annual accountability hearings: responses and further issues

Fifteenth Report of Session 2010–12

Report incorporating combined responses from the Government, Nursing and Midwifery Council, General Medical Council, Care Quality Commission and Monitor; together with formal minutes

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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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Additional written evidence may be published on the internet only.

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¹ Mr Stephen Dorrell was elected as the Chair of the Committee on 9 June 2010, in accordance with Standing Order No. 122B (see House of Commons Votes and Proceedings, 10 June 2010).

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1 Report

1. We are publishing with this report the responses of the Government and the four regulatory bodies themselves to the accountability reports that the Committee produced last year.² The Committee believes that it proved to be a very useful and illuminating exercise and we shall be undertaking similar hearings this year once the organisations have published their annual reports.

2. We have decided to take this opportunity to flag up what we see as some of the significant issues that we will want to discuss further this year, in the light of comments in these responses and of other relevant events.

Regulation of healthcare professionals

3. The idea for instituting these annual accountability sessions came from our inquiry into the revalidation of doctors, the report of which was published in February last year. As current legislation makes the GMC accountable to the Privy Council, and given that there is no mechanism to make that accountability effective, the Committee proposed to exercise that function itself, on behalf of Parliament.³

4. In its report on the GMC published in July 2011 the Committee argued that the Council still had a considerable amount of work to do before the implementation of revalidation as proposed in late 2012.⁴ In its response, the GMC says that revalidation “remains [its] number one priority. We are determined and on track to introduce a system by late 2012 (subject to the Secretary of State’s approval).”⁵ **The Committee welcomes this statement. In the light of the importance of this process to the quality of services delivered to patients, and of the status of the GMC as an independent regulator, the Committee looks to the GMC to give early and public notice if it concludes that delivery of this timetable is at risk.**

5. In its report on the Nursing and Midwifery Council, the Committee also raised concerns in respect of the revalidation process for nurses and midwives. It drew attention to the fact that, although minimum standards are set for hours of practice and professional development for nurses and midwives, the Council provides no mechanism either to establish whether even those minimum levels have been reached or to assess the quality of an individual’s practice.⁶

2 Health Committee: Seventh Report of Session 2010–12, *Annual accountability hearing with the Nursing and Midwifery Council*, HC 1428; Eighth Report of Session 2010–12, *Annual accountability hearing with the General Medical Council*, HC 1429; Ninth Report of Session 2010–12, *Annual accountability hearing with the Care Quality Commission*, HC 1430; Tenth Report of Session 2010–12, *Annual accountability hearing with Monitor*, HC 1431.

3 Health Committee, Fourth Report of Session 2010–12, *Revalidation of Doctors*, HC 557, para 7.

4 Health Committee, Eighth Report of Session 2010–12, *Annual accountability hearing with the General Medical Council*, HC 1429, para 12.

5 Ev 37

6 Health Committee, Seventh Report of Session 2010–12, *Annual accountability hearing with the Nursing and Midwifery Council*, HC 1428, para 31

6. The Committee noted separately the complete lack of regulation for healthcare assistants, and argued that mandatory statutory regulation will be needed to maximise public protection. It also concluded, however, that the first priority of the NMC needs to be to improve its work on its current core functions before asking it to address additional responsibilities.⁷

7. In its response to that recommendation, the NMC said that it welcomed the Committee's support "for a mandatory statutory regulatory model for healthcare support workers working under the direct supervision of nurses and midwives." It added that "We have begun a project to fully scope the cost, standards and training requirements needed for us to establish such a mandatory model".⁸

8. The Committee received that initial response in October last year. Since then, there have been a number of developments at the NMC. The Chief Executive and Registrar has left for personal reasons, and the Department of Health has announced that the Commission for Healthcare Regulatory Excellence is to undertake a strategic review of the organisation.⁹ We have now received an addendum to its response from the NMC.¹⁰ In this it says:

We therefore support the government's announcement that Skills for Health and Skills for Care have been commissioned to develop common training standards and a code of conduct for healthcare support workers. We believe that together with the proposals for assured voluntary registration to be administered by the Council for Healthcare Regulatory Excellence (CHRE) and our own development of a delegation standard for nurses and midwives, this provides an effective framework for public protection.

The NMC has a challenging programme of work that we are committed to delivering particularly in making operational improvements to our fitness to practise service and developing a system of revalidation for nurses and midwives – two key recommendations of the Committee. The focus of our work and resources has to be on these priorities and therefore it is neither appropriate nor feasible for us to develop a mandatory model of regulation of healthcare support workers.¹¹

9. The Committee supports the NMC's intention to focus, as its first priority, on the revalidation and fitness to practise procedures for nurses and midwives. We also support additional focus on training for healthcare support workers, and believe the NMC should keep the regulatory structure for this element of the caring workforce under regular review.

10. In its next meeting with the NMC, the Committee will wish to review the progress it has made towards strengthening its revalidation and fitness to practise procedures. The Committee will also wish to discuss with the NMC the outcome of the CHRE's review,

7 Health Committee, Seventh Report of Session 2010–12, *Annual accountability hearing with the Nursing and Midwifery Council*, HC 1428, para 64

8 Ev 23

9 Written Ministerial statement, *Nursing and Midwifery Council*, Official Report, 26 January 2012, Col 25WS.

10 Ev 24

11 *ibid*

and review those recommendations which may help the Council better to perform its core functions.

Professional responsibility

11. In each of its reports on the GMC,¹² NMC¹³ and the Care Quality Commission,¹⁴ the Committee raised the issue of the professional responsibility of healthcare professionals. In particular healthcare professionals, as well as being required to meet all appropriate standards themselves, have a responsibility to report concerns about the work of those around them if they feel it fails to meet those standards.

12. The Committee also acknowledged, however, that “doctors and other practitioners who have raised concerns about other staff have sometimes been subject to suspension, dismissal or other sanctions”.¹⁵ It held an evidence session on that issue in December, following press reports that doctors (and presumably other professional staff) were being asked, as part of the termination of employment process, to sign clauses in compromise agreements that were alleged to be quite clearly inconsistent with the obligations of those same doctors to raise concerns about the quality of practice within the employing organisation with the General Medical Council, their professional regulator. That session was useful, not least because the three NHS organisations which had been identified as entering into such agreements all said to the Committee that they had reviewed the situation and would no longer use such provisions.

13. Gavin Larner, Director of Professional Standards at the Department of Health, told the Committee:

Most of us absolutely agree that such clauses are inconsistent with the [Public Interest Disclosure] Act and are not acceptable. As a result of *The Times* article, I wrote, on 28 November, to the two trusts concerned to draw this to their attention and to ask them to review their policies. Ministers have also agreed that, following this evidence session, we will write to all NHS organisations to remind them of their responsibilities. Monitor will be writing to foundation trusts on this matter as well. There is a consensus here that we need to encourage people to speak out. With anything that hits against that, and in particular that crosses the Act, we need to make sure the Service understands its responsibilities.¹⁶

14. The Committee was pleased to have such a clear statement from the Department on the position, and this particular issue at least should now have been effectively dealt with. **The Committee continues to believe that the effective exercise of professional responsibility is the bedrock on which high standards of patient care are built. It also continues to believe that there is an essential public interest in ensuring that professionals are protected against punitive action when they raise concerns about professional**

12 Health Committee, Eighth Report, paras 43 and 44

13 Health Committee, Seventh Report, para 19

14 Health Committee, Ninth Report, para 53

15 Health Committee, Eighth Report of Session 2010–12, *Annual accountability hearing with the General Medical Council*, HC 1429, para 44.

16 *Professional responsibility of healthcare practitioners*, 7 December 2011, HC 1699-i, Q83

standards at their place of work. In view of the importance of these issues we intend to continue to pursue them in our sessions with the professional regulators later in the year.

15. The Committee also looks forward to the findings of the Francis Committee of Inquiry into Mid Staffordshire NHS Foundation Trust and what it may have to say about the conduct of professionals there.

Care Quality Commission

16. The Committee raised some serious concerns about the work of the Care Quality Commission in its report on that body. The main recommendations bear repeating:

“6. The Committee concluded that the bias in the work of the CQC away from its core function of inspection and towards the essentially administrative task of registration represented a significant distortion of priorities. Although the evidence presented by the CQC acknowledged this distortion of priorities and argues that corrective action has now been taken, the Committee believes it is important to understand how this misallocation of resources arose, not least in order to reduce the risk of the same thing happening again.

7. The Committee has identified the following factors which contributed to this distortion of priorities:

- The CQC was originally established without a sufficiently clear and realistic definition of its priorities and objectives;
- The timescale and resource implications of the functions of the CQC, in particular the legal requirement to introduce universal registration of primary and social care providers, were not properly analysed;
- The registration process itself was not properly tested and proven before it was rolled out; and
- The CQC failed to draw the implications of these failures adequately to the attention of ministers, Parliament and the public.”¹⁷

17. In its response, the Department of Health says that it

accepts the comments of the Committee and is aware of the challenges that CQC has faced in registering providers under the new registration framework to a challenging timetable. The Government looks to CQC as the independent regulator to undertake its regulatory functions efficiently and effectively, learning lessons from its experiences.¹⁸

17 Health Committee, Ninth Report of Session 2010–12, *Annual accountability hearing with the Care Quality Commission*, HC 1430, paras 6 and 7

18 Ev 49

18. In fact the Department has done more than “look to” CQC, and undertook a performance and capability review of the organisation between October 2011 and February this year, conducted by a panel of senior officials and external reviewers, led by the Permanent Secretary.¹⁹ This review has made twenty three recommendations under six headings.²⁰ It notes achievements by the CQC, acknowledges the problems, argues that the organisation is showing a greater focus on its core purpose and sets out issues to be addressed for the future. It is also critical of the Department’s role as well as of CQC’s performance.

19. The performance and capability review is a substantial document which sets out some real challenges for the CQC. In our next session with CQC the Committee will wish to review the progress it has made against the twenty three recommendations of the review.

20. It will also wish to review the progress of the CQC in responding to the recommendations of the Francis inquiry and the extent to which there are issues for the organisation beyond those identified in the performance and capability review.

Monitor

21. Of all the regulatory organisations that we met last year, the position of Monitor was the least certain. This was not due to any particular failings on the part of the organisation, but because its role is proposed to be changed under the provisions of the Health and Social Care Bill, and the precise nature of its new role was still a matter of debate. Several months later, the position remains unchanged. By the time we meet Monitor again later in the year, there should be greater clarity whatever happens to the Health and Social Care Bill. We look forward to discussing its future role in that context.

19 Performance and Capability Review, *Care Quality Commission*, Department of Health, 23 February 2012.

20 The headings are; strategy, resources and prioritisation, accountability, engagement and communications, development of the regulatory model and delivery of the regulatory model.

Conclusions and recommendations

Regulation of healthcare professionals

1. The Committee welcomes this statement. In the light of the importance of this process to the quality of services delivered to patients, and of the status of the GMC as an independent regulator, the Committee looks to the GMC to give early and public notice if it concludes that delivery of this timetable is at risk. (Paragraph 4)
2. The Committee supports the NMC's intention to focus, as its first priority, on the revalidation and fitness to practise procedures for nurses and midwives. We also support additional focus on training for healthcare support workers, and believe the NMC should keep the regulatory structure for this element of the caring workforce under regular review. (Paragraph 9)
3. In its next meeting with the NMC, the Committee will wish to review the progress it has made towards strengthening its revalidation and fitness to practise procedures. The Committee will also wish to discuss with the NMC the outcome of the CHRE's review, and review those recommendations which may help the Council better to perform its core functions. (Paragraph 10)

Professional responsibility

4. The Committee continues to believe that the effective exercise of professional responsibility is the bedrock on which high standards of patient care are built. It also continues to believe that there is an essential public interest in ensuring that professionals are protected against punitive action when they raise concerns about professional standards at their place of work. In view of the importance of these issues we intend to continue to pursue them in our sessions with the professional regulators later in the year. (Paragraph 14)
5. The Committee also looks forward to the findings of the Francis Committee of Inquiry into Mid Staffordshire NHS Foundation Trust and what it may have to say about the conduct of professionals there. (Paragraph 15)

Care Quality Commission

6. The performance and capability review is a substantial document which sets out some real challenges for the CQC. In our next session with CQC the Committee will wish to review the progress it has made against the twenty three recommendations of the review. (Paragraph 19)
7. It will also wish to review the progress of the CQC in responding to the recommendations of the Francis inquiry and the extent to which there are issues for the organisation beyond those identified in the performance and capability review (Paragraph 20)

Annex – combined responses

On 26 July 2011 the Health Committee published its Seventh Report of Session 2010–12, *Annual Accountability Hearing with the Nursing and Midwifery Council*. The Department of Health's response to the report was received by this Committee on 19 September 2011 and is published as Appendix 1 to this report. The response from the Nursing and Midwifery Council was received on 17 October 2011 and is published as Appendix 2 to this report.

On 22 February 2012 the Health Committee received an addendum from the Nursing and Midwifery Council to its response of 17 October 2011. This is published at the end of Appendix 2.

On 26 July 2011 the Health Committee published its Eighth Report of Session 2010–12, *Annual Accountability Hearing with the General Medical Council*. The Department of Health's response to the report was received by this Committee on 19 September 2011 and is published as Appendix 3 to this report. The response from the General Medical Council was received on 17 October 2011 and is published as Appendix 4 to this report.

On 14 September 2011 the Health Committee published its Ninth Report of Session 2010–12, *Annual accountability hearing with the Care Quality Commission*. The Department of Health's Response to the report was received by this Committee on 28 November 2011 and is published as Appendix 5 to this report. The response from the Care Quality Commission was received on 14 November 2011 and is published as Appendix 6 to this report.

On 14 September 2011 the Health Committee published its Tenth Report of Session 2010–12, *Annual accountability hearing with Monitor*. The Department of Health's Response to the report was received by this Committee on 28 November 2011 and is published as Appendix 7 to this report. The response from Monitor was received on 24 October 2011 and is published as Appendix 8 to this report.

Appendix 1 – Government’s Response – Annual Accountability Hearing with the Nursing and Midwifery Council

Introduction

On 26 July 2011, the House of Commons Health Committee (the Committee) published the report: *Annual Accountability Hearing with the Nursing and Midwifery Council (NMC)*.

The driver for the hearing was a recommendation made in the Health Select Committee’s Fourth Report on Revalidation of Doctors, published on 8 February 2011, in which the Committee said that it intended to exercise on behalf of Parliament the power nominally held by the Privy Council to hold the General Medical Council (GMC) to account. The Committee subsequently agreed that this approach should be extended to include the Nursing and Midwifery Council (NMC).

The Department strongly believes that these hearings are of great value in strengthening the accountability of the professional regulatory bodies to Parliament and to the wider public.

Departmental response

We welcome this report and have carefully considered the Committee’s recommendations and the issues it raises. The Government’s Command Paper, *Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff*, published on 16 February 2011, set out a comprehensive strategy for ensuring that professional regulation systems is robust and proportionate.

The Government’s response to each of the recommendations made in relation to the NMC is shown below. Though many of the Committee’s recommendations were clearly for the NMC to take forward, we have commented on all recommendations.

Introduction

Recommendation Para 3

The NMC has requested Department of Health support for further amendments to the legislation that governs its operation. The Committee broadly supports this request, as improvement to the performance of the NMC in some key areas is hampered by its current legal framework. The Government must prioritise this work if it wishes to see further improvement in the performance of the NMC.

Response

The Department is working with the NMC to reform its legislation. Following the Select Committee hearing, at which the NMC gave evidence, Departmental officials met with counterparts at the NMC and agreed that many of the immediate legislative changes that the NMC were seeking could be achieved through changes to the NMC’s rules, rather than

through more time consuming changes to the Nursing and Midwifery Order 2001. The Department is now supporting the NMC to make the necessary changes to its rules.

The Government has also commissioned a more fundamental simplification review of the legislative framework for regulation of health professions from the Law Commission with a view to giving greater autonomy to the regulatory bodies to decide how best to meet their statutory duties.

Recommendation Para 4

The Committee welcomes the improved financial performance of the NMC in recent years, but is concerned about the affordability of the registration fee for many lower paid registrants. We would urge the NMC to avoid further fee rises and to consider fee reductions for new entrants to the register.

Response

The health professions regulators are independent bodies and so are responsible for setting their own fees.

The Government notes that the NMC's registration fee, alongside the fee charged by the Health Professions Council (HPC), is the lowest of all the fees charged by health professions regulatory bodies at only £76 per head.

However, as the Government said in its Command Paper *Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff*, "At a time of pay restraint in both the public and private sectors, the burden of fees on individual registrants needs to be minimised".

The Government would not expect registration fees to increase beyond their current levels, unless there is a clear and robust business case that any increase is essential to ensure the exercise of statutory duties.

Recommendation Para 9

The NMC is now leaving behind its previous organisational and financial instability, and is improving in many areas of its work. There remains however a significant amount of work to be done in order for it to be an effective regulator that has public protection as its principal concern.

Response

The Government welcomes improvements at the NMC but would urge it not to be distracted from the delivery of its core functions by activities outside of its current statutory remit, when improvements in its current performance could still be achieved.

Recommendation Para 10

Although, therefore, the Committee recognises that the NMC is developing a higher level of operational competence, it remains concerned that the leadership function of the NMC remains underdeveloped, particularly in the areas of fitness to practise, revalidation, education and training and proactive regulation. The Committee hopes

that the NMC will embrace more ambitious objectives for professional leadership, some of which are described in this report.

Response

The Government agrees that the NMC should take a strong lead in setting high standards of practice and accountability for its registrants. In doing so, however, it needs to continue to see its primary purpose as public protection and public service, and not as a body that represents the profession.

The Government welcomed the launch of the NHS Leadership Framework in June. At the heart of the new framework is the Clinical Leadership Competency Framework which applies to every clinician at all stages of their professional journey – from the time they enter formal training, become qualified as a practitioner and throughout their continuing professional development as experienced practitioners. We would encourage the NMC to consider the contribution of the framework to revising existing standards for education, in fitness to practise cases and in developing the model for revalidation for registrants.

Fitness to practise

Recommendation Para 13

The Committee is very concerned about the recent dramatic rise in the numbers of NMC referrals of nurses and midwives, and that NMC reports make it difficult to distinguish between referrals made about nurses or midwives. We are surprised that the NMC has no clear answer to why referrals are increasing, and recommend that the NMC undertakes urgent research to establish the reasons for this increase. This data could and should be used to support the development of revalidation and a more proactive approach to regulation.

Response

We would encourage the NMC to make progress in this area and we understand that the Council for Healthcare Regulatory Excellence (CHRE) is giving consideration to the issue of the underlying causes of fitness to practise referral rises across professions.

Recommendation Para 14

The Committee is also concerned that an analysis of ethnicity data on the nursing and midwifery register is still not available despite having made assurances that this would take place in 2010. Of more concern is the fact that, according to its own records, the NMC is still not recording ethnicity or other diversity monitoring in fitness to practise cases. Without this, neither the professions nor the public can have confidence that the NMC discharges its functions in a manner that is fair and equitable to minorities.

Response

We agree with the Committee's comments.

Recommendation Para 17

Following our earlier report into complaints and litigation, the Committee remains very concerned about the existence of low standards of basic nursing care in our acute hospitals and care homes, which appear to be in breach of the code of conduct for nurses and midwives. We are particularly concerned about this in light of the ongoing inquiry into Mid Staffordshire NHS Foundation Trust, the Winterbourne View scandal and the recent Health Service Ombudsman report into care of the elderly in hospital.

Response

The Department shares the Committee's commitment to the highest standards of nursing in all care settings and welcomes the more proactive approach that the NMC has taken on particular incidents over the past two years. The Government will be studying carefully the conclusions of the public inquiry into events at Mid-Staffordshire NHS Foundation Trust to consider whether any changes are needed, including to the professional regulatory system to address these concerns.

Recommendation Para 18

This evidence presents a challenge to the NMC which is responsible for professional standards in the nursing and midwifery professions. Based on its existing guidance on care of the elderly, we propose that the NMC should develop a programme of action to deliver a demonstrable improvement in outcomes for this vulnerable group.

Response

The Department acknowledges the comments made by the Committee, which are a matter for the NMC as the independent regulator for nurses and midwives. We would be interested to see any programme of action that the NMC develops regarding this issue.

Recommendation Para 19

Furthermore, the NMC needs to send a clear signal to nurses and midwives that they are at as much risk of being investigated by their regulator for failing to report concerns about a fellow registrant as they are from poor practice on their own part.

Response

There is a long standing duty upon nurses and midwives – including students – to act upon / report any concerns they have about anything which puts patients in their care at risk, including the performance of other individuals. The NMC has published guidance on its website called 'Raising and Escalating Concerns' which provides details of individual roles and responsibilities and information on where to go for advice in such situations. Paragraph 3 of the guidance makes it clear to the professional that failure to raise concerns is unacceptable and may call into question their own fitness to practise.

It would also be open to nurses to refer concerns about NHS organisations or management through a public interest disclosure to the Care Quality Commission (CQC) or Monitor.

The NHS Constitution draws attention to the protection available to staff and the handbook to the constitution specifically cites the Public Interest Disclosure Act 1998 and staff rights to “protection from detriment in employment and the right not to be unfairly dismissed” under the Act.

Recommendation Para 22

The Government is proposing to have one Act of Parliament that establishes the core functions of professional regulators, leaving them to decide how they discharge these. The Committee welcome the Governments plans for simplification of the legislation that underpins professional regulation in the UK.

Response

The Government has commissioned a simplification review of the legislative framework for professional regulation from the Law Commission with a view to giving greater autonomy to the regulatory bodies to decide how best to meet their statutory duties.

The Department intends to seek Parliament’s agreement in due course to create an enabling legislative framework for the regulatory bodies, under which the regulators would have statutory duties both to inform the public of their functions and to consult on the way they delivered them.

Recommendation Para 23

However, in the light of criticisms by the CHRE about “significant weaknesses” with the process, the Committee urges the Government to bring forward amendments as soon as possible to the Nursing and Midwifery Order 2001 so that the NMC can streamline its fitness to practise procedures.

Response

We are working very closely with the NMC on this issue, particularly around whether changes to the 2001 Order are needed in this context. In particular, it is our shared belief that changes to the NMC’s own underpinning rules (which can be delivered more quickly than changes to the 2001 Order) can successfully address this issue.

See the response to the recommendation at paragraph 3 for further details of the Government’s action.

Recommendation Para 25

The Committee supports the proposal that nurses and midwives be able to voluntarily remove themselves from the register. However, where concerns have been raised about a nurse or midwife seeking erasure, or where an investigation is taking place into fitness to practise, erasure must only take place with the consent of the complainant and on publication of the full details of the case against the registrant.

Response

The NMC and the Department are working on proposals that are intended to lead to efficiencies in how voluntary removal cases are processed.

The purpose of fitness to practise action is to ensure that the public are appropriately protected from the activities of poorly performing professionals. Its purpose is not to provide a means of direct redress for the victim of the actions of a poorly performing professional. Whilst sanctions such as suspension, removal from the register or conditions on practice may have a punitive effect, that is not their primary purpose. As such, the Department does not believe it is appropriate that voluntary erasure should only take place with the consent of a complainant. That should be a matter for the regulator, after consideration of all relevant evidence. Where complainants wish to seek individual redress against civil or criminal offences committed by health professionals, this would be a matter for the police and the courts.

The Nursing and Midwifery Order 2001 restricts rules from allowing lapsing of registration on administrative or voluntary grounds where the registrant has been suspended, or is subject to a conditions of practice order, or an interim order which imposes conditions or suspension.

The Department and the NMC are collaborating on reforms to its voluntary erasure rules at present and will take the Committee's views into account when so doing.

Revalidation of Nurses

Recommendation Para 31

The current standard for re-registration – completing 450 hours of practice and 35 hours of professional development – is wholly inadequate, as this tells patients and the public nothing about the quality of nursing and midwifery practice undertaken by the registrant. There is also no routine assessment of whether nurses and midwives have even met this minimal standard. The NMC instead relies on honesty within the profession and “whistle-blowing” when registrants are dishonest. For many nurses and midwives this may well be adequate, but for a significant minority, including those most at risk of manifesting low professional standards, it may not be.

Response

Enabling Excellence asked the regulatory bodies for the non-medical healthcare professionals to continue to develop the evidence base that will inform their proposals for revalidation over the next year.

Recommendation Para 32

The Committee supports the NMC's risk-based approach to the current reregistration process. However, we are concerned that there are nurses and midwives who could be failing to meet the already unacceptably low standards for reregistration but who do not come to the attention of the NMC and are therefore reregistered unchallenged. Registrants must feel that their regulator could call in

their re-registration evidence at any time and as such the NMC should undertake an annual random audit of the registration renewal evidence supplied by a sample of registrants.

Response

Revalidation involves additional centralised regulatory effort. For those professions where there is evidence to suggest that this effort gives significant added value (in terms of increased safety or quality of care for users of health care services), the Government will agree the next steps for implementation with the relevant regulators, the Devolved Administrations, employers and the relevant professionals.

Recommendation Para 33

The Committee will monitor progress against the 2014 deadline for the introduction of revalidation by the NMC at subsequent accountability hearings.

Response

The Department looks forward to receiving and reviewing the NMC's proposed model for revalidation in due course.

Recommendation Para 39

Revalidation of nurses and midwives is a significant undertaking that the NMC is progressing with due caution. The Committee notes that statutory supervision of midwives is a tried and trusted means of assuring the quality of midwifery practice. The NMC should consider the costs and benefits of extending the statutory supervision framework as a potential means of delivering an effective revalidation process for all registrants.

Response

The Department of Health looks forward to receiving the NMC's proposed model for revalidation in due course. It is sensible that the NMC looks at this model when gathering evidence on which to base their decisions on a cost effective, risk based and proportionate model of revalidation.

Recommendation Para 40

The NMC needs to ensure that it monitors the number of nurses and midwives who retire, leave the profession, have conditions placed on their practice or fail revalidation. It must develop and share this evidence with employers to ensure that the future workforce planning includes the developing outcome of the revalidation process.

Response

For the past two years, the NMC has concentrated on developing a robust evidence base for revalidation by commissioning research to assess the potential risks posed by their respective registrant groups. Last year the Department of Health (England) gave a grant to the NMC to enable the next stage of development. This grant allowed the NMC to

look closely at what their fitness to practise data (historical and current) could tell them about risk. This piece of work is essential in allowing the NMC to develop a risk-based and proportionate proposal for a framework for revalidation.

Recommendation Para 41

The Department of Health must clarify how it will maintain the continuity of statutory supervision of midwives through Local Supervising Authorities once Strategic Health Authorities are abolished.

Response

The Local Supervisory Authority (LSA) for midwives is a statutory function currently held by Strategic Health Authority Chief Executives; each SHA employs an LSA Midwifery Officer to deliver this function. The NHS is in the process of mapping functions currently held by SHAs to determine which are required to continue and where these will reside in the design of the new NHS. We recognise the need to provide clarity about the future of LSAs in the new NHS structures.

Recommendation Para 45

Nurses and midwives from the European Economic Area and Switzerland seeking to practise in the UK cannot routinely be language and competence tested by the NMC. The NMC, along with other professional regulators and the Government is working towards resolution of this with partner organisations across Europe. The Committee takes the view that the current legal framework is at odds with good clinical practice, which is clearly unacceptable.

Response

Employers and those contracting with health care workers can and should verify the language knowledge of any person they appoint but we recognise the need to strengthen the system of checks to ensure that local checks are applied consistently. Our intention now is to work with a wide range of partners including the European Commission and the Devolved Administrations to develop a proportionate new system of checks to ensure that any person appointed to a clinical post in the NHS has the necessary skills for the role, before they take up post.

The relevant piece of European Legislation that governs the movement of health professionals across Europe (Directive 2005/36/EC) is currently under review. The European Commission has consulted on the possibility of a change in the relevant European law in a recent Green Paper, with firm proposals due before the end of 2011. The Government sought evidence of the extent of concerns about the issue as part of the consultation and the UK's response to the consultation will be published shortly.

Recommendation Para 46 and 47

The Government, the NMC and the other health professions regulators must now grasp this as a significant risk to patients and dramatically pick up the pace in resolving or mitigating it.

The Committee is concerned that waiting for regulatory action at a European level will expose patients to a high risk over an unacceptably long period of time. We would like to see prompt action on this matter along the lines taken by the GMC where Responsible Officers sign off a doctor as competent and fit to practise.

Response

Any changes to the Directive will take time to deliver and it remains essential that employers carry out their checks effectively. On the issue of competence, it is vital that employers and contracting bodies continue to ensure that those nurses and midwives whom they seek to engage are competent to carry out the duties expected of them.

Proactive Regulation

Recommendation Para 50

We welcome the NMC's initiative in opening proactive investigations into registrants without a formal referral from an employer, a member of the public or another professional.

Response

The Department also welcomes this initiative, which relies on powers available to the NMC in its governing legislation.

Recommendation Para 55

The NMC's plans for investigation of and intervention in a healthcare organisation where concerns are being raised is a creative and interesting approach to regulating what is a large group of professionals working across a variety of settings. It offers the NMC another tool to strengthen public protection.

Response

The Department welcomes the steps that the NMC are taking in this regard, working closely with other regulators (such as the system regulator in England, the CQC) to ensure that the regulatory frameworks for professionals and providers work effectively to identify and resolve issues of concern.

Recommendation Para 56

We do feel however that whilst the power to look at the quality of educational environments gives the NMC "a foot in the door", clear power must be established in law for further expansion of this role, and we encourage the Government and the NMC to work together to develop this approach. The Committee would particularly like to see the NMC responding to trends in outcome and complaints data from NHS and social care providers.

Response

We broadly accept the recommendation of the Health Select Committee. We rely on the skills, knowledge and values of frontline health professionals and we need their training

and education to be of the highest quality. While it is important that there is effective quality assurance of education and training providers, it is also important that quality assurance processes do not create an unnecessary burden on education and training providers.

We would consider any specific proposals from the NMC for new powers.

To reinforce the importance of ensuring high quality education and training for healthcare workers, we intend to introduce an explicit duty for the Secretary of State to maintain a system for professional education and training as part of the comprehensive health service.

We are also developing a national education and training outcomes framework, setting out the outcomes that the new body for education and training for health, Health Education England, which is planned to go fully operational in April 2013, will expect providers of education and training to meet. These outcomes will be designed to help health and care professionals, including nurses and midwives, to meet the clinical outcomes set out in the NHS, public health and social care outcomes frameworks.

Future of Regulation

Recommendation Para 63

As previously mentioned, the Committee has ongoing concerns about the care and treatment of older people both in hospitals and care homes. Of particular concern to the Committee is the lack of regulation of a range of groups who undertake many basic nursing care tasks.

Response

The Government's view, as set out in *Enabling Excellence*, is that national statutory regulation must be proportionate and targeted.

Employers of unregulated workers must take responsibility for the quality of services provided and ensure appropriate use of existing systems such as referrals to the Independent Safeguarding Authority, which has the power to bar unsuitable workers from the sector.

It is essential that appropriate professional responsibility is taken for effectively supervising any unregulated support staff to whom tasks are delegated by qualified professionals. The NMC is currently updating its guidance to make this crystal clear.

The Government intends to establish the Professional Standards Authority for Health and Social Care (currently the CHRE) as the national accrediting body for a system of assured voluntary registers for groups that are currently not subject to statutory professional regulation.

It is the Government's view that voluntary registration should be encouraged for healthcare support workers and we will explore scope for the Health and Care Professions Council to establish a voluntary register of such workers in England by 2013.

Recommendation Para 64

The Committee endorses mandatory statutory regulation of healthcare assistants and support workers and we believe that this is the only approach which maximises public protection. The Committee notes that the Government intends to give powers to the relevant regulators to establish voluntary registers for non-regulated professionals and workers, but would urge it to see healthcare assistants, support workers and assistant practitioners as exceptions to this approach who should be subject to mandatory statutory regulation. However, the NMC needs to make significant improvements in the conduct of its existing core functions (such as in how it manages fitness to practise cases) before powers to register these groups are handed to it.

Response

Despite the seriousness of what was highlighted in the recent BBC Panorama programme, the Government does not believe that the extension of statutory regulation to all workers in the health sector across the UK and the social care sector would necessarily be a proportionate response. Employers of workers, unregulated by statute, must take responsibility for the quality of services provided and ensure appropriate use of existing systems such as internal governance arrangements and referrals to (in the case of England) the Independent Safeguarding Authority, which has the power to bar unsuitable workers from the sector.

In addition, under the Health and Social Care Act 2008 all providers of regulated activities in England, including NHS and independent providers, have to register with CQC and meet a set of essential requirements of safety and quality. The requirements include a requirement to operate effective recruitment procedures to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person is of good character and has the qualifications, skills and experience which are necessary. The registered person must also have suitable arrangements in place to ensure that staff are appropriately supported in relation to their responsibilities, including by receiving appropriate training, professional development.

It is also essential that appropriate professional responsibility is taken and accountability demonstrated for effectively supervising any unregulated support staff and we note that the NMC is investigating the nurses responsible for ensuring that was provided in the way that patients and their families have a right to expect with a focus on the interests of service users.

The Government's view, as set out in *Enabling Excellence*, is that national statutory regulation must be proportionate and targeted. We do not believe that statutory regulation should be used as a 'cure all' for matters that are largely the responsibility of local care providers.

The Government intends to establish the Professional Standards Authority for Health and Social Care (currently the CHRE) as the national accrediting body for a system of assured voluntary registers for groups which are currently not subject to statutory professional regulation.

We think that it makes sense to explore how far assured voluntary registration might provide a suitable alternative to statutory regulation for this group of workers, in the first instance. It is our view that voluntary registration should be encouraged for the adult social care workforce and we will explore scope for the Health and Care Professions Council (currently the HPC) to establish a voluntary register of social care workers in England by 2013.

Appendix 2: Nursing and Midwifery Council's Response

22. The Nursing and Midwifery Council (NMC) welcomes the report of the House of Commons Health Committee and its support for changes in a number of critical areas that would enable us to become a more effective regulator. The Committee's support for legislative changes to improve the speed and effectiveness of our fitness to practise processes and the mandatory statutory regulation of healthcare support workers is particularly important.

23. Nursing and midwifery regulation is pivotal in safeguarding the health and wellbeing of the public. We therefore fully support the Committee's commitment to hold annual accountability hearings to scrutinise and help us to improve our work.

24. This memorandum sets out our response to the Committee's conclusions and recommendations.

Introduction

Recommendation 1, 11 and 12

25. We welcome the Committee's support for changes to our legislation that will improve the efficiency and effectiveness of our procedures, enabling us to take action to protect patients and the public more quickly.

26. Since our oral evidence session on 14 June 2011, we have held detailed discussions with the Department of Health about the legislative changes that we require. We have developed proposals to change our rules relating to the investigation of fitness to practise allegations, procedures for seeking and making interim orders in fitness to practise cases and arrangements for allowing nurses and midwives to voluntarily remove themselves from the register.

27. We opened a public consultation on these proposed changes on 1 September 2011 which concluded on 14 October 2011. We anticipate that our Council will approve the proposals on 24 November 2011. With the cooperation of the Department of Health we hope to have the new rules laid before Parliament in December 2011 coming into force by February 2012.

28. The proposals do not address the Committee's recommendation that voluntary removal must only take place with the consent of the complainant. However, the rules will require that the complainant must be given a reasonable opportunity to comment before the application is considered and for their comments to be taken into account. This is in line with the approach taken by other healthcare regulators.

29. Further safeguards have been put in place to ensure voluntary removal will only apply where specific criteria are met and not in cases where the public interest demands further investigation. In addition, the Registrar will take into account the fitness to practise history of any nurse or midwife who subsequently applies for readmission to the register.

30. We are also strengthening the competencies required of the people who chair our fitness to practise panels. We will be recruiting against these competencies to drive up the standard of our panels' decision making.

Recommendation 2

31. Since 2007 the NMC has had, along with the Health Professions Council (HPC) the lowest fee of the nine health professions regulators. We have considered arguments for a lower registration fee for new entrants. However the administrative costs would be considerable and the costs of regulating new entrants would remain. We also felt that it would be unfair to give a reduction to some and not all of those nurses and midwives on our register.

32. Any future fee level will have to be considered against the dramatic increase in fitness to practise referrals. We received 4,211 referrals in 2010–11 compared to 2,988 in 2009–2010 – an increase of 41 per cent. Rising public awareness and media scrutiny of poor standards of care will mean this trend is likely to continue in the near future. This increased workload is putting more pressure on our resources. The legislative changes to streamline our fitness to practise operations will help mitigate these pressures to a degree.

33. Even disregarding the financial impact of the increasing pressure on our fitness to practise function, the Government's proposals to make the Council for Healthcare Regulatory Excellence (CHRE) a self funding organisation via a levy on the healthcare professions regulators may have the unintended consequence of forcing us to increase the registration fee. Under the current options presented by the CHRE to the Department of Health, we would be expected to fund 35.5 per cent of their annual operating costs or £993,000 which equates to an additional £1.50 for every nurse and midwife on the register.

34. We do not support the proposed levy options. We undertook an assessment of the projected running costs of the CHRE and, based on activities they currently perform for us in terms of time and seniority of staff undertaking those tasks, we believe the costs are overestimated. We believe the work of CHRE could be undertaken - and paid for - on a case-by-case basis. This approach would be more proportionate, economical and less likely to impact on the current registration fee.

Recommendation 3 and 4

35. We welcome the Committee's recognition that the NMC is a much improved organisation. However, we are not complacent and remain committed to making further improvements to our fitness to practise function and all other areas of our work. This includes proactive project work to develop UK regulatory policy where we believe it will further safeguard the health and wellbeing of the public. This would include, for example, exploring a mandatory model for regulation of healthcare support workers.

36. We believe initiating projects in this way demonstrates to the public our leading role in enhancing patient safety and standards of professional practice in the public interest. Recent examples of this include:

15.1. Launching the *Meet the NMC* monthly engagement events where directors of nursing, heads of midwifery and HR directors are invited to our offices to learn more about fitness to practise and emerging policy initiatives.

15.2. Opening a new office in Edinburgh to increase our hearings capacity and to provide a focus for engagement with our stakeholders in Scotland. We are exploring options for opening an office in Wales.

15.3. Making greater use of the proactive powers given to us under Article 22(6) of the Nursing and Midwifery Order 2001 to intervene where we become aware of poor standards of patient care.

37. CHRE's most recent performance review acknowledges these achievements, and refers to our project helping to "**protect the safety of some of the most vulnerable patients**" (paragraph 16:17) and "**contribute to improvements in patient safety.**" (paragraph 16:18).

38. We are committed to demonstrating our leadership role not just to nurses and midwives but to the public and other stakeholders. Our new publication *NMC Review*, launched in spring 2011, provides policy news, features and comment of for leaders and managers in the nursing and midwifery professions. More than 70,000 have subscribed to the publication (October 2011).

39. Other channels of communication include our Facebook page which communicates our work to over 20,000 people and our email newsletters which are targeted to specific audiences such as employers and reaches over 130,000 subscribers. In November 2011 we will commence distribution of a new leaflet: *Complaints against nurses and midwives: Helping you support patients and the public* - which tells patient support organisations what they can expect from a nurse or a midwife, and what action we can take if they make a complaint to us.

40. In January 2012 we will launch a new service for nurses and midwives: the standards and ethics helpline. This will provide a direct communications channel for nurses and midwives to seek advice about ethical dilemmas they face in practice.

Fitness to Practise

Recommendation 5

41. We acknowledged in our written evidence that we need to understand what is driving the increase in the number of referrals. We have recently completed a key piece of work funded by the Department of Health to consolidate fitness to practise historical data into a single database. This will enable us to compare our analysis of recent referrals with historical trends and should add to our understanding of why referrals are increasing and demonstrate concentrated areas of risk. The findings will be reported to our Council in January 2012 and will feed into revalidation and other areas of work.

Recommendation 6

42. In August 2011 we appointed a new Head of Equality and Inclusion who is currently analysing the diversity data contained in our register. A preliminary report will be made to our Council by the end of the year. Once this work is complete we will examine how the data can be captured at each of the significant stages of our fitness to practise process.

Recommendation 7 and 8

43. We share the Committee's concerns about poor standards of care. There is no excuse for abusive behaviour, neglect or failure to deliver basic standards of care.

44. It is clearly stated in the code, that nurses or a midwives have a professional obligation to "make the care of people your first concern, treating them as individuals and respecting their dignity". As soon as we become aware of situations in which nurses or midwives may have fallen short of the code, we take action. Our response to critical incidents such as Mid Staffordshire NHS Foundation Trust, the Parliamentary Health Service Ombudsmen report and Winterbourne View is detailed in our evidence to the Committee.

45. The majority of these cases involved vulnerable adults, particularly older people. We are determined to drive up the standards of care for these groups. The Committee noted that our *Guidance for the care of older people*, which outlines best care practice, provides a good platform on which to build. Since its launch in March 2009 we have distributed almost 400,000 copies of the guidance, which includes a leaflet for the public.

46. In the autumn of 2010 we launched our safeguarding hub: an online information and training resource focused on safeguarding adults. The hub is designed around an award winning suite of films depicting challenging scenarios relating to the care of vulnerable people. The hub is designed to facilitate discussion and promote local solutions to help improve the care of vulnerable people.

47. The importance of providing safe, effective and fundamental care to older people and other vulnerable groups is being built into all existing project work and will be embedded in our review of the code which is currently underway.

48. However, driving up standards of care requires a multi-track approach that includes ensuring nurses and midwives report incidents of poor care, keep their professional knowledge and development up to date and ensuring the fundamentals of nursing and midwifery care are reflected in all the training programmes we approve.

Recommendation 9

49. Nurses and midwives are required by the code to report their concerns about poor practice and we encourage employers to foster a collaborative approach and clinical culture that welcomes reporting.

50. Our *Guidance on raising and escalating concerns* provides a step by step guide on how to raise a concern, when to escalate it and to whom. It acknowledges local whistle blowing policies and safeguarding procedures and makes clear that nurses and midwives have a professional duty to put the interests of the people in their care first and to act to protect them if they consider they may be at risk. The guidance also states that not acting in this

way could result in a nurse or midwife being subject to fitness to practise proceedings. We recognise how vital it is to patient safety to promote this message and have in recent months made it a priority to do so. Our Chief Executive made a clear statement on this point following the publication of the Committee's report on 26 July 2011 and again in response to the Care Quality Commission's (CQC) report into the quality of care in the homes in the Castlebeck Group on 28 July 2011.

51. However, creating an open reporting culture will require collaborative working from healthcare regulators, employers and healthcare professionals. We therefore welcome recommendation 19 in the Committee's report on the Annual Accountability Hearing with the CQC. The recommendation states "it should be a key objective of CQC inspections to ensure that the culture of each provider organisation recognises and respects this professional obligation, and provides proper security to those professional staff who discharge it effectively." We will work closely with the CQC through our memorandum of understanding to ensure this happens.

Recommendation 10

52. We strongly support the Government's proposed review of the legislative framework to give greater autonomy to regulators to discharge their statutory duties. We are at the very early stages of engagement with the Law Commission in its work to create a single Act of Parliament to cover all existing health professions by 2014.

Revalidation

Recommendation 13 and 14

53. The NMC is committed to delivering a revalidation system that will address the concerns raised by the Committee. It will require nurses and midwives to demonstrate that: they continue to be fit to practise; their knowledge and skills are up to date and specific to their current area and scope of practice; and the learning activities they undertake help them improve their practice.

54. In the meantime we are working to strengthen the existing post registration education and practice (Prep) system to increase the safeguards for the public. We have refreshed the handbook that contains the Prep standards, by removing the examples, which no longer reflect contemporary practice. The new version of the handbook has been published and became effective on Wednesday 12 October 2011. We are also increasing the scrutiny of nurses and midwives who apply to be readmitted to the register within five years of their registration lapsing. They must now demonstrate that they meet our post registration practice requirements by providing a full record of practice undertaken during the period since their last renewal of registration.

55. To further emphasise the importance of keeping practice up to date, our registrations department will in the new year, commence the annual calling in of re-registration information of a random sample of nurses and midwives on the register.

Recommendation 15

56. We are confident that we will be able to deliver a system for revalidation by 2014. We have already engaged with 1,700 stakeholders to validate our initial proposals, address key

issues and ensure that contributions to the development of the system are visible. This includes ongoing engagement with the Department of Health who gave their support for our high-level principles for revalidation.

57. In early 2012 we will consult on a draft revalidation standard which clearly sets revalidation against the revised code, together with a draft revalidation guidance or advice focused on revalidation processes. We will also define options, assess their respective costs and benefits (both for the NMC and for nurses and midwives) and select the preferred option. We will pilot the system in late 2012 before starting to roll it out to the whole register in 2014.

58. Revalidation and any legislative changes needed to implement it will be developed in close cooperation with the four UK departments of health.

Recommendation 16

59. We welcome the Committee's recognition of the effectiveness of the midwifery supervisory model. The model provides expert advice, clinical leadership and support to midwives and acts as an independent monitor of safe midwifery practice.

60. However the model is sustainable largely because of the number of midwives on our register, approximately 40,000 across the UK. The current phase of the revalidation programme focuses on consolidating the evidence base for revalidation. Part of this phase will focus on exploring the potential costs and benefits of extending to nurses a statutory supervision model. However, with over 630,000 nurses on our register it is unlikely this would prove economically sustainable.

Recommendation 17

61. We already record on our register those nurses and midwives who have conditions imposed on their registration or who retire, leave the profession and inform us or if their registration lapses. This will continue to be done when revalidation is implemented.

62. We are happy to co-operate with workforce planners to share any data we hold. It should be remembered that not all nurses and midwives work within the NHS. We therefore need to explore how any trends emerging for revalidation can be incorporated into planning both inside and outside the NHS.

Recommendation 18

63. Since the Government's proposed abolition of the strategic health authorities in England, we have written to the Department of Health several times to express our concern about the impact this would have on the current hosting and functions of local supervisory authorities and local supervisory authority midwifery officers (LSAMOs). We would not want to see this valuable and effective system lost as part of the reorganisation and any changes may necessitate legislative changes to the Nursing and Midwifery Order 2001 and the NMC Midwives Rules 2004. We welcome the Committee's continued support in seeking further information.

European Issues

Recommendation 19, 20 and 21

64. We welcome the Committee's view that the current legal framework governing the automatic recognition of European Economic Area (EEA) trained healthcare professionals, the EU Directive 2005/36/EC on Mutual Recognition of Professional Qualifications (the directive), needs to be changed to reflect modern practice and to better safeguard the public.

65. Since our oral evidence to the Committee in June we made a submission to the European Commission's Green Paper consultation making our recommendations for changes to the directive. The recommendations included: the ability for healthcare regulators to undertake mandatory checks for language competence; updating of the minimum training requirements that allow healthcare professionals to qualify for automatic recognition and introducing mandatory continuous professional development. The next stage will be the consideration of draft legislative proposals by the Commission to the European Parliament and Council of Ministers later this year.

66. In their Green Paper submission the Government broadly supports our proposals except those in relation to compulsory language testing at registration stage. In the meantime, we will continue to make our case at a European level.

67. We strongly agree with the Committee that measures must be taken to mitigate the risk under the existing legislation. We welcome the Government's announcement on 4 October 2011 regarding the introduction of powers for "responsible officers" to have a mandatory duty to check all non-UK doctors that apply to work in the UK have sufficient English language skills. We believe that this is a positive step towards a more robust approach that includes the regulator as well as the employer, although we continue to believe that checks should be made before registration rather than after.

68. The "responsible officer" model is part of the GMC's revalidation framework and not currently applicable to the NMC. We are therefore in the process of discussing with the Department of Health, other possible models that could be applied.

69. In the meantime we plan to write to directors of nursing highlighting their duty under the code to escalate concerns they may have regarding the communication competencies of registrants they interview for prospective employment, regardless of the outcome of the interview. We will also continue to work with CQC to help enforce the responsibility of employers to ensure that their staff have sufficient knowledge of English.

Proactive regulation

Recommendation 22, 23 and 24

70. We welcome the Committee's support for our proactive approach as we strongly believe this will help to drive up standards of care within the professions. So far in 2011, we have opened 241 cases where we have proactively found evidence of poor care.

71. Since our oral evidence to the Committee we have appointed a Head of Critical Standards Intervention who will manage and further develop a knowledge management

framework that responds proactively to the identification of poor practice. As part of this work they will consider trends in NHS and social care provider outcome and complaints data and take action accordingly.

72. As part of the Law Commission work to help create a single Act of Parliament we will explore the scope to make clearer our existing powers of proactive investigation and where appropriate extend them.

The future of regulation

Recommendation 25 and 26

73. We welcome the Committee's support for a mandatory statutory regulatory model for healthcare support workers working under the direct supervision of nurses and midwives.

74. We agree with the Committee's view that only a mandatory regulatory model will be sufficiently robust to fully safeguard against those workers that present the greatest risk to patient safety and public wellbeing. Any final regulatory response to this risk should include:

53.1. consistent UK wide standards of training and practice for healthcare support workers that would assure the public and employers they have the knowledge and skills to practise safely

53.2. a mandatory register to keep track of a nationally mobile workforce and ensure workers who have been struck off the register maintained by the NMC are not re-employed in a healthcare support role

53.3. statutory powers to take action to prevent those support workers that present the highest risk to the public from practising elsewhere.

75. We have begun a project to fully scope the cost, standards and training requirements needed for us to establish such a mandatory model. We would welcome assurance from Government that clauses 225 and 226 of the Health and Social Care Bill as submitted to the House of Lords – which legislates for the powers for regulators to establish voluntary registers – will not bias against any future considerations of proposals for a mandatory model.

76. In the absence of regulation of healthcare support workers, we believe that the only way to ensure public protection is to provide standards that will give nurses and midwives real clarity about safe delegation. Inappropriate delegation of care to healthcare support workers is a serious public protection issue. Delegation of nursing or midwifery care must be appropriate, safe and in the best interests of the person in the care of the nurse or midwife. We are therefore developing standards that will enable the registered nurse or midwife to be confident in the tasks they delegate. The standards will also ensure they recognise that they are accountable for the delegation of the task while at the same time retaining responsibility for the standards of care delivered in their areas.

Addendum to the Nursing and Midwifery Council's (NMC) response to the House of Commons Health Committee's annual accountability hearing with the NMC

Recommendation 26

The NMC's response to its annual accountability hearing with the Health Committee submitted in October 2011 stated that we would "develop a plan to work towards regulating healthcare assistants, support workers and assistant practitioners". Since the submission of our response, over the last few months there have been a number of developments which have led us to clarify our policy position.

We believe that any initiative which enhances the skills, knowledge and competence of healthcare support workers in enhancing patient and public protection is to be welcomed. We were clear in our response to the Committee that consistent national standards of training and practice for healthcare support workers will help to assure the public they have the knowledge and skills to practise safely.

We therefore support the government's announcement that Skills for Health and Skills for Care have been commissioned to develop common training standards and a code of conduct for healthcare support workers. We believe that together with the proposals for assured voluntary registration to be administered by the Council for Healthcare Regulatory Excellence (CHRE) and our own development of a delegation standard for nurses and midwives, this provides an effective framework for public protection.

The NMC has a challenging programme of work that we are committed to delivering particularly in making operational improvements to our fitness to practise service and developing a system of revalidation for nurses and midwives – two key recommendations of the Committee. The focus of our work and resources has to be on these priorities and therefore it is neither appropriate nor feasible for us to develop a mandatory model of regulation of healthcare support workers.

Appendix 3: Government's Response – Annual Accountability Hearing with the General Medical Council

Introduction

On 26 July 2011, the House of Commons Health Committee (the Committee) published the report: *Annual Accountability Hearing with the General Medical Council (GMC)*.

The driver for the hearing was a recommendation made in the Health Select Committee's Fourth Report on Revalidation of Doctors, published on 8 February 2011, in which the Committee said that it intended to exercise, on behalf of Parliament, the power nominally held by the Privy Council to hold the General Medical Council (GMC) to account.

The Department strongly believes that these hearings are of great value in strengthening the accountability of the professional regulatory bodies to Parliament and the wider public.

Departmental response

We welcome this report and have carefully considered the Committee's recommendations and the issues it raises. The Government's Command Paper, *Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff*, published on 16 February 2011, set out a comprehensive strategy for ensuring that professional regulation system is robust and proportionate.

The Government's response to each of the recommendations made in relation to the GMC is shown below. Though many of the Committee's recommendations were clearly for the GMC to take forward, we have commented on all recommendations.

Introduction

Recommendation Para 4

Although, therefore, the Committee recognises that the GMC achieves a high level of operational competence, it remains concerned that the leadership function of the GMC within the medical profession, and within the wider health community, remains underdeveloped particularly in the areas of fitness to practise, revalidation, education and training and voluntary erasure. We hope that the GMC will embrace more ambitious objectives for professional leadership, some of which are described in this report.

Response

The Government understands the comments of the Committee on this issue and agrees that the GMC should take a strong lead in carrying out its statutory duties. In doing so, however, it needs to continue to see its primary purpose as public protection and public service, and not as a body that represents the profession.

Revalidation

Recommendation Para 11

The work undertaken by the Society of Cardiothoracic Surgery of Great Britain and Ireland in setting standards for that part of the medical profession is commendable. Its transparency will be welcomed by patients and should be a template (where clinically relevant) for further refinement of the revalidation process.

Response

The Government agrees that the work undertaken by the Society of Cardiothoracic Surgery of Great Britain and Ireland in publishing their outcomes data is commendable. The Society has been collecting outcome data since 1977 and has continued to develop sophisticated systems in line with technological advances, with the patient being integral to the process.

This approach of patient-focussed care with open publication of results sits comfortably within the aspiration of the White Paper *'Equity and excellence: liberating the NHS.'*

The Government is pleased to note that the GMC will continue to have discussions with the Society of Cardiothoracic Surgery of Great Britain and Ireland so that the regulator, employers and the profession can benefit from their ongoing work.

In addition to this standard-setting for individual practitioners, the Committee will wish to note that responsible officers in England have a duty to ensure the robust, efficient and reliable functioning of systems of clinical governance. The focus on clinical governance systems should be on quality improvement, in terms of the quality of care not only delivered by each doctor but also by the entire team of which the doctor is part.

The Academy of Medical Royal Colleges is working with the individual medical colleges to produce guidance on the supporting information relevant for appraisal discussions and revalidation for each specialty. It supports the White Paper's vision for the NHS to focus on delivering improved health outcomes for patients. The NHS Outcomes Framework 2011/12 sets out how this will be achieved. The Government's Transparency and Open Data commitments for Health and Adult Social Care also support the publication of clinical outcomes data across a range of healthcare conditions.

In future, the revalidation decision will be based on a series of annual appraisals with doctors using supporting information to demonstrate they are continuing to meet the principles and values set out in the General Medical Council guidance, Good Medical Practice.

The General Medical Council (GMC) has recently published its expectations of doctors in terms of the six types of supporting information that the doctor would be expected to provide and discuss at appraisal. They include CPD, significant events, feedback from colleagues, patients (where applicable), reviews of complaints and compliments and quality improvement activity. Quality improvement activities include evidence of effective participation in clinical audit or an equivalent quality improvement exercise that measures the care with which an individual doctor has been directly involved,

reviews of clinical outcomes where robust, attributable and validated data are available. This could include morbidity and mortality statistics or complication rates where these are routinely recorded for local or national reports.

Recommendation Para 12

The GMC clearly has a considerable amount of work to undertake between now and the implementation of revalidation in 2012. Although we agree that all disciplines will not have developed their standards to an advanced level by that date, the GMC needs to accelerate its work with the medical royal colleges to further refine the standards for revalidation in specialist areas and to ensure that the process is meaningful to clinicians and transparent to the public.

Response

The Department recognises that the GMC has made significant progress in driving forward revalidation since the last Health Select Committee report on the '*Revalidation of Doctors*' published 8 February 2011. Revalidation remains the number one priority in the GMC Business Plan for 2011.

The GMC has confirmed to its Council and the Health Select Committee that it continues to develop its own internal processes and governance arrangements so that it can be ready to accept recommendations and make revalidation decisions from the end of 2012.

The GMC has also confirmed to the Health Select Committee that it has accelerated its work with the Academy of Medical Royal Colleges and individual colleges to define the speciality specific guidance for each item of supporting information. A number of the medical colleges have produced draft guidance and consultations are currently underway.

The GMC has recently published guidance on developing, administering and implementing patient and colleague questionnaires for revalidation. The Government welcomes patient and colleague involvement in the revalidation process. In England, the NHS White Paper *Equity and excellence: liberating the NHS* aims to put patients at the heart of the NHS and to strengthen the collective voice of patients.

Recommendation Para 14

As the GMC states, some doctors may decide to retire rather than undergo the process of revalidation; of those who pursue revalidation, some may require retraining and some may fail to meet the required standards. The GMC needs to ensure that it monitors the number of doctors who retire, leave the profession, have conditions placed on their practice or fail revalidation. It must develop and share this evidence with employers to ensure that future workforce planning includes the developing outcome of the revalidation process.

Response

The Government agrees with the Health Select Committee's recommendation. We will look to the GMC to develop and share this evidence to inform future workforce planning.

Recommendation Para 15

Of the Officers who will have to make recommendations about revalidating doctors, only a minority feel that the process will help with the early identification of doctors with performance issues. Early identification of problem doctors is a core task of the professional regulatory system, and the GMC needs to ensure that its systems of appraisal and revalidation achieve this task.

Response

The introduction of responsible officers in January 2011 has been an important change in clinical governance and key to putting in place the building blocks for introducing medical revalidation.

The Department's view is that dealing with doctors whose conduct and performance is a cause for concern is primarily a clinical governance issue and is usually best dealt with at a local level. For the small proportion of doctors about whom there may be concerns, the strengthening of local clinical governance and a more objective annual appraisal provides the means for identifying problems earlier and either putting in place remediation or, if not possible, taking steps to remove them from clinical practice.

The clinical governance functions of responsible officers in England are set out in Part III of the Medical Profession (Responsible Officers) Regulations 2010. These include monitoring conduct and performance of doctors, reviewing performance information and identifying any issues which emerge from that, as well as ensuring the organisation concerned takes steps to address any such issues. Where concerns arise in relation to individual practitioners, the responsible officer has powers to initiate investigations and ensure that suitable action is taken.

Training for those doctors appointed as responsible officers is underway and covers the statutory responsibilities and provisions of the role, obligations on a designated body to resource the responsible officers' work and how to deal with potential conflicts of interest or appearance of bias. Training also addresses monitoring of clinical quality and performance, identifying concerns and quality assurance processes to support appraisal systems and organisational governance. The training will be completed for all responsible officers by the end of the year.

Responsible officer networks are established to ensure ongoing support is available, local expertise is shared and that thresholds for intervention and management of conflicts of interest are consistent.

In addition, the GMC has also appointed Employment Liaison Advisers who will work with responsible officers and organisations to provide advice and guidance on specific cases of poor conduct and performance to ensure that issues are managed at the most appropriate level.

We understand that the GMC is in the process of developing guidance for responsible officers, which will build on existing advice for Medical Directors and other health professionals about the types of concerns that should be referred to the GMC.

Recommendation Para 18

The Committee notes the negative media reports about the time taken to undertake revalidation and hopes that the GMC will ensure that lessons are learned from the revalidation pilots, particularly in how it can support locum doctors. It also needs to ensure that the underlying processes that doctors are expected to undertake are not unwieldy and overly time-consuming, and that they are an effective means of gathering the required evidence.

Response

The Revalidation Pathfinder Pilots concluded in March 2011. The independent evaluation report was published in July 2011 and has provided significant data for partners to take forward to ensure that the final model for revalidation is proportionate, affordable and streamlined, whilst adding value for both patients and doctors.

The report noted a number of areas that need further exploration and testing but the overriding message was that pilot organisations recognise the importance of appraisal and revalidation in delivering high standards of care. The report revealed that 96 per cent of pilot organisations expect revalidation to lead to improved quality of care, 82 per cent expect improvements to patient safety and 80 per cent expect improvements to patient experience.

Eighty-six per cent of doctors appraised in the pilot felt that their appraiser performed their appraisal well and 91 per cent felt that their appraisal was objective.

The GMC's consultation findings on revalidation (published 18 Oct 2010) demonstrate that doctors value a common approach to appraisal and one that is both clear and straightforward. In response, the GMC published in April 2011, 'Good Medical Practice Framework for appraisal and revalidation' setting out the broad areas which should be covered in medical appraisal and on which recommendations to revalidate doctors will be based. The Framework is based on Good Medical Practice.

At the same time the GMC also published 'Supporting information for appraisal and revalidation', which sets out its expectations of doctors in terms of the six types of supporting information that the doctor would be expected to provide and discuss at appraisal. The medical Royal Colleges, Faculties, and many of the specialty associations are providing guidance on how this supporting information applies in specialist practice.

The Revalidation Support Team (RST) has produced clear and effective appraisal guidance in the form of a draft Medical Appraisal Guide (MAG). It underpins the two GMC guidance documents described above. In response to requests from the medical community, the RST has published the MAG on its website and is seeking feedback. It is available for all organisations to use, should they wish, but will also be formally tested during this year. A final version will be published in early 2012, taking account the

evaluation findings and feedback from employers and the profession. The guide will lie at the centre of appraisal and revalidation, ensuring a consistent approach for all doctors, regardless of where they work.

The additional year of testing announced by the Secretary of State in his letter of June 2010 to the GMC, in response to the revalidation consultation will widen the scope to test whether the model is applicable to doctors working across different environments, specialties and with varied work patterns. It will test the proposed model with SAS doctors, doctors in training, locums in secondary care and clinical academics.

It will provide the robust data to determine a model that is straightforward and proportionate, applicable for all doctors and not place excessive burdens on doctors or employers.

Recommendation Para 21, 22 and 23

Doctors from the European Economic Area and Switzerland seeking to practice in the UK cannot routinely be language and competence tested by the GMC.

The GMC along with the Government is working towards resolution of this with partner organisations across Europe. The Committee takes the view that current legal framework is at odds with good clinical practice, which is clearly unacceptable. The GMC has plans, within the boundaries of UK law and the EU Directive, to manage the constraints on language and competence testing by using the Responsible Officer role to establish that EEA (the EU plus several other European countries) doctors are fit to practise in the UK. The Committee accepts this way forward as a short term measure.

Although this short term measure is welcome, the committee believes that public confidence in the medical profession requires the issue to be addressed authoritatively. It is clearly unsatisfactory that the competence to practise of health professionals should be assured by a work-around, and we look to the government, GMC and the relevant European bodies to work as a matter of urgency to produce a long-term solution to this problem.

Response

Employers and those contracting with healthcare workers can and should verify the language knowledge of any person they appoint, but we recognise the need for a stronger, more effective, system of checks on all doctors.

The Department has worked closely with the GMC to produce a proposal for a strengthened system of local checks on the suitability of doctors, which will include consideration of their communication skills.

We have already taken steps to strengthen the current system and as of 1 January 2011, all designated bodies must nominate or appoint a responsible officer.

Responsible officers in England have a duty to ensure that medical practitioners have qualifications and experience appropriate to the work to be performed and that appropriate references are obtained and checked.

Our intention now is to work with a wide range of partners including the European Commission and the Devolved Administrations to develop a proportionate new system of checks through enhanced duties on responsible officers to ensure that any person appointed to a medical post has the necessary skills for the role, before they take up post.

The European Commission has consulted on the possibility of a change in the relevant European law in a recent Green Paper, with firm proposals due before the end of 2011. The Government sought evidence of the extent of concerns about the issue as part of the consultation and the UK's response to the consultation will be published shortly.

Fitness to Practise

Recommendation Para 27

The Committee notes that there is an increase in referrals of doctors to the GMC, and of nurses to the NMC, as well as an increase in the number of general NHS complaints. The Committee welcomes the fact the GMC has commissioned research into this phenomenon in order to better understand what is driving this increase, and to ensure that their systems and processes are adequate for meeting the future needs of the public. We look forward to reviewing the preliminary findings of this with the GMC at our next accountability hearing.

Response

The Department supports the GMC's ongoing research to understand the increase in fitness to practise referrals. The Department looks forward to learning of the GMC's findings, and any associated action plan. We are conscious that the causes of the rise in fitness to practise referrals are not yet fully understood, are likely to be being influenced by complex and multiple factors, and so the work which the GMC is doing to understand the causes is very important.

Recommendation Para 29

The Committee welcomes the ongoing good performance of the General Medical Council (GMC) in resolving 90% fitness to practise cases within fifteen months. However, we agree with the GMC that fifteen months is indeed too long to conclude such cases and we recommend that the Council for Healthcare Regulatory Excellence (CHRE) their regulatory body should set the GMC a more demanding target for future years.

Response

The statutory role of the Council for Healthcare Regulatory Excellence (CHRE) is to scrutinise and oversee the work of nine regulatory bodies, including the GMC. In undertaking this function, CHRE reviews whether the regulatory bodies meet their statutory functions and provide best practice guidance for the regulators. CHRE does not have the powers to set targets as such in relation to the regulators' performance of

their statutory functions. We understand that the target referred to by the GMC is an internal performance measure.

CHRE are, however, in the process of working with all the regulatory bodies in the development of a common data set of key performance indicators, in order to allow the comparative performance of the regulators across a range of areas to be more readily compared.

The Department is collaborating with the GMC to produce revised legislation that will enable more efficient handling of fitness to practise cases at hearing stage. Following full, public consultation, the GMC Council reviewed proposals for changes to the GMC's fitness to practise adjudication function, on 19 July 2011. These proposals include changes to procedures, including changes to pre-hearing case management, which should help reduce the time a case takes to reach a hearing and the time each hearing takes.

Recommendation Para 35

Some of the decisions made by fitness to practise panels of the GMC defy logic and go against the core task of the GMC in maintaining the confidence of its stakeholders. Furthermore, they put the public at risk of poor medical practice.

Response

The Department notes the findings of the Committee regarding the GMC's decisions in fitness to practise cases.

A number of proposals to strengthen the independence and quality of the GMC's fitness to practise panels – by setting up a Medical Practitioners' Tribunal Service (MPTS) – were subject to full public consultation conducted by the GMC from March–June 2011, and subsequently agreed by the GMC Council. Departmental officials are working with the GMC to take this work forward through changes to legislation.

As part of the CHRE function in overseeing the performance of the regulators, including the GMC, it reviews all final decisions made by the regulators' fitness to practise committees. CHRE has the power to refer those decisions to court if they consider them to be unduly lenient or if the decisions do not protect the public. Available statistics show that very few cases decided by GMC panels present such concerns.

Recommendation Para 36

The GMC holds the dual but potentially conflicting roles of prosecutor and adjudicator in fitness to practise cases. The GMC proposes to establish an Independent Medical Practitioner Tribunal Service to create a greater separation between these functions, and the Committee supports this proposal. We also urge that performance management of fitness to practise panellists commence as soon as is practicable.

Response

Departmental officials are working with the GMC to take forward the proposed move towards the MPTS to separate further the GMC's investigation and adjudication functions.

A number of proposals concerning the setting up of the MPTS were subject to full public consultation from March–June 2011, and subsequently agreed by the GMC Council. Departmental officials are working with the GMC to take this work forward.

Many proposals under consultation fall squarely within the GMC's remit to implement through changes to secondary legislation. It is right that the GMC should make changes in order to improve its functions.

Where proposals require a change to primary legislation, the Department will seek approval from the Privy Council and Parliament under section 60 of the Health Act 1999, which would be subject to a separate consultation exercise and Parliamentary debate. This piece of work is scheduled for completion by the end of 2013.

Matters relating to the performance management of fitness to practise panellists are for the GMC.

Recommendation Para 40

The GMC currently has no right of appeal over decisions made by independent fitness to practise panels. The Committee does not seek to undermine the existing power of appeal held by the Commission for Healthcare Regulatory Excellence, but agrees that the GMC needs also to have a right of appeal in cases where it thinks panellists have been too lenient. We urge the Government to move quickly to make the necessary legislative amendments.

Response

The Department notes the Committee's recommendation that the GMC should have a right of appeal.

Following full public consultation by the GMC, and subsequent agreement by the GMC Council, Departmental officials are working with both the GMC and CHRE to consider the potential for the GMC to be given such a right of appeal in legislation.

Recommendation Para 43

Doctors from Mid Staffordshire NHS Foundation Trust whose practice was in itself blameless but who failed to act and raise concerns about colleagues are now also under investigation by the GMC. A clear signal needs to be sent by the GMC to doctors that they are at as much risk of being investigated by their regulator for failing to report concerns about a fellow registrant as they are from poor practice on their own part.

Response

There is a current and long standing professional duty upon doctors to act upon/report any concerns they have about a colleague's practice. Paragraphs 43–45 of Good Medical Practice "Conduct and performance of colleagues" provides details about how the GMC expects its registrants to behave where they have concerns.

It would also be open to doctors to refer concerns about NHS organisations or management through a public interest disclosure to the Care Quality Commission (CQC) or Monitor.

The NHS Constitution draws attention to the protection available to staff and the handbook to the constitution specifically cites the Public Interest Disclosure Act 1998 and staff rights to "protection from detriment in employment and the right not to be unfairly dismissed" under the Act.

Recommendation Para 44

The Committee recognises, however that doctors and other practitioners who have raised concerns by other staff have sometimes been subject to suspension, dismissal or other sanctions. The Committee therefore intends to examine this issue in more detail in due course.

Response

There is a long standing professional duty where a doctor has good reason to think that patient safety is or may be seriously compromised by inadequate premises, equipment, or other resources, policies or systems, to put the matter right if that is possible.

In all other cases, they should draw the matter to the attention of their employing or contracting body. If that body does not take adequate action, the doctor raising the concern should take independent advice on how to take the matter further. The doctor must record their concerns and the steps they have taken to try to resolve them. This is set out in Good Medical Practice at paragraph 6.

The Public Interest Disclosure Act 1998 inserted provisions into the Employment Rights Act 1996 (sections 43A–L) which is owned by the Department for Business, Innovation and Skills. It forms part of the wider employment rights legislation and gives the legal protection to all staff (employees and workers as defined in the Act) who make qualifying disclosures in the public interest, providing they follow the procedures set out in the Act. It therefore applies to all staff working in the NHS.

Although PIDA does not require organisations to set up whistleblowing policies and procedures, it does provide an impetus for doing so. Guidance issued in 2003 made clear that NHS organisations should put in place local policies and procedures that comply with the Act and set out minimum requirements for such policies.

The Department of Health also provides funding to the charity Public Concern at Work, which provides an independent source of advice for NHS workers seeking to raise concerns in the public interest.

In all cases, professionals must consider the wider implications of failing to report such concerns and the risks to patient safety, which is their primary responsibility. In March 2011, the GMC began a process of consultation on additional guidance to supplement Good Medical Practice, for doctors (as individuals or managers/employers) about raising concerns about patient safety. This additional guidance also includes information on how to make a concern public – i.e. how to whistleblow.

To help all employers (including doctors) to build a culture where staff feel able to raise concerns about poor practice or potential risks to patient safety *Speak up for a healthy NHS* was commissioned by the Social Partnership Forum. The guide, written by the independent whistleblowing charity Public Concern at Work, was launched at the NHS Confederation conference on 25 June 2010. It sets out simple steps to help employers ensure their whistleblowing arrangements work.

The reasons for suspension (exclusion) or dismissal of NHS staff are varied. The Department would therefore be interested in giving evidence to the Committee should they examine in more detail consequences that some individuals experience when they have raised concerns.

Recommendation Para 45

In contrast to the approach of the Nursing and Midwifery Council, the GMC has put its fitness to practise cases relating to Mid Staffordshire “on hold” until the inquiry has concluded. The Committee believes that this is neither fair to the public, or to the registrants under investigation. We urge the GMC to set out its rationale for this, publicly and clearly.

Response

The Department acknowledges the Committee’s view. This is a matter for the GMC as the independent regulator for doctors.

Recommendation Para 49

We suggest that the GMC further considers risk-based approaches to proactive regulation and how these could be developed with its employer liaison services.

Response

The Department welcomes the Committee’s suggestions in this regard.

Recommendation Para 53

The Committee appreciates the seriousness with which the GMC has treated the suggestion that doctors from black and minority ethnic backgrounds are overrepresented in fitness to practise cases. The finding that this relates to overseas trained doctors and not ethnicity per se does not alter the fact that a problem exists.

Response

The Department supports the Committee's comments on this, and welcomes the GMC's previous and ongoing work to understand whether and why black and minority ethnic doctors might be overrepresented in fitness to practise cases.

Recommendation Para 54

The GMC needs, as matter of urgency, to do more to understand the risks associated with overseas-qualified doctors. It should offer timely induction and needs to assure itself that those doctors in peripatetic locum positions are adequately supervised and supported. If a doctor is not safe to practise in the UK then the GMC must ensure that they do not do so.

Response

The GMC does not have the statutory ability to impose standards of supervision and support upon those engaging overseas doctors in peripatetic locum positions and it is the Department's belief that they should not. Similarly, matters relating to induction arrangements are the responsibility of employing and contracting organisations addressing the needs of the work the doctor will be doing within and for their organisation.

The GMC has a robust process for establishing the suitability for registration of migrants from third countries relying on third country qualifications. (EEA migrants have been covered above.)

Under the Health and Social Care Act 2008, providers of regulated activities (which would include NHS trusts and locum agencies that also provide regulated activities) must register with the Care Quality Commission (CQC) in England. As such, they must ensure that they meet the registration requirements set by the CQC, which include requirements around staffing skills, experience and fitness. The responsibility for ensuring that staff employed to carry out a regulated activity are fit to practise rests with the provider, and CQC can take enforcement action against the provider if it does not meet the requirements.

Voluntary Erasure

Recommendation Para 61, 62 and 64

Several cases have been brought to the attention of the Committee of doctors applying to remove themselves from the register during an ongoing investigation into their practice by the GMC (so called voluntary erasure). The Committee has no objection to the principle of voluntary erasure as it can be a useful tool to protect the public. However, in some cases, interested parties have been given little or no time to raise an objection to applications for voluntary erasure, and the GMC was not able to offer a clear explanation of this.

Applications for voluntary erasure must not be granted by the GMC unless interested parties have been given adequate notice of an application and have been offered an opportunity to voice an opinion on the matter.

The Committee fully supports the publication of the facts of any case of voluntary erasure where there is a fitness to practise allegation about the doctor concerned. The GMC needs to ensure that turning voluntary erasure into an admission of guilt does not have a perverse impact in reducing the numbers seeking it and therefore erode public protection.

Response

The purpose of fitness to practise action is to ensure that the public are appropriately protected from the activities of poorly performing professionals. Its purpose is not to provide a means of direct redress for the victim of the actions of a poorly performing professional. Whilst sanctions such as suspension, removal from the register or conditions on practice may have a punitive effect, that is not their primary purpose.

As the Committee has highlighted, voluntary erasure is a valuable tool for protecting the public. The GMC has published a transparent process (underpinned by legislation) for the handling of voluntary erasure applications. Current GMC guidance on these matters makes it clear that decision makers on applications for voluntary erasure should balance the interests of complainants against the interests of doctors, before deciding whether voluntary erasure is appropriate in all the circumstances. This guidance also makes clear that there will be cases where the public interest dictates that it is appropriate to refuse such applications, and pursue fitness to practise action against the doctor concerned.

The guidance recognises the importance that, in the event of a voluntary erasure application being granted, details of the allegations admitted should be made available to relevant enquirers (including potential employers and overseas medical authorities). The guidance makes clear that allegations admitted would also be considered if the doctor subsequently applies for restoration to the register.

Appendix 4: General Medical Council's Response

Introduction

We welcome the Health Select Committee's report on the GMC, which will help us drive forward our already ambitious reform agenda.

We are committed to meeting the challenge set by the Committee to provide leadership to the profession, particularly in relation to the standards of performance and conduct we expect of doctors, so that patients across the UK get the highest quality care.

This document sets out our response to each of the Committee's recommendations. We will continue to keep the Committee informed of our progress throughout the year and we look forward to exploring these issues further at our next annual accountability hearing.

1. Although, therefore, the Committee recognises that the GMC achieves a high level of operational competence, it remains concerned that the leadership function of the GMC within the medical profession, and within the wider health community, remains underdeveloped particularly in the areas of fitness to practise, revalidation, education and training and voluntary erasure. We hope that the GMC will embrace more ambitious objectives for professional leadership, some of which are described in this report. (Paragraph 4)

We are pleased that the Committee has recognised the GMC's high level of operational competence, and accept that there is no room for complacency. We remain determined to deliver ever more efficient and effective protection for patients.

We have outlined, in the course of our responses to the specific points raised by the Committee, the ways in which we will work to address the challenge of showing leadership as a regulator working alongside the medical profession and wider health community.

Revalidation of doctors

2. The work undertaken by the Society of Cardiothoracic Surgery of Great Britain and Ireland in setting standards for that part of the medical profession is commendable. Its transparency will be welcomed by patients and should be a template (where clinically relevant) for further refinement of the revalidation process. (Paragraph 11)

3. The GMC clearly has a considerable amount of work to undertake between now and the implementation of revalidation in 2012. Although we agree that all disciplines will not have developed their standards to an advanced level by that date, the GMC needs to accelerate its work with the medical royal colleges to further refine the standards for revalidation in specialist areas and to ensure that the process is meaningful to clinicians and transparent to the public. (Paragraph 12)

Revalidation remains the GMC's number one priority. We are determined and on track to introduce a system by late 2012 (subject to the Secretary of State's approval). Over time,

revalidation will provide increased assurance that licensed doctors are up to date with and practising to the appropriate professional standards.

There are a number of key areas of work underway with our partners in the Health Departments, the Royal Colleges, Employers and others across England, Scotland, Wales and Northern Ireland, to ensure that local systems of clinical governance are in place and fit to support revalidation. These are led by the four health departments with support from the GMC.

At the same time, we have a major programme of work underway to ensure our own systems and processes are ready to support implementation.

We acknowledge there is still work to be done, to ensure doctors understand the implications of revalidation for their practice, including in specialist areas. We are committed to doing this, both in the lead up to implementation and beyond.

The Academy of Medical Royal Colleges is co-ordinating the development of supporting information guidance from each of the medical royal colleges and faculties for GPs and specialist doctors. Doctors are being advised that participation in national audits will be expected where these are relevant to the specialty or subspecialty in which they practice.

The Society of Cardiothoracic Surgery of Great Britain and Ireland (SCTS) has done commendable work in setting standards and they are more advanced in this regard compared to other specialities. This reflects two main factors. First, the enthusiasm of that specialty and the very hard work its leaders have done over a considerable number of years. Secondly, it is less difficult to measure outcomes for cardiothoracic surgery than in many other areas, for example general practice and psychogeriatrics.

We are working with the SCTS to explore lessons that can be learnt from their experience and we will continue to work closely with our partners in order to ensure that over time the information all doctors bring into their appraisals becomes more outcome based.

4. As the GMC states, some doctors may decide to retire rather than undergo the process of revalidation; of those who pursue revalidation, some may require retraining and some may fail to meet the required standards. The GMC needs to ensure that it monitors the number of doctors who retire, leave the profession, have conditions placed on their practice or fail revalidation. It must develop and share this evidence with employers to ensure that future workforce planning includes the developing outcome of the revalidation process. (Paragraph 14)

We recognise that we will need to monitor the number of doctors who retire, leave the profession, have conditions placed on their practice or are referred to our fitness to practise procedures. We are currently developing our internal systems, processes and supporting technology. These monitoring requirements will be considered in all of that work.

The outcomes of all revalidation decisions will be shared with the relevant employers so that they can make the appropriate workforce planning and development arrangements.

Revalidation provides the formal context in which local systems of clinical governance must now be established. One of the benefits of this process is that as a result of yearly appraisals of their doctors, employers will have a more regular and informed understanding of their workforce planning and development needs without necessarily having to wait on a revalidation decision in consultation with the GMC every five years.

Outside of revalidation, as further evidence of our commitment to develop and share information which may support future workforce planning, we have recently published a report, *The State of Medical Education and Practice*. This report uses the wide range of information held by the GMC from across our Education, Registration and Fitness to Practice functions to provide a picture of today's medical profession and some of the key challenges it faces. In publishing this report, we hope to initiate an important debate with employers, educators, the profession and other regulators on what action is required to respond to these challenges for the doctors of today and tomorrow including in workforce planning.

5. Of the Officers who will have to make recommendations about revalidating doctors, only a minority feel that the process will help with the early identification of doctors with performance issues. Early identification of problem doctors is a core task of the professional regulatory system, and the GMC needs to ensure that its systems of appraisal and revalidation achieve this task. (Paragraph 15)

We believe in a four layer model of regulation

Personal regulation. The individual practitioner's values, supported by their professional ethos, should be what most effectively ensures good care for every person that they care for.

Team regulation. Peers and colleagues should provide assurance, with everyone working together to ensure that each other's care is safe, effective and respectful.

Workplace regulation. The culture of care in the team should in turn be embedded and sustained by effective leadership, management and clinical governance in the organisation that provides, or arranges the provision of, care.

National regulation. Professional regulatory bodies and the bodies that regulate the providers of health and social care services provide a national framework of assurance.

We believe that each of these four layers of regulation will be strengthened and formalised by the implementation and roll out of revalidation:

Encouragingly, the independent report on the Revalidation Pathfinder Pilots, published in June found that 70% of the responding Responsible Officers expect the full roll-out of revalidation to lead to improved patient safety, improved quality of care and improvements in patient experience. In addition, of those Responsible Officers who participated in the most recent pilots, 53% expected the full roll out of revalidation to result in a reduction in the amount of time it takes to "identify and rectify poor practice".

While there is still work to do to refine and improve the systems of local clinical governance on which recommendations for revalidation rely, these findings suggest good progress is being made in this important area.

To support the early identification of problem doctors we are taking steps that will create better links between the GMC and employers for identifying, investigating and managing concerns. This year we are introducing a network of dedicated Employer Liaison Advisers. Their role will include developing good links with Responsible Officers across the UK to support an earlier two-way exchange of information and advice on poorly performing doctors or those about whom the employer has potential concerns.

We will continue to work with employers and Responsible Officers to support them in making sure there are robust local systems of clinical governance and appraisal in place within their organisations which support doctors with their appraisal and revalidation.

6. The Committee notes the negative media reports about the time taken to undertake revalidation and hopes that the GMC will ensure that lessons are learned from the revalidation pilots, particularly in how it can support locum doctors. It also needs to ensure that the underlying processes that doctors are expected to undertake are not unwieldy and overly time-consuming, and that they are an effective means of gathering the required evidence. (Paragraph 18)

The Responsible Officer Regulations, together with revalidation, establish the principle that gathering and reflecting on information about their practice will become a part of every doctor's professional life.

However, we understand doctors' concerns that introducing revalidation should not unduly add administrative requirements over and above that necessary for good medical practice.

We remain committed to ensuring that our proposals for revalidation are robust but proportionate and flexible for all practising doctors. Following our consultation last year, we streamlined and simplified the supporting information required for appraisal so that all doctors regardless of their practice will collect a common set of core information.

We have also learnt from the pilot findings. Specifically, the IT system developed by the NHS Revalidation Support Team was intended to support appraisal (as distinct from revalidation) and was only designed for the pilot. The NHS Revalidation Support Team has now started a second year of piloting, as part of which they will be testing the process with locum doctors.

We want better safer care for patients; to achieve that we must give doctors the space to reflect on their practice, to gather information about their performance and to benchmark their results, however we understand that doctors need to find the process both rewarding and effective.

The next year of preparation will help to ensure the system works well for all doctors, wherever and however they practise.

7. Doctors from the European Economic Area and Switzerland seeking to practice in the UK cannot routinely be language and competence tested by the GMC. (Paragraph 21)

8. The GMC along with the Government is working towards resolution of this with partner organisations across Europe. The Committee takes the view that current legal framework is at odds with good clinical practice, which is clearly unacceptable. The GMC has plans, within the boundaries of UK law and the EU Directive, to manage the constraints on language and competence testing by using the Responsible Officer role to establish that EEA (the EU plus several other European countries) doctors are fit to practise in the UK. The Committee accepts this way forward as a short term measure. (Paragraph 22)

9. Although this short term measure is welcome, the Committee believes that public confidence in the medical profession requires the issue to be addressed authoritatively. It is clearly unsatisfactory that the competence to practise of health professionals should be assured by a work-around, and we look to the Government, GMC and the relevant European bodies to work as a matter of urgency to produce a long-term solution to this problem. (Paragraph 23)

On Tuesday 4 October, the Secretary of State for Health announced that the Government will introduce measures that will ensure all doctors who come from overseas to work in the UK must not only have the right qualifications, but also the language skills needed to practise medicine safely.

The changes have two main components. First, the Medical Act will be amended to give the GMC explicit new powers to take action where we identify concerns about the language skills of EEA trained doctors as part of the registration process, including in the small number of cases where we have a doubt about their language skills, if for example they use a translator or say that they cannot speak English. Secondly, Responsible Officers across England will have a mandatory duty at a local level to check the English language skills of all overseas doctors before they can be employed. Discussions are ongoing with the administrations in Scotland, Wales and Northern Ireland to see if the Responsible Officer scheme could also apply or whether there is a more appropriate local system.

These measures mark the culmination of many months of hard work to close this loophole in UK law, which has been causing so much concern to patients and their families. We will continue to work with the Department of Health to implement the changes as quickly as possible.

This proposed scheme, which is compliant with European law, will be a significant improvement on the current situation and will provide greater protection to UK patients.

We do not regard it as a short-term measure. We would however like to have even more power to assess the linguistic and clinical competence of doctors from the EEA in the same way that we can for doctors that qualified outside of Europe. We will therefore continue to engage, together with other UK and EU healthcare professional regulators, in the review of the recognition of professional qualifications Directive in the coming months.

Fitness to practise

10. The Committee notes that there is an increase in referrals of doctors to the GMC, and of nurses to the NMC, as well as an increase in the number of general NHS complaints. The Committee welcomes the fact the GMC has commissioned research into this phenomenon in order to better understand what is driving this increase, and to ensure that

their systems and processes are adequate for meeting the future needs of the public. We look forward to reviewing the preliminary findings of this with the GMC at our next accountability hearing. (Paragraph 27)

This trend in increasing referrals to the GMC is something that we are keen to understand in detail and we welcome the Committee's support for the work we have commissioned in this area.

We will use the findings of this research to ensure our systems and processes are adequate for meeting future public need.

11. The Committee welcomes the ongoing good performance of the General Medical Council (GMC) in resolving 90% fitness to practise cases within fifteen months. However, we agree with the GMC that fifteen months is indeed too long to conclude such cases and we recommend that the Council for Healthcare Regulatory Excellence (CHRE) their regulatory body, should set the GMC a more demanding target for future years. (Paragraph 29)

We have launched a significant series of reforms to our fitness to practise procedures so that cases can be resolved more quickly and in a manner that is less stressful for all involved while ensuring the principle of patient protection is upheld at all times. We consulted widely on these reforms earlier this year and have now begun work to implement these changes. Some of them will require legislative change.

In the meantime, we are determined to continue meeting our target of resolving 90% of fitness to practise cases within 15 months.

12. Some of the decisions made by fitness to practise panels of the GMC defy logic and go against the core task of the GMC in maintaining the confidence of its stakeholders. Furthermore, they put the public at risk of poor medical practice. (Paragraph 35)

13. The GMC holds the dual but potentially conflicting roles of prosecutor and adjudicator in fitness to practise cases. The GMC proposes to establish an Independent Medical Practitioner Tribunal Service to create a greater separation between these functions, and the Committee supports this proposal. We also urge that performance management of fitness to practise panellists commence as soon as is practicable. (Paragraph 36)

14. The GMC currently has no right of appeal over decisions made by independent fitness to practise panels. The Committee does not seek to undermine the existing power of appeal held by the Commission for Healthcare Regulatory Excellence, but agrees that the GMC needs also to have a right of appeal in cases where it thinks panellists have been too lenient. We urge the Government to move quickly to make the necessary legislative amendments. (Paragraph 40)

We welcome the Committee's support for our proposal to modernise the GMC's fitness to practise procedures, including the establishment of the independent Medical Practitioner Tribunal Service (MPTS).

We also welcome the Committee's recommendation to allow the GMC a right of appeal against independent panel decisions we feel do not adequately protect the public.

Both these measures were also supported by the majority of respondents to our public consultations earlier this year.

Now that these proposals have been approved by the GMC's Council we are now moving as quickly as possible to appoint the first chair of the MPTS and we will continue to work with the Department of Health (England) to make the necessary legislative changes.

15. Doctors from Mid Staffordshire NHS Foundation Trust whose practice was in itself blameless but who failed to act and raise concerns about colleagues are now also under investigation by the GMC. A clear signal needs to be sent by the GMC to doctors that they are at as much risk of being investigated by their regulator for failing to report concerns about a fellow registrant as they are from poor practice on their own part. (Paragraph 43)

16. The Committee recognises, however that doctors and other practitioners who have raised concerns by other staff have sometimes been subject to suspension, dismissal or other sanctions. The Committee therefore intends to examine this issue in more detail in due course. (Paragraph 44)

The Committee rightly challenges us to send a clear signal to doctors of the importance of speaking out if they are aware of poor patient care. We know there is more we can do in this area and we are committed to taking up this challenge. We also believe it is incumbent on healthcare employers to ensure that they create an open and transparent working culture in which all staff feel able to raise concerns, and indeed are encouraged to do so.

Later this year, we will be consulting on an updated version of our core guidance, *Good Medical Practice*, and producing new advice about raising concerns.

However, we recognise this is not just about releasing guidance - the important point is that we work to ensure doctors are aware of these issues and their obligations to act appropriately in every instance. We will be working with the wider profession including employers and other professional and system regulators to take this forward.

With specific regard to Mid Staffordshire, we are investigating a number of doctors who allegedly failed to take appropriate action despite being aware of the concerns surrounding the quality of care being provided. This includes two doctors in management positions at the Trust itself and one at the SHA. We are also investigating one further doctor who allegedly failed to implement an action plan to address concerns which had been identified and were known to the Trust's management.

17. In contrast to the approach of the Nursing and Midwifery Council, the GMC has put its fitness to practise cases relating to Mid Staffordshire "on hold" until the inquiry has concluded. The Committee believes that this is neither fair to the public, or to the registrants under investigation. We urge the GMC to set out its rationale for this, publicly and clearly. (Paragraph 45)

Investigations into doctors working at Mid Staffordshire NHS Foundation Trust have been ongoing. In line with our usual practice, we had decided not to close any investigations while the Public Inquiry was still receiving evidence which might have changed our view of a case.

However, given that the Inquiry will not be receiving any more evidence and the length of time since these investigations were opened, we wrote to the Inquiry to ask if it had any further information which might be relevant to our investigations so that our decisions on individual cases can be fully informed.

They have advised that they do not have any further information which touches on any individual practitioner at the Trust, and that any relevant information that has already been provided to the Inquiry will have been referred to in oral evidence or exhibited to relevant statements and is therefore in the public domain.

As a result we are now deciding what action should be taken in regard to these cases and will be progressing them in line with our normal procedure.

18. We suggest that the GMC further considers risk-based approaches to proactive regulation and how these could be developed with its employer liaison services. (Paragraph 49)

We are taking proactive steps that will create better links between the GMC and employers for identifying, investigating and managing concerns.

This year we are introducing a network of dedicated Employer Liaison Advisers. Their role will include developing good links with Responsible Officers across the UK to support an earlier two-way exchange of information and advice on poorly performing doctors or those about whom the employer has potential concerns.

As this service matures, the Employer Liaison Service should maximise the potential risk based regulatory benefits of revalidation, encouraging and supporting employers in earlier, meaningful interventions where concerns or risks about doctors are identified in the context of anticipated systems of local clinical governance.

19. The Committee appreciates the seriousness with which the GMC has treated the suggestion that doctors from black and minority ethnic backgrounds are overrepresented in fitness to practise cases. The finding that this relates to overseas trained doctors and not ethnicity *per se* does not alter the fact that a problem exists. (Paragraph 53)

20. The GMC needs, as matter of urgency, to do more to understand the risks associated with overseas-qualified doctors. It should offer timely induction and needs to assure itself that those doctors in peripatetic locum positions are adequately supervised and supported. If a doctor is not safe to practise in the UK then the GMC must ensure that they do not do so. (Paragraph 54)

We are committed to ensuring that our processes and procedures are fair for all doctors, including those from BME backgrounds and those who trained overseas.

We will continue towards gaining a better understanding of why some groups of doctors, in particular those who qualified outside the UK, are over represented both in the proportion of complaints we receive and in our fitness to practise procedures.

Related to this and as evidence of our recognition of the Committee's challenge for us to show leadership within the profession, we have published a report, *The State of Medical Education and Practice*, which uses the wide range of information held by the GMC from

across our Education, Registration and Fitness to Practice functions, provides a unique picture of the make-up of today's medical profession including an assessment of the demographic trends which characterise and challenge the profession of today and tomorrow.

We agree that there should be more thorough induction processes for overseas medical graduates coming to work in the UK and that there is more work that the GMC can do in this area. For many newly-arrived doctors an adequate induction is often unavailable. As a result they are not always aware of the ethical and professional standards that they will be expected to meet, how the health service in the UK operates or how medical practice is managed and regulated. As a contribution to help support doctors who are new to UK practice, we intend to work with employers and professional organisations to develop a basic induction programme for all doctors new to the register. Ideally we believe that all doctors should have to complete the programme before they practise, whether they are trained in the UK, elsewhere in Europe or further afield as everyone who treats patients needs to be supported to do that safely.

As the Committee highlights, we are not currently permitted by law to test the skills or language competency of doctors entering the UK from the EEA. However, as stated above, the Secretary of State for Health has recently announced that the Government will introduce measures that will allow us to ensure that all doctors who come from overseas to work in the UK must not only have the right qualifications, but also the language skills needed to practise medicine safely.

Voluntary erasure

21. Several cases have been brought to the attention of the Committee of doctors applying to remove themselves from the register during an ongoing investigation into their practice by the GMC (so called voluntary erasure). The Committee has no objection to the principle of voluntary erasure as it can be a useful tool to protect the public. However, in some cases, interested parties have been given little or no time to raise an objection to applications for voluntary erasure, and the GMC was not able to offer a clear explanation of this. (Paragraph 61)

22. Applications for voluntary erasure must not be granted by the GMC unless interested parties have been given adequate notice of an application and have been offered an opportunity to voice an opinion on the matter. (Paragraph 62)

23. The Committee fully supports the publication of the facts of any case of voluntary erasure where there is a fitness to practise allegation about the doctor concerned. The GMC needs to ensure that turning voluntary erasure into an admission of guilt does not have a perverse impact in reducing the numbers seeking it and therefore erode public protection. (Paragraph 64)

We welcome the Committee's support for our proposals outlined in our consultation paper published earlier this year to reform the GMC's fitness to practise procedures in a way that will provide quicker resolution and less stress and anxiety for all concerned while upholding our commitment to ensuring patient safety.

At present, under our current legislation, in cases where the doctor would be willing to accept our proposed sanction the majority still go to a public hearing. We believe that this is not always the most proportionate or effective way of protecting patients. The consultation paper (attached for reference)²¹ proposed that where there is no significant dispute about the facts of a case, doctors should be able to accept sanctions, including suspension and erasure, without their cases going to a hearing. The proposals in the consultation paper received support from both medical professionals and the public.

The central change proposed in the consultation paper is to hold face-to-face meetings with doctors at the end of our investigation to encourage them to accept the sanction necessary to protect the public without the need for a public hearing. We envisage that doctors will be advised of our proposed sanction based on the available evidence and invited to provide any new information which may alter our view of the seriousness of the matter prior to the meeting.

Where the doctor accepts the sanction necessary to protect the public, we propose to publish the outcome on our website with sufficient information to enable the public to understand the appropriateness of the sanction. Our intention is to be able to extend this approach to the full range of sanctions (including suspension and erasure) however this will require amendments to the Medical Act 1983 before we are able to fully implement the programme. In the meantime we intend to pilot the new model in all cases other than suspension and erasure cases to test the new process.

We would like to clarify that, under these proposals, where erasure is accepted by the doctor, this would not be the same as voluntary erasure. Voluntary erasure allows a doctor to relinquish their registration and therefore no longer need to pay our registration fee. This is mostly used by doctors retiring, changing career, taking maternity leave or moving abroad. In exceptional circumstances voluntary erasure may be granted to doctors where there is a fitness to practise concern when the doctor is too sick to respond to our procedures or take part in a public hearing or is unlikely to return to medical practice and we are satisfied that it is in the public interest to remove them from the register. We are sorry if this has caused some confusion and we are currently considering whether we may need to use different terms to better distinguish between the two processes.

The Committee has raised concerns that in some cases we did not provide sufficient advance notice to the complainant about an application for voluntary erasure. We would like to assure the Committee that our policy is to inform complainants and offer them an opportunity to submit comments, regardless of whether voluntary erasure has been requested prior to or during a hearing. Clearly in the instance highlighted to the Committee, this did not happen and we are sorry that insufficient notice was given in this case. We will take steps to ensure that this does not happen in the future.

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Appendix 5: Government's Response – Annual Accountability Hearing with the Care Quality Commission

Introduction

On 14 September 2011, the House of Commons Health Committee (the Committee) published the report: *Annual Accountability Hearing with the Care Quality Commission*.

When the Committee held a pre-appointment hearing to assess the proposed appointment of Dame Jo Williams (then a CQC commissioner and acting Chair of CQC), its report indicated the Committee's intention to review the work of CQC on an annual basis, given the breadth of CQC's agenda and the vital place it occupies in regulating standards of care.

The Department strongly believes that these hearings are of great value in strengthening the accountability of the Department's independent Arm's Length Bodies to Parliament and the wider public.

Departmental response

We welcome this report and have carefully considered the Committee's recommendations and the issues it raises. The changes proposed for CQC in the Health and Social Care Bill will strengthen CQC as a quality inspectorate giving the public and patient a stronger voice.

Through the forthcoming social care white paper to be published next spring, the Department will be looking at how to drive quality improvement in social care and the role that the regulator may play in this.

The Government's response to each of the recommendations made in relation to CQC is shown in the table below. Though many of the Committee's recommendations were clearly for CQC to take forward, we have commented on all recommendations. Many of the recommendations reflect matters which have come to light in recent months and CQC already has action underway to address these. In particular, CQC has already taken action to increase its compliance activity and is taking steps to ensure that there is an appropriate balance between its registration and compliance work at all times. CQC also has work underway to refine the registration process for future tranches of registration.

Additionally, in line with the recommendation from the Committee, CQC is exploring the impact of changes proposed as a result of the passage of the Health Bill and implementation of the Department of Health's Arm's Length Bodies review. The Department will work with CQC to ensure that these changes do not adversely affect CQC's other core functions.

CQC has advised us that it will be responding in more detail on what it is doing in relation to the recommendations and so the Department has kept its response relatively high level.

Department of Health response to the Health Select Committee Recommendations – the Care Quality Commission

The balance between registration and compliance activity

1. The Committee concluded that the bias in the work of the CQC away from its core function of inspection and towards the essentially administrative task of registration represented a significant distortion of priorities. Although the evidence presented by the CQC acknowledged this distortion of priorities and argues that corrective action has now been taken, the Committee believes it is important to understand how this misallocation of resources arose, not least in order to reduce the risk of the same thing happening again.

The Government accepts the comments of the Committee and is aware of the challenges CQC has faced registering providers under the new registration framework to a challenging timetable. The Government looks to CQC as the independent regulator to undertake its regulatory functions efficiently and effectively, learning lessons from its experiences.

CQC has acknowledged that the registration process was cumbersome and that this had a negative impact on its compliance activity. CQC recognises the need to learn from this experience. CQC has assured the Department that whilst there was a reduction in the number of planned reviews undertaken, it continued to respond appropriately with responsive reviews, taking action where risks were identified.

In light of the challenges that CQC has faced in registering 22,000 providers in the last 18 months, the Government implemented proposals to delay bringing the vast majority of NHS primary medical care providers into the new system until April 2013. This delay will give CQC time to find ways in which the registration process can be improved, and to increase its compliance activity of those providers already registered with CQC.

2. The Committee has identified the following factors which contributed to this distortion of priorities:

The Government welcomes the Committee's analysis of the contributory factors as to why registration was prioritised over inspection and we respond to each in turn:

The CQC was originally established without a sufficiently clear and realistic definition of its priorities and objectives;

Sections 2 and 3 of the Health and Social Care Act 2008 set out CQC's functions and main objective. Its main objective is to perform its functions to protect and promote the health, safety and welfare of people who use health and social care services. Section 3 also requires CQC to perform its functions for the general purpose of encouraging improvement in health and social care services; encouraging a focus on peoples' needs and experiences of services; and encouraging the efficient and effective use of resources in the provision of services.

The Department worked closely with CQC and its predecessor bodies in developing these

objectives to ensure that CQC's objectives and priorities would be clear when it took over as the regulator in April 2009.

We have made a commitment to review the role and functions of CQC within five years of its establishment. That review will take on board lessons learnt in the implementation of the Health and Social Care Act 2008 and make clarifications where these are found to be necessary to clarify CQC's role.

In terms of setting specific priorities, as an independent body, these are for CQC to determine based on the functions it has been given.

The timescale and resource implications of the functions of the CQC, in particular the legal requirement to introduce universal registration of primary and social care providers, were not properly analysed;

In drafting the regulations to implement the new registration system, the Department of Health discussed proposals with CQC and its predecessors, and agreed a phased approach to bring providers into the new system. This brought in NHS providers into the new registration system first and then independent healthcare and adult social care providers followed by primary dental care providers. This timetable was developed following discussion with CQC. CQC was given transitional funding to support the one off task of bringing providers into the new registration system and its budget was kept under review.

The impact assessments that accompanied the regulations analysed the costs of bringing providers into the new registration system. The estimated transition costs were based on the costs to CQC of registering providers under previous legislation (the Care Standards Act 2000). Having registered around 22,000 providers in an 18-month period, CQC has carried out a difficult programme well.

However, we recognise that the one-off task of bringing independent health care and adult social care providers into registration has impacted on CQC's core functions. This is why the Department implemented proposals to delay bringing the vast majority of NHS primary medical care providers into the new system until April 2013. This delay will allow CQC to implement the lessons of previous registration rounds and to focus more on monitoring the compliance of existing registered providers with the essential levels of safety and quality.

The registration process itself was not properly tested and proven before it was rolled out; and

Whilst the Health and Social Care Act 2008 and subordinate legislation set out the registration framework, as an independent body, CQC is responsible for developing, consulting on and implementing the detailed working of the new system. We know that CQC worked with stakeholders to develop the system in advance of implementation, and CQC has made a public commitment to evaluate its model in order to improve its processes and performance management for future tranches of registration.

The CQC failed to draw the implications of these failures adequately to the attention of ministers, Parliament and the public.

Whilst the Department of Health does not get involved in CQC's day-to-day operations it expects to be kept apprised of risks and how CQC is mitigating these, including changes to the levels of inspections, through quarterly accountability meetings between CQC's Chief Executive and the Department's Director General for Policy, Strategy and Finance, and other less formal mechanisms. As part of these monitoring arrangements we expect CQC to keep the Department informed of changes to operational activity and the mitigating action being taken against any associated risks.

The Government looks to CQC to monitor and report on its performance on an on-going basis to assure the public it is carrying out its functions efficiently and effectively. The Department expects CQC to inform it in a timely manner if inspection levels drop in the future.

3. We are extremely concerned that CQC's compliance activity fell to such low levels in the course of 2010–11. We recognise that the CQC was obliged to work within the deadlines for registration imposed by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. We also recognise that it was in order to meet these deadlines that resources were diverted from compliance activity to registration. Yet the fact that this was done to the extent that inspections fell by an unacceptable 70% demonstrates a failure to manage resource and activity in line with the main statutory objective of the CQC to 'protect and promote the health, safety and welfare of people who use health and social care services'. In the current climate of financial constraint and reorganisation of the health service it is more important than ever to have a regulator that maintains a clear focus on its primary duties. In this instance that did not happen.

The Government agrees that the focus on registration should not have affected CQC's compliance activity to the extent that it did. However, in order to be registered under the new system, providers were not simply "passported in" and this has meant that each provider has undergone a registration check and CQC has built up baseline information for each provider registered with it.

CQC has assured the Department that whilst there was a reduction in the number of planned reviews undertaken, it continued to respond appropriately with responsive reviews, taking action where risks were identified. CQC has now taken corrective action and the number of inspections has increased and continues to increase.

As the Committee is aware, CQC's compliance activity has been steadily increasing and it is now undertaking around 1,000 inspections a month. The Department has also been assured that CQC has taken steps to ensure a similar situation will not happen again.

By taking time now to evaluate the registration process, CQC will be able to learn the lessons from the previous registration rounds to ensure that when it brings further providers into the registration system in 2012 and 2013, registration does not have an adverse effect on monitoring the compliance of existing registered providers with the essential levels of safety and quality. We acknowledge that this tranche will bring a different set of challenges, but we have agreed to delay the registration of the majority of providers to allow CQC to develop and implement better processes.

4. The long-standing vacancies for CQC inspectors are a further cause for concern. The eight months taken to recruit the extra 70 inspectors for which the Department of Health gave permission in October 2010 is unacceptable given the urgent need to raise compliance activity. The CQC should also have been pushing the Government for permission to recruit outside the initial limited pool much sooner. These delays indicate a failure to react with urgency to a problem that was severely undermining the organisation's compliance function.

The Department has worked with CQC to find solutions within the given recruitment controls that would allow CQC to recruit to business critical posts.

Whilst the Department has been concerned by the initial delay in recruitment, we acknowledge CQC is now making much better

progress in increasing the number of compliance inspectors and the Department looks to CQC to assure the Government that it has the right workforce in post on a continuing basis, and that staffing levels do not fall to unacceptable levels thereby ensuring compliance activity is not adversely affected.

Notwithstanding the refocusing of resources on compliance, the Department of Health has now agreed a business case submitted by CQC seeking approval to recruit additional compliance inspectors and compliance managers. This approval has been given as part of the 2012/13 finance and business planning round, and CQC's indicative revenue budget for 2012/13 includes sufficient funding to allow CQC to recruit the additional 229 (full time equivalent) compliance inspectors and the additional 19 compliance managers that CQC identified as necessary.

5. The CQC should have identified the difficulties inherent in the regulations early in the registration process and made clear to the Government that unless modifications were made it would not be able adequately to fulfil its duty to monitor and inspect providers. The senior leadership of the organisation had a responsibility to communicate this to the Government persuasively and persistently. The decisions to delay GP registration and review the regulations for registration have come too late. The Government and the CQC should set out what discussions were had and why action was not taken earlier to modify the regulations.

Any changes to the regulations are subject to Parliamentary process, and require formal consultation. The Department moved quickly to implement a delay to the registration of most providers of NHS primary medical providers once a request to do so was made by CQC.

CQC first raised the possibility of delaying registration of these providers in a letter of 11 March 2011 to the Secretary of State. A delay of 12 months was agreed in principle at meeting between Ministers and CQC's senior leadership team on 4 May 2011. The Department carried out a six week consultation on this proposal between 17 June and 29 July. On 12 August, the Department announced its intention to proceed with a delay to the registration of providers of NHS primary medical services. The Regulations to enable this delay have now concluded their parliamentary approval passage and been approved by Parliament.

Working closely with CQC, the Department has carried out an initial review of the regulations that underpin the registration system, responding to early lessons from implementation. Providers were registered against the full set of registration requirements for the first time in April 2010, and the Department has moved quickly to consult on preliminary proposals for changes within eighteen months. We have also made a commitment to carry out a full review of the registration system in the near future and will bring forward further changes to the regulations as required.

6. It is encouraging that inspection levels are again rising, but the challenging context for CQC work remains. Even following the Government's decision to defer GP registration until April 2013, the CQC will still need to spend 2011-12 registering the remaining dental providers and ambulance services, and then out-of-hours primary care, not to mention addressing the constant flow of applications to vary registration. The balance between registration and compliance activity will always remain an issue and if it is to maintain the confidence of the public and this Committee, the CQC must demonstrate that it is prioritising its compliance activity.

The Government welcomes the Committee's recognition that CQC's compliance activity is increasing and recognises the importance of ensuring that the right balance between compliance and registration activity is maintained consistently even when new providers are introduced into the registration system from April 2012.

The registration of dental providers and independent ambulance services is now largely complete. This, together with the delay to registration of most providers of NHS primary medical services, will allow CQC to increase its inspection and scrutiny of those providers that are already registered.

We expect the primary medical care providers to be the last significant tranche of registration. Any future changes to the scope of regulation are unlikely to bring large numbers into registration in one go. However, we will work with CQC to ensure lessons are learnt for the future to avoid the burden of registration impacting on compliance work.

The Government looks to CQC to monitor and report on its performance on an on-going basis to assure the public it is carrying out its functions efficiently and effectively. The Department expects CQC to inform it in a timely manner if inspection levels drop in the future.

7. Furthermore the Committee regards it as regrettable that the CQC should have launched the process of registration of dental practices without undertaking adequate proving of the registration model. It strongly recommends that each future extension of the scope of registration should be preceded by a properly planned and executed piloting process.

The Government accepts the Committee's recommendation. The Care Quality Commission is the independent regulator of health and adult social care providers in England. While the Department of Health drew up the legal framework that underpins the registration system, the implementation of registration has been developed by CQC. We understand that CQC has piloted the process for the registration of primary medical providers when they are brought into the registration system in due course, and we would expect it to do the same for any future extensions of registration.

8. We expect to see clear evidence by next year of the CQC leadership openly acknowledging challenges and setting priorities that reflect its core duty to ensure the safety and quality of care.

The Department notes the Committee's expectation, and looks to CQC to report on progress to the Committee at next year's accountability hearing.

9. We note the CQC's request for an additional 10% of resources to fund its inspection regime. We already have concerns about the way the CQC has handled and prioritised its existing resources and do not believe that additional resources will address these concerns unless they are deployed as part of a clear strategy. We would therefore welcome a breakdown from the CQC of how it arrived at the figure of 10% and exactly how it would intend to deploy these resources.

The Government agrees with the Committee that it is important that resources are deployed appropriately and that it is clear how any additional resource will be used, particularly given the current financial climate. As set out above, the Department has now agreed CQC's business case requesting approval to recruit additional compliance inspectors and compliance managers.

The inspection and review process

10. CQC must seek to address growing inspector caseloads through recruitment and should also bolster the support provided to inspectors to allow them to focus on their core frontline duties.

The Government notes the Committee's recommendation that CQC needs to increase its inspector staffing complement and strengthen the support given to compliance inspectors. As set out above, the Department has approved CQC's business case to recruit additional inspectors and compliance managers. The Department of Health looks to CQC to monitor its staffing requirements for the future.

11. The number of providers regulated by the CQC means that the organisation must necessarily operate a risk-based system. It is also right that the CQC should focus its resources on providers where there is an indication of a problem. However, it is difficult to see how the CQC can have confidence in a provider meeting standards if it has not visited the organisation for more than two years, no matter how good its record. Unannounced inspections must form the core of compliance assessment.

CQC has recognised the need to "cross the threshold" of most providers at least once a year and it is currently consulting on proposals to strengthen and simplify its regulatory framework. The Department now looks to CQC to build on the regulatory model it has developed and to strengthen it in order to provide the public with assurance that providers of regulated activities are meeting, and continue to meet the safety and quality requirements and that where they are not, CQC will take action.

12. The Committee welcomes recent announcements that the CQC intends to undertake annual visits of all NHS and social care providers, irrespective of the performance of the provider. We note that the CQC is seeking to operate as a 'light touch' provider, but we do not consider an unannounced annual inspection of NHS

and social care providers to be an unreasonable expectation, even for the best providers. The CQC should carefully monitor its performance against this annual target and ensure that its key performance indicators are published on a quarterly basis.

The Government notes the Committee's recommendation. CQC is currently consulting on proposals to increase the minimum frequency of inspections and as indicated above, CQC is currently consulting on proposals to strengthen its regulatory framework. This consultation gives all those with an interest the opportunity to give their views on the proposals.

As CQC is an independent arms length body, the Department does not assess CQC's inspection or monitoring of specific providers, but monitors CQC's financial and operational performance and risks at a general and strategic level through regular formal accountability meetings. The Department looks to CQC to monitor and report on its own performance in an open and transparent manner for example through the publication of its scorecard.

13. The fact that CQC responded to a freedom of information request saying that “its systems and processes were ‘not [yet] set up in such a way as to allow the reliable and robust collation of statistical information on [enforcement] activity” does not give confidence in the ability of CQC central management to monitor, review and manage its compliance activity in the field, and we expect this issue to be addressed.

The Government agrees that it is essential that CQC is able to monitor and report on the activity it is undertaking in carrying out its functions. As an organisation that has been created by merging three separate bodies, there have been challenges for CQC in bringing together three different systems. This has meant that CQC has not always been able to provide information readily. CQC has said that its new website and provider profiles will significantly improve information available publicly and the Department of Health looks to CQC to strengthen its management systems and reporting capability so that robust and transparent information is available to the public and Parliament.

14. We welcome the CQC developing alternative assessment models that involve ‘experts with experience’, provided that this approach complements rather than supplants CQC inspections.

As an independent body, CQC's approach to assuring compliance with the registration requirements is a matter for CQC. CQC has assured the Department that whilst it uses experts by experience, these are as part of an inspection team, they are not an alternative to inspection. Inspection teams may also include professionals or carers as appropriate.

15. Quality and Risk Profiles have the potential to be a useful auxiliary tool for inspectors, but in their present form the quality of data is limited in its reliability and coverage. The CQC should work towards broadening the range of data included, in particular where there is little data available to support a particular outcome.

The tools that CQC uses to carry out its functions efficiently and effectively are primarily matters for CQC. However we ask the Committee to recognise that the availability of data varies depending on the type of provider and data for small, privately owned care homes for example, is likely to be fairly limited. For these providers, physical inspections and

feedback from people using the services are therefore increasingly important in providing assurance that providers are complying with regulatory requirements. CQC has assured us that it is looking at how it can best harness this information to complement other data sources.

16. We acknowledge that the CQC operates within a regulatory framework that focuses on outcomes rather than inputs. However, low staffing ratios can have such an exceptional impact on the quality of care that we believe monitoring of staff levels is an essential part of ensuring quality outcomes. The CQC should work to develop a mechanism whereby it can keep a closer track of staffing ratios in private care homes, in a way that can feed through into the QRP. Although it would be difficult for the CQC to mandate minimum staffing levels, it should develop indicative ratios that will assist inspectors to identify potentially inadequate staffing.

Providers registered with the CQC must comply with 16 safety and quality requirements set out in regulations made under the Health and Social Care Act 2008. These 16 requirements include a requirement on staffing. This requires the registered provider to take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably qualified, skilled and experienced persons employed to safeguard the health, safety and welfare of service users. The Regulations apply to providers of a wide range of services and do not therefore specify staffing ratios. CQC's Guidance about Compliance sets out how providers can comply with the registration requirements and is informed by guidance from professional bodies.

17. The CQC must ensure its inspectors do not become over-reliant on QRPs. Even if the quality of data included in QRPs was excellent, such a tool could only ever present a patchy picture of the quality of care.

The Government agrees with the Committee's conclusion. QRPs are a tool for gathering information in one place, but should not be over-relied on. The Department of Health is assured by CQC that it is not over-reliant on QRPs and that judgements are made by the inspectors themselves. QRPs can properly be used to highlight concerns that may need further examination. The Committee should be further reassured by CQC's proposals to increase the minimum frequencies of physical inspections, ensuring that there is not an over-reliance on data to assess compliance.

18. It is right that the CQC places trust in the judgement of its inspectors when assessing risks and deciding on appropriate action. But this judgement can only be consistently exercised if the CQC provides a clear framework and guidance. It would be easy for active inspection activity to regress at this time of increased pressure on inspectors. The CQC must therefore ensure there is a consistency of approach by reiterating risk thresholds.

As an independent body, CQC's methodologies and enforcement policy are matters for it to take forward. CQC is consulting on changes to its judgement framework and enforcement policy to strengthen its regulatory framework. As a national body, we would expect CQC to ensure that inspectors are acting appropriately and that there is consistency in the judgements it makes and action it takes. The Department looks to CQC to consider the Committee's recommendation.

19. In its recent reports on the work of the General Medical Council and the Nursing and Midwifery Council, the Committee emphasised the importance which it attaches to the obligation which rests on all healthcare professionals to raise concerns if they recognise, or ought to have recognised, evidence of failure of professional standards. The Committee believes it should be a key objective of CQC inspections to ensure that the culture of each provider organisation recognises and respects this professional obligation, and provides proper security to those professional staff who discharge it effectively.

CQC's registration function requires it to assure the safety and quality of regulated activities. It does this by assuring registered providers are complying with the registration requirements which set out the essential levels of safety and quality of care that people should be able to expect and are built around the main risks that are inherent in the provision of health and social care services.

CQC responds to concerns about services but the most powerful tool to prevent abuse is to ensure that people working in health and social care do not tolerate abuse. Health and care professionals have a responsibility to make sure abuse is stopped.

The registration requirements include a requirement for providers to respond appropriately to any allegation of abuse, and to take appropriate steps in relation to a person who is no longer fit to work – including informing the relevant professional body. We are assured by CQC that in undertaking reviews of compliance, it will seek assurance that providers are complying with this regulation where it has concerns about a provider's compliance.

Whistleblowers are protected under the Public Interest Disclosure Act. CQC is a prescribed body under that act but it is not CQC's role to enforce that legislation. However, CQC considers all concerns raised with it, and has powers to take action if the information suggests a registration requirement is not being met.

20. Although healthcare professionals have a particular obligation, arising from their professional status, to take an interest in the quality of care being provided around them, this obligation is, in truth, a particularly focused form of the general duty of care owed by all staff of care providers to their patients, and indeed of the natural human desire of all citizens to see high quality care provided to the sick and vulnerable. Information is available from all these sources to measure the performance of care providers. The Committee believes it should be a key part of the inspection process to ensure that proper processes are in place in each care provider, including proper Board accountability, to ensure that these responsibilities are met.

CQC's role is to assure the safety and quality of regulated activities. The registered provider is ultimately responsible for the quality of care it provides and how it provides it.

The registration requirements set by the Department include requirements on providers to: have processes in place for assessing and monitoring the quality of service provision; safeguard service users from abuse; and keep proper records. CQC is responsible for developing and implementing its inspection methodology on how it assures compliance with the requirements.

21. The calls coming in following Winterbourne View could be only the tip of the iceberg. We look to the CQC, in addition to encouraging cultural change within care providers, to take action to encourage direct information supply in cases where local structures fail.

CQC is responsible for assuring registered providers are complying with the essential safety and quality requirements, taking action where they are not. Whilst CQC encourages people to raise concerns about care providers with it, which then feed into all the information CQC holds on a provider and informs decisions about compliance activity. Whistleblowers are protected under the Public Interest Disclosure Act. CQC is a prescribed body under that act but it is not CQC's role to enforce that legislation. However, CQC considers all concerns raised with it, and has powers to take action if the information suggests a registration requirement is not being met.

CQC has published new guidance for staff and organisations on whistleblowing. The Department has been advised that CQC has also introduced a centralised system to ensure that all whistleblowing concerns are tracked from receipt through to conclusion.

22. The CQC must ensure it makes the most of information provided to it. All relevant communications should be followed up in order to establish the usefulness of the information and to inform the CQC's own judgement. This sort of information should be a trigger for CQC action – a note appearing on the QRP is not enough.

How CQC uses information in carrying out its functions is a matter for CQC. However, we have been assured by CQC that there are a number of actions it may take. Where concerns about the safety and quality of care services are raised, CQC will consider whether there is evidence that justifies a site visit and further regulatory action.

Where CQC is not able to take action as the concerns are not about the safety and quality of care services, and therefore the issues are outside of CQC's remit, CQC will refer the person raising concerns to the appropriate body or raise the concerns directly.

23. Action in the case of Winterbourne View was woefully inadequate: the CQC failed to 'actively follow up' the local authority process, or conduct its own assessment, or even contact Mr Bryan for further information. The CQC should have done all of these things.

The Government accepts that there were significant failures in the case of Winterbourne View. CQC has publicly acknowledged that there were indications of problems which should have led to it acting sooner, and it issued an unreserved apology to those it has let down. CQC is fully committed to learning the lessons from this tragic case and to making sure that when there are signs of poor care, it acts quickly to protect vulnerable people.

Following the events at Winterbourne View, CQC reviewed all the referrals it made to local safeguarding boards to ensure that all concerns were followed up. It also reviewed its processes for handling concerns and is making changes to improve them.

Whilst there were failures by CQC, the Government asks the Committee to recognise that there were failures by other bodies too – first and foremost the provider itself. The bodies involved in the case are all undertaking reviews and there is a Serious Case Review

underway. Once these are all complete, the Department of Health will be pulling the findings together and looking at the lessons to be learned for policy and practice.

24. The Committee believes that the CQC should be obliged to carry out an investigation in response to a recommendation from its HealthWatch sub-committee that the CQC investigate the quality of care provided by a particular provider.

HealthWatch England will have ‘editorial independence’ and be able to make recommendations to CQC when it has concerns about a provider. However, as an independent regulator of health and social care, CQC must make its own judgements of the risk that providers represent and the regulatory action it should take. HealthWatch England will be able to offer CQC useful advice and information, however, CQC has many sources of information to take into account when making its decisions and it must be able to justify them. It must also be free to take action that is appropriate and proportionate. It would therefore not be appropriate for the Government to specify what action it should take as a result of a recommendation by one of its own Committees, in relation to the exercise of its statutory functions.

The registration process

25. The Committee has already reported its views that the priority attached by the CQC over the past 12 months to the registration of new providers represented a distortion of priorities. If this extension of registration activity was required, management should have ensured that it was resourced in a way which did not affect the core existing activity of the CQC and should have resisted pressure from Ministers or elsewhere to adopt a registration policy which it is now clear was inadequately prepared or resourced.

The timetable for introducing providers into the new registration was set out in Regulations that were approved by Parliament in March 2010. These put in place several waves of registration starting with the registration of NHS providers in April 2010 and ending with the registration of providers of NHS primary medical services in April 2012, now deferred to April 2013. This timetable was developed following discussion with the Commission and CQC was given transitional funding to bring providers into the new registration system. The Department kept CQC’s budget under review and CQC did not request any additional resources.

The Department agreed to CQC’s request for a delay to the date of primary medical care registration and has put regulations in place that achieve this.

26. The current regulations governing registration have imposed difficult and occasionally inflexible restrictions on the CQC’s procedures. It is regrettable that this was neither foreseen nor addressed before the vast majority of providers had already fought through the process. Nevertheless we welcome the Government’s review of the regulations. We urge the CQC and the Government to work closely together and with providers during this consultation period to ensure that all future registrations (and in particular that of primary care providers) can be conducted in a proportionate manner within adequate timeframes.

The Government's regulatory reform agenda commits Departments to review primary and secondary legislation relating to their arms length bodies. As part of this, our consultation on changes to the registration regulations confirmed our commitment to undertake a wider review of the regulations underpinning the registration system and sought views on the issues that we should consider as part of this. We will consider the responses to the consultation alongside information gathered as part of the social care engagement exercise, and issues raised with us by CQC and stakeholders. We will then draw up proposals for change and publish these for consultation next year.

Any proposals for changes will be consistent with the approach taken in the legislative framework for registration. The registration requirements are set at a high level which sets the outcomes that patients and service users have a right to expect, but are not prescriptive about how a provider should achieve these outcomes. CQC, as an independent regulator, is responsible for developing the methodology to assess compliance with the registration requirements.

27. The CQC must also accept responsibility for its poor handling of registration and adapt its processes accordingly. In particular, the process could have been made significantly simpler and swifter for all involved had the CQC adapted registration procedures to different types of services. It is astonishing that it could ever have been considered sensible for small dental practices to work through the same process as a large hospital.

As the independent regulator of health and adult social care providers in England, the Care Quality Commission has been solely responsible for designing the processes to fulfil its statutory functions set out in the Health and Social Care Act 2008. The Commission is now consulting on proposed changes to its regulatory methodology and enforcement policy informed by its experience of operating the registration system since April 2010. The Department expects that in future the process for registration will be improved and streamlined.

28. Following the postponement of the deadline for registration of GP practices until April 2013 the Government and the CQC have some time to put things right. But this is no time for complacency. Action must be swift if procedures and especially regulations are to be reviewed, altered and put into practice in good time. We expect to see significant progress on this matter by the time of our next accountability session with the CQC.

CQC will use the delay to the registration of most primary medical care services until April 2013 to review and streamline its registration processes. As set out above, we understand that CQC has piloted the process for the registration of primary medical providers already.

29. It is right that the CQC approval should be required for significant variations to registrations, but this requirement will remain a significant burden on both providers and the CQC unless the procedure is greatly streamlined. We welcome the action the CQC has already taken to improve the system and bring processing times down to a more reasonable level. The CQC should do all it can within the regulations further to improve the procedures, including consulting with providers and professions and bringing forward development of a system of electronic submission and processing.

The CQC must work closely with the Government's review of the registration regulations to identify where changes are necessary.

The Department of Health has already started working with CQC, to compile a list of issues that we may want to tackle as part of the review and will engage with stakeholders to seek further views early on in the review. The consultation on changes to regulations that recently came to an end sought views on issues that the wider review should address.

We will consider any proposals to amend regulations in order to reduce the workload involved in varying registration as part of this review.

Provision of information to the public

30. The information currently provided by the CQC on adult social care providers is unhelpful and often out of date. We welcome the introduction of an 'under review' label where the CQC is investigating a provider, but we find it surprising that it has taken so long to provide the public with such essential information. The delay in developing provider profiles is particularly frustrating as they could have been a useful interim guide for the public until a successor is developed for the star rating system. The constant slippage in the planned roll-out of the profiles is further evidence of a lack of control within the organisation.

The Government recognises the importance of the provision of information on adult social care providers to help people make choices about the care they purchase. CQC has recently launched its new website and we look to CQC to ensure that the information provided on it is accurate and robust.

31. The proposed Adult Social Care Excellence Award has been roundly rejected in evidence submitted to us. We share these concerns and recommend that the project is dropped.

The Department of Health asked CQC to develop proposals for an award to recognise excellence in adult social care. The Department remains committed to the development of a scheme that helps people choose between providers, recognises quality beyond the essential safety and quality requirements and encourages quality improvement by providers. We now intend to use the responses to CQC's consultation to inform consideration of these issues in the "Caring for our Future" engagement that we are undertaking as part of the social care white paper.

Appendix 6: Care Quality Commission's Response

The balance between registration and compliance activity

1. *Paragraph 1 – Prioritisation during transitional registration*
 - 1.1. CQC acknowledges that there were difficulties for providers in the transitional registration process and we have apologised for a number of issues which arose. The external pressures under which CQC was operating and their impact on its priorities have been well-rehearsed, including in Dame Jo Williams' letter to the Committee's Chair of 30 June.
 - 1.2. CQC has published figures that make clear that compliance activity was significantly affected by transitional registration, particularly that of adult social care providers. This was by far the largest piece of registration the Commission faced and it was this that had the most significant impact on CQC's work – and not dental registration as the Committee has suggested.
 - 1.3. It is worth emphasising that transitional registration is a one-off process by which existing or new sectors are brought in to the scope of CQC's governing legislation in a large single 'tranche' (a batch of registration – e.g. the registration of the NHS was 'tranche one'). This large-scale processing is significantly different to 'business as usual' registration – a process by which, for example, new care home would register with CQC.
 - 1.4. This means the NHS, adult social care, independent healthcare, private ambulance services and dental providers will never again have to go through sector-wide registration under this legislation.
 - 1.5. Transitional registration was, in itself, a check of a provider. The Health and Social Care Act 2008 brought with it a new set of regulations, and in order to register providers against them we needed to satisfy ourselves they were compliant. Our checks did not always involve a site visit, and did not result in a detailed report, but no service was left unchecked and the fall in inspections needs to be seen in this context.
 - 1.6. During transitional registration CQC continued to respond to signs of risk as and when they were identified. Responsive reviews and enforcement action continued during this period, including under the Care Standards Act 2000 (which was in force for adult social care and independent health until 30 September 2010). Although inspection levels fell, poor care was not ignored.
 - 1.7. The Committee's report highlights the problems that were faced in the earlier tranches of registration. CQC now has breathing space as a result of the delay in the registration of primary medical services. We have learned a great deal about registration – both the process of bringing new sectors into CQC's scope, and of

bringing in new providers as part of ‘business as usual’ – and have made significant improvements in performance in this area.

- 1.8. CQC continues to consider the impact that taking on new and additional responsibilities may have on its core business and will seek to ensure that these impacts are always made clear to stakeholders. This includes raising concerns with Ministers when appropriate. For example, the Chair of the Commission wrote to the Minister of State for Health Services, Simon Burns MP, on 31 October to raise concerns about the possible impact of CQC’s taking on some functions of the HFEA and HTA [ANNEX 1].²²

2. *Paragraphs 2 and 7 – Piloting transitional registration*

- 2.1. The Committee’s report makes specific reference to planning and preparation for transitional registration. We would like to set out some of the background that went into this.

Early testing

- 2.2. From early 2009 onwards CQC conducted a series of pilots covering the transitional registration process and the processes and documentation for the monitoring of ongoing compliance. These included pilots with service providers who were going to be registered and workshops with provider representative bodies.
- 2.3. In August and September 2009 we conducted a focused pilot of the transitional registration process. One key aim was to capture and incorporate into registration the views of providers as well as those of our inspectors and assessors.
- 2.4. The testing involved 21 providers from the North West, which ranged from large NHS trusts to small providers with one care home or clinic. The providers included those from the private, voluntary, and public sector. The quality of service they provided to service users at the time varied. The feedback from the pilot was used to improve our registration documents, tools and guidance.
- 2.5. Due to time constraints, pre-launch testing was limited to assessing the technical processes that underpinned transition, rather than testing under full operational conditions. There was no time for extensive testing of the technical system in a ‘live’ environment before it was launched. The role of our national processing centre, National Customer Service Centre, and allocation for processing applications had to be tested when registration was more developed.
- 2.6. In October 2009 an Office of Government Commerce Gateway Review was conducted by the Department of Health into the CQC transitional registration programme. It made a number of recommendations for the registration programme given the very tight timescales and also identified areas of strength.

22 Annex 1 – Letter from Dame Jo Williams to Minister of State for Health Services, 31 October 2011 (not printed here)

- 2.7. Strengths included the programme's comprehensive and effective governance arrangements, and exemplar best practice engagement with internal and external stakeholders, including on the co-production of documents and processes.
- 2.8. This early stage testing was completed against tight timescales and against other constraints and demands (e.g. continuing to regulate social care under the Care Standards Act 2000), including a lack of certainty over the affirmative regulations to underpin registration which were not submitted to Parliament until a late stage.

Improving the process

- 2.9. We have sought to apply the learning from one transitional registration tranche to the next and improve our methods and guidance. It is, however, important to note that the three tranches to date have been fundamentally different from each other. Additionally, the need for the application window to open for adult social care registration in April 2010 – the same month we concluded NHS registration – meant there was limited scope to apply the learning from the NHS to adult social care and independent health.
- 2.10. We carried out a 'lessons learned' exercise and an internal audit after the first two tranches (NHS and adult social care / independent health). In light of this we sought to modify and simplify our application process. This enabled better planning and monitoring of resources and meant that CQC delivered dental and private ambulance registration (for April 2011) without affecting front line inspection activity.
- 2.11. We have looked at our processes to see how these could be refined to meet the twin objective of safeguarding people who use services while improving the provider's experience of registration. Examples of this include assessing the value of medical, professional and personal references for applicants. These checks were time consuming for both the applicant and CQC but did not add significant value. This has resulted in us making improvements to the application form and providing guidance to our staff as to the circumstance under which such references should be taken.
- 2.12. The greatest opportunity to implement learning and deliver improvement comes between dentists and primary medical services (including GPs), which are the most similar sectors (in terms of configurations of services) and share the same transitional arrangements. Now that we have secured a delay in primary medical services' registration to April 2013 we are making the most of this opportunity.

Dentists and private ambulances – pilot details

- 2.13. The Committee makes specific reference to the lack of adequate piloting of the model ahead of dental registration. We would like to provide more detail about our work in this area.

- 2.14. In summer 2010 we conducted a transitional registration pilot with 17 primary dental care services across three PCT areas. Providers used guidance provided to complete and submit a provider application and declaration form and a registered manager application form, if applicable. As a result of the pilot we improved our documentation and advice in a number of areas, including legal definitions of dental partnerships and associates, signposting the regulated activities most dentists needed to apply for and where certain declarations were required. A similar pilot was also undertaken with six independent ambulance providers in summer 2010.
- 2.15. We had an advisory group for the registration of dental providers. Members of the group included the British Dental Association, General Dental Council, Department of Health, Royal College representatives, Denplan, individual dental providers and others. The group met regularly from spring 2010 until June 2011. The meetings were used to give updates on CQC's progress both in registration and the compliance pilot as well as for stakeholders to share concerns. In addition more detailed meetings were also held with individual stakeholders to discuss items such as information sharing, working together and other matters they brought to CQC's attention.
- 2.16. We did use the time ahead of dental registration to develop new policies to improve our risk assessment. A lighter-touch process was developed whereby assurance from Primary Care Trusts (notably Criminal Records Bureau checks) was accepted and we encouraged online processing. We registered 8,000 dental providers without diverting resources from inspection and inspection rates increased rapidly during this period. Coordination with Primary Care Trusts did not work as well as planned, partly due to their reorganisation.

Improving registration overall – transition and business as usual

- 2.17. Looking ahead, we are further refining the processes for primary medical services and for all future registration activity through a full end-to-end review of our registration processes. This review started in November 2011 and is focused on further refinement to the changes we have already implemented, and to seek to improve the provider's experience of the registration process while maintaining a focus on safeguarding users.

3. Paragraphs 3, 6 and 11 – inspection activity and frequency

- 3.1. As the Committee highlighted, CQC's inspection activity reduced during the period of registration of adult social care providers. The registration model at that stage involved using inspectors and therefore reduced their capacity to undertake routine inspections. We learned lessons and made changes for dental and private ambulance registration, which was delivered without any detrimental effect on inspection activity.
- 3.2. No front-line inspection staff will be used in the delivery of transitional registration for primary medical services (including GPs) in 2013.

- 3.3. Our new compliance model, to be introduced from April next year assuming a positive response to our current consultation (see paragraphs 6.1 to 6.4) will see an inspection at least once every business year of all registered hospitals, care homes and domiciliary care providers. We will carry out an inspection of all registered primary dental services and primary medical services at least once every two years.
- 3.4. These inspections will be unannounced unless there are exceptional circumstances (e.g. entering a one-to-one environment between a professional and patient; or the need to interview a specific member of staff). This is now and always has been CQC's position on inspections.
- 3.5. A table showing completed reviews of compliance of regulated services by sector since the creation of CQC is attached [ANNEX 2].²³ It indicates how many of these involved a site visit. In all but exceptional cases, these are unannounced visits in line with existing policy.

4. *Paragraph 4 – Vacancy levels and requests to recruit outside the NHS*

Current and future compliance inspector vacancy levels

- 4.1. CQC expects to have a full complement of compliance inspectors by the end of January 2012. We have interviewed and made offers to fill all but 25 compliance inspector posts, and more than 50 new inspectors are already in post. We are pleased that our relationship with the Department over recruitment is much improved.
- 4.2. **In the most recent recruitment round CQC received over 3,500 applications for the 50 posts advertised on 14 July 2011.** In addition to those offers made, we identified sufficient talent to fill over 200 further compliance inspector posts.
- 4.3. On 27 October 2011 we received approval for our business case to employ further inspectors above our current establishment level, as discussed with the Committee (see paragraphs 8.1 to 8.6). We have plans in place to conduct the final assessment, recruitment and induction of additional compliance inspectors above our current establishment target to take advantage of this. We are now contacting the applicants identified to invite them to the final recruitment assessment centre.
- 4.4. We have looked at how our new compliance model will operate and how many inspectors will be required. More than 400 operations employees (including those piloting the new compliance model) have been completing time sheets as they undertake their regulatory and other tasks. This provided an accurate picture of the resource required to operate both our current and proposed compliance models.

²³ Annex 2 – Reviews of compliance (including site visits) completed by CQC from 1 April 2010 to September 2011 (not printed here)

- 4.5. Compliance inspectors have also supplied a number of comments and innovative ideas about managing their role, their professional views on good inspection practice, and what makes for a manageable portfolio.
- 4.6. Our judgement is that we need 950 compliance inspectors for the new compliance model to work effectively in 2012/13. This would provide a reduction in average portfolio size, excluding primary medical services, to just over 40 locations per inspector. Including primary medical services this will increase to just over 45 locations per inspector, based on the current predicted number of locations due to register with CQC.
5. ***Paragraph 5 – Correspondence with the Department of Health regarding delaying primary medical service registration and the review of the regulations***

Regulations

- 5.1. CQC has always met the Department of Health regularly and has kept officials there fully informed of problems in implementing regulations. This has included weekly reviews at senior level during key points in the transitional registration application periods.
- 5.2. Given the scope and scale of the legislation, it is not clear that there were opportunities to make changes to the regulations ahead of transitional registration. Amending the regulations for primary medical care provider registration (the GP tranche) took nine months and required exceptional procedures to speed through the process, including shortened public consultation and cross-government clearance periods.
- 5.3. In the case of adult social care registration, had we asked the Department to amend the regulations on 1 April 2010 (the day CQC's regulations came into force and before we had any experience of implementing them) it would not have affected our adult social care registration deadline of October 2010. As stated above, it was this tranche of transitional registration that had an impact on inspection.
- 5.4. We raised concerns about the impact of the regulations on transitional registration with the Department on various occasions and formally wrote to the Secretary of State in March 2011 to ask for a delay to give both us and GPs more time to prepare for their registration [ANNEX 3].²⁴
6. ***Paragraph 6 – Balancing registration and compliance work: revising our Judgement framework and Enforcement policy (September 2011)***
- 6.1. We have learned a lot about our model in the past 18 months from listening to the public and providers, and through thousands of inspections, and it has been clear that we can make improvements to the way we register and inspect services. Improvements in our model will better enable us to balance the

²⁴ Annex 3 – Letter from Dame Jo Williams to Permanent Secretary, Department of Health, 28 March 2011 (not printed here)

challenges of registration and compliance, notwithstanding comments on this already made.

- 6.2. In September we opened a public consultation on improvements to our regulatory model. This closes in December and we have included our consultation document [ANNEX 4].²⁵ This consultation sets out proposals to move to more regular inspections, and to be clearer about whether providers are or are not meeting the essential standards. We want to simplify and strengthen the model and remove some of the ambiguity in the current judgement framework. This should help providers and the public understand what our view is, and should also deliver more consistency in our judgements.
- 6.3. Almost all of the changes we are suggesting are a direct result of feedback from care providers, members of the public, CQC's inspectors, and from trade associations. We hope the proposals will be welcome, although we will of course consider any further views that come to light through the consultation process. The consultation's proposals, if adopted, will come in to force from April 2012.
- 6.4. As part of our consultation we are piloting changes to our compliance model to ensure we make the best use of our resources. Rather than assessing all providers against all 16 outcomes, inspectors are piloting an approach where we focus on the most appropriate outcomes for the service type, and use information we have about risk at that provider, to carry out a targeted inspection. This allows our inspectors to focus on the most relevant outcomes and make the best use of their (and the providers') time.

7. *Paragraph 8 – leadership and priority setting*

- 7.1. Jo Williams' covering letter with this appendix sets out some of CQC's core priorities for the year ahead. The Commission has robust business planning processes and procedures in place, including a range of measures to publicly demonstrate performance against targets (see section 10).
- 7.2. Priorities and progress against these are subject to regular internal scrutiny at Board and executive level, and to external scrutiny via quarterly director level meetings with the Department of Health, and quarterly accountability meetings between CQC's chief executive and the Department's Director General of Policy, Strategy and Finance. Regular meetings also take place between CQC's chair and chief executive and Ministers, the NHS Chief Executive, and the Department of Health's Permanent Secretary.
- 7.3. Dame Jo looks forward to updating the Committee in CQC's annual accountability hearing in 2012.

25 Annex 4 – CQC consultation on judgement framework and enforcement policy (not printed here)

8. ***Paragraph 9 – Request for further resources to fund improvements to the regulatory model***
- 8.1. On 16 June 2011 Dame Jo Williams met the Minister of State for Health Services, Simon Burns, and informed him that CQC continued to look for efficiencies. Dame Jo told the Minister CQC was undertaking a detailed analysis of inspector caseloads but on the basis of risk CQC was considering the need for more inspectors.
- 8.2. On 12 August 2011 CQC sent the Department of Health a business case outlining efficiency savings we propose to make and requesting further resources to fund improvements to our regulatory model.
- 8.3. The strategic principles that underpin our future resourcing model are as follows. Where we refer to inspections, these will be unannounced in all but exceptional cases at all times (as is currently the case).
- 8.3.1. Either a scheduled, responsive or thematic inspection each business year, for most adult social care and independent healthcare services; all NHS acute hospitals; all NHS Ambulance Trusts; and at least one service type in all other trusts and at least once every other business year, carry out either a scheduled, responsive or thematic inspection of all primary dental and primary medical services.
- 8.3.2. Our inspectors will have an in-depth knowledge of the services in their portfolio. This is supported by our regulatory model and the intention to reduce the size of an inspector's portfolio.
- 8.3.3. During our inspections we can be accompanied by people who are experts in certain aspects of care, (for example maternity) and/or by people who have extensive experience of using care services, who we call Experts by Experience. They supplement our inspection activity, not supplant it.
- 8.4. The proposed resource model with increased inspection activity and lower inspector caseload will require 950 compliance inspectors. This is 200 more full time equivalent inspectors and 20 more full time compliance managers than we have at present.
- 8.5. This will increase our operating costs by around £15m per year from 2012/13. This is the basis for the 10% increase on existing budget that was discussed at the Committee.
- 8.6. However, we plan to deliver additional efficiency savings in 2012/13 to the value of £5m. The additional £10m will be financed by an increase in Grant in aid from the Department of Health (although this includes funding for HealthWatch England). Our business case received written approval from the Department on 27 October 2011.

Future context

- 8.7. Factors outside CQC's direct control can, of course, affect our use of resources. Regulating poor care is far more resource-intensive than regulating compliant care. The standards of evidence required, legal preparation for enforcement, and follow-up needed to check whether action has been taken means that any increase in the overall prevalence of poor care will have a direct impact on CQC's performance.
- 8.8. A good example of this is our activity at Barking, Havering and Redbridge NHS Trust. Since registration against the Health and Social Care Act 2008 in April 2010, we have carried out eight unannounced inspections, which amount to 31 days in the Trust's hospitals since April 2010.

The inspection and review process

9. *Paragraph 10 – Inspector caseload and support*

- 9.1. CQC is actively monitoring the size of inspector caseloads. We are working to ensure caseloads are at a manageable level through recruitment, improvements to our compliance model and making our internal systems more efficient.
- 9.2. A range of support from specialist clinical advice to legal support is available to inspectors. We are currently developing and extending the use of clinical and professional 'expertise' in our regulatory activity.

Improvements to the compliance model and streamlined processes

- 9.3. There are a number of improvements within the new compliance model that will speed up the inspection and report writing process. This is designed to make inspector caseloads more manageable.
- 9.4. We have focused on improving our report writing tools and methodology, aspects which can take up to 25% of an inspector's working time. The system we currently use to capture reports is being modified from November 2011. Testing and training will follow thereafter, with an expectation that the system is implemented from April. Reducing report writing by just two hours per report for adult social care services would achieve a 10% reduction in the time taken to carry out a review – freeing up more time for more inspections.

Support for compliance inspectors

- 9.5. All compliance inspectors have access to the following guidance resources to support them in their regulatory work:
 - 9.5.1. Compliance inspectors – where necessary compliance inspectors can call on the support of other compliance inspectors, for example where a larger team of inspectors is required to carry out a visit.

- 9.5.2. Compliance managers – line managers are able to offer day to day advice and support to compliance inspectors, including regarding appropriate regulatory action in the individual circumstances of each service.
- 9.5.3. Guidance documentation – the CQC intranet includes a library of underpinning documents and advice, including items such as ‘how to request support from a Pharmacist regarding a medicines risk at a service’.
- 9.5.4. Senior analytical advisers and regional intelligence and evidence officers – regional intelligence teams provide support to compliance inspectors in interpreting data to analyse risk and support regulatory judgements.
- 9.5.5. Experts by experience – inspectors can call on people who have recent experience of care in a given setting to attend an inspection with them to provide a more patient-centered view of the care provided.
- 9.5.6. Specialist advice – professionals and clinicians who currently work in front line posts which inspectors can call upon for specific or clinical advice. We have national leads on safeguarding, healthcare associated infections and pharmacy available to assist and advise.
- 9.5.7. National Professional Advisors – some of our professional advisors also provide sector-specific and clinical advice to compliance inspectors as required.
- 9.5.8. Legal advice – our legal team is on call to provide advice to compliance inspectors and managers where required in the course of their regulatory and enforcement activity.
- 9.5.9. Training –
 - 9.5.9.1. On joining the Commission all compliance inspectors undertake an eight week induction and training programme, including shadowing with experienced inspectors. New inspectors are also supported through a buddy system in addition to their line manager. In their individual reviews at the end of the induction programme new inspectors discuss bespoke further training needs. This is delivered before the end of the inspector’s probation period (six months into post). The programme has been well received:
 - 9.5.9.2. *“In addition to learning about the procedures and tools we will be using, we also spent a day or two a week shadowing inspections in our regions which were a great introduction to the practicalities of the job and an opportunity to meet some of our colleagues.” Tim Brackpool, Compliance Inspector*
 - 9.5.9.3. Training after probation is undertaken by inspectors when required based on business priorities and changes to our

methodology, guidance and systems. Inspector training requirements are also identified and monitored by line managers through our performance and development review process, with refresher courses and further training available.

10. ***Paragraphs 12 and 13 – Key Performance Indicators***

- 10.1. CQC has made significant progress in developing effective performance indicators and enclosed is the latest performance scorecard [ANNEX 5].²⁶ This is published on our website on a quarterly basis and includes data on our inspection performance against our internal targets.
- 10.2. The scorecard is underpinned by more frequent weekly and monthly reporting on progress to the Operations Management Team meetings and the CQC executive team. A scheduled programme of inspection activity ensures everyone is clear about all the inspections that are required by our own internal targets.
- 10.3. The targets under our current methodology are to inspect 100% of NHS providers; 62.5% of adult social care and independent health care locations; and 15% of dentist locations by March 2012. These targets are based on the date each sector came into regulation and the need to inspect at least once within two years of registration, and the capacity available to carry out the programme.
- 10.4. Targets for 2012–13 are being developed against the new model of compliance to be introduced next year.

Developing our Key Performance Indicators

- 10.5. Our key performance indicators and supporting management information systems have been developed since 2009 against a background of CQC's changing remit, roles, and transfer between data systems. An audit of our performance framework reported earlier in 2011 and was positive about our approach, the progress and improvements we have made and plan to make, and the developments we are taking forward.
- 10.6. We have made a number of data quality improvements this year, and as part of this programme (from November 2011) we have fully automated collection of data on enforcement. This will make it possible to deal more effectively with information requests for enforcement data for future periods which require national analysis or collation.
- 10.7. In summer 2011 we worked to improve the reliability of information on numbers of compliance inspections completed. We are now reporting publicly on our performance against our own internal targets of inspections required for each sector, as based on the date each sector came into regulation and the need to inspect at least once within two years of registration (under our current methodology).

- 10.8. During the early part of 2011 we focused on developing more reliable information on the processing of new and variation registration applications against a target of eight weeks for processing. This target halves the time which our predecessor bodies took to carry out similar processes.
- 10.9. We continually work to develop our suite of performance measures. We are currently looking to include more outcome based measures in our scorecard, such as reporting on the numbers of compliant vs. non-compliant providers; the numbers of inspections resulting in compliance or enforcement actions; and the time taken to move non-compliant providers into compliance. This is likely to involve some further work to our management information systems. We also want to broaden the scorecard and evaluation activity further into areas of quality and impact measurement.
11. ***Paragraph 14 – Experts by experience***
- 11.1. We welcome the Committee’s support for CQC’s use of ‘experts by experience.’ They played an important role in our ‘dignity and nutrition’ inspection programme and we intend to expand our use of them in 2012. At present, we are making active use of experts in our reviews of learning disability services prompted by Winterbourne View. We can confirm that these experts are additional to our core inspection workforce and are not intended to supplant CQC’s work.
12. ***Paragraphs 15 and 17 – Quality and Risk Profiles***
- 12.1. We are pleased to reassure the Committee that the quality and risk profile (QRP) is a tool that aims to gather what we know about a provider in one place, enabling us to assess where risks may lie and prompt front line regulatory activity, such as inspections. QRPs are not a judgement on compliance or a substitute for inspection. We would welcome the opportunity to demonstrate the QRP to members of the Committee and, crucially, to explain the part they play in our regulatory work.
- 12.2. While they are primarily for our own staff we share live QRPs with providers, commissioners and others (such as the Department of Health, Monitor and Strategic Health Authority clusters) through a secure section of our website.
- 12.3. We flag where we have insufficient data and accept that across the 16 essential standards, there is a wide variation in the volume of information available. It is inherently more difficult to gather information around some outcomes, such as outcome 2 ‘consent to care and treatment’. This data will organically grow as it is populated as a result of inspection activity.
- 12.4. The core philosophy of QRPs is that they will never be ‘finished’: we are constantly looking for new sources of high quality data or ways to use existing data more innovatively. There will always be new ways to assess risk and we will seek to feed these in as and when they emerge. By way of example we are currently planning to include information from clinical audits and clinical research in the NHS, with a division of some outcomes by clinical speciality.

- 12.5. We are developing approaches to deal with the need to adapt to new sources of information and make the most of existing ones. This includes seeking ways to capture more intelligence from CQC staff networks, placing a form on our new website to feed public information into the QRP, and specific projects to develop new indicators relevant to social care.

QRPs in the NHS

- 12.6. NHS QRPs contain around 500 items each (over 150,000 pieces of data overall) and we disagree with the Committee that the data is of limited reliability. Data coverage is variable but in areas we have a hugely rich data set. It should be noted that with the benefit of the QRP we are confident that the problems at Mid Staffordshire would have been picked up 18 months earlier than was the case.
- 12.7. We mostly rely on third-party data collections, such as those of the Department of Health, the NHS Information Centre and Skills for Care, since we wish to make the best use of information that is already available. It is counterproductive for regulation to unnecessarily increase burdens on providers by partially or wholly duplicating requests for data which already exists in accessible formats.
- 12.8. We believe the weakness of *Patient Environment Action Team (PEAT)* data is overstated in the Committee's report. In the latest round of PEAT inspections, a fifth of all inspections included an external validator and more than three quarters included a user or user representative. PEAT cannot be categorised as self assessment in the pejorative sense.

QRPs in adult social care

- 12.9. The amount of data in adult social care QRPs is lower than for the NHS at around 50 items each (over 1 million items of data in total). Data on adult social care has always historically been less readily available, and where it is available often less robust. We acknowledge this disparity and are endeavouring to improve this but it will remain a challenge. Due to the nature of the sector adult social care will never reach parity with the NHS in data terms, which is why we are prioritising other sources of information – from the user voice, and through more frequent inspections.
- 12.10. One key project is our close working with ADASS to develop a way to share information via an online portal. This would provide us with more information on where local authorities, that is commissioners of adult social care, have issues with individual care homes. We also have other specific projects to develop new indicators relevant to social care, such as prescription patterns in care homes.

13. Paragraph 16 – Monitoring front-line staffing ratios in care homes

- 13.1. The Committee raised the issue of CQC monitoring front-line staffing ratios in care homes. CQC focuses on the outcomes people receive in the quality of their care, and when relevant looks at the impact of staffing on this. Our recent 'dignity and nutrition' inspection programme demonstrated to us that no hard

rule could be arrived at to set the minimum number of staff or a staffing ratio required to provide good quality care to service users. Good care can be delivered in understaffed units, and poor care in well-staffed areas. Setting a minimum staffing level or ratio creates the risk of giving false assurances about the quality of care.

- 13.2. We also question the feasibility of keeping track of staffing ratios in care homes. Staffing levels and the skill mix of those staff need to be based on the needs of service users and these can change considerably from day to day and week to week. Staffing ratios are therefore a matter for senior managers within services. Some professional bodies have produced excellent guidance to support senior managers in their staff resource planning but have not felt able to stipulate staffing ratios.
- 13.3. What CQC can and does do is to train inspectors to spot the signs of inadequate staffing numbers and / or a poor skill mix. Inspectors can call upon our national professional advisors for advice if they are concerned about these issues and follow up through enforcement action if required.

14. ***Paragraph 18 – Maintaining consistency of judgement***

- 14.1. As outlined in paragraphs 6.1 to 6.4, we are currently publically consulting on a revised and simplified judgement framework and enforcement policy which CQC staff use to guide their decision about taking regulatory action.
- 14.2. These improvements will make it easier for our inspectors to make a clear and transparent judgement about compliance and will make it easier for the public to understand the information we publish about providers. For example, we will no longer expect our inspectors to factor in issues such as confidence in the provider to make improvements when coming to their judgement.
- 14.3. Our eight-week training and induction programme for new inspectors is designed to equip them with a thorough understanding of how to make judgements about compliance and appropriate enforcement action. This includes spending time shadowing experienced compliance inspectors. All inspectors have access to formal and informal support to aid them in making robust decisions.
- 14.4. While consistency across regions and within compliance teams is important, this does not equate to benchmarking. Judgements need to be made based on all available information. While the QRP of a service is one source of intelligence for our inspectors, they will use their local knowledge and networks to add a qualitative perspective to inspections and assessments of compliance.

Report writing and quality assurance

- 14.5. The Committee may find it helpful to understand our internal assurance processes for report writing. Checkpoints are in place throughout the inspection process to ensure inspectors consider the integrity of the process. Furthermore,

peer review at local level is a central part of quality assurance around regulatory judgements and the production of reports.

- 14.6. During the planning phase of a review of compliance (the overall process that usually includes an inspection), inspectors consider all the information CQC has about a service and then decide what specific issues to explore. For example, if the inspection will need to cover detailed aspects of medicines management, the inspector will talk to our pharmacy specialists to request advice and if necessary to attend the inspection.
- 14.7. The inspector may also call on a range of clinical specialists for advice. This can include taking specialists along during an inspection (e.g. the use of practising nurses in our 'dignity and nutrition' inspections, or working with midwifery experts as part of our investigation into Barking, Havering and Redbridge NHS Trust).
- 14.8. The planning stage is followed by the inspection, which will be unannounced in all but exceptional cases. During the inspection, the inspector will look for evidence to see whether or not the care service is compliant with CQC's essential standards. The planning stage will usually involve making decisions about which standards are most relevant to the provider. The subsequent inspection will seek to gather evidence most relevant to these.
- 14.9. During our inspections we ask people about their experiences of receiving care, talk to carers and family, observe care being delivered, talk to staff, check that the right systems and processes are in place, and look for evidence that suggests care might not be meeting the essential standards. We can follow up an inspection by asking for further evidence, and inspectors can seek expert advice at this stage if needs be.
- 14.10. Following the inspection and collection of evidence there are several stages to ensure that the judgement made by the inspector is fair and evidence-based. The inspector who led the inspection produces a draft report, including their judgements. This report is reviewed by another inspector who comments on the judgements, the flow and readability of the report. The amended report is then sent to the inspector's line manager (the compliance manager) for approval. Once approved, the report is sent to the provider for them to comment only on its factual accuracy. The inspector will consider all comments and make changes where appropriate.
- 14.11. If an inspection uncovers a 'major concern' with the care provided, an internal CQC management review meeting will be convened. The meeting is chaired by the compliance manager and attended by the inspector and where necessary a legal advisor. The purpose of the meeting is to decide what regulatory or enforcement action will be taken, based on ensuring fairness, consistency and making an evidence based judgement.
- 14.12. The final draft of any report is sent to the compliance manager for approval prior to publication. For themed inspections, such as the recent 'dignity and nutrition' inspections, a national quality assurance panel is used.

15. ***Paragraphs 19, 20, 21 and 22 – Whistleblowing, and building a culture of raising concerns within provider organisations***

- 15.1. CQC must ensure our handling of whistleblowing concerns is as robust as possible, and we have improved our processes to do this following Winterbourne View [ANNEX 6].²⁷
- 15.2. We expect that the organisations we regulate will develop a culture in which it is safe and acceptable for all employees and stakeholders to raise concerns about poor or unacceptable practice and misconduct.

Handling whistleblower information

- 15.3. We can confirm that the process for handling ‘whistleblowing’ information has been reviewed and strengthened since the undercover filming of abuse at Winterbourne View. In June 2011, CQC set up a dedicated team in its National Customer Service Centre to log the details of any whistleblowing calls or correspondence received; this includes allocating the information to an inspector who must then confirm receipt and action resulting from the information. This ‘track and chase’ process ensures no piece of information is left open.
- 15.4. The changes made to the system have been subject to a three-month review which has confirmed that the ‘track and chase’ process is now embedded. The quality of the process – including the information received and action taken has also been subject to review.
- 15.5. There was a significant increase in the amount of this type of information received by CQC after Panorama, but the Committee should be aware that we are assessing whether the increase in quantity was matched by an increase in quality. The findings of these audits will be used to inform future developments in the management of whistleblowing information by CQC.

Whistleblowing and the QRP

- 15.6. There is a clear distinction between information which requires immediate action and that which is less immediate but can be used to help spot patterns. Whistleblowing alerts fall into the former category and receive higher precedence in the QRP. They also generate a note for the benefit of compliance inspectors assessing a service at a later date.

Changing organisational cultures across health and social care

- 15.7. CQC believes that a system-wide approach to whistleblowing is vital to create a culture that encourages openness within organisations. We firmly believe that the organisations we regulate should develop a culture in which it is safe and acceptable for all employees and stakeholders to raise concerns.

27 Annex 6 – Updated CQC whistleblowing procedures (not printed here)

- 15.8. Whistleblowing is covered in Outcome 16 of CQC's Essential Standards (on assessing and monitoring the quality of service provision), which prompts registered providers to: "Make sure there is a confidential way for staff to raise concerns about risks to people, poor practice and adverse events. Staff understand the reporting system and feel confident to use it, without fear that they will be treated unfairly as a result of raising a concern.
- 15.9. Where we see evidence that this is not the case, we can take action, although interpreting data around this is complex. For example, a decrease in whistleblowing might reflect an improvement in care or a greater openness by management to engage with staff concerns which means whistleblowing is unnecessary; or it could reflect a punitive attitude towards raising concerns that was intimidating staff.
- 15.10. As a result of this complexity, CQC has neither the remit nor the capacity to routinely monitor how effectively organisations are developing an open culture. What CQC can do is follow up and take action where we have evidence that an organisation is not supporting staff in the way expected and that this is compromising the quality and safety of care for service users. We have made significant improvements on this front.
- 15.11. We also acknowledge it is rightly a key concern of the Committee that we work closely with professional regulators and share concerns wherever appropriate. This is built into our whistleblowing handling procedures and is taken very seriously by the Commission.
- 15.12. We agree with the Committee's recommendation about provider Board accountability and the importance of inspecting for proper processes, particularly where there are signs that this may be contributing to poor care. One of CQC's essential standards requires that a provider regularly assess and monitors the quality of the services provided in carrying out the regulated activity. This is clearly a board and senior management responsibility and CQC would expect the provider to demonstrate compliance with the regulation.

16. *Paragraph 23 – Winterbourne View*

- 16.1. The Committee referred to the abuse at Winterbourne View, shown in the BBC's Panorama programme. As the Committee is no doubt aware, CQC has been open from the outset that its actions in the Winterbourne View case were not acceptable. The decision to rely on the local authority safeguarding process was the wrong one. Our extensive improvements to our handling of whistleblowing data are set out above.
- 16.2. CQC has conducted an end to end internal management review of the regulation of Winterbourne View hospital from the time of its registration to the time of its closure. The review will be CQC's formal contribution to the Serious Case Review commissioned by South Gloucestershire Safeguarding Adults Team, which is currently underway.

- 16.3. Immediately after the broadcast we wrote to the Minister of State for Care Services, Paul Burstow MP, with a proposal for a programme of risk-based and random unannounced inspections of the 150 hospitals providing care for people with learning disabilities across England. This is now underway, supported by an advisory group and experts by experience.

17. *Paragraph 24 – Healthwatch*

- 17.1. We note the Committee’s comments with regard to HealthWatch. This is a matter for Parliament to decide, although CQC will of course work with HealthWatch England to explore matters of concern about poor care wherever appropriate. We have work underway with LINKs to manage their relationship with CQC while they transition to become local HealthWatch organisations. This is complementary to CQC’s extensive programme of engagement with the broader range of user and carer voices that we draw on to make assessments of risk in care services across England.

The registration process

18. *Paragraphs 25, 26, 27 and 29 – Improving providers’ experience of registration*

- 18.1. We continue to work hard to transform and improve the ways providers communicate with us. This spans the registration process, our National Customer Service Centre and our Online Services project for providers, which is currently in development.
- 18.2. From 1 July 2011 we streamlined registration to provide a better customer experience. This included improved application forms with clearer guidance and asking for references only on a ‘need to know’ basis.
- 18.3. We are also currently considering our long term approach to registration and plan to engage providers and stakeholders in this work. The aim is to enable us to better flex our model to individual circumstances. We need to ensure we maintain the right balance of ensuring registration is a robust process that acts as a quality check to market entry but is not unnecessarily burdensome or time consuming.

Case study: Southern Cross

- 18.4. The recent situation with Southern Cross provided an opportunity to review our processes to ensure that our focus was on the essential requirements to safeguard users and comply with legislation. An example of this review’s impact is how we have refined CQC’s requirements around registered managers to improve the process.
- 18.5. The transfer of Southern Cross homes to a range of new providers has taken place smoothly with a minimum of disruption for those using services. In order to deliver an effective transfer, we focused on the legislative and registration requirements for managers. In doing so we considered that managers should be able to maintain their registration when they would be remaining at the same

location and providing the same regulated activities but employed by a new provider.

- 18.6. In making this change we used information from our inspection activity to inform our knowledge and judgements about individual registered managers. This means in most cases managers maintained their registration while the registration of the service itself changed. We are content this continued to safeguard users, complied with the legislation and removed unnecessary burden for providers.
- 18.7. Greater reliance was placed on what we know of these managers from our review of compliance of the services they manage. The changes made in response to applications in relation to Southern Cross are being incorporated into our usual registration activity.

National Customer Service Centre

- 18.8. We have asked providers their views on their interactions with CQC, especially with our National Customer Service Centre. While aspects of the feedback have been positive we are aware also of areas where we need to improve and have started acting to correct these issues. A summary of the latest survey of providers suggests that we are moving firmly in the right direction [ANNEX 7].²⁸ We undertake this survey quarterly to make sure we are aware of what providers think about our service.
- 18.9. We worked to ensure a marked upturn in the volumes of registration applications we are able to process in an effort to minimise the chance of backlogs developing in future. By way of example, we reduced the time taken to process registration applications meaning that by April 2011 we hit a record of 1,700 applications processed in one week, at the same time as answering over 90% of calls within 20 seconds.

Online Services

- 18.10. We will start a pilot of the first release of Online Services in December 2011 – for example, allowing providers to submit notifications online rather than in written form. This both reduces the number of transactions and improves the delivery of information to the right place. We envisage that these online account management tools will become the main way that providers interact with the Commission on a day to day basis. This pilot will be used to evaluate the effectiveness of the services.
- 18.11. If the pilot is successful, by April 2012 we expect that over 95% of notifications which are submitted to us could begin to move online. We anticipate this will improve the provider experience of sending us information and also improve our data quality.

19. ***Paragraph 28 – Improving transitional registration for primary medical services (including GP practices)***

Primary medical services (including GPs)

- 19.1. We are now using the delay of the transitional registration of primary medical services to review and improve the registration process. This will include developing an online application and tracking service, improving our guidance, and working closely with stakeholders to ensure the registration process is fit for the sector. The streamlining of the process is already underway; including reducing the occasions where we require a CQC-countersigned enhanced Criminal Records Bureau check.
- 19.2. We have held an early focus group with GPs and practice managers to examine the proposed approach to application forms using our new online services for providers. Further focus groups and pilots will test the usability of this approach and the final online forms.
- 19.3. A primary medical services advisory group has been set up with key stakeholders, including the General Medical Council and British Medical Association, allowing them to take part in the development of the transitional registration process. We are also directly engaged with providers through our online Provider Reference Group which regularly hosts live web chats and examines our documentation. Membership of this is open to any provider.

Provision of information to the public

20. ***Paragraph 30 – Information for the public***

- 20.1. CQC wants to put as much information into the public domain as possible to help people make informed judgements about their care. The main way we do this is through our website, the new version of which launched in October 2011 and which is designed to give the public essential information to help inform their choices about health and social care.
- 20.2. Every service registered with CQC has a ‘provider profile’ on the site where services users, their carers and members of the public can see a clear and up to date summary of our judgement of the service. More detailed information from our reports about what our inspectors found and what people using services told them is only a click away. Where we are conducting a review of a service this is highlighted on the provider profile. Our new reports are added to the website on a weekly basis.
- 20.3. To help us capture as much information as possible about the services we regulate, each provider profile has a tab where people who use services can share their experience with us. This feedback is triaged and then fed into the QRP for the service where our inspectors can pick it up.
- 20.4. We acknowledge that there were delays to the launch of the website for which we apologise and are due to a number of technical and resource factors:

- 20.4.1. Recruitment – in her letter to Una O’Brien at the Department of Health on 22 November 2010, Jo Williams raised concerns about recruitment to business critical posts in the website team, which at that point had a vacancy rate of 50 per cent. It was highlighted that this team was critical to fulfilling the legislative requirement of making information available and accessible to people who commission, choose and use services.
 - 20.4.2. Complexity of task – turning a highly complex data set into meaningful information that was also easily digestible for a public audience required a considerable amount of work.
 - 20.4.3. Consultation and testing – we wanted to make sure we got the website right, making it a valuable resource for service users, their carers and the public. This involved a lot of iterative testing, the full timescales for which were difficult to accurately map in advance.
 - 20.4.4. Technical challenges – the alignment of internal systems, processes and data quality required overcoming a large number of time consuming challenges to support our new digital approach. The work done sets us in good stead for our future digital platform.
- 20.5. It has taken longer than we would have liked to launch this site, but our view is that the delays have been justified by the final result. In building the site, CQC had to work to transform highly complex data into meaningful information, easily digestible for the public. The Commission carried out extensive consultation and testing with the public and providers to build a site that works for our many audiences. Internal systems had to be adapted to ensure that the publication of clear, timely information about our compliance monitoring was embedded in our ways of working.
- 20.6. The site will continue to develop and improve in the short- and medium-term. The increase in CQC’s inspection activity will see us build a better and richer picture of the quality of care across England over time, and the quality of information on the website will improve in line with this.

21. *Paragraph 31 – Adult Social Care Excellence Award*

- 21.1 The Department of Health has confirmed that CQC will not be proceeding with the adult social care excellence award, following the feedback received during our recent consultation exercise.
- 21.2 The social care white paper, to be published next year, will look at how to drive quality improvement in social care and the role CQC might play in this.

Appendix 7: Government's Response – Annual Accountability Hearing with Monitor

Introduction

On 14 September 2011, the House of Commons Health Committee (the Committee) published the report: *Annual Accountability Hearing with Monitor*.

The Committee proposed to review the work of Monitor on an annual basis starting in Summer 2011. The Committee decided to take a similar approach in relation to CQC.

The Department strongly believes that these hearings are of great value in strengthening the accountability of the Department's independent Arm's Length Bodies to Parliament and the wider public.

Departmental response

We welcome this report and have carefully considered the Committee's recommendations and the issues it raises. The changes proposed for Monitor in the Health and Social Care Bill will expand and change Monitor's role from being the Independent Regulator of Foundation trusts. However, the Bill makes provision for Monitor to retain its intervention powers for a transitional period. The powers will be reviewed in 2015 and may be extended if necessary.

The Government's response to each of the recommendations made in relation to CQC is shown in the table below. Many of the Committee's recommendations were clearly for Monitor to take forward and we have indicated where we feel this is the case.

Department of Health response to the Health Select Committee Recommendations – Monitor

Introduction

Foundation Trusts – Monitor's continuing duties

Monitor faces a significant challenge in assessing and authorising for foundation trust status the remaining NHS trusts. We welcome the Government's decision to change April 2014 from the legal deadline for the completion of this process to a less rigid target, albeit one the Government strongly expects to be met for the majority of Trusts. Nevertheless, sheer numbers alone make the assessment task formidable, and the Government must be prepared to be even more flexible if circumstances demand it. (Paragraph 13)

Removing the 2014 date from the Bill is about responding to the NHS Future Forum recommendation to not have a cut –off date in legislation and enabling the minority of more challenged NHS trusts to make the necessary developments so they can achieve FT status on their own, with an existing FT or in another organisational form beyond 2014 and over an updated timescale to be specifically agreed. These trusts will continue to work

towards FT status under new management arrangements. The Government's position remains unchanged and the aim is for the creation of a full FT sector so that there is a full cohort of sustainable providers of high quality healthcare services.

Monitor needs to be in a position to respond to the demands of applicant trusts, rather than trusts' programmes being artificially accelerated or delayed in line with Monitor's capacity. Monitor will, however, only be able to function effectively if the flow of applicants through the pipeline is phased and not back-loaded. The Department of Health therefore needs to manage the progress of applications as far as possible to ensure Monitor is able to work effectively. Where this is not possible, the Department must either provide Monitor with the necessary resources to temporarily increase its assessment capacity, or should relax deadlines for a particular trust to enable assessment to be undertaken with due care and consideration. (Paragraph 17)

Tripartite Formal Agreements (TFAs) are agreed documents that are now going into the public domain which set out a Trust's journey to FT status on their own, as part of an FT or in another organisational form. The development of the TFAs has enabled us to further clarify the trajectory to FT status. The Department is currently working with SHAs on how best to manage the trajectory and will continue to discuss this with Monitor.

The Department must resist the temptation to artificially accelerate the process by referring trusts to Monitor before they have reached the appropriate level – to do so would hinder Monitor's capacity to handle more realistic applications. (Paragraph 18)

SHAs are responsible for working with NHS Trusts to ensure when an application is submitted to the Department of Health, it is robust and fully able to stand up to the Monitor assessment process to ensure it is able to achieve FT status.

The Committee strongly supports the view that the standards for authorising foundation trusts must not fall as a result of the Government's desire to see all remaining NHS trusts become foundation trusts. We welcome the assurances on this point from both Monitor and the Government. We note that Monitor intends to review its approach to assessment in order to accommodate the extra demands on its capacity. It is imperative that any change in process does not alter the standards expected of aspiring foundation trusts, either directly or as a result of the space created by a less comprehensive process. (Paragraph 25)

There will be no lowering of the bar to Ft status. Since Mid Staffordshire, there has been much more focus on quality in FT applications. Both Monitor and the DH have established quality metrics as part of their assessments of Trusts, and, Monitor and the Department of Health work much more directly with CQC to assure quality in aspirant FTs.

Within the FT Pipeline work, the Provider Executive Group (PEG) commissioned and has now implemented an additional quality framework which is now used by all Medical Directors across the country when assuring quality aspects of all FT applications they are asked to review. This process includes the use of a clinically endorsed set of quality indicators which are used to explicitly consider the outcomes of care provided at aspirant FTs alongside the more general clinical governance issues that are considered as part of an FT application. This work is now formalised as part of the process for reviewing FT

applications and has been used on the most recent applicants, and will do so for those being reviewed going forward.

In addition, this processes for reviewing quality in FT applications will continue to be reviewed to ensure that quality of care remains the focus of organisations making the changes needed to progress to FT status. These reviews will be undertaken as part of the development of the single operating model for reviewing FT applications which will help the current 10 SHA model move forward effectively into one model for the clustered SHAs from January 2012 and ultimately for the NTDA.

Monitor's assessments of foundation trust performance show that although many foundation trusts are performing well, a significant proportion are struggling to meet financial and government standards. (Paragraph 27)

We acknowledge that the operating environment in the NHS has become increasingly challenging. The requirement for hospitals to remain fully focussed on delivering quality healthcare services for patients whilst the financial situation has become more demanding means it is arguably more challenging now to achieve FT status than before. We have not changed the requirements for achieving FT status and in fact the changing financial context, in particular the increasing efficiency requirements, has meant the test to become an FT has become more challenging. This is only right given the assessment for FT status is around preparing organisations to operate with more autonomy, in testing operating conditions but has impacted on the speed of applications.

It is for Monitor as the independent regulator to ensure that where FTs are struggling to meet requirements that appropriate actions are put in place to address them.

It is clear that some of the improvement in the numbers of foundation trusts in significant breach is accounted for by changes in targets which have been introduced by the Government. We agree that Monitor's compliance criteria should reflect performance measurements used by NHS Commissioners, the CQC and the Government. (Paragraph 29)

Operational and therefore for Monitor to respond to.

The Committee believes that the parallel existence of Monitor and the CQC creates a significant risk of cost and process duplication between the two bodies. It is essential that the scope and function of each body is clearly defined and that both bodies observe the limits of their responsibilities, while retaining a holistic view of the regulated organisations. (Paragraph 31)

Operational and therefore for Monitor to respond to.

It is right that Monitor adapts its regulatory approach and its use of formal intervention powers to reflect the circumstances of individual cases and we accept Monitor's reasons for not using its formal intervention powers in 2010-11. Nevertheless, we encourage Monitor not to be reticent to use its formal powers when necessary, and to regularly review the progress of trusts in significant breach. (Paragraph 33)

Operational and therefore for Monitor to respond to.

Over the next year, Monitor's foundation trust compliance role will become harder and more important. It must be prepared and resourced to meet this challenge. There will be more foundation trusts, many of them newly authorised, struggling to make demanding efficiency gains and to manage upheaval in the health landscape. Existing foundation trusts will also be affected. In this light, we welcome the fact that Monitor is increasing its monitoring of financial risk. We encourage Monitor to remain vigilant for further areas where closer scrutiny is needed. (Paragraph 36)

Operational and therefore for Monitor to respond to.

We are concerned about the proposals in the Health and Social Care Bill to reduce the financial oversight role of Monitor and increase the responsibilities of foundation trust governors in this area. We draw the attention of the House to the fact that Monitor reported in March 2011 that failures of governance within existing foundation trusts were a significant contributory cause to cases of significant breach during 2010 and we see little or no evidence that this position has changed sufficiently to justify the additional responsibility being placed on foundation trust governors. (Paragraph 41)

Foundation trusts were established to be autonomous and self-governing. We recognise that it can take some time to build up the capability of governors in a newly-authorized foundation trust. In response to the NHS Future Forum's recommendation, we have said we will give more time for governors to build capability in holding boards to account by extending the transitional period where Monitor retains specific intervention powers over them. This will apply to all foundation trusts and will last until 2016. For foundation trusts authorised after 31 March 2016, the powers will apply to them for up to two years after their authorisation. The powers will be reviewed in 2015, and may be extended if necessary.

We are actively seeking to build governor capability. The Health and Social Care Bill proposes to lay a duty on foundation trust directors to take steps to ensure that their governors are equipped with the skills and knowledge they need to perform their enhanced role of representing the interests of their members and holding directors to account for the performance of the trust. We are supplementing this with non-legislative measures: we are funding a project by Foundation Trust Governors' Association, the Foundation Trust Network and Monitor to develop induction, core and specialist training for governors. We will also encourage foundation trusts to take up existing training by the Foundation Trust Network to inform and improve pre-election processes so that governor candidates are better informed about the role and can assess their suitability and inclination to take it on. We will also encourage foundation trusts to build closer working relationships between their directors and governors so that the latter are better informed about the trust's operation and more able to identify risks and issues about its performance.

There will be other financial oversight of foundation trusts as well as through Monitor. Under our proposals the Foundation Trust Funding Facility (FTFF) terms and conditions would be developed to ensure that foundation trusts are financially viable and would restrict actions that are materially risky.

Development will be necessary if foundation trust governors are to have the skills required to successfully take on their new responsibilities and operate effectively in the new landscape. We noted that Monitor's ability to provide development at the required

level may be limited by spending controls on arm's-length bodies. When we next meet Monitor, we expect to see clear evidence of their programme to support development for foundation trust governors. In the meantime the Government should provide additional resources to Monitor if required, or consider delaying the devolution of responsibilities until there is evidence that the effectiveness of foundation trust governors has been enhanced. (Paragraph 45)

Findings from recent reports by Monitor and the Foundation Trust Governors' Association show that the system of local accountability at foundation trusts is maturing and strengthening. Foundation trust governors have made good progress in understanding their role, and feeling better informed by their trusts, over the last three years (Monitor governors' 2010 survey, published in July 2011). Over 80% have received initial training and further training or briefings to develop them in the role. As a result more governors are clear about representing their stakeholders, understanding the trust's strategy and undertaking work on sub-committees.

We are actively seeking to build governor capability. The Health and Social Care Bill proposes to lay a duty on foundation trust directors to take steps to ensure that their governors are equipped with the skills and knowledge they need to perform their enhanced role of representing the interests of their members and holding directors to account for the performance of the trust. We are supplementing this with non-legislative measures: we are funding a project by Foundation Trust Governors' Association, the Foundation Trust Network and Monitor to develop induction, core and specialist training for governors. We will also encourage foundation trusts to take up existing training by the Foundation Trust Network to inform and improve pre-election processes so that governor candidates are better informed about the role and can assess their suitability and inclination to take it on. We will also encourage foundation trusts to build closer working relationships between their directors and governors so that the latter are better informed about the trust's operation and more able to identify risks and issues about its performance.

In response to the NHS Future Forum's recommendation, we have said we will give more time for governors to build capability in holding boards to account by extending the transitional period where Monitor retains specific intervention powers over them. This will apply to all foundation trusts and will last until 2016. For foundation trusts authorised after 31 March 2016, the powers will apply to them for up to two years after their authorisation. The powers will be reviewed in 2015, and may be extended if necessary.

We welcome the extension of Monitor's oversight powers for foundation trusts to 2016, and the fact that the powers will then be reviewed. (Paragraph 46)

See response to para 13.

The Government's reforms and the financial context have placed Monitor in a position where its foundation trust duties have escalated, albeit on a temporary basis, and where its activities in both authorisation and compliance are likely to increase. Maintaining standards at this time will be vital. Monitor will need to adapt if it is to take on this additional workload without lowering standards. The Government must ensure that Monitor has the resources necessary to maintain standards across foundation trusts while it retains responsibilities in this area. The next five years will be critical in

ensuring that foundation trusts are in a fit state to survive and thrive in the new health landscape. (Paragraph 47)

See response to para 45. The Department will continue to discuss managing the transitional period with Monitor including the issue of resources.

Monitor's new role under the Health and Social Care Bill

We welcome the fact that Monitor's new role, as set out in the Health and Social Care Bill, has been more clearly defined following the Future Forum process. The change in 'signal' from 'economic regulator' to 'sector regulator' is also welcome, and will address some of the concerns raised following the introduction of the Bill. It is unclear whether the change will result in challenges under competition law being handled in the way the Government hopes. It is also the case, as has been acknowledged by Monitor, that competition law in this area is largely untested. This is another area where Monitor's future workload is somewhat unpredictable. Monitor will need to plan for a range of contingencies, and the Government will need to adapt its support as appropriate. (Paragraph 55)

Monitor to comment on operational aspects.

The Department will continue to discuss such issues with Monitor as they develop.

The scale of change in Monitor's operations is significant and many parts of Monitor's future role remain uncertain or unclear. This continuing uncertainty further complicates an already complex and challenging process of adapting to a substantial new role while maintaining residual foundation trust responsibilities. It is vital that the transition period is carefully managed, with each of Monitor's responsibilities, both old and new, being executed to a high standard. We are confident that Monitor is aware of the scale of this challenge, and we note that Monitor has begun to plan for the transition to its new role, as far as possible. When we revisit this topic next year we will evaluate how well Monitor has undertaken this transition. (Paragraph 61)

Monitor to comment on operational aspects.

The Health and Social Care Bill further increase the level of cooperation required between Monitor and the Care Quality Commission, with the joint licensing scheme requiring particularly close interaction. In consequence, we discussed with Monitor the potential for merging the two organisations. We note that there are strong arguments in favour of retaining a separate regulator for quality issues; a single regulator would require substantial safeguards to ensure that quality and safety did not come second to financial concerns. We are also concerned about the scale of challenges facing Monitor and the CQC, both of which are going through complicated transition periods, coupled with continuing uncertainty and financial risk in the health landscape. Given these factors, and despite the obvious risk of overlap, we do not think it would be appropriate to consider merging the two organisations at this time. (Paragraph 69)

The Department agrees that it would not be appropriate to consider merging the two organisations at this time.

Appendix 8: Monitor's Response

Introduction

This memorandum is Monitor's response to the Health Select Committee's tenth report,²⁹ following its annual accountability hearing with Monitor.

Monitor welcomes the Health Select Committee's annual accountability hearing and subsequent report into Monitor. The Committee has identified a number of key areas where Monitor is performing well, including maintaining its rigorous assessment process for prospective foundation trusts and increasing its monitoring of financial risk.

The Committee has also made helpful suggestions for example in relation to the proposals outlined in the Health and Social Care Bill which will inform Monitor's thinking as it takes forward its proposed new role.

Our response to each of the conclusions and recommendations set out in the Health Select Committee's report is given below

Responses to the Committee's conclusions and recommendations (the points in bold are the recommendations made by the Committee)

24. Monitor's operations over the past year have taken place in an extremely challenging context—not only in terms of its own changing role under the Health and Social Care Bill and the arm's-length bodies review, but also in terms of the wider pressures and change in the healthcare landscape. Although the proposed revisions to the Health and Social Care Bill have helped to define Monitor's future role more clearly, and some uncertainty will be removed as the Bill progresses through Parliament, Monitor will continue to operate in an extremely challenging context in the years to come. (Paragraph 10)

Monitor's response

As the Committee acknowledges, Monitor has faced a number of challenges over the past year, and we look forward to greater clarity on our proposed new role once the Health and Social Care Bill has completed its passage through Parliament.

In terms of the challenges to our workload, there have been five key reasons for this increase:

- first, the increase in risk-assessing transactions, in particular resulting from the Department of Health's Transforming Community Services (TCS) initiative;
- second, our ongoing assistance with the Mid Staffordshire Public Inquiry;
- third, more assessments for foundation trust status have been carried out;

²⁹ Health Committee – Tenth Report Annual accountability hearing with Monitor, September 2011
<http://www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1431/143102.htm>

fourth, more problems have been identified within foundation trusts;

finally, supporting the Department of Health in the development of proposals for Monitor's new role.

In order to address this increased workload, we have reviewed the capacity and capability of these teams and increased staff levels as a result. We are likely to see a further increase in staff numbers over the next year. We will need to plan and manage that resource around specific areas of need. This includes the Government's target to authorise all remaining NHS trusts as foundation trusts by 2014. On compliance, an increase in inspections by the Care Quality Commission and the effect on trusts of the increasingly difficult financial environment are expected to present the main challenges to our capacity. To ensure that we remain a tightly-resourced and focused organisation which is as cost-effective as possible, we will continue to rely on buying-in expertise during times of peak activity and for work on specialised subjects/projects. This includes additional IT and legal support as necessary, as well as additional capacity around our Annual Planning Round, specific projects and other busy periods.

25. Monitor faces a significant challenge in assessing and authorising for foundation trust status the remaining NHS trusts. We welcome the Government's decision to change April 2014 from a legal deadline for the completion of this process to a less rigid target, albeit one the Government expects to be met. Nevertheless, sheer numbers alone make the assessment task formidable, and the Government must be prepared to be even more flexible if circumstances demand it. (Paragraph 13)

Monitor's response

Monitor welcomes the Government's commitment to an all foundation trust sector. We believe that the process of preparing for, applying and achieving foundation trust status improves the quality of governance and financial management at a trust, to the benefit of patients and taxpayers, and there is analytical evidence to support this view.

To become a foundation trust, the organisation must be able to demonstrate that it has strong governance, is providing quality care, and has sound finances. In Monitor's view, these are standards that all providers of NHS care should be expected to meet, and we remain supportive of all trusts achieving the standards necessary to become foundation trusts, including ambulance and community trusts.

However, 2010/11 saw only 11 trusts referred to Monitor by the Department of Health. Out of these, seven were authorised. Approximately³⁰ 115 NHS trusts (70 acute trusts; 19 community trusts; 15 mental health trusts; nine ambulance trusts; and two care/ learning disability trusts) are yet to become foundation trusts or find an alternative solution.

This situation will have to improve significantly in 2011/12 if we are to assess and authorise all trusts (including ambulance and community trusts) by the Department of Health's April 2014 target date. This could mean starting up to five assessments a month.

30 There is no exact figure as some trusts may merge

We agree with the view of the National Audit Office (NAO) that the Department of Health has made a concerted effort to identify the challenges faced by the remaining NHS trusts seeking foundation status.³¹ All trusts have now signed tripartite agreements setting out how they intend to move forward and we will continue to work closely with the Department of Health to support the process as much as we can.

26. Monitor needs to be in a position to respond to the demands of applicant trusts, rather than trusts' programmes being artificially accelerated or delayed in line with Monitor's capacity. Monitor will, however, only be able to function effectively if the flow of applications through the pipeline is phased and not back-loaded. The Department of Health therefore needs to manage the progress of applications as far as possible to ensure Monitor is able to work effectively. Where this is not possible, the Department must either provide Monitor with the necessary resources to temporarily increase its assessment capacity, or should relax deadlines for a particular trust to enable assessment to be undertaken with due care and consideration. (Paragraph 17)

Monitor's response

Monitor welcomes this recommendation. We have been clear that, providing we have a steady flow of applicants which are well prepared by the time they enter our assessment process, it is possible that the majority of NHS trusts will be able to be considered by Monitor for foundation trust status by the 2014 deadline. However, it will not be possible to carry out the thorough assessment that Monitor's process requires if the majority of the remaining NHS trusts enter the Monitor pipeline at the same time.

It is difficult to increase capacity rapidly in our assessment teams and maintain the rigorous standards of the process. We are taking steps to address this problem by working closely with the Department and we will batch trusts into groups based on an initial assessment of their application. With careful planning we believe it will be possible to increase capacity on a temporary basis to meet this challenge, but it would not be possible to deal with the majority of the remaining trusts simultaneously.

27. The Department must resist the temptation to artificially accelerate the process by referring trusts to Monitor before they have reached an appropriate level – to do so would only hinder Monitor's capacity to handle more realistic applications. (Paragraph 18)

Monitor's response

We agree that referring trusts to us too early could unnecessarily overburden our assessment team.

Monitor's main priority is to ensure that our assessment standards remain rigorous and consistent throughout the drive to ensure all eligible trusts reach foundation trust status. The rigour of our assessment process is widely acknowledged and we will continue to maintain our high standards and to obtain assurance from the CQC to ensure that only

31 Amyas Morse, head of the National Audit Office (13 October, 2011)
http://www.nao.org.uk/publications/1012/foundation_trusts.aspx

those organisations that are providing quality care and are financially and clinically viable, well-governed and legally constituted are authorised. It is not in the interests of patients and the public for trusts that are not well run or financially strong to be granted the independence and autonomy that comes with foundation trust status, and we therefore do not and will not approve trusts for foundation trust status unless they can demonstrate this. Our experience of working with the Department shows that it is taking its role of referring trusts when they are ready to enter our assessment process very seriously. If they were not, there would be an increased number of deferred applications and inefficient use of Monitor's assessment capacity. The Government has stated that it has no intention of asking Monitor to lower its assessment standards, and Monitor welcomes this commitment.

28. The Committee strongly supports the view that the standards for authorising foundation trusts must not fall as a result of the Government's desire to see all remaining NHS trusts become foundation trusts. We welcome the assurances on this point from both Monitor and the Government. We note that Monitor intends to review its approach to assessment in order to accommodate the extra demands on its capacity. It is imperative that any change in process does not alter the standards expected of aspiring foundation trusts, either directly or as a result of the space created by a less comprehensive process. (Paragraph 25)

Monitor's response

As stated above, it is our priority to maintain the rigorous standards of our assessment process. There is no question of Monitor lowering its assessment bar or relaxing standards for authorisation as an NHS Foundation Trust.

29. Monitor's assessments of Foundation Trust performance show that although many foundation trusts are performing well, a significant proportion are still struggling to meet financial and governance standards. (Paragraph 27)

Monitor's response

The most recent review of foundation trust performance was for the first quarter of 2011/12.³² On finances, the results for the first three months indicate that overall the foundation trust sector is performing slightly ahead of plan. This is encouraging in the context of the financial pressure on the NHS. However, there is an increase in the number of foundation trusts facing significant financial challenges. We are looking closely at these and taking regulatory action in several cases to make sure that the issues are addressed. We will be working closely with the most financially challenged trusts to ensure they focus on long term solutions bringing to bear our growing experience of doing this.

The NHS as a whole, and the foundation trust sector within it, faces the challenge of improving value – increasing the quality and quantity of care provided for every pound spent. Foundation trusts are planning to deliver the most challenging Cost Improvement Plans to date. While they are slightly behind their plan in delivering these, they are ahead of where they were this time last year. We are clear that proper planning should make the

32 NHS foundation trusts: review of three months to 30 June 2011 <http://www.monitor-nhsft.gov.uk/home/our-publications/reports-about-foundation-trusts/nhs-foundation-trusts-quarterly-reports>

plans achievable and we are equally clear that efficiencies must never be made at the expense of the quality of care patients receive.

There is also a higher number of foundation trusts with outstanding compliance actions with the Care Quality Commission (CQC) than was anticipated in their annual plans. This is due to an increase since quarter four 2010/11 in the number of trusts where the CQC has moderate concerns. We have reflected this in our risk ratings, resulting in a higher number of trusts assigned an amber-red risk rating to indicate that there could be some concerns about the overall governance of these trusts. We will take action if we establish that is the case.

30. It is clear that some of the improvement in the numbers of foundation trusts in significant breach is accounted for by changes in targets which have been introduced by the Government. We agree that Monitor's compliance criteria should reflect the performance measurements used by NHS Commissioners, the CQC and the Government. (Paragraph 29)

Monitor's response

Monitor welcomes the fact that the Committee supports our use of national standards and targets as proxy indicators for effective governance. However, we will continue to review the appropriateness of this approach.

31. The Committee believes that the parallel existence of Monitor and the CQC creates a significant risk of cost and process duplication between the two bodies. It is essential that the scope and function of each body is clearly defined and that both bodies observe the limits of their responsibilities, while retaining a holistic view of the regulated organisations. (Paragraph 31)

And 17. The Health and Social Care Bill further increases the level of cooperation required between Monitor and the Care Quality Commission, with the joint licensing scheme requiring particularly close interaction. In consequence, we discussed with Monitor the potential for merging the two organisations. We note that there are strong arguments in favour of retaining a separate regulator for quality issues: a single regulator would require substantial safeguards to ensure that quality and safety did not come second to financial concerns. We are also concerned about the scale of the challenges facing Monitor and the CQC, both of which are going through complicated transition periods, coupled with continuing uncertainty and financial risk in the healthcare landscape. Given these factors, and despite the obvious risk of overlap, we do not think it would be appropriate to consider merging the two organisations at this time. (Paragraph 69)

Monitor's response

We welcome the fact that the Committee recognises the important arguments in favour of retaining the current regulatory system. We believe it is important that patients know that one regulator is directly responsible for looking after what they care about most - safety and quality. This is the CQC's role. To be able to do this important job properly, it is desirable that there is no risk of the CQC being influenced or distracted by financial considerations, especially given the complex nature of quality measurement in healthcare.

Of course, there is a need to look at quality and financial performance together. This is first and foremost the job of trust boards. Monitor's job is to make sure that trust boards are undertaking this critical role effectively, and to take action if they are not.

Monitor set out its full views on this issue in its supplementary evidence to the Committee. We agree that it is important that the scope and function of Monitor and the CQC are clearly defined and that there is no duplication. Monitor and the CQC work closely together and have distinct but complementary roles. Both organisations are committed to working together to identify where improvement is needed, and to ensuring that our approach is co-ordinated in order to deliver real benefits for patients.

32. It is right that Monitor adapts its regulatory approach and its use of formal intervention powers to reflect the circumstances of individual cases and we accept Monitor's reasons for not using its formal powers in 2010–11. Nevertheless, we encourage Monitor not to be reticent to use its formal powers when necessary, and to regularly review the progress of trusts in significant breach. (Paragraph 33)

Monitor's response

Monitor welcomes the Committee's finding that Monitor is right to consider its regulatory approach and use of formal intervention powers on a case by case basis.

Where we feel that we need to use our powers to make improvements at foundation trusts that are in difficulty, we will not hesitate to do so. Indeed, since the Committee met with Monitor we have used our powers to intervene at University Hospitals Morecambe Bay NHS Foundation Trust, requiring the Trust to take actions to address our governance concerns.

33. Over the next year, Monitor's foundation trust compliance role will become harder and more important. It must be prepared and resourced to meet this challenge. There will be more foundation trusts, many of them newly authorised, struggling to make demanding efficiency gains and to manage upheaval in the health landscape. Existing foundation trusts will also be affected. In this light, we welcome the fact that Monitor is increasing its monitoring of financial risk. We encourage Monitor to remain vigilant for further areas where closer scrutiny is needed. (Paragraph 36)

Monitor's response

Monitor agrees with the Committee that its compliance role will become increasingly important as the economic environment becomes more challenging. Our approach is designed to focus foundation trust boards on identifying emerging challenges and future risks and we will seek to continue to ensure that they prepare effectively for the tough financial challenges they face.

For example, we have developed our approach on quality governance to place extra scrutiny on boards' understanding of potential risks to patient services. Quality governance looks at how boards identify and manage risks to quality, act against poor performance, and implement plans to drive continuous improvement in patient care. We also work closely with the CQC in this respect, using their judgements on standards of care to inform our own decisions about the effectiveness of trust boards' focus on quality governance

We also anticipate an increase in the number of mergers and acquisitions involving NHS foundation trusts and other providers that will require risk assessment by Monitor's compliance teams.

We will consider any necessary changes to our regulatory approach to ensure it remains fit for purpose as circumstances evolve. For example, we have included in our Compliance Framework measures to scrutinise the performance of community services provided by foundation trusts.

34. We are concerned about the proposals in the Health and Social Care Bill to reduce the financial oversight role of Monitor and increase the responsibilities of foundation trust governors in this area. We draw the attention of the House to the fact that Monitor reported in March 2011 that failures of governance within existing foundation trusts were a significant contributory cause to cases of significant breach during 2010 and we see little or no evidence that this position has changed sufficiently to justify the additional responsibility being placed on foundation trust governors. (Paragraph 41)

And 13. We welcome the extension of Monitor's oversight powers for foundation trusts to 2016, and the fact that the powers will then be reviewed. (Paragraph 46)

Monitor's response

We welcome the amendments to the Health and Social Care Bill which outline that Monitor's compliance regime will now continue until 2016. This should give time to develop appropriate governance arrangements for foundation trusts, and will give governors the time to learn how to use their powers effectively, which is in the best interest of patients.

As the Committee highlights, it is not yet clear what will happen post-2016. However the proposed new responsibilities for governors mean that a step-change is needed in the capability of governors. This is a major development challenge where an early start is needed if it is to be effectively addressed.

35. Development will be necessary if foundation trust governors are to have the skills required to successfully take on their new responsibilities and operate effectively in the new landscape. We note that Monitor's ability to provide development at the required level may be limited by spending controls on arm's-length bodies. When we next meet with Monitor, we expect to see clear evidence of their programme to support development for foundation trust governors. In the meantime the Government should provide additional resources to Monitor if required, or consider delaying the devolution of responsibilities until there is evidence that the effectiveness of foundation trust governors has been enhanced. (Paragraph 45)

Monitor's response

The Department of Health is leading on the development of governors to take on their new responsibilities. We are contributing to this work, along with others including the FTN and FTGA.

36. The Government's reforms and the financial context have placed Monitor in a position where its foundation trust duties have escalated, albeit on a temporary basis,

and where its activities in both authorisation and compliance are likely to increase. Maintaining standards at this time will be vital. Monitor will need to adapt if it is to take on this additional workload without lowering its standards. The Government must ensure that Monitor has the resources necessary to maintain standards across foundation trusts while it retains responsibilities in this area. The next five years will be critical in ensuring that foundation trusts are in a fit state to survive and thrive in the new health landscape. (Paragraph 47)

Monitor's response

Monitor welcomes this recommendation. We are determined to ensure that high standards are maintained. To achieve this, our approach is centred on trying to identify problems as early as we can. We have an effective process to identify foundation trusts that are at risk of getting into difficulty in their financial or quality governance and to intervene if necessary. If we find that we are at any time resource constrained our first priority will be to focus on ensuring the ongoing quality of governance at existing foundation trusts.

37. We welcome the fact that Monitor's new role, as set out in the Health and Social Care Bill, has been more clearly defined following the Future Forum process. The change in 'signal' from 'economic regulator' to 'sector regulator' is also welcome, and will address some of the concerns raised following the introduction of the Bill. It is unclear whether the change will result in challenges under competition law being handled in the way the Government hopes. It is also the case, as has been acknowledged by Monitor, that competition law in this area is largely untested. This is another area where Monitor's future workload is somewhat unpredictable. Monitor will need to plan for a range of contingencies, and the Government will need to adapt its support as appropriate. (Paragraph 55)

Monitor's response

Monitor also welcomes the clearer definition of its role following the Future Forum process. The changes provide helpful clarity and constraints on Monitor's role and how Monitor acts. They make it clear that our role would be to put patients first and to protect and promote their interests. In our view, this is absolutely right.

In terms of the Committee's point on Monitor's workload, we agree there is a need to plan for a range of contingencies and will ensure that this recommendation is reflected in our planning.

38. The scale of change in Monitor's operations is significant, and many parts of Monitor's future role remain uncertain or unclear. This continuing uncertainty further complicates an already complex and challenging process of adapting to a substantial new role while maintaining residual foundation trust responsibilities. It is vital that the transition period is carefully managed, with each of Monitor's responsibilities, both old and new, being executed to a high standard. We are confident that Monitor is aware of the scale of this challenge, and we note that Monitor has begun to plan for the transition to its new role, as far as this is possible. When we revisit this topic next year we will evaluate how well Monitor has undertaken this transition. (Paragraph 61)

Monitor's response

Monitor agrees it is vital that the transition period is carefully managed. As we outlined in our oral evidence, and as the Committee acknowledges, Monitor has begun to plan for the transition to the new role. Once the Parliamentary process has been completed, Monitor's priority will be to ensure that arrangements are put in place as quickly as possible to manage the transition effectively. We are keen to move into the detailed implementation phase.

Formal Minutes

Tuesday 28 February 2012

Members present:

Mr Stephen Dorrell, in the Chair

Barbara Keeley
Mr Virendra Sharma

Chris Skidmore
David Tredinnick

Draft Report (*Annual accountability hearings: responses and further issues*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 21 read and agreed to.

Annex agreed to.

Resolved, That the Report be the Fifteenth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be reported to the House for printing with the Report.

Written evidence was ordered to be reported to the House for publishing on the Internet.

[Adjourned till Tuesday 6 March at 10.00 am

List of Reports from the Committee during the current Parliament

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2010–12

First Report	Appointment of the Chair of the Care Quality Commission	HC 461-I
Second Report	Public Expenditure	HC 512 (Cm 8007)
Third Report	Commissioning	HC 513 (Cm 8009)
Fourth Report	Revalidation of Doctors	HC 557 (Cm 8028)
Fifth Report	Commissioning: further issues	HC 796 (Cm 8100)
First Special Report	Revalidation of Doctors: General Medical Council's Response to the Committee's Fourth Report of Session 2010–11	HC 1033
Sixth Report	Complaints and Litigation	HC 786 (Cm 8180)
Seventh Report	Annual accountability hearing with the Nursing and Midwifery Council	HC 1428 (HC 1699)
Eighth Report	Annual accountability hearing with the General Medical Council	HC 1429 (HC 1699)
Ninth Report	Annual accountability hearing with the Care Quality Commission	HC 1430 (HC 1699)
Tenth Report	Annual accountability hearing with Monitor	HC 1431 (HC 1699)
Eleventh Report	Appointment of the Chair of the NHS Commissioning Board	HC 1562-I
Twelfth Report	Public Health	HC 1048-I (Cm 8290)
Thirteenth Report	Public Expenditure	HC 1499 (Cm 8283)
Fourteenth Report	Social Care	HC 1583-I
Fifteenth Report	Annual accountability hearings: responses and further issues	HC 1699