House of Commons

Science and Technology Committee

The Cooksey Review

Third Report of Session 2006–07

Report, together with formal minutes, oral and written evidence

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The Science and Technology Committee

The Science and Technology Committee is appointed by the House of Commons to examine the expenditure, administration and policy of the Office of Science and Innovation and its associated public bodies.

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A list of Reports from the Committee in this Parliament is included at the back of this volume.

Committee staff

The current staff of the Committee are: Dr Lynn Gardner (Clerk); Dr Celia Blacklock (Second Clerk); Dr Anne Simpson (Committee Specialist); Dr Sarah Bunn (Committee Specialist); Ana Ferreira (Committee Assistant); Robert Long (Senior Office Clerk); and Christine McGrane (Committee Secretary).

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1 Introduction

Background to the Cooksey Review

1. In the March 2006 Budget, the Chancellor of the Exchequer, the Rt Hon Gordon Brown MP, announced a proposal to allocate £1 billion for funding UK health research through a new Single Fund. Under existing arrangements this research is funded in two separate streams through the Medical Research Council (MRC) and through the Department of Health (DH) NHS Research & Development (R&D) function. There has long been widely-held concern that the NHS R&D budget was not being spent effectively on R&D. An independent review, chaired by Sir David Cooksey, was commissioned by the Government to examine the best design and institutional arrangements for this new Single Fund for health research and how these arrangements would be implemented. The terms of reference for the Review included:

a) ensuring that research priorities are closely matched to the Government's health objectives;

b) funding and delivering world-class scientific research in basic, clinical and public health; and

c) the translation of UK health research into economic and health benefits.

2. The final report was published on 6 December 2006[1] and accepted by the Chancellor, who announced in the December 2006 Pre-Budget Report that he would be "taking forward the recommendations of the Cooksey Review".[2]

3. The Review concluded that although good progress has been made in some areas, further work is needed to ensure that publicly-funded health research is carried out in the most effective and efficient way, and to facilitate translation of research findings into health and economic benefits. The report outlined a number of recommendations to the Government. In order to deliver an overarching health research strategy that brings together the separate funding streams administered by the MRC and the NHS Research and Development, it is proposed that two new bodies will be established. These are the Office for Strategic Co-ordination of Health Research (OSCHR) and the Translational Medicine Funding Board (TMFB). The OSCHR will be the central co-ordinating body for all health research (carried out by both the MRC and the NHS) and will report to the Department of Health and the Office of Science and Innovation (OSI). It will set the research budget and submit a single Spending Review bid to the Treasury. It will also work with the pharmaceutical and bioscience sectors, and identify public and private sector projects that address unmet health needs which will be designated 'UK Priority Health Research Projects'. The OSCHR will also develop expedited drug development pathways for new treatments. The existing institutional structures within the MRC will remain unchanged but the National Institute for Health Research (NIHR) will become a real,

1 HM Treasury, *A Review of UK Health Research Funding*, December 2006; www.hm-treasury.gov.uk./media/56F/62/pbr06_cooksey_final_report_636.pdf

2 HM Treasury, 2006 *Pre-Budget Report*, Cm 6984, p 56, para 3.68

rather than a virtual, agency to co-ordinate NHS Research and Development. The TMFB will lead on developing a translational research strategy in order to maximise the economic and health benefits of innovation.

The Committee's inquiry

4. We announced our intention to hold an evidence session with the Review author, Sir David Cooksey, on 6 December 2006. The Committee was particularly interested to explore the recommendations in the Review which will have an impact on the research funding function of the Medical Research Council, and those recommendations aimed at the OSI as part of the overall implementation of the new arrangements. These fall within the Committee's remit to scrutinise the OSI's activities. We also wished to explore more general questions surrounding the health research budget and proposed new mechanisms.

5. The transcript of the oral evidence session held on 24 January 2007 with Sir David Cooksey is published with this Report, along with the written memoranda submitted by seventeen organisations and individuals.

6. Most of the evidence we received (from organisations including The Royal Society, The Wellcome Trust, Guy's and St Thomas' and the South London Maudsley NHS Trust and Universities UK) welcomed the Review.[3] In particular, it is recognised that the UK will benefit from a coherent strategy to maximise the health benefits from the UK's research.[4] **The Committee shares this view and broadly endorses the approach taken by Sir David Cooksey in his wide-ranging review of the UK's health research framework.**

7. In this short Report we offer our comments and observations on particular issues which arose in the course of our oral evidence session with Sir David Cooksey.

3 Ev 12

4 *Royal Society response to the Cooksey Review of UK health research,* Royal Society, January 2007, www.royalsoc.ac.uk/displaypagedoc.asp?id=23824

2 The scope of the Review

8. The scope of the Review was much broader than the original terms of reference. It went beyond proposing new arrangements for the Single Fund to making wider recommendations. For example, Sir David put forward proposals regarding setting the UK's healthcare treatment priorities as well as outlining a number of tasks for OSI to address. He also recommended that OSI should analyse all public and charity funding streams applicable to the translation of health research to identify any gaps. In evidence to us, Sir David accepted that he had gone beyond the original remit but argued that the terms of reference:

> "did ask me to connect our public expenditure on health research with the health of the research community on the one hand, with the delivery of economic healthcare on another, and with the economic impact in an industry as well".[5]

We believe that Sir David was right to exceed his remit and we welcome the broad-ranging nature of the Review. However, we feel that it would have been appropriate to advertise the changes in the terms of reference to attract a broader range of opinions.

9. On the other hand, in some areas, the Review had a distinctly more narrow focus than it might have had. It considered chiefly pharmaceuticals, rather than any wider definition of 'medicine'. Evidence to the Committee from the Royal Academy of Engineering for example, argued that the Review should have been more comprehensive and should have given to other sectors associated with health interventions (such as medical technologies and engineering, preventive medicine, social care and public health research) the same analysis bestowed upon the pharmaceutical industry.[6] **Whilst the pharmaceutical sector is clearly of great importance to the UK's health research output, the Committee is concerned that allied health research sectors such as medical engineering and technology, preventive and public health research should not be overlooked. The DTI and DH must ensure that these sectors are represented within both OSCHR and TMFB.**

5 Q 2

6 Ev 23, 26, 37, 41

3 Proposed institutional and funding arrangements

10. The current combined budget of the MRC and the NHS Research and Development is £1.3 billion. The final budget for the new Single Fund will not be confirmed until the next Comprehensive Spending Review but will be at least £1 billion. Evidence received from the Association of UK University Hospitals, the Academy of Medical Sciences and the Royal Society criticised the absence of any recommendation in the Review on the overall baseline level of funding.[7] Sir David told us that:

> "[…]the £1.35 billion is there[…] That is therefore an increase over what was there previously. It is a very modest increase but it is an increase."[8]

We look forward to the announcement in the Comprehensive Spending Review regarding the Single Fund budget, and expect the current combined budget for the MRC and the NHS R&D function to be at least maintained.

11. Concerns regarding the division of funds between basic, translational and applied research were also expressed to this inquiry by the Academy of Medical Sciences.[9] Sir David recommended that the funding of translational research be increased but that funding for basic research be kept at the current level "until a more balanced portfolio is achieved" as judged by the OSCHR.[10] This suggests that any future funding increase to translational and clinical research may be at the expense of basic research. **We acknowledge and support the importance of translational and clinical research. However, it is essential that the new proposals do not result in decreased funding for basic research.**

12. The Review's proposals include new arrangements for the way in which the MRC and the NIHR bid for research funds and how this money is allocated to each. The OSCHR will submit a single bid to the Treasury for both the MRC and the NIHR. The funding is then allocated to the MRC and the NIHR through the DTI and the DH, according to allocations set for each body as determined by OSCHR. There was concern in evidence from Cancer Research UK that "the institutional arrangements do not become an extra layer of debilitating bureaucracy".[11] The Committee asked Sir David whether OSCHR would increase the administrative burden. He stated that:

> "It gets the money, it sets the strategy, and then it is up to the MRC and NIHR to deliver on that. The decisions will be made in exactly the same way as they are at the

7 Ev 15, 19; *Royal Society response to the Cooksey Review of UK health research,* Royal Society, January 2007, www.royalsoc.ac.uk/displaypagedoc.asp?id=23824

8 Q 11

9 Ev 19

10 HM Treasury, *A Review of UK Health Research Funding*, December 2006, para 4.24; www.hm-treasury.gov.uk./media/56F/62/pbr06_cooksey_final_report_636.pdf

11 Ev 38

moment […] The idea of this is to try and pull the two operations together, to try to overcome a lot of those perverse incentives that stop research moving forward."[12]

13. There was also some concern expressed about the impact of the new arrangements on the MRC and its structures. The Guy's and St Thomas' NHS Foundation Trust, South London and Maudsley NHS Trust and King's College London told us in their joint evidence submission that the MRC "is recognised throughout the world as an organisation that funds the best science through fair and equitable mechanisms driven by strategic goals. We believe that the new single funding body should be based on these principles."[13] In addition the Royal Society recommended that "OSCHR safeguards the highly effective processes for the distribution of funds that are embedded within the MRC, and provides the potential for similar standards of governance to be achieved within the NIHR."[14] **We share the concerns submitted in evidence regarding the impact of the proposed institutional arrangements and the possible effects upon the MRC. We are firmly of the view that OSCHR should operate as a light touch organisation that does not complicate the existing successful administrative mechanisms of the MRC.**

12 Q 20

13 Ev 13

14 *Royal Society response to the Cooksey Review of UK health research,* Royal Society, January 2007, www.royalsoc.ac.uk/displaypagedoc.asp?id=23824

4 Health research in the UK

14. The Review recommends that the strategy set out by the OSCHR will include targets and objectives for the MRC and the NIHR. It will also set UK health research priorities and identify those public and private sector projects that address unmet health needs so that they can benefit from some institutional and procedural advantages, for example faster approval for conducting clinical trials. The Royal Society told us that that reliance on setting health priorities targets from such a top-down approach may divert attention from "more readily soluble and innovative research".[15] We too are concerned that defining targets is not necessarily compatible with funding the most effective research, and Sir David told us:

> "In the report we are very specific about the fact that OSCHR should undertake performance measurement of what is going on. If you are measuring performance, you have to measure performance against specific objectives. We have used the word 'targets' here, but it is performance against objectives. There is no point in measuring performance if you do not have objectives against which to measure it."[16]

We were pleased to hear Sir David's explanation of his use of the word 'targets'. **We support the setting of priorities, but we expect OSCHR to ensure that the best research in all fields is funded and that research outside the priorities is adequately supported. We expect performance monitoring to be done without the use of rigid targets.**

15. The Review discussed the importance of research in the developed world that contributes to the scientific understanding and treatment of diseases that predominantly affect the developing world, particularly malaria, tuberculosis and HIV/AIDS.[17] The Committee noted that there may be a danger that research into these disease areas may suffer as priority would be given to projects that would primarily address UK healthcare concerns. Sir David agreed that part of the research spend should be available for the benefit of developing countries.[18] The allocation for this type of research expenditure would come from OSCHR, as part of its overall strategy to determine funding priorities. **In setting out its joint research plan for the MRC and the NIHR, OSCHR must ensure that research that would benefit the developing world is part of the overall strategy. We recommend that there be clear mechanisms, structures or representations to ensure that there is adequate advocacy of developing world health research priority needs within OSCHR.**

15 As above

16 Q 33

17 HM Treasury, *A Review of UK Health Research Funding*, December 2006, para 5.23; www.hm-treasury.gov.uk./media/56F/62/pbr06_cooksey_final_report_636.pdf

18 Q 61

5 Peer review

16. The role of peer review in evaluating scientific research proposals and in the allocation of funding is an important component of the MRC process. The Cooksey Review recognises the value of the peer review process in funding research, stating that "Day-to-day decision-making will continue to be left to experts through the peer review process".[19] However, it argues that while peer review is highly effective in identifying high quality basic research projects, it can in some instances "inhibit programmes in translational and applied health research."[20] We have some reservations about this, a view shared by some of the organisations who submitted evidence. The Council of Heads of Medical Schools, for example, argued that "It is critically important that the integrity of the MRC system of rigorous peer-review is not compromised under the proposed framework and that the NHS R&D system continues to embrace such existing best-practice."[21] We pressed Sir David on this and were pleased to hear him state that "peer review should apply to everything that is funded."[22] **We welcome the recognition that peer review should remain the primary tool for assessing the scientific rigour of research proposals funded through both the MRC and the NIHR.**

19 HM Treasury, *A Review of UK Health Research Funding*, December 2006, para 5.55; www.hm-treasury.gov.uk./media/56F/62/pbr06_cooksey_final_report_636.pdf

20 As above, para 4.12

21 Ev 18

22 Q 7

6 The pharmaceutical sector and a new drug development pathway

17. The private sector, in particular the pharmaceutical sector, is a major investor in health research in the UK. Cooksey identified the challenges faced by the industry to ensure that their investment delivers new medicines, diagnostics and devices at prices that reward innovation and are affordable to health systems (in the UK and abroad). The Review highlighted three main barriers in the UK to achieving these objectives:

a) a cautious NHS culture with respect to innovation;

b) regulatory barriers which have not kept pace with the science and technology associated with the drug development process;

c) uptake of new medicines and technologies has been limited by the NHS Health Technology Assessment (HTA) which assess their clinical and cost-effectiveness.

18. To lower these barriers, the Review proposed that OSCHR's UK Priority Health Research Projects would be identified at an early stage of drug development and benefit from 'conditional licensing' so that they could be assessed more quickly through clinical trials and thus be brought to market more quickly. This will be facilitated by earlier involvement from the National Institute for Health and Clinical Excellence (NICE). The Report also recommends that increased public funds should be invested in the conduct of more translational medicine (largely in the form of clinical trials) in the UK.

19. In evidence, Sir David outlined the new mechanism he has proposed to involve NICE and the HTA in Phase III of clinical trials in order to make drugs available to more patients and provide better data that NICE can use to reach decisions on whether to allow a drug to be used within the NHS.[23] However, the Association of UK University Hospitals told us that at present "there is no way that any clinical research can be fast tracked. The administrative burden on the investigator and the Trust is enormous when performing this work. As yet, there is no sign that these burdens will be reduced or simplified; this must happen before any fast track system can be developed."[24] **We support the principles behind fast-tracking crucial research. However, we remain somewhat sceptical about the ability of the current structures to respond to the demands this would make on them. This is an area in which we will monitor developments.**

23 Q 48

24 Ev 16

7 Implementation

20. In January 2007, seven weeks after the publication of the Review, Sir David told us that the early stages of implementing his recommendations had begun. The interim Acting Chair of OSCHR, Professor John Bell, appointed by the Government in December 2006, will lead OSCHR's work on setting the joint UK's health research strategy. Part of this process involves OSCHR submitting a joint bid on behalf of the MRC and NIHR to the 2007 Comprehensive Spending Review (CSR) which will cover departmental allocations for 2008–09, 2009–10 and 2010–11. Sir David told us that:

> "The team at OSCHR is being put together very rapidly and they have got to formulate their spending review bid within the next very few weeks, so there is a huge amount of effort going on there. I have been surprised at the speed at which the various recommendations are being addressed and, in some cases, already starting to be implemented. I think the signals are very positive at this moment".[25]

We welcome the initial stages in implementing the Review's recommendations. The Committee will take a close interest in reviewing progress and how the new institutional arrangements will work in practice.

25 Q 68

Conclusions and recommendations

The Committee's inquiry

1. The Committee recognises that the UK will benefit from a coherent strategy to maximise the health benefits from UK research and broadly endorses the approach taken by Sir David Cooksey in his wide-ranging review of the UK's health research framework. (Paragraph 6)

The scope of the Review

2. We believe that Sir David was right to exceed his remit and we welcome the broad-ranging nature of the Review. However, we feel that it would have been appropriate to advertise the changes in the terms of reference to attract a broader range of opinions. (Paragraph 8)

3. Whilst the pharmaceutical sector is clearly of great importance to the UK's health research output, the Committee is concerned that allied health research sectors such as medical engineering and technology, preventive and public health research should not be overlooked. The DTI and DH must ensure that these sectors are represented within both OSCHR and TMFB. (Paragraph 9)

Proposed institutional and funding arrangements

4. We look forward to the announcement in the Comprehensive Spending Review regarding the Single Fund budget, and expect the current combined budget for the MRC and the NHS R&D function to be at least maintained. (Paragraph 10)

5. We acknowledge and support the importance of translational and clinical research. However, it is essential that the new proposals do not result in decreased funding for basic research. (Paragraph 11)

6. We share the concerns submitted in evidence regarding the impact of the proposed institutional arrangements and the possible effects upon the MRC. We are firmly of the view that OSCHR should operate as a light touch organisation that does not complicate the existing successful administrative mechanisms of the MRC. (Paragraph 13)

Health research in the UK

7. We support the setting of priorities, but we expect OSCHR to ensure that the best research in all fields is funded and that research outside the priorities is adequately supported. We expect performance monitoring to be done without the use of rigid targets. (Paragraph 14)

8. In setting out its joint research plan for the MRC and the NIHR, OSCHR must ensure that research that would benefit the developing world is part of the overall strategy. We recommend that there be clear mechanisms, structures or

representations to ensure that there is adequate advocacy of developing world health research priority needs within OSCHR. (Paragraph 15)

Peer review

9. We welcome the recognition that peer review should remain the primary tool for assessing the scientific rigour of research proposals funded through both the MRC and the NIHR. (Paragraph 16)

The pharmaceutical sector and a new drug development pathway

10. We support the principles behind fast-tracking crucial research. However, we remain somewhat sceptical about the ability of the current structures to respond to the demands this would make on them. This is an area in which we will monitor developments. (Paragraph 19)

Implementation

11. We welcome the initial stages in implementing the Review's recommendations. The Committee will take a close interest in reviewing progress and how the new institutional arrangements will work in practice. (Paragraph 20)

Formal minutes

Wednesday 7 March 2007

Members present:

Mr Phil Willis, in the Chair

Dr Evan Harris	Mr Brooks Newmark
Dr Brian Iddon	Graham Stringer
Chris Mole	Dr Desmond Turner

The Committee deliberated

Draft Report, *The Cooksey Review*, proposed by the Chairman, brought up and read.

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

Paragraphs 1 to 20 read and agreed to.

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

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.

Ordered, That the Chairman do 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.

[Adjourned till Wednesday 14 March at a quarter past nine o'clock.

Witnesses

Written evidence

Reports from the Science and Technology Committee in the 2005 Parliament

Session 2006–07

First Report	Work of the Committee in 2005-06	HC 202
Second Report	Human Enhancement Technologies in Sport	HC 67
First Special Report	Scientific Advice, Risk and Evidence Based Policy Making: Government Response to the Committee's Seventh Report of Session 2005-06	HC 307

Session 2005–06

First Report	Meeting UK Energy and Climate Needs: The Role of Carbon Capture and Storage	HC 578-I
Second Report	Strategic Science Provision in English Universities: A Follow–up	HC 1011
Third Report	Research Council Support for Knowledge Transfer	HC 995-I
Fourth Report	Watching the Directives: Scientific Advice on the EU Physical Agents (Electromagnetic Fields) Directive	HC 1030
Fifth Report	Drug classification: making a hash of it?	HC 1031
Sixth Report	Identity Card Technologies: Scientific Advice, Risk and Evidence	HC 1032
Seventh Report	Scientific Advice, Risk and Evidence Based Policy Making	HC 900–I
First Special Report	Forensic Science on Trial: Government Response to the Committee's Seventh Report of Session 2004-05	HC 427
Second Special Report	Strategic Science Provision in English Universities: Government Response to the Committee's Eighth Report of Session 2004-05	HC 428
Third Special Report	Meeting UK Energy and Climate Needs: The Role of Carbon Capture and Storage: Government Response to the Committee's First Report of Session 2005-06	HC 1036
Fourth Special Report	Strategic Science Provision in English Universities: A Follow–up: Government Response to the Committee's Second Report of Session 2005-06	HC 1382
Fifth Special Report	Research Council Support for Knowledge Transfer: Government Response to the Committee's Third Report of Session 2005–06	HC 1653
Sixth Special Report	Watching the Directives: Scientific Advice on the EU Physical Agents (Electromagnetic Fields) Directive: Responses to the Committee's Fourth Report of Session 2005–06	HC 1654

Oral evidence

Taken before the Science and Technology Committee

on Wednesday 24 January 2007

Members present:

Mr Phil Willis, in the Chair

Dr Evan Harris
Dr Brian Iddon
Mr Brooks Newmark
Dr Bob Spink
Dr Desmond Turner

Witness: **Sir David Cooksey,** gave evidence.

Q1 Chairman: We very much welcome Sir David Cooksey to the Science and Technology Select Committee this morning. May I start, Sir David, by saying that the Committee not only welcomes but compliments you on an excellent report, in terms of the work that you have done in looking at the whole of the medical research, both in terms of the basic research and the translational research. We, as a Committee, are very grateful to you for that work. I wanted to put that on record, before we start finding fault!
Sir David Cooksey: I am very grateful to you for that positive start.

Q2 Chairman: You are certainly very welcome. Could I start by saying that the final report went far beyond the initial terms of reference. Why did you feel that it was necessary to go on to design institutional arrangements for the public funding of health research in the UK? You seemed to go beyond what was the original remit.
Sir David Cooksey: I think that I would dispute that. I agree with you, I went beyond the original remit; but if you look at the terms of reference that I was given, it did ask me to connect our public expenditure on health research with the health of the research community on the one hand, with the delivery of economic healthcare on another, and with the economic impact on industry as well. It therefore broadly stretched across that horizon. I probably overstepped the mark in the work we did on the development of a new drug development pathway, but that was given a very strong welcome by all concerned. So I do not think it was untoward to be doing that.

Q3 Chairman: We will return to that particular issue a little later. I think the term "everybody welcomed" it is perhaps an overstatement, but we will certainly come back to that. In terms of MRC, what discussions did you have with MRC about the impact of your proposals?
Sir David Cooksey: Throughout the development of our ideas and proposals we were in touch with the MRC, probably at least once every other week, and the ideas were well ventilated to the MRC before they were published.

Q4 Chairman: There is still a real concern—perhaps you would accept, perhaps you would not—by MRC, and people who are particularly interested in retaining the excellence of basic research, that perhaps that has been compromised by your proposals. How would you respond to that?
Sir David Cooksey: The basic science community are very, very successful at defending their patch, and they were bound to respond like that. I have made it very clear in the report that their current level of funding should be sustained. I have also made it clear that I value greatly the excellence of the research base. However, one of the things that we have done is to try and look at strategic priorities for health and to try to relate that back through to the funding stream.

Q5 Chairman: If you look at the whole of health research as a continuum rather than two separate pots—and I think that is the tenor of your report, is it not?
Sir David Cooksey: Yes.

Q6 Chairman: That we should not look at it as separate activities but as one activity which leads backwards and forwards into each area. Do you not see that there is a real danger that in fact the translational research element of it, the clinical research element of it, may well swing, if you like, into MRC's traditional area, and therefore lessen the impact of our basic research in terms of medical health?
Sir David Cooksey: I think I disagree with you fundamentally on that. What we concluded was that there was excellent basic research done. It was virtually all investigator-led, so that the focus of the research was not necessarily on the areas that were most in need of being resolved; but that is the nature of the way we arrange our science funding in this country. One of the real problems we saw, however, was this hiatus between the basic research community and what they were achieving and the lack of drawing that through for patient and economic benefit. A lot of the basic research discoveries that we make that should find their way into patient benefit do not necessarily do so. This was a flaw in the system which was identified time and time again in our consultation process.

Q7 Chairman: You also identified that there was a real concern not only about the way in which money was being spent within NHS research, or not spent in terms of research—used for bolstering up other activities, and that is not a criticism but just a statement of fact—but also one of your concerns was the excellence of translational research or clinical research, and yet you do not appear to be making any recommendation in the report. For instance, that the methodology of peer review, which is at the heart of basic research through MRC, should be extended into other areas through the single fund. How do you get excellence?
Sir David Cooksey: I am sorry, I cannot put my finger on the exact paragraph at this moment in time, but what we do say in the report is that peer review should be applied throughout the research process but that a different approach to peer review should take place in clinical and applied research, rather than the very basic process that is applied to basic research. Here, the issue is that, in basic research, you can understand the quality of the research proposal and the peer review process gives you a binary gate which says yes or no as to whether or not you proceed. Then the funding board of the MRC will choose what they consider to be the best proposals that have got to go through that gate—since not all of them get funded. However, when you get to the clinical development of a basic research discovery, you have a situation where the process becomes much more iterative and you want to design a clinical development programme and clinical trials; but very often you have to go back and redesign those as you learn during the process. The current manner in which peer review is applied in the basic research process would create a situation where, unless you could see your way through the entire clinical development programme on day one, it would be very difficult to get peer review acceptance of that proposal. What we have proposed in the report, therefore, is a more iterative approach: that a different application of peer review should take place. However, it is absolutely agreed between ourselves and Sally Davies and her team at the NHS R&D function that peer review should apply to all clinical research that is funded.

Q8 Chairman: I think it is important to put that on the record. In terms of your definition of 'medicine' which you used in the report—in fact this has been a fairly widespread criticism and you have also mentioned it earlier—it seems to refer mainly to pharmaceuticals and not, for instance, to preventative medicine or health technologies. Why do they get so much less attention in the report than pharmaceuticals? And is that a fair criticism?
Sir David Cooksey: It is a fair criticism. It is not just pharmaceuticals. I would take my criticism a bit further since there is insufficient reference to diagnostics and to medical devices as well as to the other therapies—which gets into the point that you are making about preventative medicine. Without having a rather laborious re-statement of all of the issues time and time again, I am afraid we used 'pharmaceuticals' as a bit of a shorthand for the whole thing. There are sections in the report, however, which deal with HTA, with preventative medicine, and so on. I totally agree with you: that it is very important. What we were asked to do was to ensure that, in putting the new structure in place, we put in place what was likely to have as much economic benefit as patient benefit and social benefit. It is easiest to crystallise one's proposals in terms of the pharmaceutical industry, and that is why that was done.

Q9 Chairman: It is just that, when you look at the health economy and you look at roughly £8 billion which is spent on drugs within the Health Service and then you look at how much is spent in terms of technologies to support patient care, it is a tiny fraction of the drugs bill. We understand the reason for that, but I think many would argue that there is a need to give greater emphasis to the huge technological changes that are occurring which can improve healthcare.
Sir David Cooksey: Yes, and there is a section in the report about that which explains how we have actually denied ourselves a strong medical devices industry in this country, because we have been very bad at using the purchasing power of the Health Service to succour that type of industry.

Q10 Chairman: It was fairly obvious, when the Chancellor made the original statement in terms of announcing the review that you conducted, that there were two lumps of money which initially added up to about £1.3 billion. When the Chancellor said "around £1 billion"—and in fact we have had the former secretary of state, Alan Johnson, in front of us who again reiterated that it would be around £1 billion, and that is what has come out of your report—what has happened to the missing £0.3 billion? Is that not a cut in the overall funding?
Sir David Cooksey: I think the reason why the Chancellor mentioned £1 billion was because he did not want to constrain us to taking forward inside the ring fence everything that was there at the moment. In fact, if you read the report carefully, we did recommend that everything that was in the ring fence—be it in the OSI ring fence of MRC or the NHS R&D budget ring fence—was included. So the £1.35 billion is there and, on top of that, we recommended a number of issues, such as that the funding of clinical fellowships and clinical training budgets, should be taken inside the ring fence. That is therefore an increase over what was there previously. It is a very modest increase but it is an increase.

Q11 Mr Newmark: It is not an increase, because you are just shifting something from outside the ring fence to inside the ring fence.
Sir David Cooksey: We were talking about why £1 billion rather than £1.35 billion. What I am trying to say is that the £1.35 billion is intact as far as I am concerned, plus a little more, which is an area which, rather like the NHS R&D budget, has been historically raided. There is no way, if you want to build up a good clinical research capacity in this

country, that you use it as a pot of money to raid. That is the reason why we have suggested bringing the MPET budget inside the ring fence.

Q12 Dr Turner: Could I ask you to comment on this? The cynic in me tells me that a lot of what was identified in the past as NHS R&D budget was, shall we say, not spent as effectively on research as it might have been and has gone to other NHS-related purposes. Can you comment on the effectiveness and the spending of the existing NHS R&D budget? Do they actually fund up? How much of it is funding what we would recognise as research or supporting research fellows, which is a perfectly reasonable thing to do? Does the figure that you envisage actually embrace all the genuine research-related activity and effective research activities currently being practised under the heading of the NHS R&D budget?

Sir David Cooksey: If we go back to the report I did three years ago, called *Biosciences 2015*, which was the Biosciences Innovation and Growth Team report, it identified that, at best, only £70 million of the NHS R&D budget was spent on pure R&D. It all flowed through the trusts. The result of this was that some trusts claimed that that budget was being spent on providing infrastructure to support R&D, and others just raided that budget for frontline services. I agree with you entirely. I think that the Chancellor became very frustrated with this situation because he had tried to put more resources into this area, and this is the reason why he ring-fenced the budget. If you look at what has actually happened since April of last year and if you were to have Sally Davies, the NHS R&D Director, alongside me, she would say to you that the ring fence has been extremely effective; that, at long last, they are able to plan R&D on a coherent basis. I would need to confirm these numbers, but I think that in year one, which is the current financial year that we are in, 50% of it was moved to the centre and the R&D is then being funded outwards from the centre. That increases to 90% next year and to 100% the year after. I think that ring fence will be very effective. It was one of the reasons why we required in the report that the NIHR moved from being a virtual agency to being a real agency; that is because you can then get a separate vote on that funding and ensure that that money stays inside the ring fence.

Q13 Dr Turner: It would be a mistake to focus too much on the £1.3 billion headline figure, because it is not a true expression of reality.

Sir David Cooksey: I agree with that. If I could take that a little further, there was a huge temptation for me to make a very strong case, as I could do, for increased funding for this area; but, with the NHS budget being so out of balance at this moment in time, it was clear that I was not going to get an immediate response from the Chancellor on that. What we agreed was that we should concentrate on the forthcoming Spending Review, to try and ensure an increase in the budgetary provision for this area. I think that the Treasury is reasonably sympathetic to that, as long as we put a good case together. The evidence in the report from what has happened with the Canadian Institute for Health Research and, on a much grander scale, the NIH in the United States, shows very clearly that if you want to achieve the sorts of changes we are talking about you do need to lubricate that process with more money.

Q14 Dr Harris: On the question of peer review, there is barely a page in your report on peer review, yet you make what is quite a substantial critique there and it is hard for people reading it to see the evidence of your research—in prestigious journals, and so forth. Would you accept that there is more work required on peer review, both by the Research Councils and possibly by other people—arguably this Committee might do something—before any recommendations are implemented with regard to peer review, because it is such a sensitive matter?

Sir David Cooksey: I think it is a system that is working reasonably well at this moment in time. What I was describing earlier was a situation where it needs to be adapted for various stages in the research continuum. However, I understand that RCUK at the moment is undertaking a review of the whole peer review process. We trailed that in the report, and I think it is worth waiting for that to come out, and then I think it is a subject that should be debated.

Q15 Dr Harris: I will come on, after Mr Newmark on the new institutional arrangements, to explain the sensitivities of people in research who feel they have to respond to a top-down diktat on research subjects. However, I just wanted to pick up one other thing which the Chairman mentioned. It is this issue about your not necessarily narrow definition of restricting it to pharmaceuticals in healthcare interventions. You said that you used it as an example, and your own background is as an investor in biotech and, arguably, early stages of drug development. Would it be fair to say that that was an influence on your choosing pharmaceuticals as the main example of where you wanted to speed up the ability of investors to see fruition, as well as patients seeing the benefits of research?

Sir David Cooksey: We have invested in a considerable number of devices companies and other areas, including companies offering innovative procedures and so on. So it is not just pharmaceuticals as far as my own business is concerned.

Q16 Dr Harris: I accept that. Would you say that at least some people might say, "Well, he would say that because his interest is in speeding up and reducing the costs of developing something that becomes profitable"—as is your right. Therefore, in a sense you have, not necessarily a conflict of interest but maybe a bias in saying, "The key thing is to speed these things up, and if we skimp on safety trials and regulation a little bit, then that's all right because the key aim is to give a return on investment sooner".

Sir David Cooksey: I object very strongly to you using the word 'skimp', because that is not what the report says.

Q17 Dr Harris: The term . . . ?
Sir David Cooksey: You said "skimp on trials". Perhaps we will come back to this later, when we discuss the new drug development pathway plan. I will leave it there. We were asked under the terms of reference to look at the economic impact of all of this, as well as the effect on the research community and on patient health. The situation is that healthcare and its delivery is a sure-fire growth industry (if you like to call it an industry) which is going to grow progressively year after year from now onwards, as it has done in the past. If you look at the numbers, it is quite shocking. That a business that is increasing in size, productivity, in both the delivery of healthcare and in the healthcare industries, particularly the pharmaceutical industry, has gone backwards year by year for the last 15 years. With the increasing public expenditure in healthcare and decreasing productivity, if you continue this trend out into the future it shows that—depending in which country you are, it will take longer or shorter—40 or 50 years, for the entire GDP of this country will be spent on healthcare. That is totally unsustainable, because who is going to pay for it? Therefore, we did feel that it was incumbent on us to look at ways in which there could be a step change in productivity, using new methodologies to achieve better and more productive outcomes. That is why we call for the adoption of the facilities available, or that can be made available, from *Connecting for Health* to make a huge difference to the way in which you can approach trials. We concentrated quite a lot of the report on the HTA exercise, in order to try and look at methodologies needed to help reverse that downward spiral of productivity over the years.

Q18 Mr Newmark: There is a new tier of administration being created called OSCHR. The purpose of this, I understand, is to help the administration of research funding. First, how will the joint line of reporting to the Department of Health and the DTI from a single body actually work in practice?
Sir David Cooksey: The concept of OSCHR is that it is a very light-touch organisation. It will have a small board overseeing it, and we have been fortunate in getting John Bell as the interim chair of that board. It will use people drawn from the Department of Health and OSI to develop the strategic requirements of the Government in health research in this country. We can set the strategy, but that is a joint effort by these people coming in from both sides of the equation, with both the chairmen and the chief executives of the MRC and NIHR sitting on the board of OSCHR. Its role is to set the strategy, to work with MRC and NIHR to develop a single Spending Review bid for the whole of medical research. The Spending Review bid therefore comes out of OSI and DTI and goes directly to the Treasury from OSCHR. Then the funding streams come back down, through the Secretaries of State for Health and the DTI and through the two accounting officers, who are Sir Keith O'Nions in OSI and Sally Davies in the Department of Health, in order to make sure that you have the same accountability. We felt this was very important, because if you look, for instance, at the way in which successful clinical research is developing at the moment—and basic research for that matter—it involves more and more of the use of interdisciplinary teams working in this area. We wish to maintain the strong relationship of MRC with RCUK and the other Research Councils, so that we can maintain that interdisciplinary working.

Q19 Mr Newmark: If I cut through things, you talked about productivity and what flows from that is value for money. How will creating another tier deal with the issue that you have highlighted, which is the problem of productivity from the Treasury standpoint on assuming value for money? I guess the third thing is—when I think about another tier of bureaucracy, as I would call it, though I can see the argument you have put forward—how does it prevent delays in administering research proposals? Because you have another tier thrown in there, in the process.
Sir David Cooksey: It will not make any difference to that at all.

Q20 Mr Newmark: So delay is not an issue?
Sir David Cooksey: The research proposals will not come anywhere near OSCHR. It gets the money, it sets the strategy, and then it is up to the MRC and NIHR to deliver on that. The decisions will be made in exactly the same way as they are at the moment, with one exception: the cross-cutting board, the Translational Medicine Funding Board, which will cut across the two. The idea of this is to try and pull the two operations together, to try to overcome a lot of the current perverse incentives that stop research moving forward.

Q21 Mr Newmark: Is it streamlining research spending? Is that what it is about? Is it that you are allocating? I am not quite sure what the impact of this is.
Sir David Cooksey: The impact is that the research spending will be allocated, yes, between MRC and NIHR by—

Q22 Mr Newmark: Allocated but not necessarily streamlined?
Sir David Cooksey: We talk a lot about streamlining in terms of cutting the size of boards, cutting out a lot of bureaucracy, and the idea is certainly to achieve streamlining.

Q23 Mr Newmark: That helps with your issue of productivity then. You talk about productivity and that that is an important issue. I am a simple person. I see another layer going in there. I am trying to understand how that is streamlining; how that is giving better value for money; how that is giving greater productivity.

Sir David Cooksey: Because it brings greater focus on the areas of need that we need to address.

Q24 Mr Newmark: So do you see it as an outcome from that? More productivity, better value for money?
Sir David Cooksey: Absolutely.

Q25 Chairman: May I just interrupt on that? Can I deal with the issue of financial accounting? It seems to me that you now have the Treasury to whom you have to account. The money then comes down to DTI and Health, who also have an accounting procedure. It then goes to OSCHR, who will also have to have an accounting procedure. It will then go to MRC or NIHR, who will also have to have an accounting procedure; and then down to the university or the research institutes, who will also have an accounting procedure. That is five sets of accounting for one lot of money. Surely that increases bureaucracy?
Sir David Cooksey: No, I am sorry, that is not the way it works. Essentially what we are doing is pulling it together. At the moment, you have the odd situation where the Department of Health, within its huge budget, applies in the Spending Review for a certain amount to be allocated for research and development. The OSI obtains funding for the entire Research Council budget. That is happening at the moment. All we are doing is just picking those two bits out of the NHS R&D budget and the MRC budget and putting them into a separate spending bid. The only increase in bureaucracy, or it could be seen as an alternative bureaucracy, is that separate application—

Q26 Chairman: For OSCHR to be effective it has to have a financial accounting system, does it not, because it needs to be able to move funds along that continuum in order to support wherever the emphasis is?
Sir David Cooksey: It will do exactly the same thing that Sir Keith O'Nions does in the OSI. He gets the OSI budget and then he decides how much will be needed for each Research Council. As far as OSCHR is concerned, what it will do is to decide how much goes to the NIHR and how much goes to MRC, and that will be it. That will be decided for the next Spending Review period. The actual funding does not come through OSCHR at all. OSCHR will not receive any funds at all. It will, as directed by OSCHR, flow through to the two secretaries of state and through the two accounting officers. The accounting officer stream and the whole system that is in place at the moment will continue exactly as it is at the moment, and that will not add to the bureaucracy or the layers of accountability in the system.

Q27 Mr Newmark: I look forward to seeing that work in practice.
Sir David Cooksey: There is a very complex diagram in the report.

Q28 Mr Newmark: I hear what you say. I have two other brief questions. Health interventions range from drugs to medical devices. How much scope is there for other Research Councils, for example the Engineering and Physical Research Council, to be more closely involved in OSCHR, given their record of interdisciplinary research?
Sir David Cooksey: To be involved in OSCHR?

Q29 Mr Newmark: Yes.
Sir David Cooksey: I certainly hope that OSCHR will be open to them, in terms of communicating with them. I mentioned earlier that one of the principal reasons for organising OSCHR as it is is to keep the MRC inside the Research Councils' UK organisation, which is really where that communication takes place.

Q30 Mr Newmark: What mechanisms could be considered to include significant funders of health research from the charitable sector in the agenda for a co-ordinated health research strategy?
Sir David Cooksey: For instance, we are recommending—and I believe this is proceeding—that one of the external board members of OSCHR should be a representative of the medical research charities. It is incredibly important to keep as much coherence as possible between what OSCHR is trying to do and what the medical research charities are doing, because they are such an important funding stream for basic research.

Q31 Mr Newmark: Again, part of your remit is to present a better use of funding in your decision-making. Is that why it is important to have that connection with them?
Sir David Cooksey: Yes, and it is also to make sure that, whilst a degree of competition is healthy between different research groups who have broadly the same objectives, what one wants to do is to make sure that in terms of the resources we have available in the UK—and they will never be sufficient to cover the ground that we would like to—we have a strategy for deploying the overall resources we have which gives the best possible improvement in health benefits in this country.

Q32 Dr Harris: You state in your report that you want to see targets imposed for the MRC and the NIHR, to drive an increasing proportion of funding over time to research that involves working across interdisciplinary boundaries. As far as I can tell, you do not say in the report what evidence you have that targets are the best way of achieving that and how you deal with the problem of targets distorting behaviour in an adverse way. You get gaming and re-badging and behaviour nearer target being altered, in order to achieve the target at all costs. Do you give any pause for thought—at a time when targets are going out of fashion—for suggesting for the first time ever that, in the context of peer review, however you define it, this will be target-driven, not necessarily best research-driven?

Sir David Cooksey: I think you have a situation at the moment where there are targets but they are set in a slightly different way from the way you have just described; inasmuch as, if you look at the MRC's various funding boards, the MRC council decides how much money will go to each of those. For instance, there will be very different percentages of successful applicants to the different boards, because the money is more freely available for certain areas of research than it is for others. You therefore have a situation where, by resource allocation, you are targeting at this time. I think that what we were trying to do was to extend the system right across the spectrum, because it is less specific in the NHS R&D function.

Q33 Dr Harris: I do not think that you can say that budget allocation is a target, because you say that the MRC and NIHR should allocate an increasing proportion of funding over time. That is fine; that could be a desire, presumably based on there being something to fund. I am sure that is what they might want to do, but then you say that you are going to do that by setting targets. Not monitoring performance and asking them to justify the rate at which they are doing it, but saying, "In five years' time you ought to reach this". The implication—because that is the way the Government runs targets—is that heads will roll if they do not. It could be argued that that is not compatible with funding the best research, because you are looking over your shoulder about whether or not you will meet your targets.

Sir David Cooksey: In the report we are very specific about the fact that OSCHR should undertake performance measurement of what is going on. If you are measuring performance, you have to measure performance against specific objectives. We have used the word 'targets' here, but the repeat calls for performance against objectives. There is no point in measuring performance if you do not have objectives against which to measure it.

Q34 Dr Harris: I am sorry, we could get into a debate about metrics. Clearly you measure performance under a metric. You measure it against something; but you can perfectly adequately do that without a target. Most forms of performance monitoring in business and in the public sector do not require there to be targets, which is a yes or no binary thing—"Do you reach it or not?" Some people would argue that sophisticated performance management tries to avoid distorting, yes/no, "Have you reached a target or not?".

Sir David Cooksey: I think we would agree with each other that our use of language is not intended to create false objectives in the system. I agree with you to that extent.

Q35 Dr Turner: Your report, quite rightly, sets great store by translational medicine. Of course, that means different things in some cases to different people. I would like to know what you think of as translational medicine and translational research. Perhaps you could spell out to us why you suggest that, in addition to OSCHR, you should have a translational research board, to make sure that translational research is carried out effectively?

Sir David Cooksey: As far as I am concerned, translational medicine—and we identify two gaps in translation in the report—is taking basic research discovery and developing that discovery, not necessarily purely for the advancement of the scientific ideal but for the practical application to the healthcare system and to patients, in terms of improving their healthcare outcomes. It is the applied end of the research continuum. In describing the two gaps in translation, we were identifying the fact that there is very little incentive in the current way in which we organise basic research for basic researchers to go further down the system into the applied arena. It is simply because so little credit is given to them in the Research Assessment Exercise for doing so that they can actually lose out in terms of research funding by taking their research discoveries further. There is a second problem, which is that the National Health Service is a very conservative, slow adopter of new therapies. There is a real problem in getting the adoption of successful research discoveries into regular use in patients to achieve the research continuum.

Q36 Dr Turner: I totally agree with you, Sir David, in the two problem areas that you have identified. Would you agree with me that it is equally important in terms of medical technologies as to simple molecules, or complex molecules even? In fact, most people, when they think of translation, think of 'drug'. I think that there is more to it than that. Would you agree that there is? Also, the fact that it needs to an extent to be a two-way process, so that clinical medicine offers basic scientists or basic technologists with the problems that they can help solve? Do you subscribe to this popular approach which says that you must put everybody together, so that they can share the same team in order to make this work?

Sir David Cooksey: We have a whole-page box in the report about the Weatherall Institute of Molecular Medicine at Oxford, where, in the same building, you have the basic researchers on one side of the building and you have the applied researchers, the clinical people, on the other side of the building. They all meet in the middle, in the tearoom, for discussion. Once every two weeks they have a seminar to debate a particular area of unmet clinical need. To those debates are invited people from other disciplines; it may be from physics, chemistry or engineering—whatever is needed to get to a solution. The situation there is that you have interdisciplinary teams naturally forming to take an approach to resolving those particular unmet clinical needs, which develop over time. Frequently, in the early stages of that process, the basic researchers are obviously much more involved. It is a real bedside-to-laboratory-and-back-to-bedside approach to the problem, which I think is very constructive and makes a big difference. You can see that in other places as well. The Hammersmith is another hospital where this really does take place effectively.

Q37 Dr Turner: I think the original model for that is seen at NIH in Bethesda.
Sir David Cooksey: Yes.

Q38 Dr Turner: Would you agree that, in order for this to work effectively, you need a minimum critical mass? It has to be of a certain size and involve a minimum number of disciplines, whichever they may be, in order to get these sorts of sparking interactions?
Sir David Cooksey: Exactly so, and this is why, in the evolution of *Best Research for Best Health* in the National Health Service, the identification and funding of the five centres of biomedical research excellence have been proposed and now identified, and that whole process is going forward. It completely builds on the thesis you have just proposed to me.

Q39 Chairman: Could I ask, Sir David, were you disappointed therefore that you were not able to announce, or the Government was not able to announce, on the same day that your report came out that the move of NIMR to the Temperance Hospital site and UCL was part of that vision? Because it must surely be part of the vision that you have put forward in the report.
Sir David Cooksey: Yes.

Q40 Chairman: Were you disappointed?
Sir David Cooksey: I was not disappointed because I was not expecting it. I think that whole—

Q41 Chairman: Do you support the view that Dr Turner has just put forward, in terms of that?
Sir David Cooksey: Absolutely. Just taking that a little further, it is very interesting that NIMR and the LMB at Cambridge are held up as two major examples of success in this area. LMB is embedded in Addenbrooke's Hospital and enables exactly the process we have just described to take place. I think that NIMR will benefit enormously from getting embedded into the campus where real patients are available right next door. From that point of view, I am all in favour of that type of move. Interestingly, the way in which the MRC funds those two bodies is on a quinquennial basis, without their going out to peer review on every single grant application. In other words, the researchers' teams that work in those institutions have a degree of freedom and a guarantee of funding which is much greater than your average investigator who has to rely on going to the MRC or to one of the medical research charities to get funding for his project or programme grant. As a result, the freedom to think across boundaries and to undertake more innovative research is actually much stronger in those institutions, and I think there is quite a lot to learn from that. You get the same sort of feel of what is going on at the Weatherall Institute, as I have just described, and I think that these biomedical research centres with quinquennial funding will find it much easier to make the right decisions in that area.

Q42 Dr Turner: Clearly it allows them much more stability, allows them to take much more risk—
Sir David Cooksey: Absolutely.

Q43 Dr Turner: . . . and allows them to pursue longer-term objectives than the response-mode funding system allows. There is also the issue which you raise of the priority of different research areas. I do not have to tell you that there are fashionable areas that people can get into relatively easily and make a contribution, and others which are very much more difficult and virtually impossible to approach under the response mode, because there are just not enough handles to grip on. The obvious case is ME.
Sir David Cooksey: Yes.

Q44 Dr Turner: How do you view the relationship between funding or directing funding into unfashionable but necessary areas of research and areas which are fashionable, which are active, from which you do not want to withdraw resource either?
Sir David Cooksey: This is why we proposed prioritisation. It is very easy to pile into popular areas, as you have just described, and sometimes one wants to give people the incentive to move into the areas which have a profound effect on human health or the economy. We need to ensure that we do devote sufficient resources to that area, to make as much progress as we can. I think we have to temper this with a real understanding that, whilst you might like to work solely on the highest priorities, one does not necessarily have the optimum resources available in this country in order to do that. You therefore have to look at this prioritisation against the capabilities that we have and also what is happening elsewhere in the world, so that one does not necessarily spend vast amounts of money in areas in which we can have a pretty good understanding that other people may get there first.

Q45 Dr Turner: You also refer to the importance of small businesses in R&D initiatives. Technologies tend to be the most important here, I think, and also bioscience spin-outs, recognising of course that, as you have already said, the NHS is rather conservative in adopting new therapies or therapeutic technologies. What would you like to see put in place to ensure that (a) these R&D initiatives are better supported, and (b) the Health Service is much more proactive and effective in taking them up and applying them? Because more often than not these technologies are not only therapeutically effective, in the long term they also save money; so there is a double advantage in them.
Sir David Cooksey: I could talk for an hour on this particular subject!

Q46 Chairman: Please do not, Sir David!
Sir David Cooksey: I would like to paint one or two bits of background in here. Clearly the theme running through this report is that this area—be it biotech companies, devices, or the delivery of all sorts of alternative therapies—is a prime knowledge-based industry and it is an area in which we can

succeed if we get it right. However, we have to make it attractive for companies to set up and to develop new ideas in this country. What is very necessary to understand is that these companies can go anywhere they want to. It is clear that there is now only one major pharmaceutical company in the world that makes its decisions about where it carries out its clinical trials here in the UK. All of the others make those decisions elsewhere. That is very dangerous for us in terms of developing our industry because, unless we are prepared to make this a very attractive place to undertake clinical development of new therapies, the companies will go elsewhere. We look to the United States and see what is relatively a much more successful biotech industry over there. Yet the thing that came as quite a shock to me when we visited the National Institute of Health in the United States, and is mentioned in the report, is that the NIH is spending $4.2 billion a year on clinical trials. It is no wonder that their embryonic companies succeed over there, if they are having this huge input into the drug development process from the NIH. We do not have that advantage to anything like the same extent in this country. We really do have to create an environment that it is attractive. The things that will make it attractive are getting *Connecting for Health* right—this is absolutely vital—and making sure that there is good R&D access to it. That can enable us to get access to patients for clinical trials much more quickly than we do at the moment, and more successfully. Much more importantly, it will enable us to undertake the pharmacovigilance that is necessary during the evolution of a trial and in Phase IV, after the drug has been released, so that we can really understand the implications of that drug on a broader and broader patient base, and make sure that if there are problems they are identified earlier. This is why I rejected that remark about 'skimping' earlier, because in fact what we are looking at is something which can make trials much safer, not less so.

Dr Turner: We could pursue this all morning very happily—

Chairman: But we are not going to!

Q47 Dr Turner: One final quickie. Would you expect your Translational Medicine Funding Board to get involved and facilitate these processes?

Sir David Cooksey: Absolutely, and that is fundamentally what it is for.

Q48 Dr Spink: First, I apologise, because I should perhaps have declared an interest. My son is a neurosurgeon and therefore may be involved in these areas. Did you consider during your review, Sir David, the operation of NICE on translational research? Whether the operations of NICE can pull research through or make translational research less likely?

Sir David Cooksey: The report has a considerable amount to say about NICE and about health technology assessment which is used in the NICE process, because we consider that this is a very important part about the development and evolution of new therapies. However, it does need to be involved in such a way that it improves the process rather than delays it, which is what it has done historically. In the proposals for a new drug development pathway, we suggest that NICE is brought in at the design of Phase III clinical trials, in order to make sure that we start to capture the information that they require as early in the process as we can. Obviously, the HTA will be involved in doing the assessment of that. We also suggest in the report that we can look at the prospects for conditional approval of drugs, so that they are released to defined cohorts of patients earlier in the process—if you like, part way through the Phase III trials—so that the patients that are most likely to benefit from them get early access to those drugs; but that, during that period of conditional approval, we also use the pharmacovigilance capability of *Connecting for Health*, or GPRD as an alternative in the short term, in order to identify any emerging problems. It also means that during the period of conditional approval, which I would anticipate to be 18 months to two years, you have got the drug out to an increasing number of patients; therefore, you get much better data from it and, by the time NICE has to make its decision, which will be at the end of that 18-month period, it has much more data, can make a much more positive decision, and has not inhibited the drug coming on to the market.

Q49 Dr Spink: It appears to be eminently sensible thinking, Sir David. I want to address research careers. Do funding and career structures for clinical researchers need to change, in order to deliver the objectives that your review is seeking?

Sir David Cooksey: If I might take you back a bit from there, the truth of the matter is that we have a number of holes in the training process, going back to first degree level. There are real shortages of clinical pharmacologists, biostatisticians and other, similar disciplines.

Q50 Dr Spink: Could I just interrupt and say that in certain specialities there is an oversupply of people coming out at the consultant-qualified level compared to the number of consultancy vacancies they will be finding.

Sir David Cooksey: Absolutely.

Q51 Dr Spink: Will that push more people into research careers?

Sir David Cooksey: The problem is you have got perverse incentives at the moment where people choosing a research career as opposed to a frontline clinical position take a penalty in terms of the financial rewards and also can easily—there is quite a lot of evidence of this—lose out in terms of the promotion prospects in their career advancement. It is no wonder with these perverse incentives that the number of people engaged in clinical research has dropped by a third in the last 10 years.

Q52 Dr Spink: How do you think we should improve the incentives for people taking an academic research career rather than a clinical one?

Sir David Cooksey: There are a number of initiatives which have emanated from UK Clinical Research Collaboration and from Dr Mark Walport's report on academic medical careers to try and improve that situation and put back the incentives in the system to make sure that this is an attractive option. That has got to be driven through. Also, we recommended—and this is one of these things we were talking about bringing into the ring-fence—that the monies which are available through the R&D function of the NHS to reinforce clinical academic careers are brought into the ring-fence so that funding is safe and is able to be applied for that purpose.

Q53 Dr Spink: Were you happy with the involvement of the DfES in your review given that a number of universities are involved in medical research?
Sir David Cooksey: The DfES had a fairly modest input into the review, but we did consult heavily with the universities' both at university body level and with individual universities. I think the review was characterised by a huge number of written responses, many of them from universities, but we also had a number of field visits to the universities concerned and discussed this at length.

Q54 Dr Spink: Do you think there are any risks arising from transferring funding from clinical academic training into the NHS R&D budgets? Are there any risks in that?
Sir David Cooksey: I think under the current leadership there is no risk, but it is always the concern that if you have a change in leadership there will be a change in priorities, and I think this is something one has got to keep a very close eye on.

Q55 Dr Iddon: Sir David, we all know that the National Health Service is under financial difficulty at the moment, and your arguments put forward at the beginning of this evidence session for taking out the NHS R&D money into OSCHR resonate well in this Committee, but taking that money out at this critical time when we all know that budget has been raided all over the country, is that not going to destabilise the NHS even further, and how are we going to manage that process?
Sir David Cooksey: I was not asked to investigate that per se, but let us look at it. The total spend is about 0.9% of NHS funding. The NHS funding has been increasing by seven and a $\frac{1}{2}$% in real terms per annum over the last N years. It should be perfectly possible to find the 0.3 or 0.4% which needs to be shifted across out of one year's increased spending. It is a tiny proportion of the whole.

Q56 Dr Iddon: Academics have got pretty big clout when it comes to claiming money for research to invest it in the institutes. The National Health Service clinicians do not have that clout, so by moving the NHS money into OSCHR are those doctors and consultants who are doing limited research within the National Health Service at the moment going to lose out?
Sir David Cooksey: No. The money is bid for by OSCHR but it goes through exactly the same stream once it has been allocated as it does at the moment. As I said earlier, one of the reasons why we were insistent that NIHR is made into a real agency is in order that one can get a complete ring-fence around that and make sure that money is applied for that purpose and does not get siphoned off elsewhere.

Q57 Dr Iddon: That is good to hear. The infrastructure for clinical research is not what we would want it to be, I am sure you would agree with that statement, do you think by creating OSCHR we are going to be able to improve our clinical research infrastructure?
Sir David Cooksey: When you talk of infrastructure, could you be more specific?

Q58 Dr Iddon: I am talking about buildings, obviously. NIMR are coming into central London, that is the proposal, so just improving the facilities in general for clinical research.
Sir David Cooksey: I do think that particularly the university-based institutions have seen quite an improvement in their facilities. This is as a result of JIF and SRIF programmes and so on. I do not think it is buildings that are the main problem at the moment, it is actually in developing the research careers for the people who occupy those buildings and making sure they have got a secure base from which they can undertake this research which is the most important factor.
Dr Iddon: There have been criticisms that your expectations of the Health Technology Assessment are over-optimistic. Would you like to answer those criticisms this morning?

Q59 Dr Spink: Oh, no, they are not!
Sir David Cooksey: Unless you are clear in what you want to achieve, I do not think you will ever achieve it. We have tried to raise the game as far as HTA is concerned. There is no doubt that there is a lot of value to be had from it, but what we have got to do in order to make sure that is delivered is to attract the right people into that process.

Q60 Chairman: Sir David, I do want to make sure that we do not leave you going away with the accusation that you were proposing skimping in terms of procedures, so I am going to ask if Dr Harris can come back on that issue because this issue of the clinical pathways and particularly what is going to happen at the Level 3 trial stage is important to put on the record.
Sir David Cooksey: Thank you.

Q61 Dr Harris: Yes, and as a fellow Oxford man who has been on the receiving end of a needle on an Ataxia trial at Weatherall Institutes, I would not want to offend you by suggesting that your particular background had led to necessarily wrong conclusions. Your discussion of the whole issue of what drugs should be available on the NHS is very interesting, something that I think is in the province of politicians as well to be rational and transparent

about rationing. Therefore, it is an interesting contribution to a debate which is, I think, more political than other areas that you are considering, which is why it is quite controversial. In one of your proposals you talk about the Department of Health deciding what are key priorities in terms of major UK diseases, and giving some form of direction in a top-down way, as well as a bottom-up, I accept, to OSCHR. Would you accept that there is some concern that it is wrong that clinical research should be led by what the UK Government considers to be healthcare priorities, because perforce, for example, that will concentrate on UK healthcare priorities, and many researchers in this country do not see why they should be at a further disadvantage when researching greater killers, that is diseases of the developing world, as one example of the dangers of concentrating solely on that issue?

Sir David Cooksey: In a sense, we are in dangerous territory here. If you look at public expenditure on health research in this country, I think, first and foremost, this has got to deal with the health needs of this country. I totally agree with you that a decision can be made that part of that expenditure should be more broadly available for the benefit of the developing countries, et cetera, but that should be a positive decision, not one which would allow investigators to choose to use all of the health research budget on Third World diseases. We have got to make an allocation decision on that. Going back to your first point, what is requested is that the Health Service should identify where it has the greatest unmet need and what it considers to be the priorities. It then hands that analysis over to OSCHR and OSCHR is asked to make the decisions as to where it puts the priorities, so the priorities are set not by the NHS but by OSCHR. The NHS is advising OSCHR as to what it considers to be the greatest needs. There is no reason why other bodies should not do likewise.

Q62 Dr Harris: I do take issue with your assertion, which at least you have been clear about, that the MRC, for ex ample, has a strong tradition of doing a huge amount of work in respect of diseases of the developing world, and it has done that without being told to but without being told not to, and it is good, including the Weatherall Institute, of course, as you list in your report. You are saying we should move the current position to a position where they only do that as they are told to, a budget allocation is made. Do you accept at least that has risks, that researchers will say, "I am not going to work in a country where I can only do this work if I am fortunate enough to come within that budget envelope set by a politician concentrating on what the *Daily Mail* might say about NHS services"?

Sir David Cooksey: First of all, I do not agree with you, because currently the MRC makes its bid for the spending review to OSI which then brings all the bids together and puts its bid into the Treasury. In setting its strategy and making its bid, the MRC tells OSI what proportion of its funding is going to go into the diseases for developing countries, et cetera. From that point of view, there has been this allocation process which has gone on through the bid process for a very long time. It is not complete freedom of action within the MRC, decisions on any particular proposal are entirely the MRC's, but the overall setting of the strategy is something which is done jointly with OSI.

Q63 Dr Harris: You are proposing to go further, you are saying that the DH—it is very clear in your recommendation—should identify specific disease areas that are priorities for the UK and direct funding from this Translational Medicine Funding Board through OSCHR to those, so that is going further than the current arrangements. I am not saying there is no direction at all at the moment, I am asking you whether you accept there is a risk that that sector of our research may be undermined by this greater direction that you are advocating for perhaps good reason as far as UK health is concerned.

Sir David Cooksey: What we are doing is saying that priorities should be set. You will have a situation which is very parallel to what happens now, which is the priorities are set, allocations made to the various funding boards of the MRC and through the NIHR's process, and they will consider applications as they arise. What happens is that the actual funding is guided, not determined, by the prioritisation process.

Q64 Chairman: A final point to make sure that this is clear. At the moment MRC makes a bid to OSI in terms of its research funding, as does every other research council?

Sir David Cooksey: Correct.

Q65 Chairman: Under the new procedures, MRC will continue to make a bid to OSI for that?

Sir David Cooksey: No, it will make a bid to OSCHR.

Q66 Chairman: MRC will now make a bid to OSCHR, OSCHR will then make a bid to the Treasury, the Treasury will give the money back to the DTI who will give the money to OSCHR?

Sir David Cooksey: What happens is it will tell OSCHR how much of the money it has applied for, it is going to get over the spending review period. It will then be up to OSCHR to determine the split of those monies between three bodies: MRC, NIHR, and the Translational Medicine Funding Board.

Q67 Chairman: But in reality, Sir David, the Director General of OSI, Sir Keith O'Nions is a bit player there, is he not?

Sir David Cooksey: No, because he will be very much a participant, and it is happening right now, in the process of formulating that bid. He would say to you if he was sitting here, "I need to tension the funding for MRC against the other research priorities there are". In helping to formulate how much money MRC should be applying for we will take notice of Sir Keith's overall requirements. We have agreed that this should be the case. Just to complete the

cycle, once that allocation has been made the funding streams will come down through OSI and from the Department of Health.

Q68 Dr Turner: The report is full of lots of interesting recommendations, what is your feedback from Government departments as to what they are going to do about implementing them all?
Sir David Cooksey: I cannot tell you how delighted I was that the Treasury and both Government departments agreed to implement all the recommendations on the day of publication. At least that is happening. The team at OSCHR is being put together very rapidly and they have got to formulate their spending review bid within the next very few weeks, so there is a huge amount of effort going on there. I have been surprised at the speed at which the various recommendations are being addressed and, in some cases, already starting to be implemented. I think the signals are very positive at this moment.

Q69 Dr Turner: Another feature of your recommendations, which I read with some wry amusement, is that everybody cites you in defence of their case, even if they are on opposite sides of an argument, so this has to be one of the best reports ever produced.
Sir David Cooksey: All I can do is say thank you.
Chairman: Sir David, I started this session by thanking you very much on behalf of the Committee for a far-reaching report and one which has given us a great deal of interest in terms of questioning you. We thank you for your honesty this morning, we expected nothing else. Thank you for taking on my colleague, Dr Harris, and putting him in his place. Thank you very much indeed.

Written evidence

Memorandum 1

Submission from Guy's and St Thomas' NHS Foundation Trust, South London and Maudsley NHS Trust, and King's College London

As a partnership between health service and academe, we welcome the Cooksey Review, as an opportunity to create a funding environment which will enhance our ability to create seamless pathways which link the most basic scientific research to improvements in health care delivery.

We support the Chancellor's ambition to create a single ring-fenced budget to support health research as a means of achieving this goal. A single budget, if properly managed, should reduce bureaucracy and erode the artificial separation between the research agendas of Universities and their partner NHS Trusts. It would encourage collaboration between the two entities and incentivise NHS staff to undertake research, and University staff to think about the applications of their research to patient care.

How Funds Should be Allocated

Under the present system, there are significant differences in the two funding regimes which will need to be reconciled. MRC funds are earned on the basis of research excellence, as judged by rigorous peer review, and measured against national and international priorities aligned with the MRC's mission to "encourage and support high-quality research with the aim of improving human health". Funding awarded to Universities by Research Councils and other external funders of research is ring-fenced and cannot be used for any other purpose. On the other hand, the majority of NHS R&D funds are allocated formulaically for research infrastructure, although it is often difficult to trace this income stream to specific R&D support. This is the rationale behind the "Best Research for Best Health" initiative, which is designed to ring-fence R&D funds for R&D in NHS Trusts.

Redistribution of funds under BRBH poses a substantial financial risk to NHS Trusts that are research-active—and perversely, the more research-active a Trust has been, the more it stands to lose. Even if Trusts are able to regain income equivalent to their current R&D levies through various BRBH schemes, the new income will be ring-fenced for specific research initiatives, leaving an underlying deficit in their budgets which could seriously destabilise clinical services. For this reason we believe that it would be preferable to create the £500 million DOH contribution to the joint fund by redirecting this amount into R&D from the planned growth in funding (£4 billion pa for the next two years[1]) in the NHS.

It should be noted that if it is the case that not all of the £700 million attributed to NHS R&D is being used for research purposes, then the total amount of research that could be funded out of a combined £1 billion fund should be substantially greater, which would be of benefit to the UK.

The Higher Education sector is well advanced in developing methodologies for full economic costing of research. Any new system should take advantage of the work that has already been done in this regard and extend the principles across the fund as a whole.

It will be important to re-evaluate the entire range of research interests and methodologies that exist along the biomedical research pathway from basic discovery to applied research to ensure that an appropriate proportion of spend is allocated across the spectrum. These changes are necessary to support the translational research agenda, which has come to the fore over the past few years, as research breakthroughs in basic research are beginning to be applied to clinical questions. It may be necessary to provide considerable funding at the applied end of the spectrum for training and incentives to ensure that the expertise exists to support excellent research in areas such as statistics, epidemiology, health economics, and health policy, and to attract health care professionals other than doctors into research activities.

The single fund should also consider setting aside funds for infrastructure development in areas such at IT and clinical research facilities, to support seamless working across partner organisations.

What Sort of Organisation Should Manage the Fund

There is considerable collaboration amongst the various Research Councils. Research activities undertaken outside the MRC's remit but with important consequences for health are co-ordinated and sometimes co-funded, in areas such as the physical sciences, bioinformatics, maths and social sciences. There are also strong relationships between the MRC, the DOH and the medical charity sector (for example, the Joint Infrastructure Fund and more recently, the Clinical Research Facility initiative). Any new funding regime must take care not to disrupt these important connections and collaborations.

In order to maintain its leading international position in biomedical and health research, second only to the USA, the UK funding regime must allocate resource on the basis of excellence, which is best determined through a rigorous peer-review system. The MRC has vast experience of managing such a system and is

[1] Based 6% of ≈£70 billion growth in NHS budget for next two years.

recognised throughout the world as an organisation that funds the best science through fair and equitable mechanisms driven by strategic goals. We believe that the new single funding body should be based on these principles.

Governance Issues

We believe that a novel governance model is needed which draws on the best features of the two current schemes and acknowledges the interdependence of the NHS and its academic partners. All key stakeholders should be involved—government departments, research councils, universities, the NHS, medical charities, industry and patient groups.

Two models are possible. One is that, as proposed, there is a single budget which relies on a single resource allocation methodology. The advantages of this model as we see them have been discussed above. There are potential difficulties which would have to be resolved in order for a single budget to work effectively. Principle amongst these would be to agree the appropriate proportion of the fund to be distributed to different elements of activity. Without careful management, basic research could benefit at the expense of more applied research simply because the metrics are more easily defined for laboratory-based research. It will also be difficult, we suspect, to resolve the "ownership" of a single fund in a way that both partners in the scheme felt was equitable and aimed at achieving the right set of goals.

An alternative model might be to combine the funds under a single governance arrangement with a single Board Chairman, but with two discrete funding streams, each with its own Director. One of these would be drawn from the DOH and would be responsible for building capacity in the NHS, funding research infrastructure and applied research. The other would be drawn from academe and would be responsible for funding those activities currently under the remit of the MRC. In order for this model to be successful, there would have to be a single strategic vision across the two arms of the structure. The diagram on page 3 of the Academy of Medical Sciences/Royal Society response to this consultation provides a model which we would support.

Attached to this response is an annexe, from South London and Maudsley NHS Trust, giving specific examples of the possible impact on mental health research of the proposed changes.

January 2007

South London & Maudsley NHS Trust and Institute of Psychiatry, King's College London (KCL)

RESPONSE TO COOKSEY CONSULTATION

Funding Research on the Development and Evaluation of Innovative Therapies

As a supplement to the main KCL submission with its associated NHS Trusts to the Cooksey consultation, this paper addresses the need to establish an effective system for the allocation of the excess treatment costs necessary to allow the scientific investigation of innovative therapeutic interventions to take place. This response has been prepared by senior clinical academics representing core mental health disciplines with internationally recognised expertise in developing new treatments for psychiatric conditions, including psychological therapies for anxiety disorders, bipolar disorder, schizophrenia, obsessive-compulsive disorder, eating disorders, psychosomatic problems, and conduct problems in childhood—and in evaluating these treatments in large-scale multi-site randomised controlled trials with funding from sources including the Medical Research Council, the Wellcome Trust and other NHS recognized medical charities, and the Department of Health.

1. Over the last 25 years, the UK has been a world leader in the development of new and effective treatments for mental illness, including innovatory psychological and social therapies. Many of these psychological treatments, for example, are now recommended as treatments of choice by review bodies such as NICE, to be used either in conjunction with pharmacological treatments or for many conditions as the preferred treatment on grounds of effectiveness, cost and patient preference. Much development and evaluation work remains to be done, again as highlighted by NICE.

2. However, current central funding arrangements threaten to undermine and weaken this work and the UK's pre-eminence because the allocation of the excess treatment costs necessary for such clinical investigations is complex and does not operate effectively. Definitions of treatment, and excess treatment, costs are set out in: The Department of Health Guidance Document "Attributing revenue costs of externally-funded non-commercial research in the NHS (ARCO)" (Gateway reference: 5956) of December 2005, which states:

> "Treatment Costs are the patient care costs which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped. Where patient care is provided that is either an experimental treatment or a service in a different location from where it would normally be given and it differs from the normal, standard treatment for that condition, the difference between the total Treatment Costs and the costs of the standard treatment (if any) is called Excess Treatment Costs. These costs are nonetheless part of the Treatment Costs,

not an NHS Support or Research Cost. The term Treatment Costs covers all types of patient care services, including diagnostic, preventive, continuing-care and rehabilitative-care services, and health promotion."

3. The normal expectation by the Department of Health is that these excess treatment costs, which fall outside the NHS R&D budget, are sought through commissioning arrangements via PCTs. Exceptionally it has been possible for those conducting clinical trials and other clinical studies to seek excess treatment costs from central Department of Health subvention. More recently, however, central subvention for the excess treatment costs relating to research has become more variable and increasingly difficult to establish. This threatens the capacity to run large-scale trials, such as those of psychological therapies, because:

(a) Local NHS commissioners will usually only fund existing treatments. They are often understandably reluctant to fund new therapies until they have been shown to be effective and better than those that are already available in the NHS.

(b) New therapies need to be delivered by clinicians who are fully trained in the innovative procedures. This is realisable with a centrally funded expert therapeutic teams, but difficult to achieve with routine NHS clinicians who are temporarily seconded to a project and have many competing clinical demands. In mental health care the treatment cost issue applies particularly to innovative psychological and social treatments, where individual and specifically trained therapists are required to provide the complex treatments, whereas pharmacological trials can normally be conducted by arranging for the usual clinical staff to prescribe and administer the intervention.

(c) Multi-centre trials are often needed to provide a definitive evaluation of a new treatment. Separate negotiation of therapist costs from multiple local NHS organisations is bureaucratically cumbersome, and can engender substantial delays before projects can start. Absence of central funding also undermines consistency and control of therapy delivery across sites.

4. We also wish to emphasise the need for the single fund allocation system to distribute funds in such a way that recognises different clinical environments that incur different costs. In particular, we emphasise that much mental health service provision takes place in the community and thus associated research costs need to reflect the high level of contact with community mental health teams, which are generally higher than the costs of inpatient/outpatient hospital oriented research. There are also additional costs associated with recruitment of some hard to reach participants, particularly within mental health services.

5. These points pose severe current threats to the development and evaluation of innovative treatments, including novel psychological and social therapies, with adverse implications for the UK's international position in this area as well as for the NHS. It is therefore to be hoped that new funding arrangements will address the need for combined funding of therapy provision and evaluation costs to ensure that high quality studies of new treatments that are expected to have a substantial impact on the NHS can take place.

Prepared by:

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Signed on behalf of the South London and Maudsley NHS Trust:
Mr Stuart Bell, Chief Executive

Signed on behalf of the Institute of Psychiatry, King's College London:
Dr George Szmukler, Dean

Memorandum 2

Submission from the University of Leeds

— the vision and sentiment of the Cooksey review is timely, well thought out and will strengthen British science;

— it focused on bio-medicine and pharmaceutical/biotechnology industries with little mention of bio-physics/engineering so a little narrow;

— it was (finally) decided to avoid specific changes in some funding streams so was a bit light on specific changes;

— it could work well for Leeds if we are well organised in our response;

— the key Cooksey recommendation for Leeds is that a proposal for "extensions of Biomedical Centres (BMC) in NIHR" should be put to the next PSR. This is a key ("make or break") issue for Leeds University.

At present generic BMCs have been awarded to Ox/Camb/UCL/Imperial/Kings which cover about 50% of the best biomedicine in England. Liverpool and Newcastle got smaller "specialist" awards. Several London institutions also got specialist awards.

The effects of this include:

— resources for the winners, of course;

— loss of resources for others;

— loss of reputation and thus recruitment for others.

There were powerful political forces at work, of course, but (I feel, at least) there is no point complaining but we need to push for another round (for five or six more which might include us) based on scientific excellence, capacity and regional impact.

January 2007

Memorandum 3

Submission from the Wellcome Trust

1. The Wellcome Trust is pleased to submit this written evidence to the House of Commons Science and Technology Select Committee for the Cooksey Review Evidence Session.

2. The Wellcome Trust is the largest charity in the UK and the second largest medical research charity in the world. It funds innovative biomedical research, in the UK and internationally, spending around £500 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.

3. The Trust submitted its response to the Cooksey Review consultation in July 2006, outlining its views on the high level principles and organisational arrangements for the new single fund for health research[2].

4. We welcome the Cooksey Review Team's proposal to create an overarching body, the Office for Strategic Coordination of Health Research (OSCHR), to provide strategic oversight and a shared platform for the translation of UK health research into benefits for patients. We hope that this new arrangement will provide opportunities for enhanced partnership and engagement with other research funders, including the biomedical research charities. It would be helpful to know what mechanisms are currently under consideration to take forward such opportunities.

5. We also welcome the proposal to establish the National Institute of Health Research (NIHR) as an Executive Agency of the Department of Health by April 2009. It is vital that NIHR has a transparent and robust governance structure in place and we look forward to seeing further details as they are developed.

6. Many of the proposals contained in the Cooksey Review report require developments over the medium- to long-term. An implementation plan with clear processes and timetable should be developed to ensure that the proposals are taken forward.

January 2007

Memorandum 4

Submission from the Association of UK University Hospitals (AUKUH)

AUKUH welcomes the Cooksey Report into UK Health Research funding. It is essential that the research culture within the NHS be strengthened. The critical interrelationship between specialist service provision, research and education cannot be overemphasised: without high-quality health research and education, quality of care will be at risk.

The following detailed comments focus on some of the areas of key interest to AUKUH.

Volume of Funding

The Chancellor has promised £1 billion annually research yet the combined budgets for NHS R&D and the MRC amount to more than £1.3 billion. It would be helpful if the Select Committee could probe the continuing commitment to a £1.3 billion baseline.

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[2] The Wellcome Trust submission to the Cooksey Review of UK Health Research consultation can be downloaded from: http://www.wellcome.ac.uk/node3620.html

Stronger Health Service Research Culture

This is essential. Clinical research is on a terminal decline and AUKUH very much hopes that the new strategies will reverse this. It is absolutely vital that a research culture is present in all major Acute Trusts. Care must be taken not to undermine the excellent and internationally competitive research being conducted outside the five "centres of excellence". Equally valuable are the contributions of smaller scale or blue-skies research projects.

"Fast Track" Approval Process

Presently, there is no way that any clinical research can be fast tracked. The administrative burden on the investigator and the Trust is enormous when performing this work (eg COREC application, MHRA inspections etc). As yet, there is no sign that these burdens will be reduced or simplified; this must happen before any fast track system can be developed.

Incentives for NHS Organisations and Employees to Carry Out Research

This is an admirable aim; nevertheless measuring the quality of research output is a very difficult task and open to a numbers of problems. Simple measures such as journal impact factors or paper citation numbers often fail to measure the clinical impact of research. A considerable amount of careful work is required here to deliver this. In the past, decisions have been made using a simple, inappropriate option when assessing research quality with respect to effects on clinical practice.

AUKUH agrees that incentives are very important however many potential researchers do not need incentives—they are already keen. They simply need to be given the opportunity to carry out their work eg funding, less administrative burden etc. It is vital that this new arrangement does not add to this burden.

MPET Used to Support Training of Clinical Academic Staff to be Ring-Fenced and Transferred to DH R&D Budget

AUKUH welcomes the move to protect that part of MPET funding used to support training of clinical academic staff. However transferral to the DH R&D budget may not fully protect the funding—if the R&D budget is stretched it may be that its training budget will be the first to suffer. It is of equal importance that the funding for the clinical academics associated with Medical Schools is ring-fenced; otherwise Trusts will not be able to retain and recruit top quality researchers and research-trainers.

NHS and University Collaboration

AUKUH recognises that universities have a vital contribution to make to the UK's health research agenda. The Association works closely with the Council of Heads of Medical Schools (CHMS) on issues of shared interest.

AUKUH supports the development of a national model framework to improve university-NHS collaboration. However, the UKCRC as currently configured is not best placed to develop a model framework to improve university/NHS collaboration. The UKCRC has consistently turned down requests from AUKUH and CHMS that Medical Schools and university hospitals are central to the delivery of the research agenda and must have a place on the UKCRC Board. If this policy is not reversed, CHMS and AUKUH should be charged with developing the necessary framework.

The removal of existing barriers to partnership between the NHS and universities is essential and AUKUH welcomes the development of a solution to the issue of VAT and the use of university research buildings. The AUKUH Finance Directors group would welcome the opportunity to contribute to a workable solution to this problem.

Autonomy

Autonomy is a vital concept in scientific research which needs to be free from political interference. The current ban on stem cell research in the USA is a clear example of the adverse effects of such interference. In addition one must question the practicality of requiring OSCHR to report to two masters—both the DH and DTI—how will competing priorities be resolved in practice?

January 2007

Memorandum 5

Submission from the Council of Heads of Medical Schools

CHMS congratulates Sir David Cooksey on the excellence of his report and on his perspicacity in identifying as the key issue the lack of a central coherent strategy to optimise the contribution of healthcare research to UK plc. UK Medical Schools look forward to working with OSCHR, the MRC and NIHR to develop an overarching UK health research strategy.

CHMS represents the interests and ambitions of UK Medical Schools as they relate to the generation of national health, wealth and knowledge creation through bio-medical research and the profession of medicine. CHMS seeks to exploit for the benefit of all, the unique position the organisation occupies, embracing undergraduate medical education, the entirety of health related research and a critical interface with the health service.

The CHMS Chair, Professor Sir John Tooke would be pleased to give oral evidence to the Select Committee to explain in detail how Medical Schools might optimise their contribution to the successful implementation of the Cooksey Report's laudable objectives.

CHMS seeks here to comment on a few of the key recommendations:

OSCHR

We support strongly the appointment of Professor John Bell as Chair of OSCHR. Medical Schools will be keen to assist him in developing and setting the strategy. They are ideally placed to identify tractable areas of research and contribute to the translational agenda. Too great a reliance on setting research priorities via a top-down' approach should be avoided and it must be recognised that some of the most significant medical advances have emerged from research on low incidence conditions which nonetheless involve mechanisms with far reaching implications. The work of OSCHR must complement "bottom up" approaches as pursued by many clinical researchers.

A preponderance of targets has become an intractable part of NHS culture and CHMS is keen that this is not replicated within the methods of working of OSCHR. The means by which OSCHR will set objectives and assess outcomes should be clarified. A top heavy administrative framework could potentially stifle research initiatives most particularly blue skies research.

Biomedical Research Centres

The creation of a small number of major, truly internationally excellent biomedical research centres is crucial if the UK is to be globally competitive and benefit fully from the investment in Research and Development. Increasingly sophisticated characterisation of populations including genetic studies, which the NHS is well positioned to facilitate, will be required to take advantage of the knowledge of the human genome, *inter alia*. Such studies will require the development and sustenance of national research networks supported by strong regional centres, which will in turn accelerate the productivity of the Biomedical Research Centres. Internationally competitive research and research of key relevance to high quality clinical care and Regional Economies must also be supported in regional centres if the full benefits of the UK's health research endeavours are to be realised.

Partnerships

In translating its own mission into practical outcomes, CHMS has already developed close links with AUKUH, AMS, ABPI, AMRC etc and welcomes the recognition of the importance of these relationships.

Real opportunities are available to explore links between medical schools, the NHS and industry, collaborations vital to increasing the competitiveness of the UK in health research. More needs to be done to incentivise research in the NHS. Industry needs to make industrial careers and short term industrial experience more appealing to academics and it is important that academe better recognises the value of engaging with pharma. The "Forging Partnerships" event held by CHMS in collaboration with ABPI and the Academy of Medical Sciences in December 2006 aimed to begin to strengthen these links, establishing a dialogue between universities, the health service and industrial partners which must continue.

Healthcare Commission

It is recommended that the Healthcare Commission's targets should reflect research activity in quality adjusted terms. We suggest citations, impact factors and the perceived quality of the research funders could be taken into account here, although it must be borne in mind that such simple factors often fail to measure the clinical impact of research.

Ring-fenced Funding

We welcome the suggestion that support for the training of clinical academics be ring fenced. The annual CHMS Survey of Clinical Academic Staffing numbers is recognised as the gold standard in terms of the quality of information therein and is used throughout the sector. Last year saw the number of clinical academics in the UK fall below 3,000 for the first time since 2000 when the survey was initiated. We are pleased that the need to encourage the brightest young doctors into a clinical academic career has been recognised.

The Roles of the NIHR and MRC

Changes to NHS research funding under "Best Research for Best Health" whilst promising, are as yet untested in practice whilst the MRC has a proven track-record of making competitively awarded, rigorously peer-reviewed research allocations. It is critically important that the integrity of the MRC system of rigorous peer-review is not compromised under the proposed framework and that the NHS R&D system continues to embrace such existing best-practice.

It is essential that the MRC, as well as the NIHR, and crucially the HTA, continue to fund large phase three clinical trials, particularly those complex interventions in a community-based setting.

Capacity Development

Adequate support for trials units is vital in order to allow capacity to conduct trials and well-designed studies. The chronic shortage of non-medical researchers, predominantly non-clinical methodologists such as health economists and statisticians, engaged in this area must be addressed.

RAE

CHMS would welcome clarification from the NHS R&D Directorate as to whether funding awarded from the NIHR to Trusts should be allowed to "count" in the RAE returns of the Trusts' partner universities. It is anticipated that university employed clinical academic staff, those holding an honorary NHS contract, will be those applying for research funding through the NIHR and pursuing research on this basis.

The Medical Schools are particularly pleased that the requirement further to develop their infrastructure has been recognised but would welcome clarification of how the £50 million is to be disbursed.

University/NHS Collaboration

CHMS is concerned that there is no mention of the Department for Education and Skills in the Cooksey Review. Universities have a vital contribution to make to the UK's research agenda and as such representation from the DfES as well as DH and DTI should be sought in the coordination of the UK's health research strategy.

CHMS would suggest that UKCRC as currently configured is not best placed to develop a model framework to improve university/NHS collaboration. UKCRC has consistently turned down requests from CHMS and AUKUH that Medical Schools and university hospitals are central to the delivery of the research agenda and must have a place on the UKCRC Board. If this policy is not reversed, CHMS and AUKUH should be charged with developing the necessary framework.

CHMS is delighted that the team recognised the issue around VAT and the use by others of university research buildings. We suggest that the British University Finance Directors be commissioned to develop a workable solution to the problem, in collaboration with the Association of UK University Hospitals' Finance Directors group.

Transitional Medicine Funding Board

CHMS would like to request clarification on the definition of translational medicine and, indeed, why there is a need for a new Board. Will its scope, for example, also include research likely to benefit public health, as distinct from clinical medicine? If so, secure public health representation on the board should be sought. If this is not the case, there should be a clear focus for the coordination of public health research, particularly in light of the current low investment from the DH in public health research and development.

Forum For Collaboration for Health Research in International Development

CHMS would welcome clarification on the structure of this forum. If research representation on this body is solely from members of the NIHR, CHMS is concerned that many experts with discipline specific knowledge but lacking an honorary NHS contract will be excluded from participating.

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Memorandum 6

Submission from The Academy of Sciences

1. Introduction

The Academy of Medical Sciences welcomes the opportunity to submit evidence to the House of Commons Science and Technology Committee in relation to the "Cooksey Review". We would be happy to expand on points made in this submission and to assist further with the Committee's enquiries. This submission was prepared by a working group of Academy Officers and Council members, chaired by Sir Michael Rutter FRA FBA FMedSci (see annex).

2. Sir David Cooksey's report *"A review of UK health research funding"* is likely to mark a turning point in the funding of health research in the UK. The recommendations, endorsed by the Chancellor, offer a real opportunity for revitalising UK health research. However, implementation will be challenging and the success of the proposals will depend on the level of investment and the support and engagement of scientists, health professionals and industrialists from across biomedical research areas.

3. This submission focuses on seven areas in relation to the proposals set out in the Cooksey Report: the role of OSCHR; level of investment; importance of scientific leadership; Medical Research Council; translational medicine; peer review; and evaluation.

4. Role of the Office of Strategic Coordination of Health Research (OSCHR)

The Academy welcomes the proposal to establish an Office of Strategic Coordination of Health Research (OSCHR). This reflects the joint recommendations of the Academy and the Royal Society in their response to the Cooksey consultation in July 2006.[3] The definition of OSCHR as a "light touch" organisation is particularly welcome (section 5.59). Lessons learnt from institutions overseas illustrate problems that may arise from complex and over-managed systems (3.18).

5. While we understand the arguments for identifying priority areas, we caution against too great a reliance on a top-down approach to setting research priorities. No amount of "consumer desire" will overcome the practical reality that important health problems are often very difficult, or impossible, to address with existing approaches. Furthermore, some of the most significant medical advances have emerged from research on low incidence conditions with widely applicable mechanisms.

6. Level of Investment

The Cooksey Report does not make recommendations concerning the overall level of funding for UK health research. The Academy considers there to be a very strong argument for increasing the level of investment.

7. We welcome the statement (4.24) that funding levels for basic science should be sustained. However, we are concerned by the recommendation that "*future increases in funding should be weighted towards translational and applied research until a more balanced portfolio is achieved.*" We are disappointed that the Report has not also called for additional research funds for basic science alongside an increase in funding for translational and applied research. Furthermore, if the Translational Medicine Funding Board were to take funding from both the MRC and the NIHR, the result would be a reduction of funding for basic science. In our view these should not be either/or choices, and there is a danger that under-investment in either area will limit the success of the overall endeavour.

8. Importance of Scientific Leadership

We strongly recommend that the Chief Executive Officers of both the MRC and the NIHR are individuals of significant standing in the research community. They will need to provide outstanding scientific leadership.

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[3] http://www.acmedsci.ac.uk/images/project/AMSRSres.pdf

9. The Medical Research Council

We welcome the explicit acknowledgement of the Medical Research Council's outstanding record of scientific achievement and its role in establishing a strong base of investigator-led research.

10. Translational Medicine and Boundaries Between the MRC and NIHR

Integration of the component parts of the translation pipeline is a key challenge. Structural separation of the NIHR and the MRC could hinder the necessary cross-fertilisation of basic science and its application to patients. The NIHR and MRC will need to work productively across the interface, and disputes over territory in either strategy or funding would be counter-productive. It will be important for the NIHR and MRC to develop complementary expertise. We argue strongly that Experimental Medicine should continue to develop primarily within the MRC. We welcome the Translational Medicine Board, which will need to be able to flush out opportunities, identify obstacles and encourage innovation.

11. Peer Review

The report implies that the peer review system has contributed to the comparative lack of success of some areas of UK health research. We consider that the reasons for any lack of success are much more complex. We acknowledge that the peer review system requires a substantial amount of investment in time, but it has proved effective in enforcing scientific rigour—this has been shown to be the case across the world. We consider that a move away from peer review is likely to compromise scientific standards.

12. Evaluation

The Report emphasises the need to measure success against clearly defined objectives and to evaluate the impact and outcomes of medical research (4.17, 4.18 etc). While applicable to applied research, short-term objectives are inappropriate for basic research from which important discoveries often result from many years of endeavour.

13. The Academy, in partnership with the Medical Research Council and the Wellcome Trust, will shortly be launching a new initiative to commission further work to evaluate the socio-economic benefits accruing from UK health research in exemplar disease areas. Further details regarding this study may be obtained from the Academy office. The Commissioning Team will be led by Professor Martin Roland CBE FMedSci.

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Annex

Working Group Membership

Sir Michael Rutter FRS FBA FMedSci (Chair)
Professor of Developmental Psychopathology, Institute of Psychiatry
Vice-president, Academy of Medical Sciences

Sir John Skehel FRS FMedSci
Formerly Director, National Institute for Medical Research
Vice-president, Academy of Medical Sciences

Professor Ian Lauder FMedSci
Dean, Leicester Warwick Medical School
Treasurer, Academy of Medical Sciences

Professor Patrick Maxwell FMedSci
Professor of Nephrology, Imperial College
Registrar, Academy of Medical Sciences

Professor David Delpy FRS FREng FMedSci
Vice-Provost (Research) University College London
Council Member, Academy of Medical Sciences

Professor Martin Humphries FMedSci
Professor of Biochemistry, University of Manchester
Council Member, Academy of Medical Sciences

Professor Robert Lechler FMedSci
Dean, School of Medicine Guy's, King's and St Thomas'
Council Member, Academy of Medical Sciences

Mrs Mary Manning

Executive Director, Academy of Medical Sciences

Dr Helen Munn

Policy Manager, Academy of Medical Sciences

Memorandum 7

Submission from the Association of British Healthcare Industries

1. Background

Sir Derek Wanless' first report referred to the NHS as a "late" and "slow" adopter of new technology. Against that background, the Healthcare Industries Task Force (HITF) was launched in October 2003 as a year-long initiative of industry and government "to identify opportunities where closer co-operation would bring about benefits for patients and service users, the NHS and social care, whilst also helping to improve the industry's performance". Its report was published in November 2004, and work has gone ahead since then on the systematic translation of its recommendations into practice.

The healthcare industries include manufacturers of medical devices, which are all kinds of products other than medicines used in diagnosis, prevention, monitoring or treatment of illness or handicap in humans, and regulated by the European Medical Devices Directives.

- There are estimated to be in excess of 2,000 companies engaged in medical device manufacture in the UK.
- Of these, 85% are very small companies, with a turnover around £5 million. Very few truly large companies are domiciled in the UK.
- The industry employs over 50,000 people, the second largest employer in Europe after Germany in this sector.
- UK manufacturers' sales were £4.7 billion in 2004 according to ONS figures. The trade balance in 2004 remained positive, having fallen quite rapidly over a five year period, at £83 million.
- In comparison with the pharmaceutical industry, the sector has relatively short product development cycles and draws on innovation from a wider range of sources.
- The market is globalised and increasingly consolidated, requiring continuous investment in skills, knowledge and specialised infrastructure.
- In the UK, the industry's close relationship with its market is an important strength, together with the ability to create technical solutions which address strategically important goals (laparoscopic instrumentation has enabled day surgery, for example).
- Domestic strengths are particularly in R&D and are especially important in advanced wound care, diagnostics and orthopaedics.
- Improvements in the commercial clinical trials environment have been identified as significant for the competitiveness of the UK's medical device sector and for R&D activities in particular.
- The NHS' approach to procurement has an impact on the competitiveness of domestic firms and particularly on the development of SMEs.

2. Balance of Emphasis Between MedTech and the BioTech and Pharmaceutical Sectors

The HITF report recognised the importance of the MedTech sector to both the health of patients and the UK economy. However, there is an implicit bias throughout the review towards the needs of the pharmaceutical and biotechnology sectors. Failure to maintain a correct balance to support a healthy MedTech sector would be a major potential loss for the UK economy.

1. What arrangements should be made to ensure that the governing board of OSCHR will have sufficient awareness of the issues relating to the Med Tech industry, and not just those of biotech and pharma?
2. Chapter 8 provides an entire section on a new drug development pathway: the MedTech sector needs a similar focus. How will this be achieved?

3. Visioning

The Cooksey review recognises the essential element of Visioning in underpinning all research and policy development, as laid out in the Haldane principles. The essential element which the Wanless review introduced was the shared and publicly debatable nature of such a report: we recognise that the Department of Health has always undertaken such activities, but that their outcomes have traditionally been kept relatively private. We also believe that the generation of such visioning research should be reasonably independent of the MRC and NIHR who will deliver against the priorities it establishes.

3. Will there be an explicit "visioning" activity as part of OSCHR's remit (ie to make sure we have an up to date version of Wanless etc which all stakeholders can use and debate the implications of)? There is some lack of clarity in the relevant sections of the review on this matter (paras 4.6.1 and 5.71).

4. Translational Medicine Funding Board

This is an area of real importance to all healthcare industries.

4. Can Sir David give reassurance that the definition of "Medicine" in "the Translational Medicine Funding Board" will be based on its broad definition (ie "Medicine is the branch of health science and the sector of public life concerned with maintaining or restoring human health through the study, diagnosis and treatment of disease and injury.") rather than the narrow pharmaceutical based definition?

5. SBRI Role

The industry was encouraged to see the comments relating to the potential value of the SBRI. The report "SECRETS" OF THE WORLD'S LARGEST SEED CAPITAL FUND: How the United States Government Uses its Small Business Innovation Research (SBIR) Programme and Procurement Budgets to Support Small Technology Firms' by David Connell of the Centre for Business Research, University of Cambridge suggested that this could be a very productive approach to fomenting innovation in UK.

5. Can Sir David enlarge on the role he sees for SBRI in improving the procurement of resulting products and services, and not just research, from healthcare industry SMEs? (paras 7.24 to 7.28)

6. Procurement

The industry was very encouraged to see the excellent grasp of the issues involved in Procurement and Innovation (paras 6.61 to 6.64). However, the following recommendation (6.64) was not strong.

6. Can Sir David explain what steps he feels should be taken to ensure procurement mechanisms are supportive of good innovations; and send appropriate signals to risk takers and developers of new technologies?

7. Role of Health Technology Assessment (HTA) in the Translation Pathway

The review notes that HTA "arguably happens too late in the development process". A new approach is proposed in Chart 7.1 relating to the second gap in translation. The industry has a concern that this is unduly optimistic of the HTA programme in terms of its ability to provide prospective evidence of value. If this is to happen, we must ensure that HTA will have the methodologies and capacity to be able to deliver this new role, as opposed to that of providing an evidence base on the relative effectiveness of existing health technologies which has been its traditional role: this may involve significant changes. Alternatively, there is a more creative solution which could be based on the developers of new technologies working in partnership with potential users in assessing value: this is hinted at in paras 7.49 and 6.63.

HITF proposed the development of "nationally accepted methodologies and toolkits for device evaluation that can be used locally to ensure consistency of approach whilst facilitating decision-making at an appropriate level". This would better reflect the diverse nature of medical devices and the continuous iterative nature of development. Centralised HTA activity is unlikely ever to have the capacity to address all developments in technology or to reflect the variety of opportunities for incorporation of that technology into patient care. A decentralised approach will be needed to complement central HTA processes that may be appropriate for high impact technologies.

7. Can Sir David comment on the changes he feels may be required to make HTA fit for this new purpose?

8. Can Sir David comment on the importance and methods necessary to ensure that HTA assesses the full economic impact of disease and innovative treatments on the UK economy, and does not simply focus on the cost effectiveness of providing treatment etc (cf para 5.71)?

January 2007

Memorandum 8

Submission from The British Psychological Society

The British Psychological Society is the learned and professional body for psychologists in the United Kingdom. It has a total membership of over 42,000 and is a registered charity. Under its Royal Charter, the key objective of the Society is "to promote the advancement and diffusion of the knowledge of psychology pure and applied and especially to promote the efficiency and usefulness of members by setting up a high standard of professional education and knowledge". The Society maintains the Register of Chartered Psychologists and has a code of conduct and investigatory and disciplinary systems in place to consider complaints of professional misconduct relating to its members. The Society is an examining body granting certificates and diplomas in specialist areas of professional applied psychology.

General Comments

1. We very much welcome the recommendation in the Report to maintain separate streams of funding through the Medical Research Council and the NHS R&D Programme. However, priority and strategy setting will become paramount to ensuring the success of both funding streams and maintaining strong evidence based practice in the UK.

2. We urge serious consideration of significant improvement of the support mechanisms for academic careers in health related areas, and for practitioners to undertake research. There are no straightforward or clear NHS or MRC career support pathways for these groups of highly skilled researchers. The lack of permanent funding and a proper career structure is a major deterrent to many who would otherwise pursue this route.

3. We strongly support the emphasis on developing translational research and research implementation, and the desire to develop a more research friendly culture in the NHS. However, the need for better coordination of research and research funding, and support the organizational arrangements that are proposed to achieve this must be acknowledged.

4. We accept the benefits of partnerships with the pharmaceutical industry. However, we note that some kinds of research (including psychological and social research), which are of great potential value, are unlikely to be the subject of these partnerships.

5. The importance of psychological and social factors in health and ill health is now established, but there is a clear need to improve the impact of psychological and social interventions. The limits of industry partnerships should therefore be acknowledged, along with the need to prioritize and ensure financial and organizational support for research on psychological and social interventions, particularly in the fields of mental health and public health.
We hope that these brief comments are useful.

January 2007

Memorandum 9

Submission from the Royal Academy of Engineering

1. The Royal Academy of Engineering welcomes the Cooksey Review and hopes that implementation of its recommendations will help to align medical research with health priorities in the UK. The Academy submitted a response[4] to the Cooksey Review based on the views expressed by its Fellows. This evidence is based on that response.

2. It is thought that some important issues should have received a deeper analysis and that implementation of the Report's recommendations without a fuller consideration of their implications will neglect other important areas of medical application and might actually damage the UK's excellent biomedical science base. These issues are identified in the points argued in the following paragraphs (highlighted in italic).

3. *The Review is far from comprehensive, in that the discussion is limited almost entirely to conventional drug discovery and testing. The Report appears biased toward the interests of the pharmaceutical sector rather than representing all the approaches to health research and all the major players. Notwithstanding the importance of pharmacological treatments, clarification of the excessive emphasis on technologies for drug discovery and the regulatory approval of new drugs would be welcomed.* In particular, it is asked whether engineering based health technologies will get sufficient representation on the governing board of Office for Strategic Coordination of Health Research (OSCHR).

[4] http://www.raeng.org.uk/policy/responses/pdf/cooksey_response.pdf

Health Technologies

4. The Academy wishes to draw attention to the importance of forms of medical treatment other than drugs, ie medical devices and health technologies. These have diverse applications, ranging from diagnostics to brain-machine interfaces. In the last few decades biomedical engineering has been enormously prolific. The development of such technologies is an important feature of translational medical research and many technologies have found rapid application in clinical practice.

5. Modern medicine is underpinned by biomedical engineering. Some examples of groundbreaking technologies developed for medical applications are:

- Magnetic Resonance Imaging, for which Sir Peter Mansfield shared the Nobel Prize in Physiology and Medicine in 2003.
- Computerised Tomography, for which Godfrey N Hounsfield shared the Nobel Prize for Medicine in 1979.
- Neurobionics (artificial limbs controlled by transduction of activity in the patient's brain), which will allow amputees (and those victims of the 7 July bombings who lost limbs) to regain some of the lost motor functions. This technology is still in development and in clinical trials, but is likely to progress to clinical application very soon.
- Assistive technologies of other sorts help to overcome the restrictions cause by physical and neurological handicap of various forms.
- Tissue engineering, using novel biocompatible materials, sometimes combined with cultured stem cells or differentiated cells, is gaining application in many areas of medical treatment.
- Novel transduction devices are being increasingly applied in diagnostics.
- Advanced operating theatres are being equipped to perform computer-guided surgery, remotely operated by experts.

6. The UK can claim the origin of many such ideas but too often they have been exploited in the United States and elsewhere, where they have been turned into profit-making applications. Magnetic Resonance Imaging is a prime example: the methodology was developed in this country, and the prototype machines were built here, but there is now not a single UK-based manufacturer. *Clarification as to why medical devices and health technologies, which are such an important and promising area of health research, were not fully considered in the Cooksey Review would be welcomed.*

7. *In addition, while the review recognises the need for a new Drug Development Pathway (Chapter 8), the challenges faced by the developers of medical engineering technologies are no less demanding and substantially different. An initiative to develop a similar focus on the medical engineering pathway should be considered simultaneously.*

8. Biomedical engineering is by definition a highly interdisciplinary research area and is underpinned by the most diverse blending of disciplines including medicine, engineering, physical sciences, materials, computer science, robotics and even social sciences. Clearly, MRC and DH R&D alone cannot provide all the resources needed to secure advances in this crucial area. Other Research Councils (ie EPSRC; ESRC) and the industrial sector have an important role to play. Hence, it is felt that the Review discusses too narrow a concept of health research rather than setting wider horizons for the change of culture that the Review would like to see happening within MRC and DH R&D in terms of interdisciplinarity, translation and innovation. *Clarification of the lack of discussion regarding the role that important players other than MRC and DH R&D may play in delivering the objectives set by the strategy recommended in the Review would be welcomed.*

Technology Assessment

9. There is some concern that expectation of Health Technology Assessment (HTA) in terms of its ability to provide prospective evidence of value is unduly optimistic (see Chart 7.1). If the HTA programme is to perform this role, it will be necessary to ensure that the programme will have both the methodologies and the capacity to be able to deliver this role: its traditional role has been in providing an evidence base on the relative effectiveness of existing health technologies. It is not clear that HTA can take this on without significant changes: a more creative approach to this development stage should be based on developers of new technologies working in partnership with potential users in assessing value (see also the comment in para 7.49).

Prevention

10. In the USA, the "NIH Roadmap", the initiative aimed at delivering translational research, focuses on effective prevention strategies as well as new treatments (para 3.4). By comparison, the Cooksey Report adopts a narrower definition of translational research which gives little recognition to prevention as a strategic health objective. Rather, it is focused on facilitating the movement of new drugs to the market. The Report identifies the largest future health challenges as cancer, mental health, chronic and degenerative

diseases, cardiovascular diseases, metabolic diseases and, within the context of international health, tuberculosis, malaria and HIV/AIDS. Diet and lifestyle play at least a part in the aetiology of most of these disorders and preventive measures could provide a very effective strategy.

11. The economic impact of successful prevention would be enormous. The importance of developing effective new drugs and the value of the UK's pharmaceutical sector are acknowledged. However, the Report seems aimed at addressing the current business problems of the pharmaceutical industry and encouraging those companies to conduct clinical trials in the UK, rather than strengthening health research as a whole. Why is there not more emphasis on increased public investment in epidemiological research and its underpinning methodology, in basic studies of gene-environment interaction in the aetiology of complex disease, and in research on social and behavioural determinants of health-related diet and lifestyle? *It is not clear why the Review has focused so intensely on the needs of the pharmaceutical industrial to the neglect of the importance of prevention.*

Clinical Trials

12. In para 6.25 it is stated that "the Report has not been able to carry out an economic analysis of the costs and benefits of attracting clinical trials to the UK" and that "There is a general lack of rigorous analysis of costs and benefits in this area". In subsequent paragraphs (7.20–7.23) it is argued that in the UK, small biotech and pharmaceutical firms face difficulties in attracting capital when this is most needed ie early stages of clinical trials, because UK venture capitalists are more risk-averse than their US counterparts. In addition, public investment in clinical trials in the UK is said to be modest. However, there is little evidence that those countries, such as the USA, in which there is more trial activity, gain economic benefit from it. Notwithstanding this lack of evidence, the Report recommends a substantial increase in investment of public funds to facilitate translational medicine (defined mainly as clinical trials), one of the principal aims being to encourage the pharmaceutical sector to conduct more clinical trials in the UK rather than across the Atlantic and elsewhere in the world. This recommendation is not supported by evidence that increased trial activity is likely to occur, nor that it would be sufficiently beneficial to the UK economy. *On what grounds can it be assumed that the pharmaceutical and biotech industries would increase clinical trials activity in this country to an extent that would justify the level of public investment recommended?*

Research in Clinical Settings and Training

13. Para 4.24 states that "the current funding levels for basic science should be sustained" and recommends that "future increases in funding should be weighted towards translational and applied research until a more balanced portfolio is achieved". However, the Report does not clarify how translational and applied research of high quality will be delivered in practice and what the optimal balance between basic, translational and applied research is. What evidence is there that increased investment in translation and applied research, without a parallel increase in basic funding, will yield better economic and health benefits, in the long run? Also, the Report makes its recommendations for changes in the balance of research on the assumption that the UK has the skill base to deliver translational and applied research of appropriate quality. These areas of research are notoriously difficult and the Report acknowledges that no country in the world has found a solution. Particular skills are needed and few individuals at present have such skills and experience. Where will appropriately trained researchers come from to deliver a significant increase in applied and translational research of sufficient quality to have impact? The Report acknowledges that research in clinical settings has declined in priority within the NHS because of massive pressures to deliver front line services (para 1 Foreword). Clinical training provides little time or incentive for training in research. Although implementation of the Walport Report, *Modernising Medical Careers*[5] is aimed at addressing this problem, it is likely to be many years before the decline of academic clinicians is reversed, and even longer before substantial new capacity can be built for high-quality clinical research. Translation is even more problematical, since it often requires very unusual combinations of skills and experience. *In light of the recommendations in the Report, more consideration should be given to measures to address the lack of skills necessary to deliver the proposed objectives.*

Interdisciplinary Research and Training

14. Translational research requires interdisciplinary skills that allow researchers and clinicians to communicate. With the exception of very few, unusually experienced senior scientists, researchers trained according to conventional routes struggle to gain sufficient understanding of disciplines other than their own to be able to recognise the opportunities of interdisciplinary working. Commonly, researchers have misconceptions and misunderstandings about what scientists from other backgrounds actually do, how they do it and what could potentially be achieved by working with them. In particular, exchanges at the interface between the life sciences and the physical sciences and engineering are notoriously difficult. The precision, accuracy and problem-focused nature of the numerate disciplines contrasts with the inherent unpredictability of the life sciences and the more open-ended style of research. The Report puts a heavy

[5] http://www.nccrcd.nhs.uk/intetacatrain/Medically_and_Dentally-qualified_Academic_Staff_Report.pdf

emphasis on the clinical trials "pipeline" as the essential feature of translational medicine. However, it is clear that effective translation is a much wider enterprise than this, and that the key to it is the encouragement of interdisciplinary interaction in every aspect of biomedical science, and the generation of a culture of translation among basic researchers. *There is a concern that the recommendation to establish a Translational Medicine Funding Board (TMFB), separate from the MRC's basic research, might actually decrease translational effort among the UK's excellent basic research community. In addition, if the TMFB is to achieve its full impact, it is essential that it should take its remit from the broad definition of "Medicine", ie the branch of health science and the sector of public life concerned with maintaining or restoring human health through the study, diagnosis and treatment of disease and injury (and not focus on drugs).*

15. "Research Teams of the Future" (para 3.4), which is also one of the components of the NIH Roadmap for translational research, is aimed at increasing interdisciplinary and innovative working and removing barriers to such approaches. Undoubtedly in the UK there is an urgent need to train a new generation of scientist who can engage dynamically in interdisciplinary and innovative research. This is an essential prerequisite to deliver the strategy that the Report is recommending. *However, the Report provides little insight into the deep problems that are obstacles to effective interdisciplinary collaboration and gives little guidance on how researchers who are expert in bridging disciplinary gaps can be trained. It is not clear how translational research of high quality will be delivered.*

Innovation

16. SMEs are critical to the development of many of the most innovative products and services, and to the long term health of the medical engineering industry. The comments on SBRI are welcome. It is suggested that the Cambridge report on Small Business Innovation Research (SBIR)[6] is taken as an aspirational challenge on what could be achieved through a more imaginative approach to research funding, especially in support of the development of this vital sector of the medical engineering industry.

Wanless Report

17. *The Wanless Report*[7] *has been extremely important in helping to provide a consistent vision of the challenges facing healthcare in UK, and some of the potential solutions. Will the continuation and updating of this type of visioning activity be an explicit part of OSCHR's remit which all stakeholders can use and debate the implications of?*

January 2007

Glossary

DH	Department of Health
EPSRC	Engineering and Physical Sciences Research Council
ESRC	Economic and Social Research Council
MRC	Medical Research Council
NIH	National Institute of Health
OSCHR	Office for Strategic Coordination of Health Research
R&D	Research and Development
SBIR	Small Business Innovation Research
SMEs	Small and Medium Enterprises
TMFB	Translational Medicine Funding Board

Memorandum 10

Submission from Universities UK

Introduction

1. Universities UK welcomes the Cooksey Report on UK Health Research which we believe to be of central importance to the future of health research in the UK and to the UK economy as a whole. Universities welcome the implicit recognition in the report that investments in developing the workforce and technological capability of the health research community represent a top priority for the UK in the 21st century.

[6] Secrets Of The World's Largest Seed Capital Fund: "How the United States Government Uses its SBIR Programme and Procurement Budgets to Support Small Technology Firms": David Connell, Centre for Business Research, University of Cambridge.

[7] http://www.hm-treasury.gov.uk/consultations_and_legislation/wanless/consult_wanless_final.cfm

2. Universities look forward to working with OSCHR, the MRC and NIHR in taking forward the report's recommendations. Universities UK would also be pleased to provide oral evidence to the Science and Technology Committee about the contribution that universities can make in implementing the report recommendations.

3. The Cooksey review provides an excellent opportunity to develop health research further and to support the health needs of the future. However, there is a danger that the full benefit may not be realised if the opportunity is not taken to think broadly about the implications of the future health needs of the population, and the kind of research needed to underpin future health services. With an ageing population, and health services which will be much more community based and focused on the management of chronic conditions, research effort needs to bring together public health, community health and social care in an inter-disciplinary and multi-disciplinary framework. The will have an impact on the topics for research, as well as the research expertise and professional skills required.

4. This response starts with some general comments, and then makes specific references to: bringing together the budgets; governance; the OSCHR; MRC boards; the TMFB; unmet health needs; the forum for international development; and research training funds.

General Comments

5. The move to recognise the imbalance between basic medical science research and clinical research, and the proposals to redress this imbalance, is welcomed. However the proposed changes are limited by the narrow scope of the recommendations, which will limit the impact on patient care and outcomes. In order to make a real difference to clinical care, the change in emphasis needs to incorporate clinical research and health services research, not just translational research. Translational research is that which makes the translation between basic science—the test-tube—to the clinical scenario—the bedside.

6. Although it may have been beyond the focus of this review, universities are concerned that no consideration appears to have been given to the social and environmental contributors to health and ill-health. Health research is assumed in the report to mean largely medical and disease related research. As such there is very little attention given to the pressing need for public health research, and scant acknowledgement of the need for research into non-medical aspects of health need and health care. This will require consideration of the relationship between the new OSCHR and other funding bodies such as the ESRC.

7. Throughout the report there is a strong emphasis on research carried out by medical professionals. It is assumed that the health researcher is a doctor, and the research considered is basic medical research or translational. Although occasional references are made to researchers from other professional backgrounds, and other types of research, none of the actual concrete proposals cater for them. This is a serious omission, as a much wider range of disciplines and professions are involved in health research, and this trend is likely to continue in the future.

8. Universities UK is concerned that bringing together the Department of Health and MRC research budgets may have a detrimental impact upon social care research, which is already under-funded in comparison with health care. The Department of Health is a substantial funder of research in social care and universities would not wish to see this diverted under the unified arrangements.

Bringing Together Medical Research Council (MRC) and Department of Health Research Budgets

9. Universities UK supports the recommendation to create a single ring-fenced budget to support UK health research. A single budget, if properly managed, should reduce bureaucracy and erode the artificial separation between the research agendas of universities and their partner NHS Trusts. It would encourage closer collaboration between the two sectors, focusing attention on the applications of research to patient care, at the same time incentivising NHS staff to undertake research.

10. Under the present system, there are significant differences in the funding regimes for the MRC and DH which will need to be reconciled. MRC funds are earned on the basis of research excellence, as judged by rigorous peer review, and measured against national and international priorities. Funding awarded to universities by Research Councils and other external funders is ring-fenced and cannot be used for any other purpose. The majority of NHS R&D funds are allocated formulaically for research infrastructure, although it is often difficult to trace this income stream to specific R&D support.

11. Implementing a single fund for health research will therefore depend upon the success of the "Best Research for Best Health" (BRBH) ambition to make available for direct funding of research the notional funds currently included in block grants to NHS Trusts. In its submission to the Cooksey Review, Universities UK argued that whilst this may offer opportunities to incentivise research within the NHS, it will also take out about £550 million from the NHS, at a time when it is over £500 million in deficit. Even if Trusts are able to regain income equivalent to their current R&D levies under BRBH, universities remain concerned that the new income will be ring-fenced for specific research initiatives, reducing flexibility, and leaving an underlying deficit which could seriously destabilise clinical services. This could place an enormous

strain on the university/health service research partnership, at a time when the financial impact of other reforms (for example, full economic costing, the review of SIFT funding and the introduction of payment by results), are becoming apparent. There is a risk that this combination of changes will fundamentally damage the underpinning infrastructure for health R&D. The transitional arrangements for the implementation of Cooksey's recommendations therefore need to be managed so that this does not happen.

12. Additionally, it will be important to re-evaluate the entire range of research interests and methodologies that exist along the biomedical research pathway from basic discovery to applied research to ensure that an appropriate proportion of spend is allocated across the spectrum.

13. The single fund should also consider setting aside funds for infrastructure development in areas such at IT and clinical research facilities, to support seamless working across partner organisations.

Governance

14. We believe that a novel governance model is needed which draws on the best features of the two current schemes and acknowledges the interdependence of the NHS and its academic partners. All key stakeholders should be involved—government departments, research councils, universities, the NHS, medical charities, industry and patient groups.

15. While the proposed single budget and single resource allocation methodology are attractive, there are difficulties—principally, agreeing the appropriate proportion of the fund to be distributed to different elements of activity. Without careful management, basic research could benefit at the expense of more applied research simply because the metrics are more easily defined for laboratory-based research. It will also be difficult, we suspect, to resolve the "ownership" of a single fund in a way that both partners in the scheme will find equitable.

The Office for Strategic Co-ordination of Health Research (OSCHR)

16. The OSCHR will play an important role in facilitating and co-ordinating interactions between the MRC and DH Research and Development, as well as monitoring their performance. Given the increasing emphasis placed on the independent, community and voluntary sectors as health care providers, the OSCHR also offers an opportunity to promote research for the health of the whole UK population, rather than simply responding to the needs of the NHS. The need for a greater emphasis on applied and translational research is reflected by the recommendation that the new body reports to both the Health and Trade and Industry Ministers.

17. However, universities are concerned that the establishment of the OSCHR could lead to the introduction of a further level of administration within the system. Although described as being relatively "light", any further administrative level will create inevitable delays in approval processes and a top heavy administrative framework could potentially stifle research initiatives, particularly blue skies research. It is critical that the work of the OSCHR complements the "bottom up' approaches" pursued by many clinical researchers and avoids setting research priorities via a top down approach. The means by which the OSCHR will set objectives and assess outcomes should be clarified and the longer term appropriateness of this overarching office should also be reviewed following the initial transitional period.

MRC Boards to Take on Wider Range of Health Research Representatives

18. The proposal to create a broader based MRC board is welcome. In seeking to embrace further applied and translational research and alongside the creation of the new Translational Medicine Funding Board, it is also timely for the Board membership to include representatives.

19. From a much greater range of academic disciplines and expertise.

The Translational Medicine Funding Board (TMFB)

20. Universities UK welcomes the creation of the new TMFB which should be at the forefront of funding both translational and clinical research based on peer reviewed scientific evidence to meet the future health needs of the population and to support current health service needs.

21. However, Universities UK would support CHMS's request for clarity on the scope of the new Board and in particular whether the TMFB would have responsibility for research likely to benefit public health, as distinct from clinical medicine. If this is the case, secure public health representation on the board will be necessary. If, however, this does not fall within the remit of the new Board, there should be a clear focus for the coordination of public health research, particularly in light of the current low investment from the DH in public health research and development.

Department of Health Reviews of Unmet Health Needs and Strategic Directions for Diseases

22. It is essential that he DH monitor more closely unmet health needs and consider ways of addressing them. While prioritising the major killer diseases is understandable, the social and economic impact of conditions that may not kill but cause long term morbidity must be recognised and funding for research in these areas should be enhanced.

23. While universities recognise that the setting of priorities for research under the new merged fund would be necessary and indeed desirable, Universities UK is disappointed to note that this is articulated as being wholly concerned with disease areas. This will undoubtedly be to the detriment of research into public health areas, such as obesity, where the associated morbidity will have an increasing impact on the economy as a whole. It will also be important to ensure that the new merged fund supports research into other health problems which researchers identify outside these priority disease areas.

The Forum to Facilitate Collaboration for Health Research in International Development

24. The attention given in the Cooksey Report to the need to address research in a global environment is welcome, but further detail is required on the structure of this new forum. If research representation is solely from members of the NIHR, Universities UK is concerned that many experts with discipline specific knowledge who lack an honorary NHS contract will be excluded from participation. The forum may therefore find it is not able to access the most innovative and cutting edge thinking.

Research Training Funds

25. Universities UK welcomes the suggestion that support for the training of clinical academics be ring fenced. As evidenced by the annual CHMS Survey of Clinical Academic Staffing, 2006 saw the number of clinical academics in the UK fall below 3,000 for the first time since 2000. Universities UK is pleased that the need to encourage the brightest young doctors into a clinical academic career has been recognised in the report, and expects to see the ring-fenced training extended to other professions and academic disciplines who undertake clinical roles as well.

January 2007

Memorandum 11

Submission from the Peninsula Medical School

The Peninsula Medical School welcomes Sir David Cooksey's excellent report. The School is particularly pleased that the need for a central coherent strategy has been identified to optimise the contribution of healthcare research to UK plc and national health gain. The detail of that strategy is likely to inform the precise governance arrangements and modus operandi of OSCHR.

OSCHR

The School strongly supports the appointment of Professor John Bell as Chair of OSCHR. Too great a reliance on setting research priorities via a "top-down" approach should be avoided however and it must be recognised that some of the most significant medical advances have emerged from research on low incidence conditions which nonetheless involve mechanisms with far reaching implications. The work of OSCHR must complement "bottom up" approaches as pursued by many clinical researchers.

A preponderance of targets has become an intractable part of NHS culture and the School is keen that this is not replicated within the methods of working of OSCHR. The means by which OSCHR will set objectives and assess outcomes should be clarified. A top heavy administrative framework could potentially stifle research initiatives, most particularly blue skies research, involving University partners.

Biomedical Research Centres

The creation of a small number of major, truly internationally excellent biomedical research centres is crucial if the UK is to be globally competitive and benefit fully from the investment in Research and Development. Increasingly sophisticated characterisation of populations including genetic studies, which the NHS is well positioned to facilitate, will be required to take advantage of the knowledge of the human genome, *inter alia.* Such studies will require the development and sustenance of national research networks supported by strong regional centres, which will in turn accelerate the productivity of the Biomedical Research Centres. The Peninsula Medical School is one such Regional Centre, acting as a hub for the entirety of the new NHS Local Research Networks and having secured experimental medicine funding for

population genetic studies. Internationally competitive research and research of key relevance to high quality clinical care and Regional Economies must also be supported in regional centres, such as ours, if the full benefits of the UK's health research endeavours are to be realised.

Real opportunities exist to explore links between medical schools, the NHS and industry, collaborations vital to increasing the competitiveness of the UK in health research. More needs to be done to incentivise research in the NHS. Industry needs to make industrial careers and short term industrial experience more appealing to academics and it is important that academe better recognises the value of engaging with pharma.

Healthcare Commission

It is recommended that the Healthcare Commission's targets should reflect research activity in quality adjusted terms. The School suggests citations, impact factors and the perceived quality of the research funders could be taken into account here, although it must be borne in mind that such simple factors often fail to measure the clinical impact of research.

Ring-fenced Funding

The School welcomes the suggestion that support for the training of clinical academics be ring fenced.

The Roles of the NIHR and MRC

Changes to NHS research funding under "Best Research for Best Health" whilst promising, are as yet untested in practice whilst the MRC has a proven track-record of making competitively awarded, rigorously peer-reviewed research allocations. It is critically important that the integrity of the MRC system of rigorous peer-review is not compromised under the proposed framework and that the NHS R&D system continues to embrace such existing best-practice.

It is essential that the MRC, as well as the NIHR, and crucially the HTA, continue to fund large phase three clinical trials, particularly those complex interventions in a community-based setting.

Capacity Development

Adequate support for trials units is vital in order to allow capacity to conduct trials and well-designed studies. The chronic shortage of non-medical researchers, predominantly non-clinical methodologists such as health economists and statisticians, engaged in this area must be addressed.

RAE

The School would welcome clarification from the NHS R&D Directorate as to whether funding awarded from the NIHR to Trusts should be allowed to "count" in the RAE returns of the Trusts' partner universities. It is anticipated that university employed clinical academic staff, those holding an honorary NHS contract, will be those applying for research funding through the NIHR and pursuing research on this basis.

As a "new" medical school, we are particularly pleased that the requirement to further develop our infrastructure has been recognised but would welcome clarification of how the £50 million is to be disbursed.

University/NHS Collaboration

The School is concerned that there is no mention of the Department for Education and Skills in the Cooksey Review. The School's clinical academic staff relate to non clinical researchers in both the Universities of Exeter and Plymouth. Our Universities have a vital contribution to make to the UK's research agenda and as such representation from the DfES as well as DH and DTI should be sought in the coordination of the UK's health research strategy.

We are pleased that the team recognised the issue around VAT and the use by others of university research buildings. We suggest that the British University Finance Directors be commissioned to develop a workable solution to the problem, in collaboration with the Association of UK University Hospitals' Finance Directors group.

Transitional Medicine Funding Board

The Medical School would like to request clarification on the definition of translational medicine and, indeed, why there is a need for a new Board in addition to OSCHR.

January 2007

Memorandum 12

Submission from GlaxoSmithKline

Summary

The interests of patients, industry and the UK economy are served by an environment that supports the research and development of innovative medicines that add value. The Cooksey Review identifies environmental factors that would make a difference in the UK and makes a number of very constructive suggestions to achieve this goal. GSK supports the premise on which the Cooksey Review was initiated in that healthcare research is failing to realise its full potential in the UK.

In terms of the recommendations, GSK welcomes the establishment of a single health research fund to help with the translation of basic biomedical research outputs into clinical application. In this regard, biomedical research should be viewed as a continuum; support for the UK's excellent basic biomedical research base and the continued generation of our talent pool should not therefore be neglected. To ensure improved benefits to patients, the high standard of large late stage clinical trials conducted in the UK needs must also be maintained and should remain focussed on national and international objectives.

The proposals on prioritisation of diseases, focusing government health funding on research that will aid the discovery of new medicines and earlier signalling of what medical advances will be valued by payers could also deliver real progress. The proposals to bring new medicines to patients more quickly and provide fairer reward for medicines that deliver value to patients and society are also welcome.

GSK would support the research fund being used to establish a clinical research cadre, with a medical workforce that recognises the benefits of clinical research early in their training and effective incentives being introduced to encourage institutions and physicians to engage in such research. Increasing flexibility of movement of scientific staff between academia/NHS and Industry should be a key objective in building a research cadre and would benefit all parties.

GSK has an open mind on the concept of conditional regulatory approval for new medicines, with additional post-approval monitoring once the medicine is used in clinical practice. A real opportunity to assess the scientific validity of this proposal and to accelerate change could be developed in the UK through the development of real-life pharmacovigilance, facilitated by a research-focused NHS National Programme for IT, being delivered through Connecting for Health (CfH). The recognition given in the Review to the importance of the establishment, through CfH, of a national integrated electronic healthcare information system that will give full consideration to the needs of researchers in industry, academia and public health is very welcome. In addition to the above benefits, this will be a major enabler of clinical research in the UK.

The concept of earlier dialogue between NICE and the industry to inform the development of new medicines is welcome. What is needed is advice that allows the flexibility needed in a global clinical development plan. GSK looks forward to working with NICE, the Department of Health and other stakeholders to further refine this proposal.

Industry, Government, Regulators and Academia must now work together to turn these ambitious proposals into reality, recognising the need to balance a strategy for the UK with wider European regulatory requirements and the realities of global medicine development programmes. GSK hopes to play a key role in this process and also that, over the next five years, the Cooksey Review will encourage other bolder initiatives for the establishment of a research-based culture in the UK and the expansion of a research infrastructure through effective training and career incentives, both in clinical research and other related fields.

Introduction

GSK is one of the world's leading research-based pharmaceutical and healthcare companies. We are involved in the research, development, manufacture and commercialisation of prescription pharmaceuticals, vaccines, over-the-counter medicines, and health-related consumer products. In 2005, GSK invested £3.1 billion in R&D globally with £1.3 billion of this being spent in the UK. GSK's R&D organisation employs almost 15,000 people, with 6,400 of those employed in the UK, where we have nine R&D sites.

GSK welcomed the announcement that a single, ring-fenced budget, worth at least £1 billion per annum, was to be established to support the health research funded by the Medical Research Council and the NHS R&D Programme. It is very positive that this funding has been confirmed and that a strong oversight mechanism will be established to develop clear accountabilities, thus ensuring that this investment delivers innovation in health care.

In submitting our original comments to the review by Sir David Cooksey we welcomed the fact that the review would consider the full spectrum of research, from basic biomedical science through to later stage clinical studies and improvements to patient outcomes. Key factors influencing GSK's continued long-term investment in the UK include the strength of the UK's basic biomedical research in universities and research

institutes and the quality of its skills base and talent pool. Maintaining the quality of the basic biomedical sciences base is important for the development of individuals with key skills, research output, effective collaborative research, knowledge transfer and the recruitment of talent.

GSK agrees with the Review's findings that both the translation of basic research into a clinical context and healthcare research in general has been failing to realise its potential in the UK. We welcome therefore the Review's focus on the need to strengthen the UK's expertise in translating the outputs from its basic research base into clinical practice. However, it must be appreciated that translational research is not a one way process, but a bi-directional flow requiring a strong clinical science base to understand disease processes. This means that, in addition to supporting a wider group of clinicians engaged in research and trials, the pool of clinical scientists must also be strengthened. Whilst recognising the demands of NHS service work, attention is needed to ensure that the importance of clinical work research is also appropriately recognised.

GSK Comments on the Recommendations of the Cooksey Review of UK Health Research Funding

Establishment of the Office for Strategic Coordination of Health Research (OSCHR) and the NHS National Institute of Health Research (NIHR) as an Executive Agency

For the results of basic research to be translated more efficiently and rapidly into new methods of diagnosis and treatment and improved patient benefit, the establishment of a stronger culture of joint working between all funders of biomedical research including industry and the medical charities is required. GSK is very supportive therefore of the Review's proposals for the encouragement of stronger partnerships between Government, health industries and charities.

We support the establishment of the OSCHR which could bring the best elements of the MRC—rigour of peer review and science quality—together with those of NHS R&D—immediate engagement with clinical problems of importance—into a common governance framework. We would ask however that further consideration be given to the notion that some aspects of the new research strategic umbrella should be extended over other research councils, such as the EPSRC, to help drive innovation. This could well support the excellent work that the EPSRC is doing in promoting interdisciplinary research and training and assist it to overcome the difficulties it faces in finding effective ways for medics and engineers to work together and therefore bring the best technology to problems quickly.

The Cooksey Review recommends that the MRC should continue to operate independently. As the recommendations of the Review are implemented, it is of vital importance that funding is continued to maintain excellence in the UK's basic biomedical research base and the development and generation of the UK's talent pool. The new arrangements being introduced should not negatively impact the basic sciences budget due to the focus on current health care priorities.

The creation of the virtual National Institute for Health Research is a relatively recent development and it is therefore too early to assess the impact of making the NIHR a real, rather than a virtual, institute, separated from the Department of Health as an executive agency. If this protects the ring-fencing of the research budget of the Agency and contributes to a new pro-research culture in the NHS, then it is to be supported.

GSK would welcome the communication of the government's health priorities to industry. We support the concept of identifying and badging priority projects and providing them with procedural benefits, such as faster clinical trial approval or quicker NICE review. It remains to be seen how this will occur and how priorities will be agreed. Implementation and the decision-making processes to agree priorities will require careful consideration with all stakeholders.

The Creation of a Translational Medicine Funding Board

GSK supports the creation and proposed goals of the joint MRC-NIHR Translational Medicine Funding Board and particularly welcomes that industry will form a key part of the Board. The Board will contribute to the creation of a stronger research culture in the NHS, but its remit should be crisply defined as should an effective strategic direction for funding. Progress towards achieving goals should also be periodically reviewed.

Any new Health Research fund should focus its funding on where it can add most benefit to the UK in the longer term. It is to be welcomed therefore that the MRC-NIHR Board will seek to direct funding towards projects that promise health and economic benefits.

Making the NHS more research and innovation-friendly

A number of proposals are made in the Review that would make the NHS more innovation-friendly. GSK supports the suggestions made and in particular the recommendations to develop incentives for innovation that will drive better healthcare and the establishment of a systematic approach to adopting new technologies. The incentivisation of physicians and NHS Trusts to become more involved in research will be a priority and increased funding for research training and enhanced clinical research career development opportunities should also be pursued.

The Cooksey Review does not adequately address how a clinical research cadre can be developed in an environment in which the rewards of private medicine are high, the demands on NHS appointees (with significant NHS service commitments) are significant and university support for clinical academic posts is not increasing. Major cultural and behavioural changes within the NHS and research community are needed in order to achieve this goal. Neither is the problem simply related to money, time and management practice are also contributing factors. Ground-breaking world-class clinical research will not be delivered by clinical researchers who spend only a small portion of their working time on R&D. We believe this warrants further thought.

Although progress has already been made, the excessive bureaucracy that restricts clinical research in the UK must be removed if the benefits of the single health research fund are to be achieved. Through the UK Clinical Research Collaboration and the Department of Health's R&D strategy "Best Research for Best Health", significant effort has been put into increasing the competitiveness of the UK clinical trial environment, but further work is needed. The lack of sufficient infrastructure in the UK research community to efficiently comply with the demands of safe and compliant clinical research should also be a priority as the Review is implemented.

Enhancing medicine development and the uptake of clinically- and cost-effective new technologies

The Review recognises the need to support a more pro-active approach in the NHS to the adoption of cost-effective new ideas, process improvements and technologies. This is positive as this is a significant driver of research and development as is market uptake of the products of research. GSK particularly welcomes the fact that a clearer process will be developed for ensuring that the initial assessments and recommendations made by NICE are implemented.

GSK supports greater resourcing for NICE and would welcome a focus on developing a mechanism by which advice was provided to companies to inform development planning. Pragmatism will be needed to ensure that the expectation is not generated that ever increasing quantities of data would be created prior to launch, especially as that would further add to the cost of developing a new medicine. Industry and NICE should also work together to agree how to deal more effectively with new medicines where there is insufficient data available at launch for NICE to recommend use in the NHS.

The Review recommends that a new partnership should be created between government, regulators and industry to pilot a new drug development "pathway". We understand this to mean that certain medicines might be released for community use earlier, with a reduced clinical trial dataset, and that patients taking these medicines would be monitored closely for efficacy, safety and outcome parameters. The data collected from these "early users" could also increase the volume of "real life" data available at the point in time when the approval would have been given under current approval regimes.

This concept is scientifically sound, but difficult to realise. It would be most relevant for diseases where there is high unmet medical need and these diseases may provide the basis for such a pilot.

The research potential of Connecting for Health

Many of the organisational and cultural issues in the NHS and academia identified by Sir David Cooksey need to be addressed before the benefits of Connecting of Health could be achieved. The development of the research applications of the National Programme for IT would certainly have a major impact upon clinical research in the UK: access by researchers to a national integrated healthcare information system of linked, anonymised, electronic primary and secondary healthcare records would improve the efficiency of recruitment of patients into clinical trials and will also make a significant impact on large-scale epidemiological studies and in improving patient safety through enhanced pharmacovigilance and the monitoring of real-life data.

Additional funding for clinical research to be considered in the Comprehensive Spending Review (CSR)

A number of proposals have been made for additional funding to be considered in the Comprehensive Spending Review in 2007. This would be extremely positive, particularly the creation of a sustained capital budget for NHS R&D. The fact that funding is to be allocated to support the establishment of the NHS R&D's "Best Research for Best Health" Centres of Biomedical Research excellence, the first tranche of

which have recently been announced, is also to be welcomed. It is important though that future funding be flexible so that other developing institutions are encouraged to improve the quality of their research and to benefit accordingly.

January 2007

Memorandum 13

Submission from the British Medical Association

1. The British Medical Association (BMA) is a voluntary, professional association that represents doctors from all branches of medicine all over the UK. It has a total membership of over 138,000, rising steadily, including more than 2,500 members overseas and over 19,000 medical student members.

2. The BMA's Medical Academic Staff Committee (MASC) is a UK Committee representing the interests of those employed by higher education institutions, medical schools, Research Councils and other institutions engaged in medical research. The MASC broadly supports the recommendations in the Cooksey report *A Review of UK Health Research Funding*.

3. We note that the synergistic interlinks between research, education and clinical practice are not covered in detail in the report. Excellent clinical practice should not be separated from clinical education and clinical research. It is essential that the links between education, research and clinical practice are maintained and that all academic posts involve training the next generation of academics as well as the delivery of excellent clinical services.

4. The MASC has been supportive of the proposals in *Best Research for Best Health* including the establishment of a National Institute for Health Research (NIHR). We further welcome the recommendation that the NIHR be a real agency of the Department of Health.

5. We wish to highlight our unreserved support for the recommendations around ensuring the ring fence of the R&D budget is effective and that there are appropriate incentives for the NHS to spread best practice in health research.

6. In our response to the Cooksey consultation in July 2006, the MASC expressed concern about the funding for the Walport trainees through the Multi Professional Education and Training (MPET[8]) budget. In November 2006, the MASC outlined in more detail the concern over the instability of the current funding arrangements for academic medicine in Supplementary Evidence to the Health Select Committee's 2006 inquiry into NHS deficits.

7. Previously the MPET budget was a direct central allocation to NHS organisations but in 2006, a number of budgets were given to directly Strategic Health Authorities (SHAs) for local management[9]. However, first quarter performance for the NHS[10] indicates that SHAs have been required to save £350 million which is to be used to off-set overspending elsewhere and will be held centrally by the NHS Bank as a "contingency fund". It appears that many trusts are cutting MPET budgets to meet the requirement to support the "contingency fund".

8. Medical academic salaries in England and Wales are primarily funded by a combination of monies from the Higher Education Funding Council (FC), the NHS (the SIFTand MADEL elements of MPET), with a small proportion funded by the Research Councils. However, in some medical schools, and in some specialties, the proportion of NHS funding for clinical academic posts is much higher than FC funding. This includes the medical schools at Swansea, Keele, Bristol, Leicester and Warwick[11]:

Medical school	*% posts paid for by NHS funding (SIFT/MADEL)*
Swansea	94.74%
Keele	93.14%
Bristol	71.07%
Leicester	66.75%
Warwick	58.10%
UK Average % of posts funded by the NHS—38%	

[8] See "Key to Terms" at end of evidence for definitions.

[9] The affected budgets are: public health, medical education and non-medical clinical training (ie MPET), GP performance reimbursement, clinical excellence awards and walk-in centres/OOH/NHS Direct. See *NHS financial performance—Quarter 1 2006–07*, Department of Health.

[10] *Ibid.*

[11] Clinical Academic Staffing Levels in UK Medical and Dental Schools June 2006, A data update by the Council of Heads of Medical Schools and the Council of Heads and Deans of Dental Schools.

Speciality	*% posts paid for by NHS funding (SIFT/MADEL)*
Radiology	63.83%
Anaesthetics	59.80%

9. In effect, Universities have gradually reduced the numbers of clinical academics, (primarily teaching academics), by moving the funding of teaching academic salaries away from universities into the NHS funding streams, that is, SIFT and MADEL.

10. Over the past five years, the number of medical students has increased by almost 10,000 to meet the future needs of the medical workforce, and at the same time there has been a 25% reduction in academics[12] and an associated shift of undergraduate education to the NHS. This shift has primarily been brought about by pressure from the Research Assessment Exercise, which moves the emphasis away from teaching and NHS research.

11. Despite the significant decline in the clinical academic workforce over the past five years, the number of vacant posts currently comprises 7% of the total number of academics. Vacancies have continued to increase over the past year are especially prominent in senior academic positions—there were 91 professorial vacancies across the UK in 2005[13].

12. In addition, over the last 10 years a significant number of medical academics have been made redundant (mainly arising from Research Assessment pressures which encourage universities to divest academics that are not likely be returned), but the latest round of MPET funding cuts may well disproportionately fall on academics.

13. For example in Leicester, the Chief Executive of University Hospitals Leicester Trust wrote to the Vice Chancellor of the University advising that funding for clinical academics would need to be reduced by 20% to help the SHA make savings of £52 million. The reduction in funding to NHS employed teachers has not been quantified to the BMA, but may well be significant. Making the required savings would be equivalent to a 15% reduction in Leicester's medical academic staff or 11 or 12 posts. In addition, there are approximately four senior (senior lecturer or professorial posts) that are currently vacant and the advertisements for the vitally needed Walport Academic Clinical Fellow and Clinical Lectureship posts were threatened.

14. There are financial disadvantages of undertaking a career in academic medicine that must be addressed. Clinical training in academic medicine will take longer than standard training due to periods spent undertaking research that ultimately provides tangible economic and health benefits to the NHS. These separate periods of pecuniary disadvantage accumulate over the course of a career.

15. For example, trainees that choose to spend time teaching or undertaking research are likely to be disadvantaged in terms of pay if salary is linked to the "intensity" of work, or linked to university pay scales. Attainment of academic posts equivalent to SpR level requires completion of a higher degree—at which point trainees' salaries are based securing a grant unconnected to the NHS pay rates. In addition, the length of academic training delays appearance on the consultant pay scale, there are restrictions on private practice and crucially, comparatively worse conditions and benefits by the substantive University employer.

16. Follett principles of "joint working to integrate separate responsibilities" and the synergistic nature academic work must be properly acknowledged by both employers[14]. Despite the recommendations of Follett, employers do not fully recognise the need for balance between the three core areas—clinical, research, and education and training. The BMA is aware of examples where Universities press individuals to reduce their NHS commitment especially if they have over five NHS programmed activities in their job plan, without considering the impact this may have on research and service delivery. University and NHS employers must acknowledge the pressures each sector faces. There is a long overdue need to remove the problem of the Research Assessment Exercise rewarding non-science laboratory based research, to the detriment of clinical research and the doctors that undertake this research.

17. We note that the report recommends that "the UKCRC should develop a model framework for partnership working to improve university-NHS collaboration" (p 73). We wholeheartedly support this recommendation and the Select Committee may like to note that the BMA has been working with the University and Colleges Employers Association on agreeing a Memorandum of Understanding on joint

[12] *Ibid.*

[13] *Ibid.*

[14] *A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties—A Report to the Department for Education and Skills by Professor Brian Follett and Michael Paulson-Ellis*, DfES 2001.

working. The Memorandum outlines the employment and joint working arrangements that usually apply in the case of staff engaged in both teaching and/or research as well as the delivery of patient care[15] and should be published shortly.

18. We are also pleased that the report recommends that the funds to support the leaders of health research in the UK should be moved into the new single ring fenced budget and so safeguard the workforce which delivers UK health research.

19. The MASC calls on the Select Committee to ascertain from Sir David whether the Department of Health has supported the following recommendations:

(i) That the salary component of the funds for the Walport Clinical Academic Fellows and the Clinical Lecturers currently funded though the Department of Health's Multi-Professional Education and Training Levy (MPET), be moved into the single ring-fenced budget for Research and Development and used specifically for this purpose.

(ii) That the funding for the Clinical Scientist Awards for post doctoral training of Clinical Lecturers (also currently falling within in the MPET budget) be moved into the single ring fenced budged and used specifically for this purpose.

(iii) That the funding for people doing research who are employed by both the NHS and universities whose salaries are currently funded via the patient care budget, should be identified and transferred it to the ring-fenced DH Research and Development budget and used specifically for this purpose 20. We note that the health research arrangements in Devolved Administrations included covered in the report. Being mindful that the MASC is a UK Committee, we would ask that the Select Committee seek clarification as to what extent the recommendations will apply in Devolved Administrations.

21. Finally, we further call on the Select Committee to outline the progress made by the UKCRC in discussions with the Department of Health in using incentives such as Clinical Excellence Awards to reward successful dissemination of research findings as indicated in the report (pp 78, 79).

Key to Terms

MPET

MPET stands for Multi Professional Education and Training levy (MPET). It is a funding stream from the Department of Health that funds the additional costs to the NHS of supporting the practice experience of medical and dental students. The single funding stream comprises the following levies NMET (Non Medical Education and Training), MADEL (Medical and Dental Education Levy) and SIFT (Service Increment for Training).

SIFT—The Service Increment for Teaching

The Service Increment for Teaching (SIFT) component of MPET covers the costs to the NHS of supporting the teaching of medical undergraduates. It is not a payment for teaching as such. For example, consultants in an outpatient clinic or a GP in a surgery generally see fewer patients if students are present. SIFT is intended to meet this sort of excess cost, rather than pass it on to healthcare purchasers.

MPET—Medical and Dental Education Levy (MADEL)

The MADEL component of MPET was introduced in April 1996 as a means of providing support for postgraduate medical education in the NHS and to support key central initiatives in medical education. The majority of the budget funds salary and non pay costs, which are identified as the training element of medical and dental training grade posts, as set out in EL(92)63. However study leave and the infrastructure costs of providing Postgraduate Medical and Dental Education are also funded. Funding for the salary element is based on the number of training posts accredited with the appropriate educational approval. Additional posts are funded via the Workforce Numbers Advisory Board's process of projecting national consultant requirements.

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[15] The document does not cover all staff who hold both substantive and honorary contracts with universities and NHS organisations. It covers only those staff with honorary contracts engaged in both teaching and/or research as well as the delivery of patient care. The formal agreements currently in place are likely to cover only medical and dental practitioners. However this situation is changing for other professions. The document therefore deliberately encompasses any health care professional engaged in both teaching and/or research as well as the delivery of patient care.

Memorandum 15

Submission from the Medical Research Council

1. The Medical Research Council (MRC) welcomes the opportunity to provide input to the S&T Committee. The MRC provided written evidence to the Review team. This is available on our website[16].

2. The Cooksey Review provides a perceptive analysis of the "gaps" in the translational pathway—firstly between discovery—ie lab, clinic, or population based which yields new knowledge or opportunities and the development of new treatments or interventions, and secondly between acquiring the evidence base for change, and actually introducing new policies or treatments into clinical practice. We welcome the Report's recognition of the strength of the UK health research base and share the review team's belief (Paragraph 4.24) that current funding levels for basic science should be sustained, on the understanding this means in real terms. Supporting research with the aim of improving human health is at the heart of the MRC's mission. As we said in our submission to the Review, we fully embrace the Government's vision of a more integrated health R&D system across the entire UK, and we welcome the opportunities set out in the Report.

3. The MRC is fully committed to strengthening translation of scientific discovery into benefits for society, and has been in the forefront of efforts to improve scientific links between basic, clinical, and population level research, and to strengthen applied health sciences, mostly through our Health Services and Public Health Research Board. MRC Technology has also proved highly successful in commercialising discoveries from MRC's intramural programmes, creating new high-skill jobs in the UK, and generating revenue which is ploughed back into research.

4. Other specific MRC activities relevant to addressing points made in the Review include:

- The MRC has begun a pilot scheme for "Research translators". The aim is to develop a cadre of individuals with the expertise to make new links between science and the users of the science. This initiative was supported in the Cooksey Review as addressing a skills gap (paragraph 7.17).
- A "Translational Research Workshop" planned for 20–21 February 2007. The aim of the Workshop is to identify ways of improving the assessment methods, funding criteria, and funding rules for the growing volume of applied and translational research in MRC's portfolio.
- We are holding a series of "Showcase events" involving MRC scientists and senior people from pharmaceutical and biotech companies. Four such events are planned covering different aspects of the MRC's portfolio; the first was held in December 2006, the remainder are scheduled for 2007.
- The establishment in 2006 of a Council Subcommittee on Evaluation. The Committee is developing a programme of evaluations, including one, jointly with the Wellcome Trust and the Academy of Medical Sciences, on "Assessing economic benefits of medical research in the UK".

5. We welcome the Review's endorsement of our own view, and that of the other Research Councils, that the MRC remain part of RCUK, as it is crucial that we retain, and build upon, our current links with other Research Councils (paragraph 5.68). This should help ensure that research at the boundaries of health research and other disciplines receives adequate funding and attention.

6. There are a number of topics which will need clearer definition as we go forward and put into operation the recommendations of the Review. We will also need to develop, with NIHR and OSCHR, plans for transferring responsibility for funding in areas such as HSR (Health Services Research) and Health Technology Assessment—in ways that do not disrupt the research, and which improve clarity for applicants and users of research alike.

7. We look forward to working with Professor John Bell as the interim chair of the new Office for Strategic Co-ordination of Health Research (OSCHR), and with all the other partners in the new organisational structures including in particular the NIHR and the Devolved Administrations.

8. I have already met John Bell to discuss the role of OSCHR, and have discussed with him and with OSI the possibility of seconding staff to OSCHR.

9. MRC Council will discuss the Review again at its meetings later in January (29), and in March.

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Memorandum 16

Submission from Cancer Research UK

1. Introduction

1.1 Cancer Research UK[17] is the world's largest independent organisation dedicated to cancer research, with an annual research spend of £300 million. Cancer Research UK funds research into all aspects of cancer from exploratory biology to clinical trials of novel and existing drugs as well as population-based studies

[16] www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d = MRC002600
[17] Registered charity No 1089464.

and prevention research. We are the major non-commercial funder of research into drug innovation in Europe. Our funds are raised almost entirely through public donations. More than one million people regularly donate to Cancer Research UK.

1.2 Cancer Research UK welcomes the findings of the Cooksey Review. We also congratulate Sir David and his team for the inclusive approach taken in conducting this review. As well as providing an extensive evidence submission, Cancer Research UK had the opportunity to meet with the Cooksey Review team on several occasions and we are pleased to see recommendations that reflect these positive discussions. In particular we were glad that the experience of Cancer Research Technology was of use in framing the proposals on improving innovation and knowledge transfer in the UK.

2. General Comments

2.1 The UK has an enviable global reputation for medical research. The NHS provides a unique environment and opportunity to undertake world leading scientific, clinical and population based research. We welcome the commitment in the Cooksey Review to maintaining funding for health research across the UK and the recognition of the important role that this research plays in improving the health and wealth of the nation.

2.2 In this respect we support the commitment to ring-fencing Department of Health Research and Development funding, to protect this from being redirected to other areas of NHS activity.

2.3 A continued determination to work with funding partners, especially charitable funders, such as Cancer Research UK, will be crucial if these proposals are to work in practice. We are a little disappointed that specific assurances about this are not contained within the body of the report. As the major funder of academic clinical trials in the UK, and significant funders across the spectrum of health research, we believe that this involvement should be explicitly recognised above and beyond our role as partners within the UK Clinical Research Collaboration (UKCRC). Although the UKCRC does currently have significant influence over the strategy and coordination of clinical research in the UK, there is no guarantee that this will continue once the current workstreams (Regulation and Governance, Medical Careers, Infrastructure, NHS inducements for Research) come to completion. Cancer Research UK does not wish to have such a temporary working relationship with the Government's biomedical or health research activities.

3. Institutional Arrangements

3.1 It is important when implementing the many laudable recommendations of this review that the institutional arrangements do not become an extra layer of debilitating bureaucracy. We believe that it is vital to maintain a degree of flexibility with a new system. We would also like further assurance of the political independence of the Office for Strategic Coordination of Health Research (OSCHR). While current close links between this body and the Treasury are clearly of benefit, it is important that this structure should continue to work regardless of future changes in the political landscape of the UK.

3.2 There remain concerns that the total funding available to OSCHR will be significantly less than the current £1.3 billion.

4. Non-pharmaceutical and Publicly Funded Research

4.1 We note that this review has a strong focus on the development of new drugs with which to treat disease. It is important to remember that effective medicines represent the successful end-game of extensive and lengthy medical research.

4.2 There are many areas of health research that do not necessarily lead to the development of new drugs, but focus on the psychosocial aspects of disease and non-drug related treatments, such as surgical trials and radiotherapy. Good outcomes for cancer patients are dependent on a multidisciplinary effort of which drugs are an important, but constituent, part. The new structures need to keep this in mind.

4.3 It is also important that non-industrial anti-cancer drug trials are supported within the NHS just as vigorously as commercial trials. In cancer, this is essential to ensure that patients are not disadvantaged according to the type of cancer by which they are affected.

4.4 Examples of this are the trials that Cancer Research UK funds through its Clinical Trials Advisory and Awards Committee (CTAAC). These trials often involve drugs which have already received marketing approval in the UK and which are being tested for use in different types of cancer or in an attempt to find more effective or efficient ways of using the drug in combination with others. Other similar trials look at the efficacy of combining different treatment modalities, such as surgery with chemotherapy. These trials would typically not be carried out by industry.

5. UK-wide Research

5.1 Similarly to the Medical Research Council (MRC), Cancer Research UK has UK-wide responsibilities in terms of supporting research. We therefore hope to see relationships with devolved administrations carried forward successfully. We are concerned that the Cooksey Review has not adequately addressed the question of how the proposed strategy will work on a UK-wide basis. This is particularly important for multi-centre trials which may be conducted at numerous sites across the UK.

5.2 Research carried out by Cancer Research UK-funded researchers in Scotland, Wales and Northern Ireland has contributed significantly to the progress that we have seen in cancer treatment in recent years. This collaborative success must be supported and encouraged in the future.

5.3 Cancer Research UK is keen that OSCHR takes a balanced view of nationwide investment. With over 85% of the MRC's spend focused on the south east of England and all the National Institute for Health Research (NIHR) Biomedical Centres also assigned within this region, it is important that the rest of the UK, and the devolved nations, are not neglected in terms of research spend. Our respective commitments to patients in general, and cancer patients in particular, mean that NHS R&D and Cancer Research UK should aspire to spread resources more evenly across the country. The establishment of a single research fund provides an opportunity to increase investment in some of the historically less well supported regions. This is a move which would serve to improve the country's long-term economic and medical interests.

6. Clinical Trials in the UK

6.1 It is not clear where accountability for clinical trials will lie under the proposed system. The MRC has an impressive legacy of funding and conducting clinical trials across the UK. This should be taken into consideration when drawing clearer distinctions between the funding roles of the MRC and the NIHR. This is particularly relevant for late phase clinical trials that appear to fall within the remit of both the MRC and NHS R&D funding streams (figure 7.4).

6.2 We welcome recognition of concerns about the cost of conducting clinical trials in the UK (section 6.24) and note that these difficulties are not limited to those trials run by the pharmaceutical industry[18].

7. Creating a Research-friendly Culture in the NHS

7.1 Given the significant role that charities play in funding research in the NHS, and our wealth of experience in understanding the costs involved (including the system of identifying the direct and indirect costs of research), we believe that any working group established should include membership from research charities. It is inevitable that the recommendations of this group will have a significant impact on the way research is funded in the NHS.

7.2 While we welcome proposals to improve the implementation of best practice in health service management and delivery around the NHS, we would like to see the incentives that are being piloted recognise that health professionals in the NHS already have significant demands on their time. With this in mind it is important that provisions are made to build a supportive structure in the NHS within which to conduct research and a culture that promotes research activity.

7.3 It is unfortunately also the experience of the National Cancer Research Network Clinical Studies Groups that trials are being held up because of uncertainty about NHS supportive funding for patients taking part in trials. To this end we welcome the recognition of a need for additional financial support from NHS Trusts. It is important that both Trusts and researchers know that NHS R&D money is guaranteed to follow the individual patient taking part in such research.

7.4 We note with regret that one area where the UKCRC has so far made little progress is in providing incentivisation for research in the NHS. We strongly believe that the Healthcare Commission should include research performance as one of its criteria for measuring NHS Trusts' performance to enable OSCHR to achieve its full potential.

8. Skills for Health and Medical Research

8.1 As a major funder of research fellowships and training across the UK, we believe that charities such as Cancer Research UK and the Wellcome Trust have an important role to play in identifying needs in terms of skills mix, experience and career structures across the whole spectrum of health research (paragraph 7.16). We therefore call for the inclusion of these funders in any future working group established to develop a strategy to address these needs. This will be vital to ensure that the UK develops a joined-up response to any gaps identified in this area.

[18] J Hearn, R Sullivan, The impact of the "Clinical Trials" directive on the cost and conduct of non-commercial cancer trials in the UK. Eur J Cancer(2006), doi:10.1016/j.ejca.2006.09.016

8.2 We would welcome clarification of what role it is anticipated that the UKCRC will play in coordinating the development and funding of MD-PhDs to eliminate skills gaps (paragraph 7.17) and further consideration of the appropriateness of this body to undertake such a role. Currently, the UKCRC does not have the remit to cover such training.

9. The Role of the UKCRC

9.1 With the advent of the NIHR, its transition into a "real", rather than virtual, institute and the establishment of the NIHR as an executive body of the Department of Health, the Review rightly highlights the question of what role the UKCRC, and therefore charity representation, has to play under these proposed arrangements.

9.2 The UKCRC has been highly successful in building on the achievements of the National Cancer Research Institute, which has seen enormous progress in increasing the number of cancer patients entering clinical trials. We are keen to see a clear role for this collaboration as a forum for advising on health research needs and on the interests of researchers across the UK in the future.

10. Translational Research

10.1 The establishment of a Translational Research Board is an important recognition of the increased importance of translational research in the UK. We would greatly welcome more details of how this board is to work in practice.

10.2 Through our own Clinical and Translational Research Committee, Cancer Research UK is a major funder of translational research in the UK. We believe that this may provide a good model for other types of research and a template for how a Translational Research Board might be established and run. We look forward to further engagement by OSCHR of research-funding partners, such as Cancer Research UK, in the establishment of this Board.

11. Taking Forward the Research Recommendations of the National Institute for Health and Clinical Excellence

11.1 We welcome recognition in the report of the need to address the financial challenges faced by the NHS in funding the increasing number of medicines coming onto the market. We also welcome the exploration of possible solutions to this problem.

11.2 A clearer process for following up NICE's research recommendations is important. We believe that there is a need, collectively, to be able to turn negative NICE decisions into positive action. Such decisions are harmful to all stakeholders—patients, the Government, pharmaceutical companies and the cancer charities. The public is particularly disappointed when patients in England cannot access new treatments that are routinely available in the USA, Germany, France or even Scotland.

11.3 We would therefore appreciate further discussion on how these recommendations will fit into the strategy-setting work of the OSCHR. We believe that the research community, Government and industry, need to work together to ensure that appropriate further research is conducted to identify possible specific applications for the drug, perhaps in defined patient groups.

11.4 We have already seen examples where further clinical trials might be able to specify a sub-group of the patient population which would particularly benefit from a particular drug. This could then result in new applications to NICE for approval in a more limited market and therefore at reduced total cost to the NHS. One example of this is the trial that Cancer Research UK is currently undertaking with Avastin (bevacizumab) for the treatment of colorectal cancer. We are hopeful that this will provide additional evidence to demonstrate efficacy of this treatment when given over a shorter time-scale, to improve the cost-effectiveness of this drug for treating patients in the NHS.

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Memorandum 17

Submission from Professor Crawford, London Metropolitan University

SUMMARY OF THE MAIN POINTS

The report does not adequately address research on prevention.

Author of this comment:

Professor Michael A Crawford, PhD, CBiol, FIBiol, FRCPath, Director of the Institute of Brain Chemistry and Human Nutrition, London Metropolitan University.

I have worked in several countries and been a consultant to the World Health Organisation and Food and Agricultural Organisations with regard to the links between nutrition and chronic diseases, especially on the role of fats and oils in human nutrition. My expertise is on the lipid biology and its relevance to vascular and neural development. I have published over 290 peer reviewed papers in the bio-medical literature. I am a trustee of two charities concerned with neurodevelopmental disorders and maternal and child health. The Little Foundation and the Mother and Child Foundation.

Factual information the committee should be aware of:

The UK has the highest incidence of low birthweight of any Western European country. Although low birthweight is only a crude marker of pregnancy outcome, none the less lower birthweight is the single most powerful predictor of ill health, heart disease, stroke, diabetes, poor learning abilities, mental ill health and crime. At the extreme end, very preterm, low birtweight infants, are at high risk to central nervous system disorder such as Cerebral Palsy.

Lord Warner in a recent reply to a question from Lord Morris provided data showing that the cost of mental ill health associated with hospital and institutional care has escalated over five fold in the last two decades with the latest estimate at over £5 billion. In a recent reply to a question by Lord Walton he provided data that the courts had awarded costs against the NHS Trust Hospitals of £189,000,000 for cases of Cerebral Palsy in 2004–05. This is only a fraction of the cost of Cerebral Palsy which in the UK is likely to be of the order of 4 billion/year. This however, is the tip of an iceberg of many children not reaching their genetic potential because the conditions that place the UK high in the ill health league also affect women during the pregnancy. None the less the evidence on Cerebral Palsy could be that aggressive litigation may be mistaken as the Little Foundation's European Cerebral Palsy study has concluded that few cases are genuinely due to obstetric mishap. The majority are from adverse prenatal conditions hence are potentially preventable[19] re-iterating what has been in evidence before.[20]

Moreover, the audit of the burden of ill health in the EU[21] estimates that brain disorders have overtaken all other costs and stood at €386 billion for the 25 member states at 2004 prices.

The Cooksey report whilst praising UK science does not address these issues and does not address the need for preventive research. Its graphic representations of costs show a large section related to mechanisms designed for drug research and a narrow waste for prevention. Its tenor is of the benefits derived from research on drugs and high technology to the UK economy. This strategy is curative. Prevention should come first.

In so far as health is concerned the report rightly sees that the system to date has largely failed to reduce the burden of health costs. This is reflected in an editorial in the Lancet[22] It ignores the changing panaorama. If brain disorders as predicted in 1972[23], continue to rise this century as heart disease rose last (vascular health is critical to neurodevelopment). The outlook is bleak in terms of social, educational, mental health and political costs.

Recommendations that you would like the committee to consider including in its report

Welcome as the curative approach is, the real cost savings, health, educational and social benefits will not come from cures but prevention.

A major section needs to be devoted to how to prevent disorders. Much of this should take into account epigenetics and developmental processes in which environmental, lifestyle, infectious and nutritional conditions contribute.

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[19] Bax M, Tydeman C, Flodmark O. Clinical and MRI correlates of cerebral palsy: the European Cerebral Palsy Study. JAMA. 2006 Oct 4–296(13): 1602–8.

[20] Crawford M A, Golfetto I, Bistanis D, Ghebremesle; K, Min Y, Moodley T, Poston L, Phylactos A, Cunnane S, Schmidt W. (2003) Arachidonic and Docosahexaenoic Acids in Protection Against Central Nervous System Damage in Preterm Infants. Lipids 38 (4), 303–315.

[21] European Journal of Neurology, June issue 2005.

[22] The Lancet. The catastrophic failures of public health. Lancet 2004; 363: 745.

[23] Crawford MA, Crawford SM (1972) What we eat today, Neville Spearman, London.

There are some simple initiatives that could be researched:

1. How to use existing knowledge (what are the barriers, resistance in decision makers, how to implement and test efficacy of knowledge, already so extensive and hard gained, in order to test and improve outcomes).
2. What is the cause of the rise in brain disorders and how can it be stopped.
3. The same applies to the rise in obesity (the connections with food production methods are not being investigated).
4. Research on the cause of the rise in heart disease and several cancers which are at a high level in the UK and other similar western countries. They were rare at the beginning of last century and rare in many developing countries and even developed economies such as Japan and South Korea.

There are of course many more such details but there shodl be a fundamental change in emphasis towards prevention.

There are implications in the preventive approach not only for medical research but also food and agricultural research as pointed out by the 1978 FAO/WHO Expert Consultation[24]. The approach to a re-design of research needs to be multi-disciplinary.

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[24] FAO-WHO Joint Expert Consultation on the Roel of Dietary Fats and Oils in Human Nutrition, Nutrition report No 3, FAO, Rome.

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