Response to the Review of UK Health Research

Summary

1. The Academy of Medical Sciences and the Royal Society welcome the proposal put forward in the Chancellor's 2006 Budget statement to create a single, ring-fenced budget to support UK health research and development (R&D). As highlighted in reports by the Academy of Medical Sciences[1] and Biosciences Innovation and Growth Team[2], the UK's recent achievements in basic biomedical science have not been accompanied by an appropriate development in clinical research. As a result, patients have been deprived of the best health care and opportunities for wealth generation have been lost. We stress that no other country enjoys the outstanding opportunity for clinical research represented by the NHS, which together with the world-class status of the Medical Research Council (MRC) offers an unparalleled competitive advantage for the UK. A single fund for health research can realise this potential, but it must be constituted with the appropriate leadership, governance, resources and culture.

2. We believe the aims of the new institutional arrangements should be to provide:

    - *A stronger fundamental science base, including vital blue skies research.*
    - *Transparency of funding allocations, governance and decision-making.*
    - *High standards of quality assurance and peer review.*
    - *A culture of enquiry and innovation in the NHS, and a sense of ownership of the research agenda by NHS staff, health professionals and Trust managers.*
    - *Engagement with the major research funders from the charitable and commercial sectors.*
    - *Improved translation of research findings into clinical, health service and population health applications.*
    - *Facilitation of multidisciplinary work, e.g. between different types of health researcher, between research councils and between academic departments outside medicine.*
    - *Enhanced support for research in international health*.

    The two Academies are keen to be involved in the future development of the single fund for UK health research and are committed to monitoring whether these aims are fulfilled in the new institutional arrangements.

[1] Academy of Medical Sciences (2003) Strengthening Clinical Research. http://www.acmedsci.ac.uk/images/project/Report.pdf
[2] Bioscience and Innovation Growth Team (2003) Bioscience 2015: Improving national health, increasing national wealth. http://www.bioindustry.org/bigtreport/

3. We propose a model in which an overarching body holds the ring-fenced single health research budget and distributes funds in a transparent manner between the Medical Research Council (MRC) and a new Health Innovation Council (HIC) (see diagram on page 3 and answer to consultation question 10).

4. The over-arching body, or 'Board of the National Councils for Health Research', provides the channel for Government funding of UK health research: it would be responsible for advocating the case for health research to Government and securing necessary funding support. Relationships with both the Department for Trade and Industry (more specifically, the Office for Science and Innovation) and the Department of Health must be maintained and could be facilitated through a Ministerial Committee for Health Research. The Board must defend the Haldane principle and protect the independence of the health research agenda from short-term political pressures.

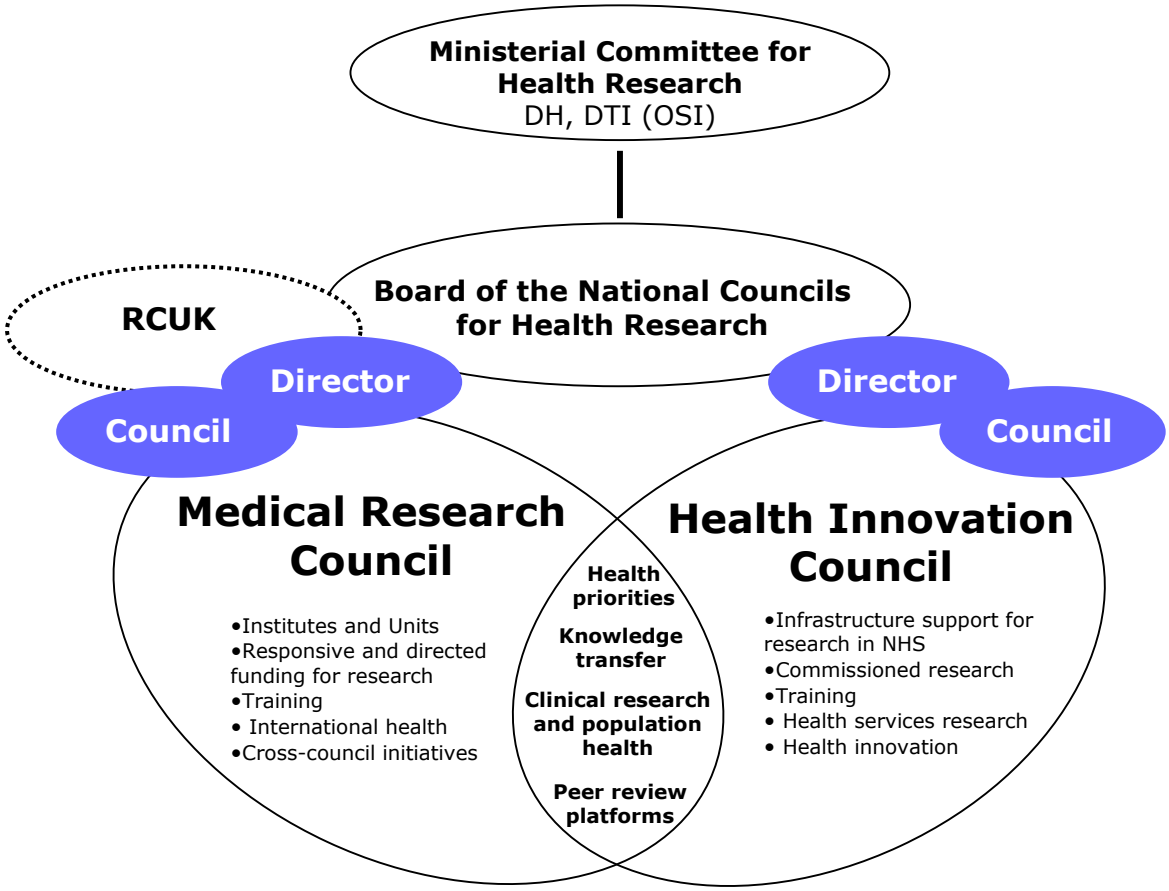
5. The Board would approve strategies developed by the two Councils to ensure coherence across the spectrum of health research, from basic biomedical science, through experimental medicine and clinical trials to population health, health services research and service innovation. The Board would ensure complementarity between research and infrastructure and maintain relationships with other research bodies, including Research Councils UK (RCUK), the medical research charities and industry. The Board must be led by a Chairman of international standing, with an appreciation of research in the basic, clinical and public health spheres.

6. The proposed structure maintains the current strengths of the MRC, preserving its systems and values and protecting its international reputation for research excellence. The HIC will be charged with enhancing health research and innovation and should further encourage NHS ownership of the research agenda. The HIC will be the vehicle for managing relationships with the health research agendas of the Devolved Administrations and will facilitate health innovation and research within NHS regions.

7. The establishment of two Councils under a unified Board brings several advantages, notably in:
   - Maintaining an element of pluralism in funding.
   - Balancing the NHS R&D and MRC relationship with other charitable and commercial research funders.
   - Avoiding undue disruption of current operating procedures.
   - Providing the basis for further evolution.

   We stress that, while it is important to maintain current momentum, the new institutional arrangements should be implemented in an evolutionary way to sustain and enhance (and in no way jeopardise) the international reputation of UK biomedical science.

Diagram: Proposed model for institutional arrangements



Introduction

8. The Academy of Medical Sciences and the Royal Society welcome the opportunity to contribute to the 'Review of UK Health Research'. This submission has been prepared in consultation with Fellows drawn from both Academies, including basic biomedical, clinical, social and population scientists. We are most grateful to Fellows for their time and efforts in contributing to this response.

Consultation questions

1. What are the strengths and weaknesses of the MRC and NHS R&D programmes at present? How do each of these support the research and training needs of the NHS, social care, industry and academia? Does more need to be done?

9. **MRC**
   The MRC has an international reputation for research excellence and a distinguished record of providing institutional and programmatic support for first class science. This owes much to the quality of MRC research strategy and assessment. It has been responsible for major advances in molecular and cellular biology, epidemiology and clinical medicine; the latter exemplified by the development of the randomised controlled trial and, more recently, the Bayesian approach to clinical trials[3]. The MRC Institutes and Units, with their history of supporting long-term research in important but difficult problems, play a key role in promoting world-class science. The MRC has a deserved high reputation for training scientists across a wide spectrum of research disciplines and its practices have been widely adopted by other research funders. The MRC has also made significant contributions to UK innovation and technology transfer, with the development of humanised monoclonal antibodies and confocal microscopy being notable examples.

10. Despite recent improvements, the MRC's success in basic science has not yet been matched by its support for clinical, translational and applied health research. It has experienced increasing pressure on research funds, resulting in falling success rates for research proposals and the subsequent rejection of excellent projects. Increasing clinical research activity must not be at the expense of basic science: specific funding will be required for the proposed enhanced activity in clinical and translational research.

11. The MRC enjoys a good relationship with the UK academic community, whose direct involvement in funding decisions and broader research strategies fosters a sense of transparent and accountable governance. Under our proposed model, this approach to research governance would be key to the success of the new arrangements.

12. **NHS R&D**
    The NHS has made valuable contributions to academic medicine, particularly at regional and local level through support for senior clinical academic posts. Over the years the Department of Health has recognised the contribution of research to the delivery of effective, coherent and evidence-based patient care. A particular success has been the UK Health

[3] Notably the work of Dr David Speigelhalter OBE FRS at the MRC Biostatistics Unit. Cambridge

Technology Assessment programme[4], which has a reputation for both quality and innovation. DH support was integral to the development of the UK Cochrane Centre[5], the NHS Centre for Reviews and Dissemination[6] and the NHS R&D Policy Research Programme.

13. However, weaknesses in health services research have been recognised in recent years.[7] More generally, poor links between researchers and policy makers have weakened health care strategy across the NHS.

14. Variability in peer-review and difficulties in ring-fencing research time for NHS-employed clinician scientists are notable areas for improvement. We draw attention to the loss of locally organised NHS R&D funding, which has in the past helped to get pilot projects off the ground and given clinicians and health professionals their first exposure to research.

15. It is recognised that R&D in the NHS has suffered through the diversion of money intended for research and infrastructure support into direct patient care. NHS Trust managers are subject to intense pressures to deliver immediate health care targets and understandably afford a low priority to research. The NHS is therefore perceived by the academic and commercial research community to be a difficult and variable place in which to conduct research. The DH's recent 'Best Research for Best Health' was therefore a timely and welcome initiative, although overcoming the historical NHS R&D problems remains a formidable challenge.

16. **Supporting the NHS, social care, industry and academia**
Through enhancing the profile of research within the NHS and more clearly demarcating NHS R&D duties, the proposed model affords significant opportunities to use research to inform decisions on the management of the health service. Clinical trials could, for example, provide better information to the National Institute for Clinical Excellence (NICE) on novel therapies, and enhanced health services research could inform decisions on the cost-effectiveness of various diagnostic and management approaches.

17. Ring fencing of R&D money will do much to ensure prioritisation of the research agenda amidst the health care pressures on NHS Trusts. But this requires the full engagement of NHS Trust managers, who should be rewarded for supporting research in their institutions. As one option, it may be useful to consider how an internal market might operate, in which Trusts are awarded funds in relation to research quality. However, care must be taken not to introduce an overly bureaucratic system.[8]

18. We strongly emphasise that realising the research potential of the NHS requires a significant shift in NHS culture, where researchers are nurtured and valued and staff are encouraged to identify and pursue research questions. Incentives for Trusts should depend on their effective joint working with universities, research institutes and industry, i.e. advocating the value of research to patients, facilitating access to patient cohorts, data and tissues, and ensuring appropriate staff contracts and training. Consideration should be given to the impact on research and training of

[4] http://www.hta.nhsweb.nhs.uk/
[5] http://www.cochrane.co.uk/en/index.htm
[6] http://www.york.ac.uk/inst/crd/
[7] Lomas, J, (2003) Health services research. BMJ 327: 1301-2
[8] We would not advocate introducing an NHS RAE, but there should be an assessment of research quality (output), rather than just an account of money spent on research activity.

trends towards greater delivery of health care in community and private settings. The latter is especially relevant to clinical areas where a large proportion of care is delivered in the private sector, e.g. dermatology, ophthalmology and orthopaedics.

19. Money allocated for research in the NHS must be diverted back from supporting health care services. Care will be needed during the transition period: we note that planned increases in the DH budget could be helpful in maintaining the stability of Trusts, particularly in London. We emphasise the need for transparency: if it is clear which elements of funding allocations support infrastructure, training and enhanced service provision for research, it will then be possible to ascertain which elements can justifiably be moved to follow the best research.

20. The establishment of a single health research fund offers a notable opportunity to embed research within the culture of the NHS by ensuring the active engagement of patients and the public as research participants, consumers and stakeholders. The research charities and medical Royal Colleges provide useful examples of incorporating patient and lay representation into governance mechanisms and decision-making. Much can be learned from on going 'Science and Society' programmes, such as that of the Royal Society,[9] in how patients and the public can be engaged in debate around research issues.

21. Relationships with the universities, charities and the other research councils will be vital to the success of a single health research fund. Engagement with the university sector, via university departments, will help to facilitate inputs into clinical research from the underpinning biological sciences, and increasingly from mathematics, chemistry, physics, engineering and the social sciences.

22. A key task for the Board will be in relating the single fund to the charitable research sector, the combined funds of which exceed those of the MRC. There is a pressing need to establish an infrastructure in the NHS that is appropriate for charity, university and other government funded research. Recent initiatives, for example the clinical research facilities established by the Wellcome Trust Millennium Awards, demonstrate the power of this approach.

23. A single health research fund has the potential to form a strong and productive relationship with industry, most notably in:
    - Fostering the supply of skilled personnel.
    - Facilitating industry research in the NHS, especially for experimental medicine and clinical trials.
    - Supporting technology and knowledge transfer through collaborative research and the generation of spinout companies.

    Creating opportunities for industry to develop products and services in a hospital setting will also promote the development of bespoke solutions to NHS patient needs.

24. There is an advantage in a single health research fund supporting the totality of the research environment. Greater industry investment will be encouraged by the establishment of a joined-up system incorporating:
    - MRC's world-class **fundamental science base**.

[9] Royal Society, Science in Society programme. http://www.royalsoc.ac.uk/page.asp?id=1988

- Opportunities to develop world-leading capability for small-scale and intelligent **experimental medicine.**[10]
- Increased recruitment into research and the facilitation of large-scale epidemiology and post-marketing surveillance through **'Connecting for Health'**.

We argue that a natural consequence of the above, together with the work of the clinical networks, would be an increase in Phase III clinical trials.

25. Sustaining a productive relationship with industry and the charitable research funders is not only a question of budgets: there is a need to develop a rational and proportionate governance framework around clinical research, especially - but not exclusively - in the context of the utilisation of personal health datasets.[11],[12]

26. The slow adoption of innovative products and services through NHS procurement is a concern. This deprives patients of the best care and weakens platforms for research and wealth generation. This is especially relevant to medical devices and diagnostics, which are generally less protected by patents and must therefore be exposed to a large market as quickly as possible. Procurement is undoubtedly a complex problem. We suggest that the development of strategy in this area, to be owned by the NHS as a whole, should be led by the HIC in conjunction with NICE.

2. What do you believe are the key scientific and organisational challenges facing health research, and underpinning training, in the UK over the next decade? How might the UK Government best help address those challenges? What do you believe should be the Government's objectives for health research, and why?

27. The primary objectives of the UK health research fund should be to generate knowledge through excellent biomedical and clinical research, translate that knowledge into medical practice and ensure that UK research is internationally competitive.

28. The challenging questions for research funding agencies are generic[13]:
    - How to allocate money in the best way to support research?
    - How to select the best scientists and how to train the next generation of biomedical researchers?
    - How, and whether, to set research priorities?
    - How to balance 'priorities-led' and 'investigator-led' modes of funding?
    - How to determine whether the funding is making a difference?

29. The Academy's report *'Strengthening Clinical Research'* offers suggestions for tackling the key challenges, particularly in maintaining flexibility in the management of science, supporting exceptional individuals and emphasising technology transfer. The following points should also be taken into account:

[10] i.e. clinical investigation directed at establishing disease causation and 'proof of concept' research to test the validity and importance of potential treatments.
[11] Academy of Medical Sciences (2006) Personal data for public good: using health information in medical research. http://www.acmedsci.ac.uk/images/project/Personal.pdf
[12] Council for Science & Technology (2005) Better use of personal information: opportunities and risks http://www.cst.gov.uk/cst/reports/#10
[13] M Walport, FST Journal, November 2005

- The need to ensure that a focus on UK health research priorities is not at the expense of the MRC's commitment to international health. This area is ripe for investment and the MRC is well placed to utilise further funding.
- The importance of broad distribution of clinical trial networks across regional health care settings. Care is needed to ensure that focused investment in centres of excellence does not lead to an erosion of the commitment by the multiple healthcare providers needed to sustain these networks. Special provisions are needed to support epidemiological research requiring large collaborations and research in non-university hospitals and other health care settings.
- The requirement for progress in streamlining research governance.

3. What should be the Government's priorities for health research? Is there anything it should stop doing or funding? What is it not doing or funding that it should do, and, in the absence of further sources of support, what can it lower in order to release the necessary funds?

30. The Government's priority for health research should be support for excellent science and its effective translation into patient benefit. This requires the maintenance of a powerful research base and support for outstanding individuals, in addition to the more effective utilisation of the NHS through capacity building in research infrastructure and human capital.

31. Investigator-led research plays a vital role in priority setting: gifted researchers identify questions that are both tractable and important. However, this mode of funding can leave gaps in fields of importance to patient care. Enhanced coordination between the MRC and HIC would permit investigator-led research to be supplemented by a system in which calls for competitive proposals are issued in areas of unmet clinical research need, with responses judged by peer review. With regard to support for particular research areas, attention must be paid to fields that fall outside the remit of the disease-specific medical research charities (noting that these charities will vary in size and the amount of funding support they can provide for their chosen areas). The UKCRC's recent "UK Health Research Analysis" provides a useful tool to monitor combined UK research activity in relation to health needs.[14]

32. The pace of research is such that any priorities we highlight here are simply those that we see as important at the present time. One of the on-going functions of the Academy and the Royal Society is to facilitate evidence-based discussion, bringing together interested parties from academia, NHS, industry, charities, and other research funders, to identify what is already known, what is still uncertain, and how UK capacity can be developed to exploit scientific advances. Recent work has noted the research opportunities in the fields of stem cells, experimental medicine[15], nanotechnology[16], pharmacogenetics[17], obesity[18], systems biology[19] and ageing[20].

[14] http://www.ukcrc.org/PDF/UKCRC_Health_Research_Analysis_Report.pdf
[15] Academy of Medical Sciences (2006) Report of Experimental Medicine Symposium http://www.acmedsci.ac.uk/images/event/EMsummar.pdf
[16] Royal Society (2004) Nanoscience and nanotechnologies: opportunities and uncertainties. http://www.nanotec.org.uk/finalReport.htm
[17] Royal Society (2005) Personalised medicines: hopes and realities. http://www.royalsoc.ac.uk/displaypagedoc.asp?id=17570
[18] Royal Society (2006) Report of a Royal Society policy seminar on the scientific understanding of obesity. http://www.royalsoc.ac.uk/document.asp?tip=0&id=4127

4. How should decisions be taken on the balance between the long-term economic and social benefits of a high quality biomedical research base and the needs for research to improve healthcare and other public services? What is the appropriate balance between public funding for investigator-led and priorities-led research? How do we balance funding for basic science, translational science and applied science? Is this something that should vary over time? What mechanisms should be used to make judgements about this balance?

33. The balance of funding will vary over time and should be influenced by patient need and determined by scientific opportunity – creative ideas, the availability of talented researchers, and advances in technology. We stress the need for continued basic research to fuel the pipeline for translational exploitation.

34. However, a pressing medical need may not be soluble at a given time with the given state of knowledge and technology. Too much emphasis on priorities-led research brings the danger of sequestering money away from more readily soluble research problems. Top-down identification of priorities must be informed by knowledge of scientific tractability, and accompanied by solicitation of innovative and challenging ideas from the scientific community.

35. Scientific advances must not only be translated into clinical applications, but into health care policy. We again note the success of the HTA programme and its process of active consultation with clinical teams and service users to identify gaps, commissioning of appropriate research and collaboration with NICE and others to shape policy.

36. The establishment of a single fund for health research will provide opportunities to address challenges in public health research, including health promotion and disease prevention. The new structure would have a significant role in promoting the public health research agenda across the Department of Health and other Government Departments, ensuring that a better evidence base for proposed public health policies is sought and policies and programmes are implemented in a way that allows rigorous evaluation.

37. We emphasise the need for breadth in publicly funded research, as the only means of addressing changing, and sometimes dramatically unexpected, health needs. This is exemplified by the emergence of SARS in 2003, when the UK was fortunate to have coronavirus expertise at Bristol University.

38. It is important to consider who broadly sets the priorities for medical research. The medical research community itself is influential through its involvement in advising research funders. Society-at-large expresses its priorities though support for the medical charities, which then take the lead in pursuing those research goals. However, important areas of clinical need (e.g. mental health, respiratory medicine, diseases of the digestive

[19] Joint Academy of Medical Sciences/Royal Academy of Engineering working group on systems biology. http://www.acmedsci.ac.uk/p47prid4.html

[20] Academy of Medical Sciences (2004) Response to the House of Lords Science and Technology Committee inquiry into the science of ageing. http://www.acmedsci.ac.uk/images/project/1127317176.pdf

system, urinary incontinence) receive very little charity money. Such areas must be considered carefully by government funding agencies.

39. An important question, and one that is not explicitly addressed in the consultation, concerns how the UK should balance its mixture of basic and applied research so as to maximise global competitive advantage. In this respect, we emphasise the issue of timescales: many NHS research priorities are driven by short-term considerations, but a sustainable research base for patient welfare and wealth generation also demands a longer-term perspective.

5. In your experience, how have the results of publicly-funded health research in the UK been used, both in the development of new treatments and to influence/change wider policy and healthcare practices? What lessons can usefully be learned to improve the uptake of advances in science and medicine?

40. Medical research produces a wide range of socio-economic benefits, but systematic evaluation of research outcomes is difficult and both national and international research funders continue to grapple with the methodological and organisational challenges involved. Such evaluation must take account of: the international nature of the research enterprise; the value of negative research findings; non-incremental developments in knowledge; the importance of blue-skies research; and the long interval between scientific advance and tangible clinical and/or commercial benefit.

41. Publicly funded UK health research has produced many successes - too many to list here. However, the timescales over which such successes should be judged are exemplified by the work of the late Richard Doll, who began to investigate the link between smoking and lung cancer in the 1940s, and that of César Milstein and Peter Mansfield, who in the 1970s devised techniques leading to the development of, respectively, monoclonal antibodies and Magnetic Resonance Imaging.

42. We note the potential role of specialist societies as vehicles for scientists to translate research findings into practice. The following example illustrates the importance of an integrated approach to translation: the Wellcome Trust supported key developments in cognitive behaviour therapy, but realising its potential for patient benefit needed NHS support to train and maintain cognitive behaviour therapists, NICE involvement to evaluate efficiency and further input from NHS Trusts to assess the effects of new training schemes.

43. The Academy of Medical Sciences has recently joined with the MRC and Wellcome Trust to constitute the UK Evaluation Forum. Its recent report *'Medical research: assessing the benefits to society'* (May 2006) describes some of the evaluation methods used by health research funders and provides international and national examples of research impact.[21] It identifies clear lessons to be learned by the UK research community in developing improved evaluation methods, gaining consistency in evaluation practices and demonstrating research achievements more actively. A single health research fund should lead the research community in the systematic embedding of evaluation principles into management practices, the active dissemination of information about

[21] Academy of Medical Sciences, Medical Research Council, Wellcome Trust (2006) Medical research: assessing the benefits to society. http://www.acmedsci.ac.uk/images/project/Medicalr.pdf

research achievements and the translation of research outputs into health care benefits.

6. How might better links be forged between "basic", translational and applied researchers, working across the whole field of health research, from the laboratory bench to the front line of the NHS? How might better links be forged across disciplines, e.g. with engineers, physicists, and social scientists?

44. A single health research fund has the potential to enhance research at the interface of basic, translational and applied fields. The aim should be to foster a culture where researchers are able to move seamlessly and iteratively between research on disease states and normal physiology, interfacing with studies of disease-related behaviours. The fields of ageing and obesity illustrate very well the need to integrate basic research that elucidates fundamental mechanisms of normal and abnormal states, with clinical and applied research investigating prevention and treatment strategies.

45. Key to these links will be effective relationships with the Higher Education Funding Councils and the universities, especially in enhancing input from the biological sciences, social sciences, physics, engineering and chemistry. However, in creating a larger, single health research fund, care must be taken to avoid the creation of artificial barriers with other scientific disciplines. The role of the institutional environment should be emphasised in this respect: the cross-fertilisation of ideas and formation of collaborative partnerships demand organisational planning that promotes spontaneous interaction between researchers. We also note that, unlike many clinical departments, MRC Units benefit from tenured posts for basic scientists in fields such as computer science, chemistry and physics.

46. Promoting a culture of multi-disciplinarity will be a crucial role for the Board. Constructive relationships between MRC, RCUK and the other Research Councils must be maintained and will be aided by the on-going involvement of the Office for Science and Innovation. We emphasise the need for both good management, in which heads of university departments establish a culture of collaboration between research groups, and for funding streams that encourage joint initiatives across Research Councils. In particular there is a role for interdisciplinary and joint-funded training schemes, with the resulting trainees becoming the active links between disciplines.

7. How can the Government encourage translation, entrepreneurship and innovation in health research to improve public services in the UK?

47. Training of research-minded clinicians and other health professionals is an integral part of bridging the gap between the laboratory and the clinic. There have been welcome initiatives in this area, namely the 2005 MMC/UKCRC report[22] and the establishment of the National Faculty for Health Research under 'Best Research for Best Health'. A specific focus is needed on both the recruitment of younger clinical researchers and mechanisms to protect the research time of established NHS clinicians. Translation, entrepreneurship and innovation would be encouraged by

[22] http://www.ukcrc.org/PDF/Medically_and_Dentally-qualified_Academic_Staff_Report.pdf

greater mobility of staff between industry and NHS/academia[23] and improved training of academic scientists in business opportunities and patenting processes.

48. Building a culture of enquiry and innovation within the NHS must be augmented by a productive interaction with industry to capitalise on R&D advances and the promotion of innovation by the intelligent procurement of novel products and services. Early dialogue between industry and the NHS is vital: first to allow the NHS to plan the introduction of new medicines and devices and second to encourage industry to incorporate NHS needs into product development. We emphasise that translational research is challenging, expensive and develops over a long time scale. We also highlight that the UK is well placed to take a global lead in experimental medicine, with its two-way process between the bedside and the bench.[24]

49. Historically, the NHS has experienced difficulties in identifying and protecting its Intellectual Property and its 'innovation hubs' have enjoyed only limited success. It seems likely that there are lessons to be learnt from the activities of MRC Technology, Cancer Research Technology and certain universities, which now have over twenty years of experience in technology transfer.

50. We suggest investment in areas of science that are considered by industry to be pre-competitive, with such investment taking the form of a public-private partnership. Linkage with publicly funded research into, for instance, toxicology, imaging technologies and the identification of biomarkers, could significantly increase the likelihood of downstream commercial and clinical success. Innovation and knowledge transfer by researchers, research institutions and NHS Trusts must be both integrated and rewarded appropriately: consideration should be given to developing appropriate financial and tax incentives.

8. How can UK health research funding be most efficiently used to provide the appropriate infrastructure for basic, translational and applied research, whether funded by the UK public sector or other sectors? How can UK health research funding be most effectively used to support the work of NICE, facilitate innovation and collaboration with industry, and address market failures in the application of healthcare?

51. We have already drawn attention to the loss of locally organised NHS research funding, which previously provided support for local pilot projects. Consideration should be given to establishing a fund for local initiatives, which would be distributed through the new HIC to Primary Care and NHS Trusts. Applications should be subject to scientific review that is sensitive to the often pilot status of these proposals.

52. The importance of providing infrastructure for research funded by Government and others – particularly industry and the research charities – has also been noted in answers to previous questions. We reiterate that infrastructure needs to be defined broadly and we emphasise the major opportunity for UK research to capitalise on the planned investment in NHS IT infrastructure.

[23] See current Academy of Medical Sciences FORUM project 'Careers for Biomedical Scientists and Clinicians in Industry: Promoting Greater Mobility', http://www.acmedsci.ac.uk/p114.html
[24] Sir Keith Peters FRS PMedSci (2004) Exceptional Matters. The Harveian Oration. http://www.acmedsci.ac.uk/images/publication/nharveia.pdf

53. There is a role for publicly-funded health research in the early development of novel approaches, such as stem cell, siRNA and gene therapies, and in addressing market failures in the application of science in healthcare (e.g. orphan drugs). It also has a role in exploring options for marketed products that are no longer of significant interest to industry. For instance the Royal Society raised the issue of pharmacogenetics research on existing medicines, including off-patent generic medicines, and the need for further pharmacogenetic information in its 2005 report *'Personalised medicines: hopes and realities'*.[25]

54. The strength of the UK biomedical community is a key asset to the work of NICE and MHRA, who draw on its human capital and expertise. We note the opportunities presented by the Clinical Research Networks in supporting the NHS and NICE, specifically where there is inadequate data to judge whether a new drug should be added to the formulary. The Clinical Research Networks have not yet been utilised for this purpose, but they could provide a powerful tool to address important questions for the NHS and facilitate more informed decision-making.

9. What lessons should the UK learn from other countries in making the proposed changes to the institutional arrangements for the funding of health research?

55. The UK needs to be informed about best practice in other countries, especially in applied and translational research. However, we stress that no other country enjoys the outstanding opportunity for clinical research represented by the NHS, which, if its potential is realised, offers an unparalleled advantage for UK plc. The examples of the US National Institutes for Health (NIH) and the Canadian Institutes for Health Research (CIHR) are discussed below. However, US and Canadian mechanisms for providing health care mean that neither the CIHR nor the NIH have the opportunity to become embedded in a comprehensive national health service.

    (i) NIH has an outstanding reputation for large-scale funding of medical science and has recognised the need for further investment in clinical research. However, its 'roadmap' for translating basic research into clinical practice has been criticised as too obscure in its goals and having unduly diverted resources from basic science.

    (ii) The formation of the CIHR has boosted Canadian biomedical science and energised interactions between basic and applied fields. While the theory behind the joint structure has been applauded, its management has been criticised, particularly for lack of transparency in funding decisions, and for supporting too many programmes over too wide a range of objectives.

56. Lessons can also be learnt from UK examples of best practice, ranging from specific units and departments to medical schools and regions: the key is in identifying, bench-marking and disseminating these examples.

10. In implementing the single fund for health research, to what extent should the MRC and DH/NHS R&D be merged or brought together? And to

[25] Royal Society (2005) Personalised medicines: hopes and realities. http://www.royalsoc.ac.uk/displaypagedoc.asp?id=17570

whom should the single, ring-fenced fund be accountable? Please provide reasons and any supporting evidence for your response.

57. Our model for the implementation of the single fund for health research is outlined in the summary to this response. We consider that the arrangements described in the model will promote a culture of professional, rigorous management of UK health research, responsive to patient needs, with inclusive, open decision-making.

58. The Board of the National Councils for Health Research would be responsible for approving and evaluating strategies developed by the two Councils, promoting coherence across their activities by ensuring that research and infrastructure were appropriately matched and that opportunities for joint working were fully exploited. The Board would have a key advocacy role for UK health research, supported by the two Councils, in securing funds as part of the Spending Review.

59. The Board must retain relationships with both the DTI and DH: the former to facilitate productive interactions with the biological, chemical, engineering, social and physical sciences and so avoid barriers to multidisciplinary work; and the latter to ensure the necessary ownership by NHS Trusts and engagement with the pharmaceutical industry. However, we acknowledge the difficulty of reporting to two Government departments. As described in the diagram, a potential solution might be the establishment of a Ministerial Committee for Health Research.

60. The MRC and HIC would each be led by a Director, who would sit on the Board of the National Councils for Health Research. Both MRC and HIC would be supported by a Council, the former with much the same responsibilities and composition as it has currently and the latter with representation from the NHS Trusts and regions, patients, clinician scientists and industry. The Directors of the two organisations would each attend the Council meetings of the other body.

61. The MRC would continue to be responsible for the overall strategic direction of its research, including its institutes and units, programmatic funding, careers and training. The HIC would be responsible for research infrastructure in the NHS, identifying areas of unmet medical research need, promoting health innovations and meeting human capital research needs in the health professions. We emphasise the importance of cross-over functionality between the two Councils, particularly with regard to peer review, identification of health priorities, technology transfer, clinical trials and public health.

62. The establishment of the single health research fund has the potential to enhance knowledge and technology transfer across the two Councils. HIC will need to assess technology transfer candidates in relation to value for improved service delivery, an area distinct from the MRC's experience to date. Further consideration should be given as to whether MRC Technology could be extended to absorb the knowledge and technology transfer needs of the new HIC.

63. We emphasise that in a competitive research system and an era of rising research costs, in particular the cost of conducting clinical trials, the MRC has experienced a great deal of pressure for funds, resulting in a high cut-off point for funding and the rejection of good projects. There is substantial agreement on the need for enhanced funding if UK health

research is to maximise the potential of the single fund as conceived in the Chancellor's Statement.

11. To what extent does the success of recent innovation in health research (e.g. Clinical Research Networks) and the proposed structures rely on the new Connecting for Health NHS IT system, and to what extent should it do so?

64. Changing the funding mechanism alone will not be sufficient to fulfil the potential of the NHS to be a world-leading environment for clinical research. This will require improvement in the regulatory, governance and IT structures and all research stakeholders must work to ensure that new legislation and policy developments do not inadvertently hinder the practice of medical research.

65. There is agreement about the unique opportunity Connecting for Health affords to medical research in UK academia and industry, but it is too soon to judge whether this is to be successful: it is essential that the needs of research are fully integrated into its development. We therefore welcome the establishment of the UKCRC Research Advisory Board for Connecting for Health and the Care Record Development Board Working Group on Secondary Uses. The recent report from the Academy of Medical Sciences *'Personal data for public good: using health information in medical research'* (January 2006) offers recommendations on regulatory processes for research governance, the development of good practice and harnessing the opportunities of national IT programmes[26]. It emphasises that successful exploitation of Connecting for Health requires engaging patients and the public on the purpose and value of medical research using health data. These issues will be further examined in the forthcoming Royal Society report 'The impact of ICT on health and health care'.[27]

12.Given that NHS R&D is currently devolved, but that the work of Research Councils is not, how can these functions work best together to maximise the health and economic benefits to the UK?

66. Continued and seamless support for research across the UK is crucial for retaining international competitive advantage, which might be endangered by geographical fragmentation. Research funded by the MRC and conducted in the Devolved Administrations makes a significant contribution to the strength and diversity of the UK health research base. MRC must retain responsibility for UK-wide funding of research programmes, units and institutes: such research should not be isolated or sequestered from the highest level of UK competition. The new institutional arrangements must enshrine a principle of maintaining equality of access for researchers across the UK.

67. We note that the regional nature of NHS R&D funding in the Devolved Administrations has underpinned strong and innovative partnerships for the translation of health research. For example, the Chief Scientist's Office at the Scottish Executive Health Department played a crucial role in developing a £50 million, 5-year minimum translational medicine collaboration with Wyeth Pharmaceuticals. This partnership is aimed at accelerating Phase II development of new treatments and focuses on

[26] Academy of Medical Sciences (2006) Personal data for public good: using health information in medical research. http://www.acmedsci.ac.uk/images/project/Personal.pdf
[27] For further information see http://www.royalsoc.ac.uk/page.asp?changes=0&latest=1&id=3258

experimental medicine in a network of clinical research facilities. It involves four universities with clinical schools, their partner Health Boards, the relevant Regional Development Agencies (RDAs) and Scottish Enterprise, which contributed £18 million to the initiative. This model of engaging clusters of university medical schools and relevant RDAs might be usefully adapted to regional settings elsewhere in the UK.

68. The activities of the HIC, which would incorporate NHS R&D in England in the first instance, should be planned in co-ordination with the NHS R&D systems in the other administrations. This is a complex issue and we can offer no neat solution. We emphasise that close working relations and, in some vital areas, functional integration, will be necessary if medical research in the Devolved Administrations, and indeed the UK as a whole, is not to be disadvantaged. This is clearly a matter for further debate and negotiation with the Devolved Administrations and NHS regions.

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