

THE WELLCOME TRUST RESPONSE TO THE REVIEW OF UK HEALTH RESEARCH

INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to respond to the Cooksey Review of UK Health Research. Our response focuses on the goals and high level principles we believe should be enshrined in any new arrangements for the delivery of the single Health Research Fund, and outlines our preferred model.
2. The Wellcome Trust has also contributed to the response from the Association of Medical Research Charities.
3. We believe that the review of UK Health Research should be explicit about what it aims to achieve. It is critical that the review addresses real problems, fixing things that are important and in urgent need of repair.
4. Our view is that the Medical Research Council (MRC) is working well: its funding of basic and clinical research has resulted in significant achievements resulting in patient benefit and contributing to the success of the UK biotechnology and pharmaceutical industries. The MRC has robust governance systems in place and is transparent in its funding allocations and decision-making processes.
5. Conversely, NHS R&D has not enjoyed the same robust governance arrangements found in the Research Councils. We therefore welcome the Chancellor of the Exchequer's 2006 Budget Statement (22 March 2006) announcing the Government's intention to ring-fence the Department of Health's R&D budget. This will help provide some much needed transparency and opportunities for better governance. Considerable effort will be needed to identify and extract the R&D budget, particularly if it is to be done in a way that does not destabilise other parts of the health service, as much of this funding is deeply embedded in the NHS.

GOALS

6. In considering the best institutional structure to deliver health R&D any new arrangements will need to support research, training and infrastructure in order to:
 - deliver outcomes which lead to health benefits and economic prosperity;
 - build on the UK biomedical research strengths and international standing;
 - provide faster development and uptake of new technologies and innovative medicines;
 - drive the appropriate use of personal information for research for health benefits, embracing opportunities within the Connecting for Health programme and recommendations in the Council for Science and Technology and Academy of Medical Sciences reports¹; and
 - promote access for researchers to, and benefits for, the National Health Service.

¹ 'Better use of personal information: opportunities and risks' (Council for Science and Technology, November 2005); 'Personal data for public good: using health information in medical research' (Academy of Medical Sciences, January 2006)

HIGH LEVEL PRINCIPLES

7. Any new institutional structure should ensure that:
 - i. there is an appropriate mix between basic, translational and clinical research, with flexibility over the medium to long-term to adapt this mix in response to changing circumstances;
 - ii. it provides appropriate incentives for the support of R&D as an integral part of the NHS culture;
 - iii. appropriate mechanisms are in place to nurture the clinical academic career environment;
 - iv. for the benefit of patients and UK PLC, appropriate arrangements are in place to maximise access for research funders (e.g. charities, industry, Funding Councils, and universities) to the experimental medicine infrastructure, information infrastructure (Connecting for Health and other IT opportunities) and intellectual capital within the NHS;
 - v. it provides long-term stability to the sector, with appropriate transitional arrangements and an opportunity to evolve over time;
 - vi. whilst the long-term goal must be to deliver health benefits and economic return, any new arrangements recognise that most fundamental research breakthroughs have not had foreseeable economic/health implications (e.g. studies of antibody allelic exclusion that led to monoclonal antibody development);
 - vii. access to NHS infrastructure is not controlled by a single funding agency, but open to quality research funded by other public bodies, research charities and industry, which has undergone peer review and appropriate ethics approval;
 - viii. there is cost effective delivery within the NHS of clinical trials (including regulation, working with patients to identify trial participants, and value for money) for all stakeholders, including research charities and industry;
 - ix. it has the independence to provide an authoritative voice, free from political expediency or the interest of any particular stakeholder, on a range of issues such as policy and research regulation (e.g. animals in research, Human Tissue Act, stem cell research); specific disease areas (e.g. measles, mumps and rubella vaccine, pandemic flu, Gulf War related illness); and priority areas (e.g. obesity, cognitive neuroscience);
 - x. it has a strategic overview of all UK health research, where necessary through discussions with the devolved administrations and other funders;
 - xi. the single Health Research Fund is managed within the context and ethos of the other Research Councils, which between them run a model of distributing research funds which has shown great achievement over a long time. They support one another, learn from one another, and the areas of their responsibility interface so that they can discuss and foster interdisciplinary science;

- xii. there is an effective system to support knowledge transfer and Intellectual Property exploitation, building on MRC Technology and NHS translational offices;
 - xiii. an appropriate governance structure is in place, with an open and inclusive decision making process. The new structure and processes must guard against unnecessary bureaucracy. A system of independent evaluation/review should be adopted;
 - xiv. it promotes patient and public involvement, and actively engages with the public.
8. Funding provision must be underscored by the following:
- i. transparency of funding allocations and decisions: excellence must be the overarching criteria for funding decisions, informed by peer review;
 - ii. the Haldane principle (arms length decision making – from Ministers) must be maintained;
 - iii. appropriate balance of ‘top down’ vs. ‘bottom up’ direction;
 - iv. appropriate mix between basic, translational and clinical research for the full spectrum of funding (i.e. resources, infrastructure, support costs, and training and career support);
 - v. infrastructure support should be linked to research excellence;
 - vi. independent evaluation/assessment of outputs and impacts of research supported;
 - vii. continued support for international health research, both in the UK and overseas;
 - viii. existing long-term commitments with other partners are supported sustainably (e.g. Avon Longitudinal Study of Parents and Children, Biobank, Clinical Research Facilities, and clinical training fellowships).

POSSIBLE HIGH-LEVEL STRUCTURES

9. A number of models can be envisaged for the delivery of the new single Health Research Fund. We have outlined below three possible high-level structures with their advantages and disadvantages. We recognise that we are not starting with a clean sheet of paper. The MRC and NHS R&D currently have the following broad research responsibilities:

<p>MEDICAL RESEARCH COUNCIL</p> <ul style="list-style-type: none"> •Research grants •Clinical trials •Infrastructure: Centres, units, networks, platforms •Training/careers •Health Services Research •Public health research •Technology transfer 	<p>NHS R&D</p> <ul style="list-style-type: none"> •Applied research grants •Small clinical research grants •Infrastructure: National Institute for Health Research, centres, networks, platforms •Training & embedded posts •Policy research, units •Health Technology Assessment •New & Emerging Applications of Technology •Service Delivery and Organisation
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MODELS

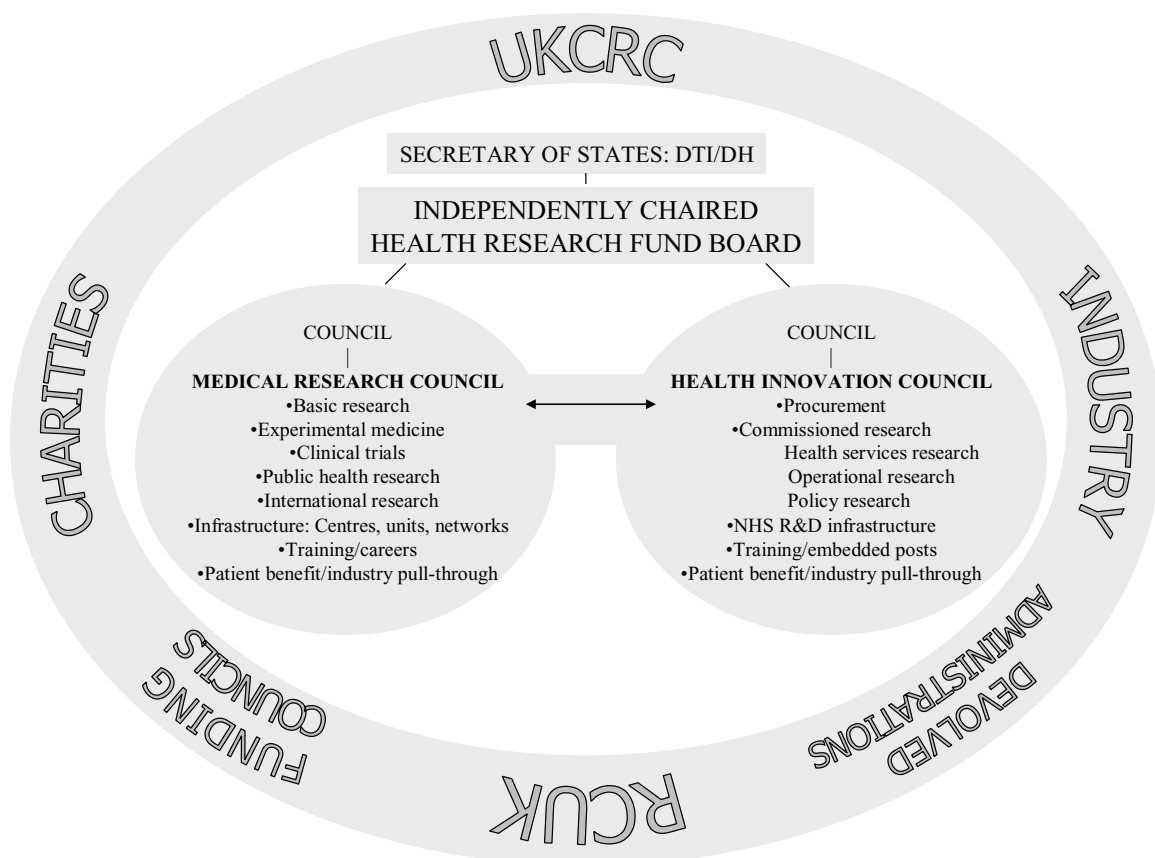
10. Our preferred model is one that maintains and builds on the strengths of the MRC (within the Office of Science and Innovation, part of the Department of Trade and Industry) and establishes a new Health Innovation Council within a new Office of Science and Innovation, part of the Department of Health. These closely linked, but separate entities will be overseen by a new overarching, strategic body, “the Health Research Fund Board”.
11. We further propose that a Ministerial post is specifically allocated to the new Office of Science and Innovation within the Department of Health. Those activities within the Department of Health that support health innovation should all be co-located within the Office of Health Innovation.
12. Details of this model (model 1) are provided in paragraphs 13 to 21.

Model 1: The MRC and NHS R&D as separate bodies with a strong overarching strategic body (see diagram)

13. The MRC will retain its current characteristics, including its relationship to the Office of Science and Innovation and RCUK, and absorb some of the responsibilities currently managed by NHS R&D. In this model, the MRC is responsible for funding and managing all responsive mode research.
14. A new Health Innovation Council, (within a new Office of Science and Innovation, part of the Department of Health), will have a commissioning and procurement role for research, technology and innovation. The Health Innovation Council will also be responsible for research infrastructure in the NHS, and support relevant training and career programmes. Analogous to the MRC, the Health Innovation Council will have its own independently chaired Council in order to ensure good governance, better transparency in decision making, and clearer accountability.
15. To ensure the necessary focus, leadership and accountability within the Department of Health, a new Office of Health Innovation with its own Minister – the Minister for Health Innovation - should be established. This Office will bring together all those activities within the Department of Health relating to health innovation. The NHS has often been seen to be resistant to health innovation as exemplified by the slow uptake of imaging techniques such as CT and MRI, invented in the UK, but financially exploited overseas.

16. The arrangements outlined in paragraphs 14 and 15 will ensure that the changes needed in the Department of Health and the NHS to fully realise the research, technology, innovation, and academic training and career opportunities are driven forward. They will also ensure that research and development remains fully embedded as a high priority within the NHS.
17. A new Health Research Fund Board, an overarching strategic body, will be responsible for providing advice to Ministers on the overall funding needs and allocations, and will set the combined strategic direction for both the MRC and the Health Innovation Council. This oversight body should have a chair who is independent of Government Departments or any specific stakeholder interest. Membership should include representation from a variety of stakeholders in the biomedical sector, including research charities and industry.
18. It is vital that with this model, measures are put in place to ensure that the interchange between the MRC and the Health Innovation Council is 'fluid' and constructive. The composition of the overarching strategic Health Research Fund Board, and the Councils for the MRC and the Health Innovation Council will be key in achieving this goal. This model will allow, over time, and on the advice of the Health Research Fund Board, the transfer of funds, activities and responsibilities between the two bodies. The diagram, below, sets out proposed new responsibilities for the MRC and the new Health Innovation Council:

Preferred Model



19. The introduction of an overarching strategic Health Research Fund Board and a Council for the new Health Innovation Council will:
 - provide a safeguard for the ring-fenced NHS R&D budget;
 - ensure greater transparency and introduce strengthened governance arrangements;
 - create opportunities for research charities and industry to work with different elements of the Health Research Fund;
 - offer a structure that can work with the devolved administrations;
 - accelerate 'pull through' from basic research for patient benefit and commercial activity, for instance in the area of personalised medicine, with the Councils of the MRC and the Health Innovation Council producing a joint implementation plan: progress will be reported to, and assessed by, the Health Research Fund Board; and
 - help catalyse the unique opportunities presented by the NHS (e.g. Connecting for Health).

20. Potential strengths of keeping the MRC and the new Health Innovation Council as closely linked, but separate bodies are that it:
 - recognises the different cultures of the MRC and NHS R&D;
 - acknowledges the current real flows of money within the NHS for R&D;
 - allows maintenance of incentives within the NHS to support R&D and innovation;
 - preserves the Haldane principle of arms length decision making from Ministers;
 - builds on the MRC's approach to funding, including international peer review;
 - allows MRC to retain its current responsibilities in the global health arena;
 - avoids creating a large agency which mixes funding of very different types: peer-reviewed, commissioned, procured;
 - allows time for NHS R&D to identify and separate true R&D funding from clinical service support;
 - allows NHS R&D space to properly analyse how it can support innovation in the NHS through support of experimental medicine, clinical trials and public/private partnership experiments with industry around drug discovery;
 - allows a top-down strategic approach to commissioning some health research activity;
 - strengthens the NHS as a procurer of new technology;
 - enhances new opportunities for joint working between the MRC, NHS, research charities and industry; and
 - avoids turmoil of creating new institutional structures that attempts to 'fix' problems that are not broken.

21. Implementation of this model will need to ensure that:
 - the independently chaired Health Research Fund Board has sufficient 'teeth' to integrate the work of the two bodies; and
 - demarcation of funding borders between these two bodies, as well as the BBSRC, ESRC and other Research Councils, are carefully defined and kept under review.

22. There are a number of other models which we have considered, including the following two – neither of which, in our view, would fully realise the UK's potential for health research.

Model 2: The MRC and NHS R&D as separate bodies, but allocating all the research funding element of NHS R&D into a reformulated and larger MRC

23. The potential strength of this model is that the increased MRC budget would allow its model of support to extend to more work at the clinical interface. Some of the strengths outlined for model 1 also apply.
24. The potential disadvantages are:
- allocating the NHS research funding element to the MRC could create pressure to move support away from basic research; and
 - the loss of a 'real' research budget in the NHS could disincentivise the whole NHS R&D operation. Consequences of such disincentivisation might include an inability to realise the full potential of the growing Clinical Research Networks and Connecting for Health.

Model 3: Creation of a single non-departmental public body with a budget of up to £1.3 billion, reporting to one, or two Secretaries of State

25. The potential strengths of this model are:
- it creates a single agency with responsibility for the whole spectrum of medical and health research;
 - the combined budget would, in theory, increase the absolute funding available for research; and
 - it could be seen as the most satisfactory outcome, politically.
26. The potential disadvantages are:
- it will dislocate the current partnership relationships that have so effectively been established under the auspices of the UK Clinical Research Collaboration (UKCRC);
 - it presents the greatest risk of unintended consequences, and perhaps of destabilising the successful current MRC structure;
 - as with model 2, this could be seen as taking the responsibility of support for research away from NHS and there is a high risk that it will disincentivise the NHS R&D operation;
 - it would be difficult to embed a research organisation into a single government department, or Non-Department Public Body (NDPB), if it is to have dual accountability (to both Trade and Industry, and Health);
 - it would be extremely difficult to achieve this structure in the short term. Removal of £750 million from the NHS budget, part of which is likely to be supporting service delivery and care, would be highly destabilising. It could, unless carefully managed, disrupt health service provision, particularly in London;
 - the mixing together of infrastructure and research funding in a single institutional budget for health research could make the budget more vulnerable to challenges from other areas.

CONCLUSION

27. The Wellcome Trust concludes the best structure will be one that maintains the MRC (within the Office of Science and Innovation, part of the Department of Trade and Industry), and establishes a new Health Innovation Council within a new Office of Science and Innovation, part of the Department of Health. These closely linked, but separate entities will be overseen by an overarching strategic body, "the Health Research Fund Board" (model 1). The new Health Innovation Council will be responsible for commissioning and procuring research and new technology, and for

providing the research infrastructure within the NHS. To ensure focus and ownership within the Department of Health and the NHS, a new Office of Health Innovation with its own Minister – the Minister for Health Innovation - should be established. This Office will bring together all those activities within the Department of Health relating to health innovation. The MRC will be responsible for funding and managing all responsive mode research. The MRC will maintain its relationship with the Office of Science and Innovation, the Minister for Science and Innovation, and RCUK. Both the MRC and the new Health Innovation Council will have their own independently chaired Councils – the chairs of which will be members of the new Health Research Fund Board. The Health Research Fund Board will have responsibility for advising Ministers on a range of issues, including: overall funding needs (in the context of Spending Reviews); funding allocations between the two entities; and setting the combined strategic direction. A first step will be to ensure that the various elements which comprise the NHS R&D budget are brought together and ring-fenced. An early task for the Health Research Fund Board will be to ensure that appropriate resources are attached to the new responsibilities for each organisation.

The Wellcome Trust
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