Department of Health

Best Research for Best Health: A New National Health Research Strategy

The NHS contribution to health research in England: a consultation

Best Research for Best Health: A New National Health Research Strategy

The NHS contribution to health research in England: a consultation

July 2005

DH INFORMATION READER BOX

Policy HR/Workforce Management Planning **Clinical**	Estates Performance IM & T Finance Partnership Working
Document Purpose	Consultation/Discussion
ROCR Ref:	**Gateway Ref:** 5221
Title	Best Research for Best Health: A new National Health Research Strategy
Author	Research and Development Directorate, Department of Health
Publication Date	29 July 2005
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs, Medical Directors, Directors of Nursing, Special HA CEs, Directors of HR, Directors of Finance, Allied Health Professionals, GPs, Organisations and individuals involved in health research
Circulation List	
Description	Consultation on the proposed new National Health Research Strategy, which aims to create a health research system in which the NHS supports those engaged in leading-edge research to focus on the needs of patients and the public
Cross Ref	N/A
Superseded Docs	
Action Required	Respond to consultation
Timing	Responses by 21 October 2005
Contact Details	Best Research for Best Health Consultation Research and Development Department of Health Area 723 Wellington House 133-155 Waterloo Road London SE1 8UG http://www.dh.gov.uk/Consultations/LiveConsultations Email: RDconsultation@dh.gsi.gov.uk
For Recipient's Use	

Contents

Foreword by the Minister of State for Quality and Patient Safety

Our society is continuously changing. For health, these changes have led to remarkable improvements in the way we identify, diagnose and manage disease. We are now able to consider the prospect of disease prevention through a clearer understanding of genetic, social and environmental risk factors and disease processes.

Society has high expectations of health and healthcare. Our ability to develop the medicines, care options and advice on lifestyle choices for the 21st century depends on rigorous applied research. Research also provides us with the evidence to make informed decisions about the benefits and costs of existing health care interventions. It is for these reasons that the Department of Health is a major contributor to health research in the UK with a current annual spend of £650 million.

This Government believes that health research plays a key role in improving our nation's health and in increasing our nation's wealth. Our 10-year *Science and Innovation Investment Framework*[1] highlighted the vital role that research plays in the knowledge economy of our country through its contribution to international competitiveness and economic growth. In July 2004, the Chancellor of the Exchequer announced that the Government's ambition was to raise the level of research and development to 2.5% of GDP by 2014. To achieve this target requires substantial growth in the underpinning investment in the public science base, both to supply the skills and research results into the economy, and to attract mobile business R&D investment into the UK. It also requires a continued strengthening of the linkages between the public and private sector research bases.

Business research and development in the UK is heavily dependent on the efforts of a few leading firms concentrated in just two sectors, one of which is pharmaceuticals. So the Government is committed to making the UK the best place in the world for health research, development and innovation. The Department of Health will ensure that the NHS contribution to health research is a centrepiece of that ambition.

This consultation document sets out our proposals for achieving this central position for the NHS. As with the proposals set out in *Creating a Patient-led NHS*[2], the proposals for this new National Health Research Strategy place patients at the centre of a system that focuses on quality, transparency, and value for money.

The changes proposed are radical. However, we believe that they are essential to create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research, focused on the needs of patients and the public.

We also believe that the time is right. The establishment of the UK Clinical Research Collaboration has created a unique opportunity with our partners to tackle the challenges that are holding back clinical research. The research community has expressed its resolve to change the current situation. We are committed to establishing a transparent and stable funding system for research in the NHS. And the Department of Health is pressing forward with a wide programme of health system reform including the introduction of Payment by Results.

Nevertheless, our new R&D strategy will only be successful if it commands widespread support from our stakeholders. The purpose of this consultation is to seek your views so that we can create the widest possible consensus about the way forward. I do hope you will respond to this consultation and let us know your views.

Rt Hon Jane Kennedy MP
Minister of State for Quality and Patient Safety

Executive Summary

Introduction

Best Research for Best Health: a New National Health Research Strategy is a consultation paper setting out proposals for the future direction of health research for the Department of Health and the NHS in England. The Government's 10-year *Science and Innovation Investment Framework*[1] set out the key role that health research must play in improving our nation's health and increasing our nation's wealth. More recently, *Creating a Patient-led NHS*[2] set out the need to put patients at the centre of a health system that focuses on quality, transparency, and value for money. To achieve these ambitions, we must fundamentally revise our research strategy. We have consulted many stakeholders, organisations and individuals on the steps that we should take to exploit the potential of the NHS to improve national health and increase national wealth by creating a world-class environment for research focused on the needs of patients. Those discussions have helped us develop this paper, which reflects what those who fund, conduct and use research have told us they would like to see in the future. Nevertheless, the policies and proposals set out here are not fixed, and we would welcome your views.

This consultation relates to the programmes, funding and structures for which the Department of Health and the NHS in England are responsible. Our proposals recognise the crucial importance of working in partnership with the other organisations, administrations and individuals that fund, conduct and use research.

Our Vision for Health

Research has the power to transform the health of our nation. The primary aim of the Department of Health is to improve the health and wellbeing of the people of England.

Our vision is to:

- support **patients** in making informed choices about health behaviour and health services
- support front-line **health professionals** to make informed decisions about the effectiveness and cost effectiveness of healthcare interventions in particular patient groups or settings
- support managers and **policy makers** in deciding how best to increase patient access and improve delivery of care
- promote an environment in which those working in and using the NHS can help to increase the **knowledge** needed to improve the Service.

We aim to achieve three things:

- Firstly, we intend to provide world-class support to those who conduct and participate in health research for the benefit of patients in the NHS and the wider public
- Secondly, we intend to create a system in which NHS organisations have the necessary support and infrastructure to enable them to conduct and support first-class research as an integral element of high-quality patient care

- Finally, we intend to strengthen our research programmes, undertaking more research in areas that are of vital importance to health, but are currently neglected or underfunded, and thus make them even more responsive to the needs of patients, the public, healthcare professionals and policy makers.

Together these three changes will enable the NHS to support outstanding individuals, working in world-class facilities, conducting leading-edge research, focused on the needs of patients and the public.

These changes will also form a major component of the Department of Health's Science and Innovation Strategy.

We will work in partnership with other government departments, the voluntary sector, industry, clinicians, researchers, NHS management, patients and the wider public to effect this vision.

Development of NHS Research

Research has been a feature of the NHS since its inception in 1947. From the early 1970s, a series of reports has sought to increase the volume of applied research relevant to the needs of the NHS.

In 1991, the first Director of R&D for the NHS was appointed[3], and subsequent reports and work led to improvements in the system for setting research priorities and established an integrated NHS research budget. Since 1998, following changes aimed at harmonising the reform of NHS R&D with the Government's modernisation programme, NHS R&D funding has comprised two systems:

- R&D to meet the priorities and needs of the NHS i.e. national R&D programmes (circa £150 million in 05/06) and funds that go to providers of NHS services for R&D they initiate (circa £100 million in 05/06)
- Resources to meet the NHS costs of hosting R&D supported by eligible external funders – NHS Support for Science (circa £400 million in 05/06).

The Department of Health aims to maximise the potential of technology and science activities and drive innovation through improving interventions for health and patient care, sustaining and developing the science base in health and, wherever possible, basing policy and practice in health on sound science and research.

It is the intention of Government to make the UK the best place in the world for health and healthcare research, development and innovation. We have acted to address challenges set out by the reports of the Bioscience, Innovation and Growth Team and the Academy of Medical Sciences[4, 5]. In partnership with other funders – industry, patients and academia – the Department of Health established the UK Clinical Research Collaboration and committed to increase the baseline R&D budget by £100 million per annum over and above inflation.

Over the coming decades our population will become 'greyer' and there will be a significant increase in the numbers of 'older old' people.

Although there is a dispute about the level of pressure this is likely to make on health and social care budgets, it will undoubtedly present challenges.

The current system faces many challenges, from lack of incentives to conduct health research in the NHS, through problems with career paths for all professionals in research, to the perception that, however well designed, applied research is somehow 'second class' research. We hear these challenges frequently in dialogue with our stakeholders and partners, and our proposals address them.

National Institute for Health Research

We propose to position, manage and maintain the research and research infrastructure of the NHS as a national research facility: the National Institute for Health Research. The aim of this **virtual** Institute will be to ensure that the NHS is seen to be a world-class and preferred host for multi-centre clinical and broader health research. This will benefit the NHS and its stakeholders as well as **supporting innovative applied and translational research.** We wish to promote increased professionalism in research by fostering the development of an 'esprit de corps' of research effort within the NHS. The Institute will provide **world-class support** to those who conduct research for the benefit of patients in the NHS and the wider public. It will help ensure that we attract and retain the outstanding clinical, health service and public health researchers needed to tackle the health challenges of the future. The establishment of this Institute will **provide coherence** and in addition **focus** for a number of strands of work relating to academic careers. It will also provide a consolidated place for our programmes of research work and a mechanism for managing other parts of our responsibility.

The National Institute for Health Research will work with other funders, industry and key partners through the UK Clinical Research Collaboration. The institute will be 'virtual' in nature. It will not be an Arm's Length Body, nor will it have a separate management structure or chief executive. Rather, it will be a bringing together, under one name, of all that NHS R&D does in order to increase the sense of coherence of our programmes, funding streams, and research management systems. The Director of NHS R&D will chair an advisory board that provides high-level strategic direction and audit for the activities of the National Institute for Health Research, supported by a contracted business support unit.

A National Institute for Health Research will bring together, for the first time, in one coherent system, all elements of NHS and Department of Health research. It will work with partners through the UK Clinical Research Collaboration. The funding will come from the NHS R&D budget and will be allocated transparently.

Provide World-Class Support to Researchers

We must provide world-class support to those involved in health research for the benefit of patients in the NHS and the wider public. It is imperative that we attract and retain the

outstanding clinical, health service and public health researchers needed to tackle the health challenges that face us, and that we support those working in and using the NHS who wish to help increase the knowledge on which quality in the NHS depends. We need to strengthen public confidence by promoting high standards of safety in research, as well as high quality research outputs. We need to manage risks well and not to over-react in ways that stifle potentially valuable research in complex bureaucracy. And we need to establish incentives to ensure that patients, managers and the institutions of the NHS value research. Lastly, we need to ensure that research is not driven out of agreed work plans by an over-emphasis on performance that does not acknowledge the importance of research and evidence.

We propose that the National Institute for Health Research, when established, will bring together a faculty tasked with delivering the research needs of the NHS. The aim will be to focus the talents of this cohort of clinical academics on applied health research that responds to the needs of the NHS and its current and potential patients.

The faculty will consist of the following staff:

- **Senior Investigators**
- **Faculty Associates**
- **Junior Investigators**

Research Funding

We propose to evolve from the current Support for Science historical mode of supporting research in the NHS to a transparent system where money follows patient involvement in health studies.

Creation of Optimum Systems to Conduct Research

We want to create a system in which NHS organisations, staff and patients have the necessary support and infrastructure to enable them to contribute to first-class research as an integral element of high-quality patient care. As part of the creation of the National Institute for Health Research, we propose to establish:

- a linked set of **technology platforms** that support clinical research in selected research-intensive hospitals/NHS providers
- a linked group of world-class competitively selected National Institute for Health Research **Academic Medical Centres** that have the clinical depth in health-related subjects to enable them to act as the leaders of scientific translation, early adopters of new insights in technologies and techniques for improving health
- **Research networks and information systems** that give expert support to everyone conducting and managing research, and help streamline essential processes and decisions.

Strengthen Research Programmes

We intend that health research will become even more responsive to the needs of patients, our communities, healthcare professionals and policy makers, actively seeking the questions that they wish to see addressed. We will continue to emphasise

opportunities to make full use of **existing evidence** where this is available, **building on capacity** for this research at the Centre for Reviews and Dissemination in York and elsewhere, and within the international Cochrane and Campbell Collaborations. Systematic review and use of existing evidence adds power to new research.

We propose to expand the current **national research programmes**, including the internationally acclaimed Health Technology Assessment (HTA) programme, Service Delivery and Organisation (SDO) and New and Emerging Applications of Technologies (NEAT). These programmes are open to everyone and serve the interests of the wider NHS. Their agendas are set following widespread consultation with key constituents.

We propose to prioritise and consolidate our smaller programmes into a simplified structure with fewer, larger funding streams and to develop new, focussed programmes in developing areas such as assistive technology and diagnostics.

We propose to simplify the management of the NHS National Research Programmes by consolidating the commissioning and management processes into a central business support unit.

We also propose the introduction of new funding schemes:

1. **Responsive funding**, modelled on the old regional funding streams for applied and practice based research in areas important to front-line staff.

2. **Programmes of applied research**, allocated competitively to NHS trusts for areas of high priority to the NHS.

3. **Challenge fund for innovation**, to encourage well-managed risk-taking and innovation in the NHS.

4. **RISC (Research for Innovation, Speculation and Creativity) awards**, to ensure that new and radical ideas can be developed and tested.

Conclusion

Best Research for Best Health: a New National Health Research Strategy is intended to provoke discussion. We would now like to hear your views on our proposals so that we can move forward by implementing a shared vision and creating a research environment in England to deliver the needs of the 21st century:

- creating, maintaining and managing the research and research infrastructure of the NHS as a 'virtual' national research facility – the **National Institute for Health Research**
- establishment of a **faculty** for the National Institute for Health Research to include Senior Investigators, Faculty Associates and Junior Investigators who will deliver the research needs of the NHS
- evolving from the current Support for Science historical mode of supporting research in the NHS, so that **funding** follows patient involvement in health studies
- establishing a concurrent set of **technology platforms** that support clinical research in selected research-intensive hospitals/NHS providers
- establishing a linked group of competitively selected National Institute for Health Research **Academic Medical Centres**
- expanding the current **NHS National Programmes** for R&D that serve the interests of the wider NHS and set agendas following widespread consultation with key constituents, rationalising smaller programmes into a simplified structure and streamlining the management of the NHS National Research Programmes via a centralised system
- introduction of **new funding schemes**, including a responsive funding scheme, a scheme for applied research in areas of high priority to the NHS, a challenge fund for innovation, and a RISC award
- reinforcing and expanding the **research networks** with capacity to provide reliable expert advice and support on regulatory and governance processes
- integrating research **information systems**, to standardise and minimise the information needed for regulation, ethics and research governance.

The process of consultation and how to contribute

When should you submit your contribution by

It is important that consultees have sufficient time to respond to this consultation document as we value your feedback. This consultation will therefore run for the full twelve week period recommended by the Cabinet Office Code of Practice on Consultation. The Department of Health welcomes contributions and would be grateful to receive them as early as possible in the consultation process. The last date for responding is **21st October 2005**.

How to Respond

Please use the template provided to respond to the consultation. The template can be downloaded from the website below. The template should be saved and emailed as an attatchment to the mailbox RDconsultation@dh.gsi.gov.uk. Hard copies can be sent to the postal address shown below.

When responding, please state whether you are responding as an individual or representing the views of a larger organisation. If responding on behalf of a larger organisation, please make it clear who that organisation represents. If responding as an individual, please mention your own interest.

Please note that responses may be made public unless confidentiality is specifically asked for. We may also publish your responses in a summary of responses to the consultation unless you specifically include a request to the contrary. If you are replying by e-mail, unless you specifically include a request to the contrary in the main text of your submission to us, we will assume your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system.

Where should you submit your contribution?

E-mail: RDconsultation@dh.gsi.gov.uk

Contact: Best Research for Best Health Consultation

Address: Research and Development
Department of Health
Area 723 Wellington House
133-135 Waterloo Road
London
SE1 8UG
United Kingdom

Further information

Further information about this consultation and copies of the consultation document are available from:

On the web at:
http://www.dh.gov.uk/Consultations/LiveConsultations

E-mail: RDconsultation@dh.gsi.gov.uk

Telephone: 020 7972 4113

Hard copies are available from:

DH Publications Orderline
PO Box 777
London SE1 6XH
E-mail: dh@prolog.uk.com
Tel: 08701 555 455
Fax: 01623 724 524

Consultation Questions

Please use the separate template to respond to the Questions. The template is available at http://www.dh.gov.uk/consultations/liveconsultations.

Challenges

Question 1

a. Are these the main challenges?

b. Are there other important challenges that we need to take account of?

Building Blocks

Question 2

a. Are these the main building blocks that we (Department of Health/National Health Service) have at our disposal?

b. Are there other important elements that we need to consider?

National Institute for Health Research

Question 3

a. Will the creation of a virtual National Institute for Health Research achieve the objectives of creating coherence and focus for the different strands of our work?

b. Would another mechanism work better?

c. If so, what?

d. Does the name National Institute for Health Research appropriately describe its role?

National Institute for Health Research Faculty

Question 4

a. Do you agree that we should create a staff structure which ensures proper support for all those engaged in research for the benefit of patients?

b. Do you agree with the concept of a National Institute for Health Research faculty?

c. If no to **a** and/or **b** above, what mechanism(s) should be used to ensure these staff are supported?

d. Do you agree with the three groupings (Senior Investigator, Faculty Associate, and Junior Investigator) as proposed?

e. If not, what groupings would you use?

f. Do the names Senior Investigator, Faculty Associate, and Junior Investigator appropriately describe the different groups?

g. If not, what names would describe them better?

h. Is it appropriate to include the NHS-funded staff in universities?

i. Should the funding for these staff be held centrally to ensure protection of research time?

j. What would appropriate 'allowances' be for the three groups of faculty staff?

Infrastructure

Question 5

a. Are the proposals for Support for Patient Research appropriate?

b. If not, what would achieve the aims better?

Question 6

a. Are the proposals for Academic Medical Centres appropriate?

b. If not, what would achieve the aims better?

c. Should we support both comprehensive centres and specialist centres?

d. How many of each can we support if they are to be truly world-class as the exemplars?

e. What time period should be awarded before a new competition round?

Question 7

a. Are the proposals for Leadership Funding appropriate?

b. If not, what would achieve the aims better?

Question 8

a. Are the proposals for Technology Platforms appropriate?

b. If not, what would achieve the aims better?

c. What should be the first area(s) for focused support?

Question 9

a. Are the proposals for Experimental Medicine appropriate?

b. If not, what would achieve the aims better?

Question 10

a. Are the proposed infrastructure elements to create optimum systems the right ones?

b. Are there other potential elements that we should consider?

c. What should the balance of investment between the different infrastructure elements be? (i.e. what should be the percentage spend on each?)

Programmes

Question 11

a. Are the proposals for research programmes appropriate?

b. If not, what should we amend, add or delete?

Research networks

Question 12

a. Are the proposals for research networks appropriate?

b. If not, what would achieve the aims better?

Bureaucracy 'busting'

Question 13

a. Do you agree with our guiding principle that procedures and data input should occur once and once only and that where duplication exists, we will seek to streamline it?

b. Are the proposals for bureaucracy 'busting' appropriate?

c. If not, what would achieve the aims better?

Transition

Question 14

a. How important is it that our funding is allocated transparently?

b. How important is it that we establish a sustainable funding system?

c. How important is it that we establish a funding system that is responsive to changes in levels of research activity?

d. How important is it that we do not lose momentum in the move to the new system?

e. If the implementation start date is 1 April 2006, how long should the transition to the new system take to complete: 1 year, 2 years, or 3 years?

f. How important is it to ensure that we do not destabilise individual institutions as we move to the new system?

Overall

Question 15

a. By what criteria will you judge us on the impact of this strategy?

b. Do you have any other comments?

PART ONE – Our vision for health research

1. OUR VISION FOR HEALTH RESEARCH

Research has the power to transform the health of the nation. Without research, there would be no penicillin, no children cured of leukaemia and no understanding that bed rest is not the best strategy for treating back pain. Research not only provides the evidence to improve healthcare in the future, but participating in research drives improvements in patient care now.

1.2 The primary aim of the Department of Health is to improve the health and wellbeing of the people of England. The financial resources that the Department has at its disposal – including its research and development budget – have been voted by Parliament to support this aim. Therefore, the Department only provides support to research with a direct focus on people and their health and wellbeing.

1.3 There are three key reasons for the Department of Health to invest money in patient-based research:

- because it is the only way to develop the evidence health professionals, patients and policy makers need if they are to understand illness and tackle health inequality effectively
- because participating in research promotes quality care, and
- because patient-based research contributes to economic growth and international competitiveness.

1.4 Our vision is to:

- support **patients** in making informed choices about health behaviour and health services
- support front-line **health professionals** make informed decisions about the effectiveness and cost effectiveness of healthcare interventions in particular patient groups or settings
- support **managers and policy makers** in deciding how best to increase patient access and improve delivery of care
- promote an environment in which those working in and using the NHS can help to increase the **knowledge** needed to improve their Service.

1.5 The scale and complexity of the health research system in the UK mean that we must **work in partnership** with others to deliver this vision. We will work in partnership with other government departments, the voluntary and private sectors, clinicians, researchers, patients and the public to **influence the strategic direction** of health research in the UK. We will work with NHS clinicians, managers and researchers to **harness the capacity** of the NHS to conduct research, and we will work with the Research Councils, other government funders, major research charities and industry to **develop the UK science base and commission research for health.** We will involve patients and carers to establish priorities, ensure appropriate study outcome measures and active dissemination of results.

PART TWO – Setting the context

2. Purpose of research

2.1 The purpose of the research supported by the Department of Health and the NHS is to provide the evidence central to improving health, reducing inequalities and increasing the wealth of the UK. Improving health not only improves the quality of life of individuals, it also lightens the burden of care placed on relatives and reduces the level of sick leave, reduced productivity, and loss of key individuals.

2.2 The most striking thing about the research that we fund is its focus and relevance. Our research aims to answer the very real questions that face people about health in their professional and private lives. These people represent diverse groups from healthcare professionals through policy makers to patients and the public. Experience has shown that, unless the unanswered questions deemed important by people working in and using the NHS are actively sought out and prioritised for investigation, their uncertainties will not be addressed in a research world that is dominated by other people's priorities.

2.3 At its core, health research has two purposes; firstly to discover **new** ways to identify, prevent and treat disease while promoting health; and secondly, to build up evidence that informs decisions about **existing** healthcare interventions. In this way research enables:

- patients and the public to understand the health issues that are relevant to them and to make informed choices about health behaviour and health services
- front-line health care professionals – clinicians and managers – to make informed decisions about the clinical effectiveness and cost effectiveness of health interventions in particular patient groups or settings
- policy makers to be properly informed about the likely costs and benefits of particular policy directions.

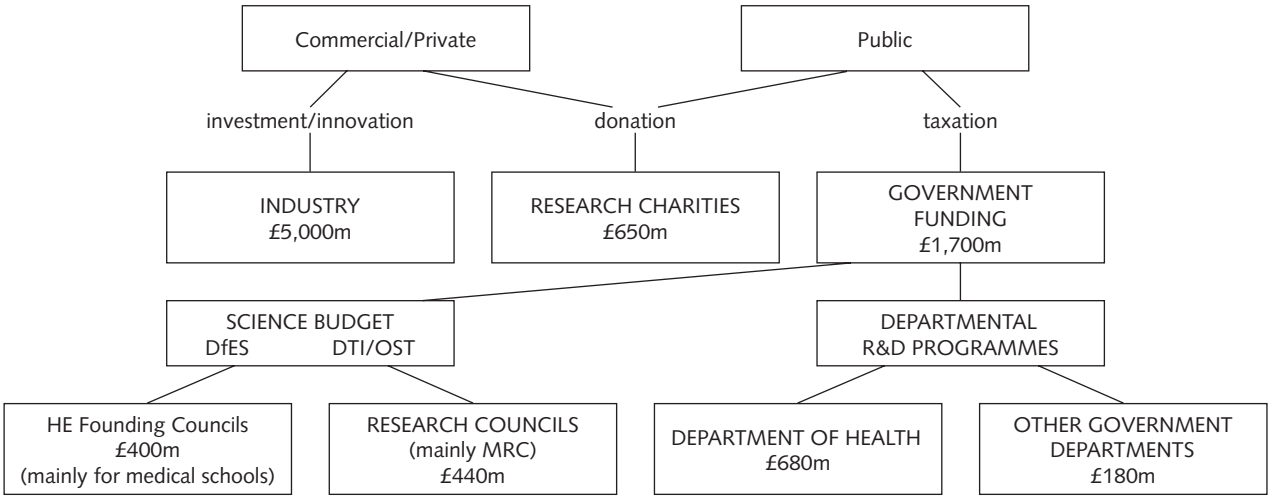
2.4 The ultimate aim is better health through research-based knowledge.

3. Development of National Health Service (NHS) research

3.1 Many bodies, including central Government, the Medical Research Council (MRC) and other Research Councils, industry, charities, and the NHS, support research in health.

Figure 1

Indicative Funding for Health Research in the UK



Note: Figures are estimates derived from a variety of sources and are intended only to give an indication of spend.

3.2 The funds for commissioning applied, patient-based research have moved back and forward between the research councils and the Health Departments, with the debate concerning the best position from which to commission applied patient-based research[6].

3.3 Research in the NHS was conducted in a piecemeal fashion with no strategy or clear leadership until the appointment of the first Director of R&D for the NHS by the Department of Health in 1991[3]. This was in response to a key report by the House of Lords Science and Technology Committee[7].

3.4 Prior to this, the funding for research, and to support the extra patient costs of participating in research in the NHS, was delivered through a variety of funding streams including:

- allocations to the London Postgraduate Special Health Authorities
- the Service Increment for Teaching and Research (SIFTR) to the undergraduate teaching hospitals
- the Locally Organised Research Scheme

- research budgets managed by the Department of Health and the Regional Health Authorities, and
- expenditure by individual hospitals from their own resources.

3.5 These streams were brought together as the NHS R&D Levy in 1997, following a review by Professor Sir Anthony Culyer[8] and a declaration of costs by NHS Trusts. This, for the first time, brought all NHS R&D budgets together into a single funding stream.

3.6 A number of National Programmes were established explicitly to address questions faced by front-line professionals and policy makers, including the internationally respected Cochrane Collaboration, the Centre for Reviews and Dissemination in York, and the Health Technology Assessment (HTA) programme, as well as the Service Delivery and Organisation (SDO) programme, and the New and Emerging Applications of Technology (NEAT) Programme.

3.7 Research governance was codified in 2001 with the publication of a framework of guidance to ensure that health and social care research is conducted to high scientific and ethical standards that earn public confidence[9]. In 2005, research governance became one of a set of national standards for health care, and a second edition of the Research Governance Framework was issued[10].

4. The clinical research environment

4.1 In 2003, two reports – from the Biotechnology Innovation and Growth Team[4] and Academy of Medical Sciences[5] – identified critical challenges:

- the serious consequences for national health and wealth resulting from inadequate support for clinical research
- the need to build a mutually advantageous collaboration between the NHS and industry for patient benefit
- the necessity of creating a public and regulatory environment supportive of innovation
- the requirement for sufficient and sustainable funding.

4.2 The Government responded to these challenges by setting up the Research for Patient Benefit Working Party[11]. This group established a strong consensus around a common vision of the future for applied health research. It recommended the establishment of the UK Clinical Research Collaboration (UKCRC), which started work in 2004. To underpin the creation of the UKCRC, the Secretary of State for Health committed in the Budget to increase NHS R&D funding by an additional £100 million per year over and above inflation.[12]

4.3 The *Government's Science & Innovation Investment Framework 2004-2014*[1] demonstrates our intention to make Britain the best place in the world for research, development and innovation. Our proposals, supported by the new investment in NHS R&D and the work of the UKCRC, will help to ensure that the NHS contribution to health research is a centrepiece of that ambition. The ten-year framework identifies moving to full transparency of the use of R&D funds allocated to NHS Trusts and achieving full sustainability for clinical research in the NHS as a priority for the Department of Health.

4.4 The creation of a public and regulatory environment supportive of innovation and people-orientated research represents a challenge. In recent years, research has become more extensively regulated. Meanwhile, some high profile cases have heightened public awareness of bad practice, affecting public confidence in clinical research. Together, these developments have made the research environment more demanding, and put a higher premium on demonstrating compliance with standard procedures. There are strong indications that it is becoming impossible for clinical researchers to operate effectively without expert support from employers, host organisations and others.

4.5 There has also been considerable concern expressed over the state of clinical academic careers[13-16]. Major change within the NHS has left clinicians under great pressure, with training and research too often taking a back seat. However, clinical academics who undertake training and research are a crucial part of the workforce. They are needed to shape the future success of the NHS. Many do or will play key leadership roles.

4.6 There has been a decline in the overall number of medical academics from 4,000 in 2001 to only 3,500 today. The number of clinical lecturers has declined by 30 per cent over the same period. Because of other priorities, universities appear reluctant to support those clinical academics that do exist. (Between 40 and 50 per cent of clinical academic posts are funded by the NHS rather than by universities).

4.7 The decline in numbers reflects in part the problems that have existed with the career paths for all professions in research. These include disincentives to entry and barriers to progression. All of these factors have resulted in difficulty in both developing capacity and then in ensuring its sustainability in key research areas such as primary care. The Walport report on Clinical Academic Careers[17] offers a framework for addressing these concerns and reversing the decline for doctors. Similar initiatives for nurses and allied health professionals will follow.

5. Changes in society

5.1 Our society is continually evolving. For health and healthcare there will be changes in human behaviour and the way we tolerate and manage risk. As we understand better the risk factors and disease processes, early detection and prevention of disease will increase in importance. The increasing chronic disease burden, due in part to our ability to prevent early death from diseases, will place increasing pressure on our health and social care systems. Also, our ageing population is likely to generate increased pressure on health and social care budgets, and new technologies will continue to impact how we diagnose and intervene to protect and sustain people's health.

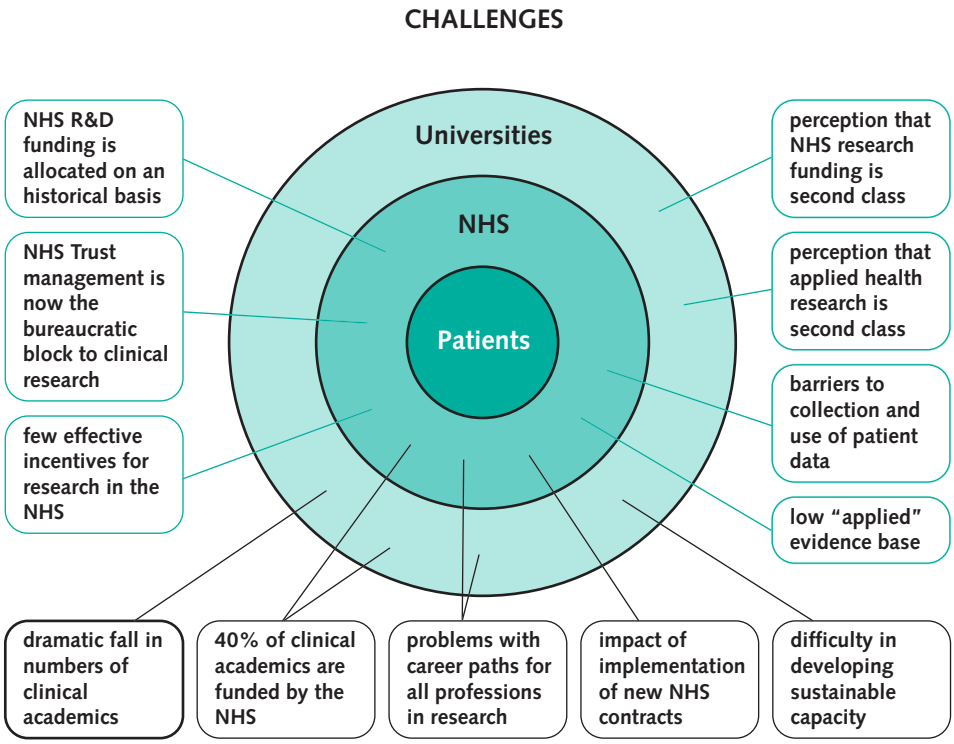
5.2 All of these changes to society – demographic, advances in science, and the expectation we have of our health and well-being – will alter how we deliver healthcare, highlighting new uncertainties and raising the need both for new evidence and better explanation of what it could mean.

6. The challenges we face

6.1 The major challenges that we face are summarised in Figure 2.

6.2 Our proposals set out to address these challenges.

Figure 2



Question 1

a. Are these the main challenges?

b. Are there other important challenges that we need to take account of?

PART THREE – What are we aiming to achieve with the changes?

7. The Building Blocks

7.1 We propose to address these challenges through three inter-linked strands of work by:

- **providing world-class support to researchers**
- **creating optimum systems to conduct and support research**
- **strengthening research programmes**

7.2 We currently allocate approximately £650 million per year through three main funding streams:

- commissioned research – through a portfolio of National Research Programmes (£150 million in 05/06)
- support for our partners' research in the NHS – Support for Science (£400 million in 05/06)
- funding trusts to research their own projects – Priorities and Needs (£100 million in 05/06)

7.3 We also support research management, the National Research Register, INVOLVE[1] and the NHS R&D Forum.

7.4 The Department of Health invests in **research networks** to support clinical research. Using cancer as the model[(18)], five additional topic-specific networks – mental health, stroke, diabetes, medicines for children, dementia and neurodegenerative disorders – have been commissioned with a National Network Co-ordinating Centre based in Leeds. In addition, we have provided substantial long-standing funding support to **academic centres** and networks in **primary care.**

7.5 A series of **experimental medicine** facilities, also known as Clinical Research Facilities, have been established across the country. These include the Wellcome/NHS Millennium Centres in Manchester, Birmingham, Southampton and Cambridge. While the Wellcome Trust funded the capital costs, the NHS R&D budget funds support for the ongoing patient-related costs. Under the auspices of the UK Clinical Research Collaboration, calls for a new tranche were advertised in summer 2005.

7.6 We fund **research units and centres** in priority areas for health and social care such as the National Centre for Primary Care in Manchester.

7.7 Through our capacity development programme, we spend £13.5 million supporting **research training for individuals** at a range of levels and across the range of disciplines required for patient-focussed research. We support studentships and fellowships through direct training schemes as well as unknown numbers of all

[1] INVOLVE aims to promote and support active public involvement in NHS, public health and social care research.

types of clinicians and career scientists through individual Trusts. Local teams are available to provide advice and support to researchers at all levels of experience including research methodology and specialist advice in areas such as protocol development.

7.8 Following the Walport report[17], we are working in partnership, under the auspices of UK Clinical Research Collaboration, to establish **career structures** for medical, dental and non-medically qualified research staff. These include clear routes of entry and transparent career structures, flexibility in the balance of clinical and academic training and in geographical mobility, with properly structured and supported posts upon completion of training. Academic training paths will be supported by expanding training opportunities for medical and dental staff and the development of clinical lectureships.

7.9 With respect to research **governance**, the Department of Health is working with partners in the UK Clinical Research Collaboration to harmonise, streamline and simplify procedures. The Research Governance Framework was revised in 2005[10], both to take account of changes in the law, and to clarify processes and procedures so as to reduce unnecessary bureaucratic process.

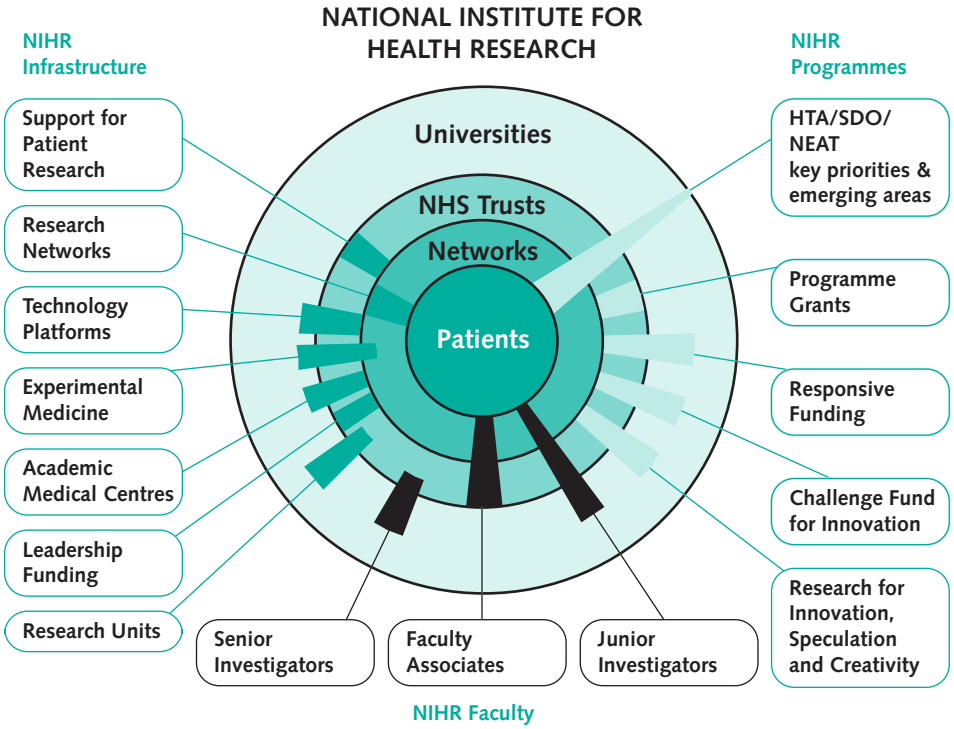
Question 2

a. Are these the main building blocks that we (Department of Health/National Health Service) have at our disposal?

b. Are there other important elements that we need to consider?

7.10 The following diagram summarises the proposals for change we are consulting on in this document:

Figure 3



8. National Institute for Health Research

8.1 We aim to create a system in which NHS organisations have the support and infrastructure they need to enable them to conduct first-class research safely alongside high-quality patient care.

8.2 We propose to position, manage and maintain the research and research infrastructure of the NHS as a virtual national research facility: **the National Institute for Health Research**. The aim of this **virtual** Institute will be to ensure that the NHS will command respect as a world-class environment and preferred host for multi-centre clinical and broader health research, as outlined in the Government's 10-year *Science and Innovation Investment Framework* [1]. This will benefit the NHS and its stakeholders as well as **supporting innovative applied and translational research**. The intent is to increase professionalism in research through developing an 'esprit de corps' of research effort. Providing **world-class support** to those who conduct research for the benefit of patients in the NHS and the wider public is essential and will help ensure that we attract and retain the outstanding clinical, health service and public health researchers needed to tackle the health challenges of the future. Badging the research and research infrastructure of the NHS as a National Institute for Health Research will create a sense of identity and belonging for those who do research for the benefit of patients in the NHS. The establishment of an Institute will **provide coherence** and, in addition, **focus** for a number of strands of work relating to academic careers. This will also provide a consolidated place for our programmes of research work and a mechanism for managing other parts of our responsibility.

8.3 A National Institute for Health Research will bring together, for the first time, in one coherent system, all elements of NHS and Department of Health research. The National Institute for Health Research, like the other NHS Institutes, the NHS Institute for Clinical Excellence (NICE) and the National Institute for Innovation and Improvement, will be a key part of the **NHS knowledge management system**. The National Institute for Health Research will create knowledge through R&D, while NICE assesses new and existing knowledge, and the new National Institute for Innovation and Improvement will use new knowledge to encourage innovation and improvement.

8.4 The National Institute for Health Research will work with other funders, industry and key partners through the UK Clinical Research Collaboration. The institute will be 'virtual' in nature. It will not be an Arm's Length Body, nor will it have a separate management structure or chief executive. Rather, it will bring together all that NHS R&D does under one name in order to increase the sense of coherence of our programmes, funding streams, and research management systems. The Director of NHS R&D will chair an advisory board that provides high-level strategic direction and audit for the activities of the National Institute for Health Research, supported by a contracted business support unit.

8.5 The funding will come from the NHS R&D budget and will be allocated transparently as described in Chapter 10 – *Creating Optimum Systems to Conduct and Support Research*. There will be no budget or staff not currently under the direct responsibility of the Department of Health/NHS Director of R&D.

8.6 The Institute will be established and become operational from 1 April 2006. Its constituent parts will join on a phased basis as each of the elements described in this consultation document are introduced.

Question 3

a. Will the creation of a virtual National Institute for Health Research achieve the objectives of creating coherence and focus for the different strands of our work?

b. Would another mechanism work better?

c. If so, what?

d. Does the name National Institute for Health Research appropriately describe its role?

9. World-class support for researchers

9.1 It is proposed that, when established, the National Institute for Health Research will have a **faculty** tasked with delivering the research needs of the NHS. The aim will be to focus the talents of this cohort of clinical academics on applied health research responding to the needs of the NHS and its current and potential patients.

9.2 The faculty will consist of the following staff:

- **Senior Investigators**
- **Faculty Associates**
- **Junior Investigators**

9.3 **Senior Investigators** will be the elite, identified from the academic clinicians currently funded by the NHS directly or through the universities. In this way, academic posts will be outside the 'Payment by Results' reference costs. The aim will be to establish an 'esprit de corps' to attract and retain current and future academics of the highest calibre and encourage them to focus on the research needs of the NHS. To join this select group, individuals will have to demonstrate quality, as judged by publications and grant income. Partners funding will continue as before.

9.4 Funding will be derived from two main sources: the current NHS funding for University-employed clinical academics doing research[2, 3] (leaving the staff employed by Universities, but holding their funding centrally); and the element of NHS R&D allocations that Trusts use to support NHS-employed academic clinicians doing research as chief investigators.

9.5 **Faculty Associates** will comprise NHS employees making a significant contribution to research. They will include NHS consultants, clinical scientists, nurses and allied health professionals. The majority, if not all of these, are presently funded by the NHS. Funding to Trusts from the Department of Health will relate to their activity.

9.6 **Junior Investigators** will include all academic trainees holding training fellowships for doctorates, clinical lecturers and clinical scientist fellowships whether funded by the NHS or our partners, doing people-based research.

9.7 We propose an allowance for members of the faculty related to seniority, in order to support consumable costs (e.g. travel and registration at key research meetings) and contribute to their research work, as appropriate. While for the junior investigators and associates, an allowance will support travel to one key meeting each year.

9.8 We will explore with the Advisory Committee on Clinical Excellence Awards the

[2] The recent survey by Council of Heads of Medical Schools reported that 39 per cent of clinical academic posts are funded by the NHS.
[3] For NHS Trusts, the consequences of this proposal will be to remove support for clinical academics from the impact on reference costs in Payment by Results.

relationship between faculty membership and Clinical Excellence Awards.

9.9 Through competition, we will continue development funding for individuals to **key areas** of NHS priority such as primary care. We will boost our commitment to awards for individuals, and support the academic training paths of doctors, healthcare professionals and other key disciplines for research in health and social care.

Question 4

a. Do you agree that we should create a staff structure which ensures proper support for all those engaged in research for the benefit of patients?

b. Do you agree with the concept of a National Institute for Health Research faculty?

c. If no to **a** and/or **b** above, what mechanism(s) should be used to ensure these staff are supported?

d. Do you agree with the three groupings (Senior Investigator, Faculty Associate, and Junior Investigator) as proposed?

e. If not, what groupings would you use?

f. Do the names Senior Investigator, Faculty Associate, and Junior Investigator appropriately describe the different groups?

g. If not, what names would describe them better?

h. Is it appropriate to include the NHS-funded staff in universities?

i. Should the funding for these staff be held centrally to ensure protection of research time?

j. What would appropriate 'allowances' be for the three groups of faculty staff?

10. Creating Optimum Systems to Conduct and Support Research

10.1 R&D funding allocations to NHS Trusts account for approximately £500 million this year, distributed to around 275 institutions. These allocations range from just a few thousand pounds to over £50 million per institution. Much of this funding is allocated on a historical basis. Today this method is bureaucratic, not transparent and fails to reflect the level of research activity conducted.

10.2 We propose to evolve from the current Support for Science mode of **funding research** in the NHS. We will continue supporting the extra NHS costs of research funded by our partners (these include the Research Councils, Wellcome Trust, Association of Medical Research Charities etc.) Payments based on a new taxonomy are being considered: patient data, human tissue, patient intervention. This process will happen incrementally over a period of two years with initial allocations based on data collected for these project-specific support costs in the annual R&D reports and the National Research Register. In the longer term, we plan to move towards a system where money follows patient involvement in studies. For research projects funded by the NHS R&D Programmes (such as Health Technology Assessment), we will aim to award the extra NHS costs as part of the research grants. All NHS Trusts and NHS Foundation Trusts in England will be eligible for this support.

10.3 We propose to introduce **incentives** to encourage health research – at an organisational and individual level – building on the recommendations from the Research for Patient Benefit Working Party. We are working with the UK Clinical Research Collaboration partners and with other bodies such as the Healthcare Commission to move these proposals forward.

Question 5

a. Are the proposals for Support for Patient Research appropriate?

b. If not, what would achieve the aims better?

10.4 We propose to establish a linked group of world-class, competitively selected **National Institute for Health Research Academic Medical Centres.** This group will comprise the top five organisations that have the world-class strengths across a broad range of clinical areas and a similar number of specialist academic medical centres, each with world-class strengths in a specific clinical area. These strengths will allow them to act as the leaders of scientific translation and early adopters of new insights in technologies and techniques for improving health and social care. They will create an environment where scientific endeavour can thrive, attracting the best talent and producing world-class outputs, thus contributing to England's competitiveness.

10.5 We envisage that these Academic Medical Centres will build strong international reputations, equivalent to those of the US Mayo clinics and Massachusetts General Clinics, the Dutch University Medical Centres and the Swedish Karolinska Institute. As such, the National Institute for Health Research

Academic Medical Centres will serve as the nations' **premier research hospitals**.

10.6 National Institute for Health Research Academic Medical Centres will be selected by open competition. An international panel of researchers, practitioners and users will judge the applicants, using the criteria of research excellence, relevance, and impact for the NHS. All NHS Trusts and NHS Foundation Trusts in England, together with their academic partners will be eligible. We plan to review this group regularly and open the competition again every seven years.

10.7 The total amount of funding proposed is £100 million per annum. The amount of funding allocated to each National Institute for Health Research Academic Medical Centre from within this total sum will be determined by the scale and nature of the research activity conducted there. This funding will be additional to, and separate from, any other NHS R&D funding received by the centre. Those that are unsuccessful will continue to receive infrastructure funding from the other available streams.

Question 6

a. Are the proposals for Academic Medical Centres appropriate?
b. If not, what would achieve the aims better?
c. Should we support both comprehensive centres and specialist centres?
d. How many of each can we support if they are to be truly world-class as the exemplars?
e. What time period should be awarded before a new competition round?

10.8 NHS providers who have lead investigators of health research grants on their staff will receive a small, but useful amount of money designated as **Leadership Funding**. These funds will be allocated according to the type of research conducted (i.e. patient intervention, patient tissue, patient data) to support time invested in leading research studies and the development of future research proposals.

Question 7

a. Are the proposals for Leadership Funding appropriate?
b. If not, what would achieve the aims better?

10.9 We propose to establish, via a public competition, a linked and limited set of **technology platforms** that support cutting-edge health research in selected research-intensive hospitals/NHS providers. This could

include imaging initially, but other areas such as post-genomics will need to be reviewed. By working in partnership with the UK Clinical Research Collaboration, we will develop a national strategy for supporting and maintaining capital-intensive research equipment essential to modern health research. This summer we are sampling NHS Trusts to collect primary information on existing **technology platforms** and their use for research purposes so that we can model and develop our strategic approach.

Question 8

a. Are the proposals for Technology Platforms appropriate?
b. If not, what would achieve the aims better?
c. What should be the first area(s) for focused support?

10.10 We will continue to fund support for the ongoing patient-related costs of **experimental medicine** facilities, including the new tranche advertised in summer 2005 under the auspices of UK Clinical Research Collaboration. As they develop, we will monitor success and make any changes necessary.

Question 9

a. Are the proposals for Experimental Medicine appropriate?
b. If not, what would achieve the aims better?

10.11 **Research infrastructure in the NHS**

Question 10

a. Are the proposed infrastructure elements to create optimum systems the right ones?
b. Are there other potential elements that we should consider?
c. What should the balance of investment between the different infrastructure elements be? (i.e. what should be the percentage spend on each?)

11. Strengthen our research programmes

11.1 We intend to **strengthen our research programmes**, undertaking more research in areas which are of vital importance to health, but which are currently neglected or underfunded, and making them even more responsive to the needs of patients, the public, health care professionals and policy makers.

11.2 We propose to expand the current national research programmes including the internationally acclaimed **Health Technology Assessment** (HTA) programme and **research synthesis**, **Service Delivery and Organisation** (SDO) and **New and Emerging Application of Technologies** (NEAT) programmes. These programmes are open to everyone, serve the interest of the wider NHS and set agendas following widespread consultation with key constituents. This will help ensure that we capture modern needs such as the role of technology in self-care and better management of ageing and illness; the impact of genetics and the post-genomic revolution; public health challenges including obesity, smoking and infection; and, assessment and evaluation of tests, both diagnostic and monitoring.

11.3 We propose to prioritise and consolidate our smaller programmes into a simplified structure with fewer, larger funding streams and develop new, focussed programmes in developing areas such as assistive technology and diagnostics.

11.4 We also propose the introduction of new funding schemes:

1. **Responsive funding** of £15 million per year – This will be modelled on the old regional funding streams for applied and practice based research. The criteria will be the relevance of research in the NHS, the quality of the research and deliverability.

2. **Programmes of applied research** – Programme grants will be allocated competitively to NHS Trusts and Foundation Trusts to enable them to tackle areas of high priority for health.

3. **Challenge fund for innovation** of £10 million per year – The aim is to encourage well-managed risk taking and innovation in the NHS by translating ideas into practice. Some one hundred studies per year will be assessed on their potential to make a difference to the NHS.

4. **RISC (Research for Innovation, Speculation and Creativity) awards** of £5 million per year. These small grants are aimed at ensuring that new and radical ideas, which have a low chance of success, but potential for high impact, can be funded in the National Institute for Health Research. There will be an annual competition, with a panel including industry and practitioners, to assess these speculative, novel proposals that are unlikely to fair well in traditional peer review processes. A fixed grant will be awarded to successful applicants and it is envisaged that follow-on funding could

occur through the responsive mode programme. This will be modelled on the venture research initiative sponsored by BP in the 1980s[4].

11.5 We aim to raise brand awareness of the NHS National Research Programmes in order to gain greater recognition of our support by ensuring that recipients of funding acknowledge the source funding in all publications and presentations.

11.6 Enhancing links between the National Programmes and the new Clinical Research Networks will be important and we are already in discussions with National Programme Directors where appropriate.

Question 11

a. Are the proposals for research programmes appropriate?

b. If not, what should we amend, add or delete?

[4] The Venture Research Initiative was set up to allow creative research ideas that were unsuccessful in traditional peer review to be supported with the acknowledgement that only about one in ten may be successful but the impact of that success would be large.

12. Research networks

12.1 We intend to create a clinical research infrastructure to:

- ensure that patients and healthcare professionals from all parts of the country are able to benefit from participating in research
- integrate health research and patient care
- improve the quality, speed, and co-ordination of clinical research
- provide an explicit means by which the NHS can meet the health research needs of industry.

12.2 To achieve this, we have already embarked on a major programme to establish a managed set of topic-specific Clinical Research Networks across the NHS as a key part of our contribution to the UK Clinical Research Collaboration. Research networks have been established in cancer and mental health, and we are in the process of establishing further networks in stroke, diabetes, medicines for children, and dementia and neurodegenerative disorders.

12.3 We now propose to amplify this with an allocation of funding for all health economies, on a per capita population basis, to establish a generic health research network across all health economies of England. This builds on the successful model of the National Cancer Research Network[18]. The generic networks will not only play the roles assigned to topic specific research networks. They will also play a key R&D management role (see Chapter 13 'Busting' bureaucracy) as well as supporting local researchers. Additionally, we will continue our support to primary care through networks.

12.4 A key aim of all NHS networks will be supporting and conducting trials for industry. These may be phases I through IV including pivotal licensing studies, on a full cost recovery basis[19].

Question 12

a. Are the proposals for Research networks appropriate?

b. If not, what would achieve the aims better?

12.5 The R&D directorate of the Department of Health will continue to work closely with 'Connecting for Health' focussing predominately on:

- remote data capture for clinical trials
- Public Health research and access to anonymised data so that data protection is ensured, but no new barriers to this important research are introduced
- pharmocovigilance
- opportunities for novel ways of developing new medicines and other therapies.

13. 'Busting' bureaucracy

This country has an excellent tradition of good practice in research, however some high profile cases have damaged public confidence. The many responsibilities of researchers and of their employers were present in our legacy health research system. These roles have however, been highlighted by recent regulatory changes including:

- Research governance framework[10]
- EU clinical trials directive[20]
- Human tissue act[21]
- Mental capacity act[22]

13.2 The varied interpretation of roles and accountabilities by different NHS trusts with repetition of tasks and review has led to a bureaucracy that is stifling many researchers and impeding the resolution of key uncertainties for health. We have already reviewed guidance to emphasise that research governance is intended to encourage well-run research as well as contain unacceptable risks. The Department of Health and its partners can do much more to simplify and harmonise the processes that use up researchers' time, and the time is right to do so. While the accountabilities will not change, we hold as a guiding principle that procedures and data input should occur once and once only and that where duplication of effort exists, we will seek ways to streamline it.

13.3 We therefore propose to develop linked initiatives designed to improve the overall system and support researchers including:

- Research passports for researchers to simplify honorary contracts[5]
- Health economy generic network management centres to advise researchers and undertake research governance checks on behalf of NHS organisations
- A 'one-stop' shop telephone help-line for regulatory advice on the impact of and working with the EU clinical trials directive
- A single IT system (or linked systems) into which the researcher inputs information once. This information then populates research ethics committee forms, R&D management information systems, the National Research Register and, with patient recruitment completed, it is a vehicle for funding allocation
- The unified IT system will also list related published papers and details of the impact of the work.

These proposals will strengthen the sources of advice about good practice at the working level and will incorporate the final Code of Practice from the Human Tissue Authority regarding the use of tissue samples.

13.4 Meanwhile, following the recent review of Research Ethics Committees[23], the Central Office of Ethics Committees (COREC) at the National Patient Safety Agency (NPSA) will

[5] As being piloted across Manchester and neighbouring areas.

work to improve further the operation of the research ethics committee system, and make it more user-friendly.

13.5 We are simplifying the management of the NHS National Research Programmes through the phased introduction of a central research commissioning and management centre.

Question 13

a. Do you agree with our guiding principle that procedures and data input should occur once and once only and that where duplication exists, we will seek to streamline it?

b. Are the proposals for bureaucracy 'busting' appropriate?

c. If not, what would achieve the aims better?

14. Transition

14.1 We propose to establish the new system starting from April 2006.

Question 14

a. How important is it that our funding is allocated transparently?

b. How important is it that we establish a sustainable funding system?

c. How important is it that we establish a funding system that is responsive to changes in levels of research activity?

d. How important is it that we do not lose momentum in the move to the new system?

e. If the implementation start date is 1 April 2006, how long should the transition to the new system take to complete: 1 year, 2 years, or 3 years?

f. How important is it to ensure that we do not destabilise individual institutions as we move to the new system?

15. Conclusion

15.1 Taken together these changes will enable the NHS to conduct leading-edge research and support outstanding individuals working in world class facilities focused on the needs of patients and the public. These changes will also form a major component of the Department of Health's Science and Innovation Strategy. *Best Research for Best Health: a New National Health Research Strategy* is intended to provoke discussion in order to hear your views on our key proposals:

- creating, maintaining and managing the research and research infrastructure of the NHS as a 'virtual' national research facility – **the National Institute for Health Research**
- establishment of a **faculty** for the National Institute for Health Research to include Senior Investigators, Faculty Associates and Junior Investigators who will deliver the research needs of the NHS
- evolving from the current Support for Science historical mode of supporting research in the NHS, so that **funding** follows patient involvement in health studies
- establishing a concurrent set of **technology platforms** that support clinical research in selected research-intensive hospitals/NHS providers
- establishing a linked group of competitively selected National Institute for Health Research **Academic Medical Centres**
- expanding the current **NHS National Programmes** for R&D that serve the interests of the wider NHS and set agendas following widespread consultation with key constituents, rationalising smaller programmes into a simplified structure and streamlining the management of the NHS National Research Programmes via a centralised system
- introduction of **new funding schemes**, including a responsive funding scheme, a scheme for applied research in areas of high priority to the NHS, a challenge fund for innovation, and a RISC award
- reinforcing and expanding the **research networks** with capacity to provide reliable expert advice and support on regulatory and governance processes
- integrating research **information systems,** to standardise and minimise the information needed for regulation, ethics and research governance.

15.2 We will know that the new strategy has been effective if more patients and clinicians participate in an increased volume of studies relevant to them and to healthcare in the NHS.

15.3 We would now like to hear your views on our proposals so that we can move forward by implementing a shared vision and creating a research environment in England to deliver the needs of the 21st century from April 1 2006.

Question 15

a. By what criteria will you judge us on the impact of this strategy?

b. Do you have any other comments?

What Will Happen Next

A summary of responses, including the next steps will be published by 30 November on http://www.dh.gov.uk/Consultations/LiveConsultations/fs/en. Paper copies will be available on request.

The Consultation Criteria

The consultation is being conducted in line with the Code of Practice on Consulatation. The criteria are listed below. The full version can be accessed at http://www.cabinet-office.gov.uk/regulation/Consultation/Code.htm

The Six Consultation Criteria

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy

2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.

3. Ensure that your consultation is clear, concise and widely accessible.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.

5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

If you feel that the consultation does not satisfy these criteria please contact:

Steve Wells
Consultation Coordinator
Department of Health
Skipton House
80 London Road
London SE1 6LH

E-mail: steve.wells@dh.gsi.gov.uk

Organisations to be consulted directly

Academy of Learned Societies in the Social Sciences
Academy of Medical Royal Colleges
Academy of Medical Sciences
Allied Health Professionals
Arts and Humanities Research Council
Association of Directors of Social Services (ADSS)
Association of Medical Research Charities (AMRC)
Association of the British Healthcare Industries
Association of the British Pharmaceutical Industry (ABPI)
Association of UK University Hospitals

Bath & Swindon R&D Support Unit
Bedfordshire R&D Support Unit
Bioscience Industries Association
Biotechnology and Biological Sciences Research Council
Bristol R&D Support Unit
British Healthcare Trade Association
British in vitro Diagnostics Association
British Medical Association

Cabinet Office
Cambridge R&D Support Unit
Canadian Health Services Research Foundation
Cancer Research UK
Cardiovascular Funders Forum
Central Office of Research Ethics Committees
Centre for Applied Medical Statistics, University of Cambridge
Centre for Health Economics, University of York
Centre for Reviews and Dissemination
Childhood Cancer Research Group, University of Oxford
Clinical Contract Research Association
Clinical Operational Research Unit
Council for the Central Laboratory of the Research Councils
Council of Deans
Council of Heads of Medical Schools

Dementias & Neurodegenerative Diseases Research Network
Dental Research Programme
Department for Education and Skills
Department for Employment and Learning, Northern Ireland
Department for International Development
Department for the Environment Food and Rural Affairs
Department for Transport
Department for Work and Pensions
Department of Mathematics, University College London
Department of Trade and Industry
Diabetes Research Network
Dorset R&D Support Unit

Economic and Social Research Council
Employers Organisation for Local Government
Engineering and Physical Sciences Research Council
Essex R&D Support Unit
European Commission

Faculty of Accident & Emergency Medicine
Faculty of Family Planning & Reproductive Health Care

Faculty of Occupational Medicine
Faculty of Pharmaceutical Medicine
Faculty of Public Health
Food Standards Agency
Foreign and Commonwealth Office

General Chiropractic Council
General Dental Council
General Medical Council
General Optical Council
General Osteopathic Council
General Practitioners
Global Forum for Health Research
Gloucester R&D Support Unit

Health and Personal Social Services Northern Ireland
Health and Safety Executive
Health Economics Research Group, Brunel University
Health Professions Council
Health R&D North West
Health Technology Assessment International (HTA(I))
Health Technology Assessment Programme (HTA)
Healthcare Commission
Healthcare Scientists
Hertfordshire R&D Support Unit
High Education Funding Council for Wales
Higher Education Funding Council for England
HM Treasury
Home Office
House of Commons Health Committee
House of Commons Science and Technology Committee
House of Lords Science and Technology Committee

Institute of Cancer Research, Cancer Screening Evaluation Unit
Institute of Psychiatry, King's College London
International Network of Agencies for Health Technology Assessment, (INAHTA)
INVOLVE (R&D consumer's group)

James Lind Alliance
Joint Committee on Higher Medical Training
Joseph Rowntree Foundation Trust

Local Government Association

Medical Care Research Unit, University of Sheffield
Medical Directors
Medical Research Council
Medicines and Healthcare Products Regulatory Agency
Medicines for Children Research Network
Mental Health Funders Forum
Mental Health Institute for England
Mental Health Research Network
Ministry of Defence

National Assembly for Wales
National Cancer Research Institute
National Cancer Research Network
National Horizon Scanning Centre
National Institute for Health and Clinical Excellence (NICE)

National Knowledge Service

National Patient Safety Agency

National Perinatal Epidemiology Unit, University of Oxford

National Primary Care R&D Centre, University of Manchester

National Screening Committee

Natural Environment Research Council

New and Emerging Applications of Technology Research Programme (NEAT)

NHS Cancer Screening Programme

NHS Confederation

NHS Institution for Innovation and Improvement

NHS Purchasing and Supply Agency

NHS R&D Forum

NHS Trust Chief Executives

- Acute Trusts
- Care Trusts
- Mental Health Trusts
- Primary Care Trusts

Norwich R&D Support Units

Nuffield Council of Bioethics

Nuffield Foundation

Nuffield Trust

Nurse Executive Directors

Nursing and Midwifery Council

Nursing Research Unit, University of London

Office of Science and Technology

Office of the Chief Social Researcher

Office of the Deputy Prime Minister

Oxford Genetics and Society Research Programme

Particle Physics and Astronomy Research Council

Patient Information Advisory Group

Patient Safety Research Programme

Peninsula R&D Support Units

Personal Social Services Research Units

- University of Kent
- University of Manchester
- London School of Economics (LSE)

Portsmouth R&D Support Unit

RDDirect / RInfo/ RD Learning

Research Capacity Development Programme

Research Councils UK

Research on Ageing and Older People Funders Forum

Royal College of Anaesthetists

Royal College of General Practitioners

Royal College of Midwives

Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

Royal College of Ophthalmologists

Royal College of Paediatrics and Child Health

Royal College of Pathologists

Royal College of Physicians

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Speech and Language Therapists

Royal College of Surgeons

Royal Institution

Royal Pharmaceutical Society

Royal Society

Royal Society of Medicine

Salisbury R&D Support Unit

Scottish Executive Health Department

Scottish Higher Education Funding Council

Service Delivery and Organisation Research Programme (SDO)

Social Care Institute for Excellence

Social Care Workforce Research Unit, University of London

Social Medicine and Health Services Research Unit

Social Policy Research Unit, University of York

Social Services Research Group (SSRG)

Somerset R&D Support Unit

South East R&D Support Unit

Southampton R&D Support Unit

Strategic Health Authorities Chief Executives

Stroke Research Network

Surgical Dressing Manufacturers Association

Technology Assessment Reviews (TARs) Team

Thames Valley R&D Support Unit

Thomas Coram Research Unit, Institute of Education, University of London

Trent R&D Support Unit

UK Clinical Research Collaboration (UKCRC):

- Academic Careers Sub-committee
- Database Working Group
- Industry Reference Group
- Industry Roadmap Group
- NHS Incentives Sub-Committee of the UK Clinical Research Collaboration
- Public Health SPG Membership
- Regulatory & Governance Project Group

UK Clinical Research Network

UK Cochrane Centre

UK Trade and Investment

Universities UK

University of London Deans

Wellcome Trust

World Health Organisation

References

(1) Science & innovation investment framework 2004 – 2014, Department for Education and Skills, Department of Trade and Industry and HM Treasury. London: HSMO. July 2004. (http://www.hm-treasury.gov.uk/spending_review/spend_sr04/associated_documents/spending_sr04_science.cfm)

(2) Creating a Patient-led NHS – Delivering the NHS Improvement Plan. Department of Health. March 2005. (http://www.dh.gov.uk/assetRoot/04/10/65/07/04106507.pdf)

(3) Peckham, M. Research and development for the National Health Service. Lancet 1991: 338 367-371.

(4) Bioscience Innovation and Growth Team (BIGT) Report. November 2003. (http://www.bioindustry.org/bigtreport)

(5) Report of an Academy working group: 'Strengthening Clinical Research' and Summary of Responses to the Call for Evidence. Academy of Medical Sciences. 6 October 2003. (http://www.acmedsci.ac.uk/p_scr.pdf)

(6) Lord Rothschild, The organisation and management of Government R&D, in: Cabinet Office, A Framework for Government Research and Development. London: HMSO. November 1971.

(7) House of Lords Select Committee on Science and Technology, Priorities in Medical Research. London: HMSO. 1988.

(8) Supporting Research and Development in the NHS. A Report to the Minister for Health by a Research and Development Task Force Chaired by Professor Anthony Culyer. London: HMSO. September 1994. (http://www.doh.gov.uk/research/rd3/pub/docs/doh/culyer11.pdf)

(9) The Research Governance Framework for Health and Social Care. Department of Health. February 2001. (http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4008777&chk=dMRd/5)

(10) The Research Governance Framework for Health and Social Care, Second Edition. Department of Health. April 2005. (www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/ResearchGovernanceArticle/fs/en?CONTENT_ID=4002112&chk=PJlaGg)

(11) Research for Patient Benefit Working Party – Final Report. Department of Health. 19 May 2004. (http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/PrioritiesForResearch/fs/en?CONTENT_ID=4082668&chk=xUzx/B)

(12) Commons Hansard: 22 Mar 2004: Column 590 (www.publications.parliament.uk/pa/cm200304/cmhansrd/vo040322/debtext/40322-12.htm)

(13) Clinical Academic Careers (*The Richard Report).* Committee of Vice-Chancellors and Principals. July 1997.

(14) The tenure-track clinician scientist: A new career pathway to promote recruitment into clinical academic medicine *(The Savill Report).* The Academy of Medical Sciences. March 2000.

(15) Clinical Academic Medicine in Jeopardy: recommendations for change. The Academy of Medical Sciences. June 2002. (http://www.academicmedicine.ac.uk/resources/development.aspx)

(16) Clinical academic staffing levels in UK medical and dental schools. The Council of Heads of Medical Schools. May 2004

(17) Medically – and dentally- qualified academic staff: recommendations for training the researchers and educators of the future *(the 'Walport report'),* The Academy of Medical Sciences, 2005. (http://www.mmc.nhs.uk/academic_medicine.asp?m=7)

(18) The National Cancer Research Network (NCRN). (www.ncrn.org.uk)

(19) Pharmaceutical Industry Competitiveness Task Force, Clinical Research Report. PICTF. March 2002

(20) Directive 2001/20/EC of the European Parliament and of the Council. 4 April 2001. (http://www.europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf)

(21) The Human Tissue Act 2004. The Stationery Office Limited. ISBN 0 10 543004 8. (http://www.opsi.gov.uk/acts/acts2004/20040030.htm)

(22) The Mental Capacity Act 2005. The Stationery Office Limited. ISBN 0 10 540905 7. (http://www.opsi.gov.uk/acts/acts2005/20050009.htm)

(23) Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees. Department of Health. June 2005.

269868 1p 1k Jul 05 (REL)

If you require further copies of this publication quote *Best Research for Best Health: A New National Health Research Strategy* contact:

DH Publications Orderline
PO Box 777
London SE1 6XH
Tel: 08701 555455
Fax: 01623 724524
E-mail: dh@prolog.uk.com

08700 102870 – Textphone (for minicom users) for the hard of hearing
8am – 6pm Monday to Friday.

269868/*Best Research for Best Health: A New National Health Research Strategy* can also be made available on request in Braille, on audio cassette tape, on disk and in large print.

www.dh.gov.uk/