Best Research for Best Health

A new national health research strategy

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Best Research for Best Health

A new national health research strategy
The NHS contribution to health research in England

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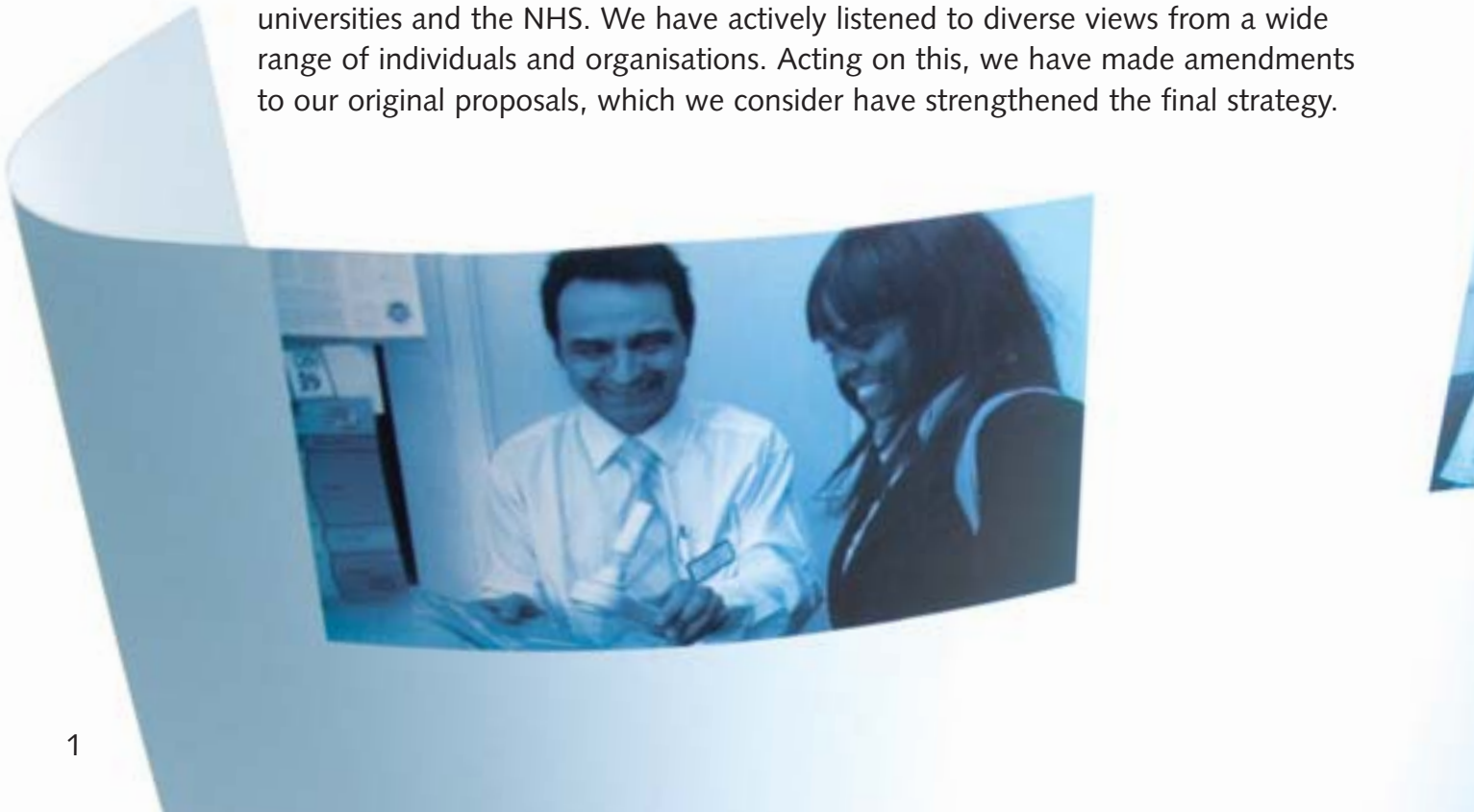
Foreword by the Secretary of State for Health

The Government is determined to make the UK the best place in the world for health research, development and innovation.

Health research provides us with the means to tackle the increasing challenges that disease and ill health are placing on our society. It also plays a key role in the knowledge economy of our country through its contribution to international competitiveness and economic growth. Without a vibrant health research system, our ability to deliver on this agenda will be severely compromised.

The vision that this strategy describes is underpinned by our determination to ensure that the NHS contribution to health research is a centrepiece of the Government's ambition to raise the level of research and development (R&D) to 2.5% of GDP by 2014. It has been developed working with key internal and external stakeholders, and following a formal public consultation.

Best Research for Best Health has been developed with input and support from other government departments and we have received comments and strong support for the direction of travel from influential stakeholders in industry, universities and the NHS. We have actively listened to diverse views from a wide range of individuals and organisations. Acting on this, we have made amendments to our original proposals, which we consider have strengthened the final strategy.



The strategy sets out our goals for R&D over the next five years:

- Establish the NHS as an internationally recognised centre of research excellence
- Attract, develop and retain the best research professionals to conduct people-based research
- Commission research focused on improving health and care
- Strengthen and streamline systems for research management and governance
- Act as sound custodians of public money for public good.

This Government believes that the changes we are putting in place 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.

Best Research for Best Health can only be successful with the widespread support and commitment of our stakeholders. As we move into implementation of the strategy, we will continue to work closely with key partners to ensure delivery matches the promise.

Rt Hon Patricia Hewitt MP
Secretary of State for Health

Introduction

***Best Research for Best Health* outlines the direction that NHS research and development (R&D) will take over the next five years to ensure a vibrant, world-class environment for conducting and using NHS health research.**

This strategy for NHS R&D has been developed to:

- Support the Government's ambitions to improve the nation's health and increase the nation's wealth as set out in the ten-year *Science and Innovation Investment Framework 2004–2014*[1]
- Place people at the centre of a research system that focuses on quality, transparency and value for money
- Respond to changes in society and the environment
- Respond to the challenges in the current system for applied health research.

Our recent public consultation has confirmed the breadth of challenges faced at all levels in the system as well as the desire for change. Analysis of comments from respondents has helped us to clarify and simplify our proposals and now, with the support of our stakeholders, we plan to work with them on their implementation.

Best Research for Best Health refers specifically to the programmes, funding and structures for which the Department of Health and the NHS in England are responsible. This builds on our previous reforms[2], published five years ago. Our focus will be on supporting and funding health-related research, which leads to improved outcomes for people. Evidence from research spanning prevention of ill health, promotion of health, disease management, patient care, delivery of healthcare and its organisation, as well as in public health and social care, is key to improving health. We will continue to commit funding to these and other important fields.

We seek to include all professionals who have a role in conducting and enabling health research in England, as both leaders and collaborators. We aim to engage patients increasingly in the identification, design, recruitment to and dissemination of research projects. To play our part well and have an impact across the range of research requires careful assessment of need and quality of research design and process. We must also support the effective translation of research results into health practice.

Over the time that the Department of Health has been responsible for R&D in the NHS[3], we have built up effective partnerships and relationships with many stakeholder groups. We will build on this strength by increasing our engagement with patients and the public and, working through the UK Clinical Research Collaboration (UKCRC), fostering deeper and more productive links with key stakeholders.

This country's outstanding record of achievement in health research is founded on a close and longstanding partnership between the NHS and the university sector. This partnership remains key to delivering our new strategy and we will continue to work closely with our partners in the university sector to sustain and develop this relationship.

Best Research for Best Health forms a major component of the Department of Health's Science and Innovation Strategy. We will monitor our progress regularly and take the action necessary to ensure that our strategic goals remain relevant and that we are on track to achieve them, and report to our stakeholders openly and transparently.

The way forward

Vision

Our vision is to improve the health and wealth of the nation through research.

Mission

We aim 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.

Strategic goals

To achieve this we will:

1. Establish the NHS as an internationally recognised centre of research excellence
2. Attract, develop and retain the best research professionals to conduct people-based research
3. Commission research focused on improving health and care
4. Strengthen and streamline systems for research management and governance
5. Act as sound custodians of public money for public good.

In five years time we will have:

- A thriving research culture within the NHS
- Fairness of access across England for patients and health professionals to take part in multi-centre studies
- More patients and health professionals participating in health research with high-quality protocols and early access to new intervention and prevention strategies
- Increased industry investment in clinical research in the NHS
- The National Programme for IT transforming our ability to recruit patients to clinical trials and gather data to support work on the health of the population and the effectiveness of health interventions
- The best research and researchers winning grants regardless of location
- Researchers working in a supportive environment to help them through the regulatory framework and conduct research relevant to the needs of patients and the population
- The NHS recognised for taking an international lead in supporting a research-led culture for health
- Researchers and healthcare professionals proud to say that they work in a research-led and evidence-based NHS
- Health and healthcare improved by research evidence.

Goal 1
Establish the NHS as an internationally recognised centre of research excellence

Objectives

- Expand and build a world-class NHS research infrastructure focused on delivering benefits to patients and the public
- Contribute to international excellence in experimental and translational medicine and innovation in healthcare
- Build on our reputation as a leading country for publicly funded research
- Become a leading country for conducting clinical research in partnership with and for industry
- Develop legislation and guidelines that create a vibrant and efficient research environment
- Respect ethical principles for health research.

To achieve these objectives by 2010 we will:

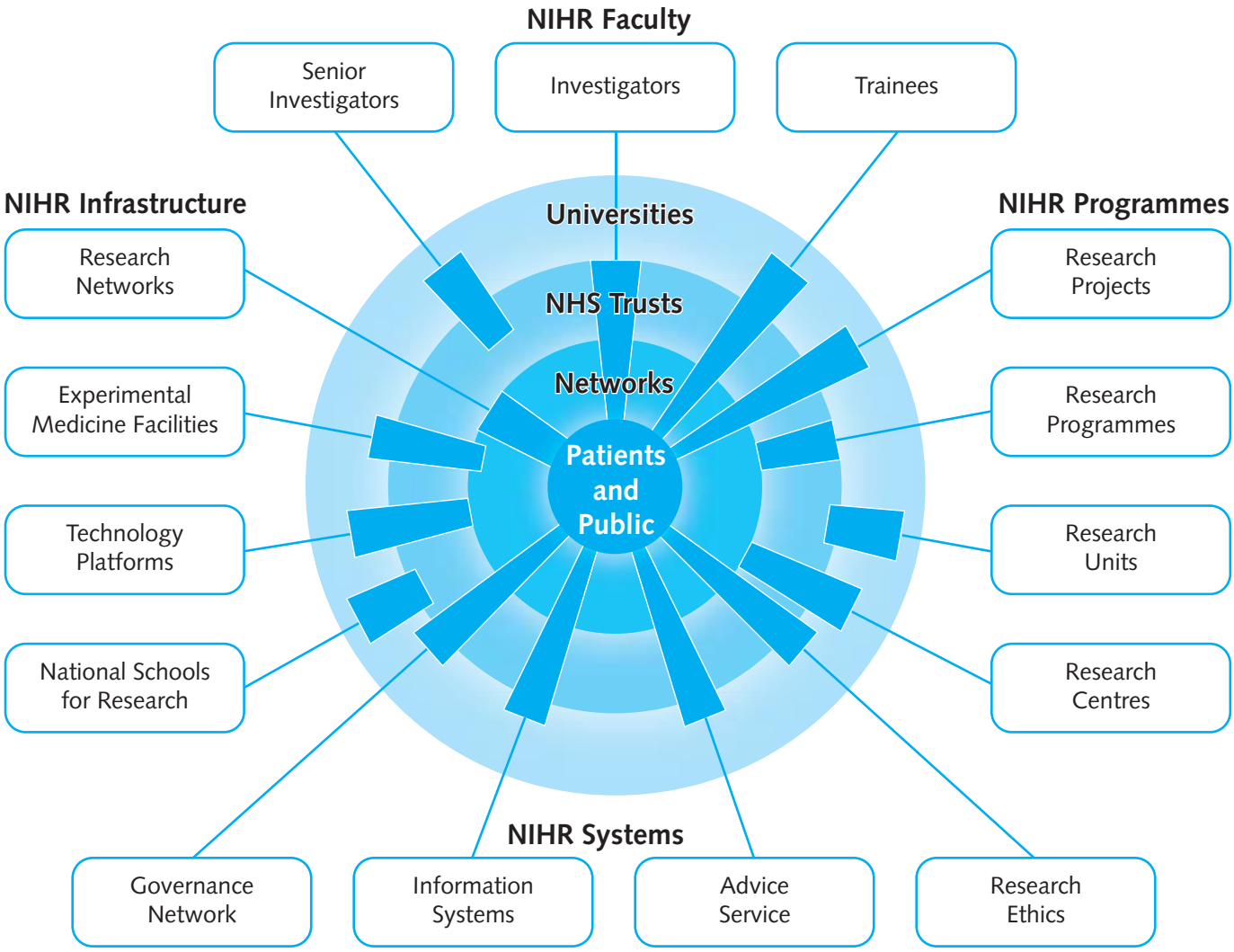
1. Establish a National Institute for Health Research in England as a virtual body
2. Establish a clinical research network covering the population of England to support high-quality research for all diseases and areas of patient need
3. Expand the NHS investment in Clinical Research Facilities for experimental medicine
4. Provide the NHS support for key technology platforms so that leading-edge research can thrive
5. Create a National School for Primary Care Research
6. Develop and embed initiatives to reduce bureaucracy and thereby create a vibrant and efficient research environment
7. Provide leadership for the development of ethical guidelines for research.

> ‘developing the NHS as a world-class environment for collaborative research in the public interest’

1.1 National Institute for Health Research in England

We will establish a National Institute for Health Research (NIHR) to provide the framework through which we can position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility. The aim is to enable the NHS to become an organisation that supports outstanding individuals (both leaders and collaborators), working in world-class facilities (both NHS and university), conducting leading-edge research focused on the needs of patients and the public.*

National Institute for Health Research



* This covers research involving patients, samples or data taken from patients, people who are not patients, populations, health technology assessment, and health services research.

The NIHR will provide the NHS with the support and infrastructure it needs to conduct first-class research funded by the Government and its partners alongside high-quality patient care. Our partners include those charities that award research funds as a result of open competition across England with peer review. This infrastructure will be open to industry partners as outlined in our partnership agreement.

Providing world-class support to those who conduct research for the benefit of patients in the NHS and the wider public is essential. This will help the NHS attract and retain the outstanding researchers from all the professions fundamental to tackling the health challenges of the future. The establishment of this institute will provide coherence and focus for all the strands of work of NHS R&D, including those related to academic careers for all professional groups. The NIHR will also provide a consolidated focus for our programmes of research commissioning.

Once established, the NIHR will seek to develop the reputation of the NHS as a world-class environment for collaborative research in the public interest and preferred host for multi-centre clinical research in partnership with and for industry, as outlined in the Government's ten-year *Science and Innovation Investment Framework 2004–2014*[1]. This will benefit patients, society, the NHS and all our stakeholders.

The Director of R&D for the Department of Health will be the Director of the NIHR. An Advisory Board will be established to provide strategic advice on the direction, implementation and programme review for this virtual institute.

The NIHR will work with key partners including other funders, academia and industry, bilaterally as well as collectively, through the UKCRC.

The NIHR together with the National Institute for Health and Clinical Excellence (NICE) and the NHS Institute for Innovation and Improvement (NIII) will play a key role in the NHS knowledge management system.

The establishment of a National Institute for Health Research will complete the trio of institutes that form our innovation, evaluation and implementation framework:

- National Institute for Health Research (NIHR)
- National Institute for Health and Clinical Excellence (NICE)
- NHS Institute for Innovation and Improvement (NIII).

Together these three institutes will provide a coherent system by which we can:

- Identify innovative ways of preventing, diagnosing and treating disease (NIHR)
- Evaluate these innovations to assess their clinical and cost effectiveness (NICE)
- Ensure that agreed innovations are implemented in the NHS (NIII).

1.2 Clinical research network covering the population of England

In England, the National Cancer Research Network was established to remove the barriers within the NHS for clinical research. This has been successful, so we are building on this concept and experience and have commissioned further networks for England in mental health, diabetes, medicines for children, stroke, and dementias and neurodegenerative diseases under the UK Clinical Research Network (UKCRN) Coordinating Centre. These networks will create a more geographically and clinically inclusive research infrastructure. In addition, building on the success of the Genetics Knowledge Parks, we will create a focused network for clinical genetics.

We believe all patients and professionals across England should be able to participate in appropriate clinical studies when they wish to. We now plan to amplify the topic networks with an allocation of funding for all health economies on a per capita population basis, to establish a set of comprehensive NHS research networks covering England. This set of networks will not only fulfil the roles assigned to topic-specific research networks, they will also play a key R&D management role and support local researchers. The UKCRN Coordinating Centre will provide the framework for this expansion. The aims of the Clinical Research Network (CRN) for England are to:

- Ensure that patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research
- Integrate health research and patient care

- Improve the quality, speed and coordination of clinical research by removing the barriers to research in the NHS
- Strengthen research collaboration with industry and ensure that the NHS can meet the health research needs of industry.

The CRN in England will also provide support for primary care through both the comprehensive and topic-specific clinical research networks and a new Primary Care Research Network in England (PCRN-E).

A key aim of all NHS networks will be to support and conduct randomised controlled trials and other well-designed studies for commercial and non-commercial sponsors. This will include pivotal licensing studies undertaken for industry on a transparent full-cost recovery basis. We will use the National Costings Framework to develop a costings tool. Our networks will normally only support work where the contract with industry is based on the Model Clinical Trials Agreement.

We will build on all our clinical research networks to ensure capability exists to create a clinical trial clearing house function to act as a 'one-stop-shop'. This will allow industry to make informed decisions about the feasibility and suitability of a trial site, raise the public profile of clinical research and the health benefits of participating, and act as a matching service between willing volunteers and clinical trials in appropriate circumstances.

We will publish research performance data for NHS Trusts relating to patient numbers, speed and quality, to provide a source of information on reliability on which to base judgements about the location of clinical trials.

We intend to increase the number of people who enter multi-centre trials and this activity will need to be underpinned by an increase in clinical trial management expertise. To support this we plan to develop a network of Clinical Trials Units with our partners. This will build, where appropriate, on existing infrastructure and complement existing provision.

1.3 Clinical Research Facilities for experimental medicine

The UK is at the international forefront of developments in basic biomedical research that have the potential to transform patient care. It is vital that we turn that potential into reality.

To achieve this, we will work in partnership with other major research funders across England under the umbrella of the UK Clinical Research Collaboration (UKCRC). We will support purpose-built, cutting-edge clinical research facilities and specialist clinical, research and support staff in locations where universities and NHS Trusts can work together on dedicated programmes of patient-orientated research. These Clinical Research Facilities for experimental medicine will ensure that advances in biomedical research result in improvements in healthcare and will nurture clinical researchers and health professionals for the future.

1.4 Technology platforms

Access to technology platforms is increasingly essential for the conduct of leading-edge health research. Current access to these platforms is inadequate across the NHS in England. We will therefore establish a dedicated funding stream to support the NHS costs of selected key technology platforms to support health research in NHS providers. The initial focus will be on diagnostic imaging, the area identified as most critical in scoping work conducted by the Academy of Medical Sciences and our recent survey of NHS providers.

1.5 Create a National School for Primary Care Research

Building on our existing successful investment in this field, we will establish a National School for Primary Care Research to improve the evidence base for the practice of care by facilitating the conduct of clinical trials and other well-designed studies in primary care and at the interface with secondary and tertiary care.

If this pilot is successful, we will explore with our partners the opportunities for creating, in the future, National Schools for research into the practice and delivery of social care services.

1.6 Bureaucracy busting

We aim to promote a regulatory and governance environment that both facilitates high-quality research and protects the rights, dignity and safety of those who agree to take part. We will promote research governance processes that are proportionate to risk. We will unify and streamline administrative procedures

associated with regulation, governance, reporting, research administration and approvals, and ensure that procedures and decisions are rationalised. To achieve this, we will set up centres of expertise in R&D management closely linked to the comprehensive NHS research networks. Each centre will coordinate the research management and governance resources in its health economy. Together, the centres will operate as a network, sharing common procedures, and supported by integrated national R&D information systems. Other key elements of this system will be research passports and a national expert advice service.

1.7 Research ethics

In 2005 the Government published an independent ad hoc review of the operation of the NHS research ethics committee system[4]. The National Patient Safety Agency (NPSA), as host of the Central Office for Research Ethics Committees (COREC), is consulting on an implementation plan based on the review. This proposes a package of measures that will strengthen expert support for the ethics committee service, speed up the review of low-risk studies, and help committees improve consistency.

We will work closely with the NPSA to harmonise and simplify the exchange of information between the research ethics committee service, the NHS, and others, while protecting the independence of ethical review.

> ‘the National Institute for Health Research will provide the NHS with the support and infrastructure it needs to conduct first-class research funded by the Government and its partners’

Goal 2
Attract, develop and retain the best research professionals to conduct people-based research

Objectives

- Build a leading research capability – the National Institute for Health Research Faculty – to attract, develop and retain the best clinical, health service and public health research professionals with a national collegiate ethos
- Focus the talents of faculty members on health research that meets the current and future needs of patients and the public
- Value both leaders and collaborators in health research
- Provide ongoing support to the academic training paths of all healthcare professionals and other key disciplines involved in health and social care research, including mentoring.

> developing the research skills of the future leaders in applied health and social care research

To achieve these objectives by 2010 we will:

1. Build a faculty tasked with delivering the research needs of the NHS and the wider public
2. Include the diversity of researchers engaged in patient and people-based research
3. Develop the skills of researchers and implement career pathways in partnership with UKCRC stakeholders
4. Provide advice for researchers on best research practice, from supporting research applications to communicating the results of research.

2.1 National Institute for Health Research Faculty

Researchers from diverse professional backgrounds and experience will be invited to join the National Institute for Health Research Faculty. Eligible faculty members may be funded by the NHS directly, or funded by the NHS indirectly through our partner universities. In addition, we will offer honorary membership for employees of our partners.

Membership categories will be:

- NIHR Senior Investigators and Honorary NIHR Senior Investigators – leaders of research
- NIHR Investigators and Honorary NIHR Investigators – key collaborators in research
- NIHR Clinical Lecturers, NIHR Academic Clinical Fellows, NIHR Fellows and NIHR Students – our next generation of researchers.

Selection standards and criteria will vary depending on membership category, profession and specialty. We will establish an implementation group of NHS, academia and partners to develop robust plans, processes and standards.

It will be important that the detailed arrangements for individual Senior Investigators are determined locally, however the funding will be held centrally in order to clearly distinguish it from the patient care budget. Funding for NIHR Investigators will be paid as 'sessions' to NHS Trusts based on the level of the investigator's contribution.

2.2 Develop skills of researchers and strengthen career pathways

NHS R&D aims to build and support a skilled workforce capable of advancing high-quality research with the aim of maintaining and improving health within a knowledge-based, patient-centred health service.

We will continue development funding for individuals in key areas of NHS priority such as primary care and public health through competition. 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.

Through our Research Capacity Development Programme we play an important role in developing the research skills of the future leaders in applied health and social care research. We do this through Career Scientist Awards, Postdoctoral Awards and Researcher Development Awards. We will expand this programme to ensure that all professions and disciplines important to applied health and social care research are developed.

We work closely with UKCRC partners to develop research careers for all key professions. We have already made a strong start on transforming academic careers for qualified medical and dental staff. Working with UKCRC partners, the Department of Health and the NHS are creating 250 Academic Clinical Fellowship and 100 Clinical Lectureship training opportunities per year. In addition, we are establishing substantial numbers of New Blood Senior Lectureships as a partnership between the Higher Education Funding Council for England and the NHS.

2.3 National advice service for researchers

We will create a national advice service to help researchers navigate regulatory processes, approvals and permissions, particularly for clinical trials and other types of research when they need to interpret the law for research in practice. The service will operate through e-mail and telephone helpline based within the national network of R&D management centres, backed up by an electronic interface that links the advice service to regulatory experts.

> ‘develop research careers for all key professions’

Goal 3
Commission research focused on improving health and social care

Objectives

- Strengthen and focus the funding mechanisms through which we commission research
- Expand and develop relevant and flexible programmes of research addressing the broad range of health priorities
- Target our health research funding to resolve uncertainties and address areas of unmet need
- Allocate NHS health research funding in a transparent manner based on quality and relevance.

To achieve these objectives by 2010 we will:

1. Strengthen and focus the funding mechanisms through which we commission research
2. Expand and strengthen our existing R&D programmes
3. Introduce a new Research for Patient Benefit responsive project funding scheme
4. Introduce Programme Grants for Applied Research in areas of high priority to the NHS
5. Continue to invest in research units focused on priority areas
6. Create Research Centres within our leading NHS/university partnerships.

3.1 Strengthen and focus the funding mechanisms through which we commission research

Our aim is to fund important research which is inadequately supported by other funders but that is essential for delivering our public services. In this way, we will develop further the reputation of the NHS for excellence through the research we commission and conduct, and consolidate NHS R&D as a major contributor to improving opportunities for high-quality health research.

We will develop a range of research funding mechanisms to enable us to achieve these different objectives. We will therefore, in future, channel our research commissioning through four main routes: projects, programmes, units, centres. The choice of funding route will be determined by the need for increasing levels of flexibility, increasing levels of funding and increasing length of contract.

We will use mechanisms for research commissioning that are specifically designed to achieve a particular purpose, because some:

- research questions can be answered relatively quickly
- require consistent effort over relatively long periods of time
- research can be relatively tightly specified
- requires more flexibility
- questions can be addressed by relatively small research teams
- require research on a larger scale.

3.2 Expand and strengthen our existing R&D programmes

We intend to expand and strengthen our existing NHS R&D programmes, and prioritise and consolidate smaller programmes, to ensure commissioning of more research of vital importance to health and social care. This will enable us to respond to opportunity and need in a flexible fashion; for example, to support agreed strategic work prioritised by the UKCRC Board in areas such as public health and microbiology and infection.

3.2.1

The purpose of the **Health Technology Assessment (HTA)** programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most effective way for those who use, manage and provide care in the NHS. In addition to addressing questions suggested by the NHS and its users, the HTA programme also provides dedicated support for the work of the National Institute for Health and Clinical Excellence (NICE) by commissioning both primary research and Technology Assessment Reviews.

As part of our response to the public health White Paper[5] and the Wanless Report[6], the Department of Health has established a new HTA panel on disease prevention. The HTA programme also supports the public health arm in NICE.

The HTA programme is starting to work with the research networks of the UK Clinical Research Network to identify and fund clinical trials of specific importance to a network's topic area.

As part of the establishment of the National Institute for Health Research, the HTA programme will initiate a major new programme of Pragmatic Clinical Trials to address questions of direct relevance to clinical practice in the NHS. This programme will therefore operate mainly in response-mode.

> Research Centres will drive progress on innovation and translational research in biomedicine and NHS service quality and safety

3.2.2

The **NHS Service Delivery and Organisation (SDO)** programme was established to consolidate and develop the evidence base on the organisation, management and delivery of healthcare services to increase the quality of patient care, ensure better patient outcomes and contribute to improved population health. This programme will be expanded. The new NHS Institute for Innovation and Improvement will be a key strategic partner of this programme.

3.2.3

We will bring together a number of our existing programmes, together with new investment, to create an **Invention for Innovation** research programme.

The **New and Emerging Applications of Technology (NEAT)** programme aims to deliver strategic and applied research across the medical sciences, which has the potential to generate both intellectual property and cost-reducing products and interventions. Outputs have wide applicability and are capable of exploitation to enhance the quality, efficiency and effectiveness of health and social care. The programme has been in operation for five years and presently operates in response mode. We plan more strategic and focused calls in the future.

The **Health Technology Devices (HTD)** programme will be incorporated into the Invention for Innovation research programme.

This fund will also support the Department of Health's contribution to piloting Healthcare Technology Co-operatives as announced in the recent Healthcare Industries Task Force Report[7].

> "targeting our health research funding to resolve uncertainties and address areas of unmet need"

A **Challenge Fund for Innovation**, aimed at effective ideas that have no obvious commercial end-point, will be managed alongside NEAT and HTD as part of the Invention for Innovation research programme. This funding stream aims to promote and accelerate the transfer of knowledge and innovation between the National Institute for Health Research and the NHS.

3.2.4

The Department's **Policy Research** programme will continue to support policy development and implementation, both by commissioning research across a broad range of the health and social care spectrum, and by funding a number of research units that have skills and experience in special priority areas.

3.2.5

The **Methodology** programme is a small programme aimed at promoting active debate on development of methodology for health research among key stakeholders including other NHS research programmes, academics, research bodies and service user organisations in order to build the best possible evidence base for health and social care research.

3.2.6

INVOLVE aims to develop strategic alliances among and across key groups in order to maximise effective public involvement and empower people to play an active role in research; and monitor the advancement and assess the effects of public involvement in NHS, social care and public health research.

3.3 Introduce a new Research for Patient Benefit responsive project funding scheme

We will establish a new **Research for Patient Benefit** programme. This national response-mode project funding scheme will support high-quality, investigator-led research of relevance to the NHS. It will fund research related to daily practice in areas identified by health service staff themselves and developed by them, with appropriate high-quality academic input. All proposals will be expected to build on evidence from systematic reviews to ensure safety and value for money. The scheme will be modelled on the former regional funding streams for applied and practice-based research. We anticipate nine local committees covering the nine Government Office regions with one National Programme Director who will chair each committee. We intend that the funds for these committees will be made available on a population basis.

This programme will replace the 'own account' research, presently funded in some NHS Trusts using their national NHS R&D allocations. It will also enable researchers to apply for funding for a project that was previously funded as part of a Priorities and Needs programme, but which is not funded as part of a new Programme Grants for Applied Research.

The Research for Patient Benefit programme will be supplemented by a new programme of **Research for Innovation, Speculation and Creativity (RISC) Awards**. This will award small, discrete grants to fund new and radical ideas for health research, which have a low chance of success but potential for high impact. These awards will be made to speculative, novel proposals that are unlikely to fare well in traditional peer review processes.

3.4 Programme Grants for Applied Research

We will introduce **Programme Grants for Applied Research** in areas of high priority or need for the NHS. These will replace programmes of research currently supported by the Priorities and Needs component of NHS R&D support funding for NHS providers.

These will be substantial, prestigious awards aimed at attracting the top researchers. They will be awarded competitively to NHS providers to tackle areas of high priority for health. These grants will allow stability, over three- to five-year periods, in order to support the development of top-quality research groups working in the NHS. Each programme will fund a series of related projects which form a coherent theme in an area of priority or need for the NHS.

3.5 Research Units

We will fund **Research Units** in order to support our different needs, including provision of research-based expert advice, sustaining research capacity in priority areas, and supporting the development and management of patient-focused research in the NHS. The funding for these units supports both research infrastructure and research activity.

Our present Research Units include Policy Research Units, Academic Units and R&D Support Units. These will continue to receive funding under their current contracts subject to the standard review process.

We will commission two new units, one to inform the interpretation and use of diagnostic tests for healthcare and a second relating to monitoring tests in primary care.

3.6 Research Centres

We will create **Research Centres** within our leading NHS/university partnerships to drive progress on innovation and translational research in biomedicine and NHS service quality and safety.

The Biomedical Research Centres will encompass those organisations that are internationally excellent across a broad range of clinical areas as well as those which are leading specialist centres. These centres will be leaders in scientific translation and early adopters of new insights in technologies, techniques and treatments for improving health. To ensure they are able to succeed, the Biomedical Research Centres will receive substantial levels of sustained funding with considerable flexibility in its use. This critical mass of people and infrastructure will create an environment where scientific endeavour can thrive, attracting the foremost talent and producing world-class outputs. The creation of these centres will be a key component of the NHS contribution to our nation's international competitiveness.

The NHS Service Quality and Safety Research Centres will focus on research into service delivery and organisation and bring together NHS professionals with other research skills, including social sciences and management schools. These centres will be leaders in driving forward improvements in quality, effectiveness and safety of NHS services. As with Biomedical Research Centres, the critical mass of internationally recognised expertise and infrastructure will create an environment where innovative services can be developed and evaluated effectively and with ease.

The centres will operate in a five-year cycle. The amount allocated to each centre will be related to the quality, scale and nature of their research activity. Awards will be made by competition and judged by peer review. This funding will be additional to, and separate from, any other NHS R&D funding received.

Goal 4
Manage our knowledge resources

Objectives

- Create a unified knowledge management system to meet the needs of stakeholders
- Use information systems to harmonise and simplify research processes
- Ensure research knowledge is made readily available to professionals in the service, researchers and the public
- Facilitate the application of research outcomes to improve health and delivery of services.

To achieve these objectives by 2010 we will:

1. Meet our strategic knowledge management requirements with a unified and coherent system
2. Work with Connecting for Health to ensure that electronic patient records and supporting infrastructure meets the needs of the research community in England
3. Continue support to organisations that conduct systematic reviews of research evidence
4. Develop effective interfaces with knowledge partners to ensure that research outputs and innovations have the potential to improve practice and patient care.

4.1 Develop a single IT system for researchers and NHS research management

We will unify and simplify the administrative procedures associated with regulation, governance, reporting and NHS research administration, ensuring that procedures and data input are, wherever possible, undertaken once for multiple uses. This system will populate information systems for the many users and parties interested in health and social care research, and will make information supporting regulatory approvals and permissions available to those who need it.

4.2 Partnership with Connecting for Health

The new national IT system for the NHS in England offers a unique and unrivalled opportunity for research into health that the Department of Health is determined to realise. The creation of cradle-to-grave electronic patient records, coupled with the fact that almost all the population receives its healthcare via the NHS, gives the potential to confer unique benefits to the UK as a site for clinical research via provision of:

- Access to a very large population which is demographically, geographically, socially and ethnically diverse
- The ability to follow the complete patient journey
- Access to coded, structured, longitudinal patient-level data that are comprehensive and rich enough to support formal, records-based epidemiological research.

The UKCRC and Department of Health R&D will work closely with the National Programme for IT/Connecting for Health to ensure that the data collected via the NHS Care Record Service and supporting infrastructure meet the needs of researchers and public health practitioners. There are two key priorities:

- Support for interventional research in which the NHS infrastructure is used to identify efficiently and comprehensively patients eligible for a specific healthcare intervention (eg therapy or preventative activity), in order to facilitate study feasibility assessments and recruitment into trials, and for remote data capture, hence enabling faster and cheaper clinical trials
- Support for observational research in which data collected during the course of routine clinical care are used to study the health of the population, the natural history of disease, the safety profile and the clinical and cost effectiveness of healthcare interventions as used in daily clinical practice.

The Department of Health will ensure that the capability exists within the NHS national IT system to facilitate, strictly within the bounds of patient confidentiality, the recruitment of patients to clinical trials and the gathering of data to support work on the health of the population and the effectiveness of health interventions.

We will work with NHS bodies to ensure that everyone using NHS care, including their families and carers, is aware that research is part of the core business of the NHS. The quality of NHS care depends on research-based evidence, and anyone using the NHS can expect to be offered opportunities to take part in studies relevant to their needs.

4.3 Getting research into practice

Our role is to develop the research evidence to support decision making by patients, professionals and policy makers, make this evidence available, and encourage its uptake and use.

To this end, we will continue to work closely with all partners by:

- Continued funding of a range of national programmes that seek to influence the dissemination of knowledge about healthcare evidence such as systematic reviews
- Continuing to support NICE from our HTA national programme
- Developing research to support the NHS Institute for Innovation and Improvement
- Continuing to contribute research evidence for the National Electronic Library for Health
- Supporting the NHS Chief Executive's Forum of the SDO programme
- Educating and supporting the leaders of today and tomorrow through the NIHR Faculty
- Involving more people, patients and healthcare professions in high-quality research
- Continued support to the World Health Organization to harmonise standards for the registration of clinical trials and develop a portal for access to registers.

Two key planks of our strategy are our contribution to the International Cochrane Collaboration and the NHS Centre for Reviews and Dissemination.

The UK Cochrane Centre (UKCC) facilitates and coordinates the preparation and maintenance of systematic reviews of randomised controlled trials of healthcare as a part of the International Cochrane Collaboration. The major product of the collaboration is the Cochrane Database of Systematic Reviews, published quarterly. The UK is the biggest contributor to the database and 22 Cochrane Review Groups are UK based and funded. The Cochrane Library, part of the Cochrane Database, contains over 2,000 completed reviews. The reviewers aim to keep these documents up to date as new evidence accumulates. Several hundred newly completed reviews and protocols are added each year. We will increase funding to this programme.

The Centre for Reviews and Dissemination at York University provides information about the effects of interventions, and the delivery and organisation of healthcare. The centre acts as a resource and provides the infrastructure to be able to respond to requests for assistance in the area of systematic review from policy makers and healthcare professionals.

Goal 5
Act as sound custodians of public money for public good

Objectives

- Behave with integrity, expressing our values in the way we behave – from developing and implementing our strategy to how we work with our partners and key stakeholders
- Conduct all NHS health research with patient dignity and safety as a core value
- Use resources efficiently and effectively
- Act transparently in the way we award, manage, conduct and report all our work
- Support research by and with people regardless of gender, ethnicity, culture or age
- Help patients and the public understand the health and socio-economic benefits of health research.

> the funding systems that underpin this strategy are based on the principles of transparency, fairness and contestability

To achieve these objectives by 2010 we will:

1. Move from the existing trust R&D allocation model which is historical and does not reflect the level, quality or relevance of research activity conducted
2. Implement methods of evaluating the equality and effectiveness of our capacity, infrastructure and direct funding
3. Work in partnership with all our stakeholders including patients and the public
4. Develop effective patient and public engagement initiatives in partnership with our partners.

5.1 R&D funding

For the past five years, the funding to support research in the NHS (£500 million out of a total R&D budget of £650 million) has been allocated to NHS Trusts through a formal NHS contract. Trust Chief Executives have reported annually to the Department of Health to account in detail for the research that has been supported with this funding. We intend to build on this to strengthen and focus the systems by which funding is allocated and awarded to support research in the NHS.

The funding systems that underpin this strategy are based on the principles of transparency, fairness and contestability. The strategy does not propose a single, 'one-size-fits-all' approach to funding. Rather it proposes a coherent set of funding mechanisms, each designed to achieve a different purpose within a clear overarching strategy.

Firstly, to ensure that all patients and all health professionals in England can benefit from participation in clinical research, we will allocate funding using a population-based model. This will result in the distribution of resources across the whole of England.

Secondly, to ensure that we fund the best research wherever it may be, we will allocate funding on an open, competitive basis to a large number of researchers. This will result in resources being allocated to all those who conduct excellent research wherever they may be across the country.

Finally, to ensure that England remains at the leading edge of health research internationally, we will allocate funding on an open, competitive basis to those organisations that are truly outstanding in international research terms. This will result in resources being allocated to a relatively small number of organisations whose location will be determined by excellence.

In this way the strategy does not aim to be either elitist or egalitarian. It simply seeks to employ a range of approaches, each of which is specifically designed to meet a purpose. Some of these will result in a wide distribution of funds, some will result in a more concentrated allocation of funds.

5.2 Management

All elements of the new strategy will operate under clear and robust management arrangements supported by programmes of evaluation, including:

- Explicit contractual agreements
- Sound financial planning, allocation, monitoring and control
- Clear lines of accountability
- Regular review of outputs, outcomes and value for money.

5.3 Placing patients at the centre of our work

We know from our experience that engaging patients and members of the public leads to research that is more relevant to people's needs and concerns, more reliable and more likely to be put into practice.

To achieve this, patients and the public must be involved in all stages of the research process:

- Priority setting
- Defining research outcomes
- Selecting research methodology
- Patient recruitment
- Interpretation of findings
- Dissemination of results.

We have established structures and mechanisms to facilitate increased involvement of patients and the public in all these stages of NHS R&D. We will continue their development. Building on the successes in the National Cancer Research Network, patients are specifically included in our plans for all research networks. We will continue funding and developing INVOLVE which aims to promote and support active public involvement in NHS, public health and social care research.

Together with our partners, we aim to provide access to well-presented, balanced information about health research and development. We will work with patients and the public to improve our mutual understanding of the wider societal issues that determine the success of the health research endeavour.

Director's postscript

When I took up the post of Director of R&D just over a year ago, it was clear to me that the NHS R&D programme had achieved a great deal since its establishment in the early 1990s and was widely held in high regard. However, it was also clear that we were facing a number of challenges which, if not dealt with clearly and quickly, would be potential show-stoppers for us.

So we went out and talked to people – our stakeholders – many of whom will be reading these words.

The key issues that you helped to identify were:

- The money for R&D in the NHS was not focused where it was needed but was locked into historical allocations
- The NHS R&D programme did not have sufficient capacity or flexibility to generate all the evidence that is of crucial importance to the delivery of high-quality health services
- Research was being squeezed out of health professionals' contracts, and researchers felt beleaguered by the increasing burden of regulation and bureaucracy
- The NHS was not exploiting its full potential as a research platform to support the country's international competitiveness.

When I asked whether you thought it was important to try to tackle these issues, your answer was clear: 'Yes…and we want to help!' So we have worked together over the last nine months, including a formal public consultation, to get to this point.

One of the things that we have found in talking to people is a tendency to focus on one or two specific aspects of the strategy to the exclusion of everything else. This is natural, but we want to emphasise that the strategy does not consist simply of one or two 'big ideas' in isolation. We have to achieve a range of objectives which, although related, are individually quite distinct. These different objectives require different strategic approaches. So, at one end of the spectrum, to ensure that patients and professionals from all parts of the country can benefit from participation in research, we will distribute funding through research networks to all parts of the country on a population basis. At the other end of the spectrum, to create a focus for particular types of research, we will establish units, schools and centres in a comparatively small number of organisations, through open competition. Both of these approaches, and all the approaches in between, are essential to achieve the different objectives that, together, make up this strategy.

We now have sign-up to the strategy set out in this document from our external stakeholders and from other government departments.

But now the really difficult part starts: the implementation of the strategy.

You have told us that you want more detail on the different elements of the strategy. We have, therefore, developed a series of detailed Implementation Plans for the different components of the strategy. Since these will almost certainly change as we work through the implementation of the strategy, we have separated them from the more enduring strategy document itself, and placed them on the Department of Health website. Here they can be readily updated and accessed. Please check the website **(www.dh.gov.uk/researchstrategy)** for the latest version.

If we are to be successful, we will need to continue to work together to make these changes so we can deliver the promise to patients and the public. We hope you will join us in doing so.

Professor Sally C Davies
Director of Research and Development
Department of Health
January 2006

DH Research and Development Management Team

From left to right

Dr Peter Sneddon
Head of Research Programmes

Dr Russell Hamilton
Deputy Director of Research and Development

Professor Sally C Davies
Director of Research and Development

C Marc Taylor
Head of R&D Systems and Governance

Wendy Russell
Head of R&D Corporate Affairs

Catherine Johns
Head of NHS Research Infrastructure

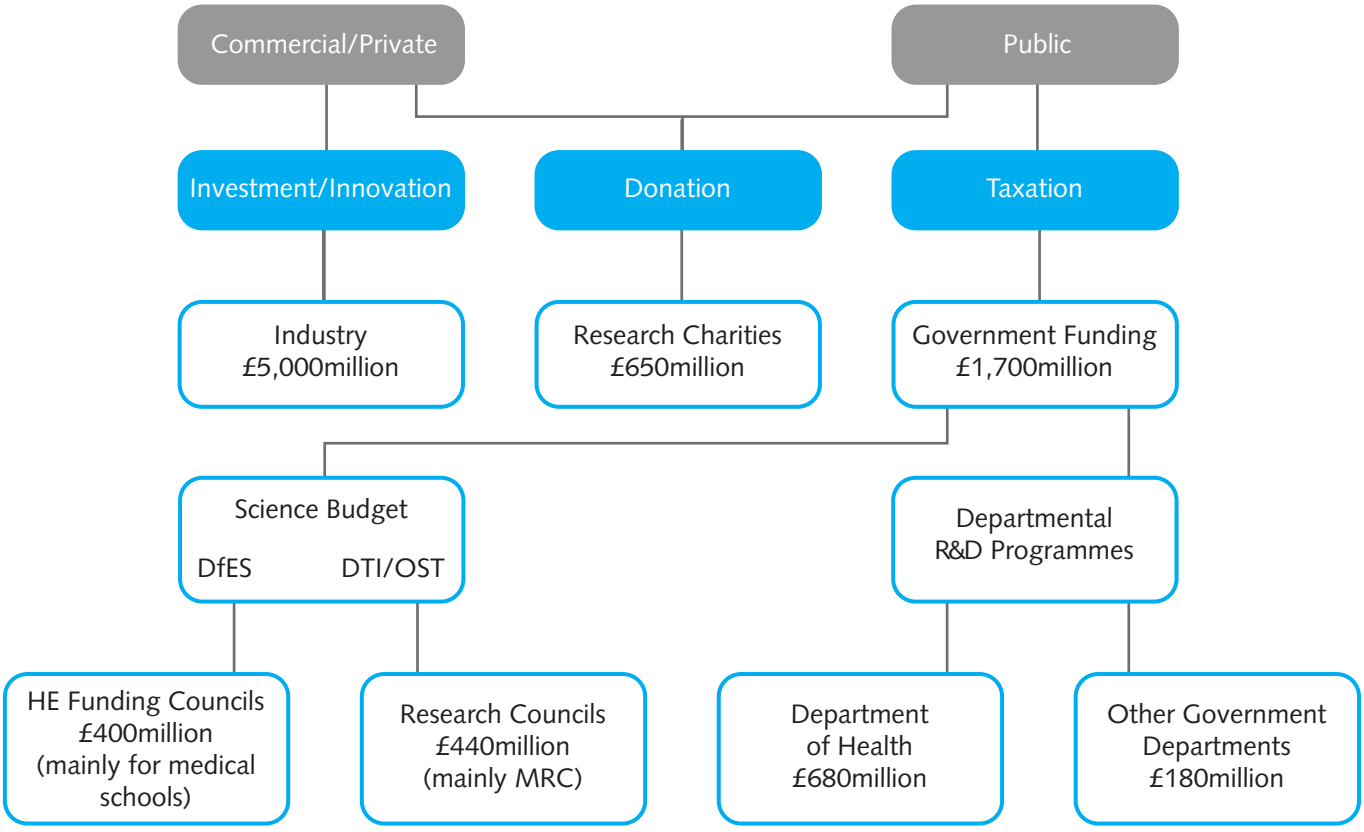
Dr Louise Wood
Head of Innovation and Industry R&D Relations

Annex
The context

Development of NHS research

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

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.

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[8].

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[9].

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.

These streams were brought together as the NHS R&D Levy in 1997, following a review by Professor Sir Anthony Culyer[10] 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.

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.

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[11]. In 2005, research governance became one of a set of national standards for healthcare, and a second edition of the Research Governance Framework was issued[12].

The clinical research environment

In 2003, two reports – from the Bioscience Innovation and Growth Team[13] and the Academy of Medical Sciences[14] – 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.

The Government responded to these challenges by setting up the Research for Patient Benefit Working Party[15]. 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[16].

The Government's *Science and 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.

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.

There has also been considerable concern expressed over the state of clinical academic careers[17–20]. 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.

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.)

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[21] offers a framework for addressing these concerns and reversing the decline for doctors. Similar initiatives for nurses and allied health professionals will follow.

Changes in society

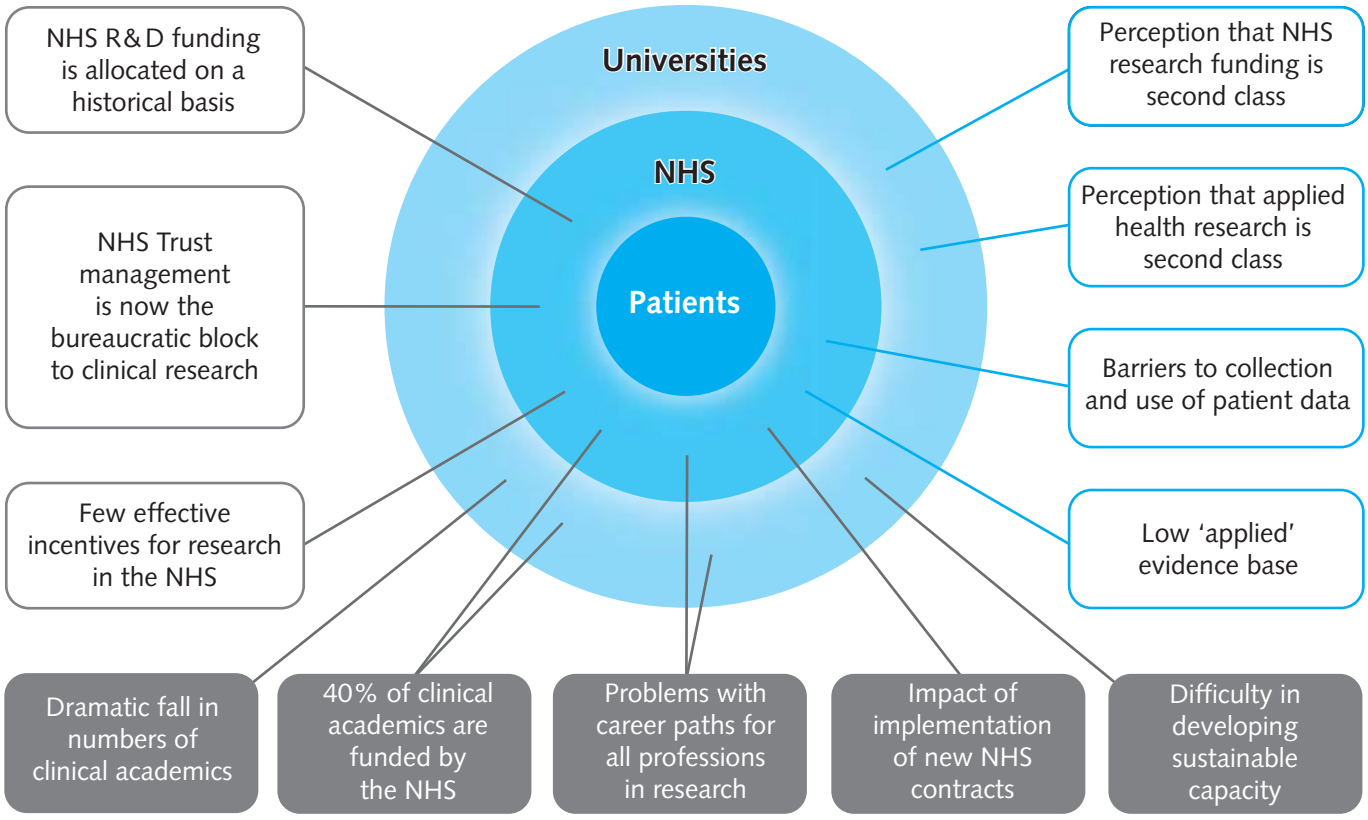
Our society is continually evolving. For health and healthcare there will be changes in human behaviour and the way we tolerate and manage risk. As we understand better the risk factors and disease processes, early detection and prevention of disease will increase in importance. The increasing chronic 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.

All of these changes to society – demographic, advances in science, and the expectation we have of our health and wellbeing – 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.

The challenges we face

The major challenges that we face are summarised in the figure below.

Challenges



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