



Reaping the rewards: a vision for UK medical science

January 2010

The Academy of Medical Sciences

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

Acknowledgements and disclaimer

The Academy of Medical Sciences is most grateful to Sir David Cooksey GBE FMedSci and the members of the working group for undertaking this project. We thank our Officers, Council and staff who contributed to this report.

This report is published by the Academy of Medical Sciences and has been endorsed by its Officers and Council. Contributions by the working group were purely in an advisory capacity. Members of the working group participated in a personal capacity and not on behalf of their affiliated organisations.

© Academy of Medical Sciences

Contents

Summary	5
Rich opportunities from medical science	9
1. To benefit patients the NHS must become a willing participant in health research	15
2. The regulatory environment is driving medical science abroad	19
3. Innovative incentives must firmly root the medical science industries in the UK	23
4. Publicly funded health research needs further coordination	27
5. Public health challenges must become cross-Departmental priorities	29
6. Health research should be used as a driver of foreign policy and international development	33
7. The UK must build a world-class biomedical workforce for our knowledge economy	35
Conclusion	39
Annex I Working group membership	41

Summary

Groundbreaking advances in medical science over the last 30 years offer the next UK Government an unprecedented opportunity to reinvigorate the economy, to enhance the productivity of the NHS and to make public services more cost-effective. Bold leadership will ensure that the UK can continue to generate world-class medical science that is translated into health and wealth benefits, and can become the best location in the world for medical research in both the public and private sectors.

The UK has historically supported vibrant research-intensive medical science industries and internationally renowned academic medical research centres as part of its knowledge economy. The UK generates over 10% of the world's clinical science and health research outputs and has created nearly a quarter of the world's top 100 medicines. Historically, both larger pharmaceutical and smaller biotechnology companies have flourished in the UK, where the availability of skilled researchers and a unified health system present a significant advantage for both basic and clinical research.

However, the future of commercial medical research in the UK is under serious threat, and much activity has already moved abroad. Between 2000 and 2006 the proportion of the world's clinical trials conducted in the UK fell from 6% to 2%, in part because of more attractive regulation and incentives elsewhere. The UK's competitors, including the USA, China, Canada and Singapore, have begun to realise the huge potential of medical research to both their economies and public services, and are implementing robust policies to grow this crucial sector. Decisive action is needed now to attract and anchor increasingly mobile medical researchers and life science industries in the UK.

No other country enjoys the outstanding opportunities for medical research represented by the NHS, which together with the world-class status of our researchers, universities, research funders, charities and companies, offers an unparalleled competitive advantage to the UK. We are uniquely positioned to attract the whole research and development (R&D) chain for new medicines to the UK - from basic science discovery to clinical application - and to improve the health of the population both here and abroad. To reap the rewards from recent public sector investment in medical science, the UK must tackle seven important challenges set out in this document. A Government that unites researchers from across academia, the NHS, industry and the charitable sector, and engages with patients and the public, can make significant progress towards addressing these challenges within five years.

1 To benefit patients the NHS must become a willing participant in health research

As one of the largest single healthcare systems in the world, the NHS offers the UK a unique strategic advantage as a resource for medical research and innovation. Despite recent progress by the National Institute for Health Research (NIHR), the research potential of the NHS remains unfulfilled. We recommend that:

- High-quality research should be an integral component of the next NHS Operating Framework and be part of the outcomes on which the performance of NHS Trusts is measured.

- Research is made a central goal of any NHS system for electronic health records, allowing researchers access to data to improve the safety of medicines, to better understand the causes of disease, to identify research participants and to locate patients who would benefit most from targeted health interventions.

2 The regulatory environment is driving medical science abroad

The combined regulatory requirements of the EU Clinical Trials Directive, European Medicines Agency (EMA), UK Medicine and Healthcare products Regulatory Agency (MHRA), NHS ethics committees, R&D offices in NHS Trusts, the National Information Governance Board and other agencies are stifling UK R&D in both the private and public sector. Medical research involving patients must be subject to robust regulation, but this regulation must be proportionate to the risks involved. Current application of data protection regulation in particular represents a serious impediment to medical research without apparently providing significant benefit to patients. Streamlining and improving current regulation represents a cost-effective approach to creating a more fertile and productive research environment. We recommend that the UK:

- Should lead the world in creating a proportionate, risk-based regulatory framework for medical research involving patients, which is fit for purpose and informed by an independent review of existing regulations.

3 Innovative incentives must firmly root the medical science industries in the UK

A flourishing industrial bioscience sector will translate scientific discoveries into new treatments and interventions, generate public revenue and create high-value jobs. We recommend:

- Using a range of instruments to drive investment and stimulate the development of novel therapeutics, diagnostics and devices, including flexible pricing, public procurement strategies, tax incentives and new pathways to support uptake and access to medicines.
- Encouraging alliances between the NHS, universities and industry to share the risk and reward associated with generating more cost-effective and novel therapeutics, diagnostics and devices.

4 Publicly funded health research needs further coordination

To maintain the UK's medical science base in the near and longer term, public investment in medical research must be sustained and delivered in a coordinated fashion. This will ensure that our investment continues to leverage many times its value in funding from industry and charities. We recommend:

- Maintaining a ring fence around the budgets held by the Medical Research Council (MRC) and NIHR.
- Protecting and building on the successes of the Office for the Strategic Coordination of Health Research (OSCHR), to ensure basic biomedical and translational science are managed in a coordinated fashion. The UK should further strengthen health research by maintaining and enhancing coordination of the MRC and NIHR, in close collaboration with the NHS. The relationship with other scientific disciplines, industry, charities and the Devolved Administrations are crucial determinants of a successful health research agenda.

5 Public health challenges must become cross-Departmental priorities

Effective public health research and delivery can provide enormous economic and health benefits to the UK, but are hindered by under-investment and fragmented responsibility and oversight. The UK lacks the necessary co-ordination to tackle health inequalities and major public health challenges such as obesity, infectious pandemics, ageing, alcohol and climate change, which cut across government departments; political engagement is required at the highest level. We recommend:

- Establishing budgets and strategies for specific public health priorities that fund research and service delivery across Government departments.
- Ensuring that all new public health policies are supported by evidence-based decision-making, robust piloting and rigorous evaluation throughout.

6 Health research should be used as a driver of foreign policy and international development

Medical science can underpin cost-effective international development measures that enable poorer countries to address their health needs and help to reduce health and security threats to the UK. To tackle three of the Millennium Development Goals that directly concern health we recommend that:

- Health research should be central to UK foreign policy and should underpin all efforts to tackle disease in resource-poor countries.
- Greater efforts are made by the UK Government to support indigenous research capacity in resource-poor countries.

7 The UK must grow and sustain its world-class biomedical workforce for our knowledge economy

To sustain the UK's world-class science base we must equip our biomedical professionals with the full range of skills needed to advance understanding and develop novel treatments for major diseases. We recommend:

- Better coordination of efforts to build UK biomedical research capacity, focusing on developing interdisciplinary researchers and workers in key areas of current and future need, including quantitative science and bioinformatics, systems biology, ageing, physiology and pharmacology.
- Promoting and supporting biomedical research training for doctors and other healthcare professionals in the NHS, and incentivising the mobility of researchers across academic, industry and healthcare sectors.

The Academy of Medical Sciences' 944 elected Fellows are the UK's leading medical scientists from hospitals, academia, general practice, industry and public service. In setting out our vision we call on the next Government to put medical research to work as the engine of Britain's future prosperity. We believe that making medical science a central pillar of government policy will produce a flourishing UK economy and alleviate the burden of ill-health on patients and public services.

Rich opportunities from medical science

The relationship between world-class medical science and national gains in health and wealth is clearly established; excellence in research leads to better medical care, attracts investment and industries, and improves the productivity and cost-effectiveness of healthcare, social and public services. This link between high quality medical research and benefits for both patients and society is clearly demonstrated in the UK:

- We have first-class universities, four of which are in the top six of a major international league table, *and* vibrant medical science industries, including two of the world's largest pharmaceuticals companies.^{1,2}
- We have world-renowned public research funders such as the Medical Research Council (MRC), *and* uniquely strong medical research charities, such as the Wellcome Trust, that contribute one-third of non-commercial spending on medical research - second only to the USA and one of the largest proportional contributions in the world.³
- We are distinguished by over 30 winners of Nobel Prizes for biomedical research, most of which were supported by the MRC, *and* we have created nearly a quarter of the world's top 100 medicines.^{4,5}
- We generate over 10% of the world's clinical science and health research output with 1% of the world's population, *and* we are scientifically the most publication productive nation in the world - ahead of the USA - in terms of citations per researcher.⁶
- We have in the NHS one of the world's largest single providers of healthcare, *and* we employ an estimated 25% of all those who work in the medical biotechnology sector in Europe.⁷

The insights generated by fundamental scientific research are at the core of the UK's scientific and innovation 'ecosystem'.⁸ Our history of supporting long-term basic research plays a key role in promoting scientific excellence, as well as generating considerable, though often unanticipated, health and economic rewards.⁹ A notable example is the development of monoclonal antibodies, funded by investment from the MRC in the 1970s, that now account for a third of all new medical treatments worldwide.¹⁰ Further details of

¹ Times Higher Education (2009). *Top 200 universities*.

<http://www.timeshighereducation.co.uk/hybrid.asp?typeCode=438>

² Association of the British Pharmaceutical Industry (2007). *Facts & statistics from the pharmaceutical industry*.

<http://www.abpi.org.uk/statistics/section.asp?sect=1>

³ Association of Medical Research Charities (2009). AMRC submission to House of Lords Science and Technology Committee Inquiry on 'Setting science and technology research funding priorities'.

<http://www.amrc.org.uk/HomePage/Default.aspx?Nav=814,932,558#2009>

⁴ Association of the British Pharmaceutical Industry (2004). *Innovating for a healthy tomorrow*.

http://www.abpi.org.uk/publications/pdfs/annual_report_05.pdf

⁵ Further information is available from www.mrc.ac.uk/Achievementsimpact/NobelPrize/index.htm

⁶ Department for Innovation, Universities and Skills (2008). *International comparative performance of the UK research base*. The Stationery Office, London.

⁷ UK Trade and Investment (2009). *Strength and opportunity*. <http://www.berr.gov.uk/files/file53947.pdf>

⁸ Academy of Medical Sciences (2008). *The UK pharmaceutical industry: what does the future hold?*

<http://www.acmedsci.ac.uk/p50evid90.html>

⁹ Health Economics Research Group at Brunel University, Office of Health Economics and RAND Europe (2008).

Medical research: what's it worth? <http://www.acmedsci.ac.uk/index.php?pid=99&puid=137>

¹⁰ Further information is available from:

<http://www.mrc.ac.uk/Achievementsimpact/Storiesofimpact/Therapeuticantibodies/index.htm>

the MRC's achievements and some of its contribution to the UK's vibrant biomedical research base are given in Box 1.

Box 1 The Medical Research Council (MRC)

The MRC has had a long tradition of producing excellent medical science since its establishment in 1913. It has a budget that falls within the health research ring fence and its research is coordinated by the Office for the Strategic Coordination of Health Research (OSCHR) alongside the National Institute for Health Research (NIHR). Its mission is to improve human health through world-class medical research.

Key achievements of the MRC include:^{11,12}

- Support for most of the UK's more than 30 winners of Nobel Prizes for biomedical research, including 14 from the MRC Laboratory of Molecular Biology (LMB) alone.
- Major advances in molecular and cellular biology, epidemiology and clinical medicine; the latter exemplified by the development of the randomised controlled trial and, more recently, the Bayesian approach to clinical trials.
- Significant contributions to UK innovation and technology transfer, with the development of humanised monoclonal antibodies and confocal microscopy being notable examples.

As part of its most recent efforts to strengthen medical research the MRC has:¹³

- Built on its support for translational medicine with a focus on research leading to patient benefit; this has included establishing the Developmental Pathway Funding Scheme to strengthen the biotechnology sector, help universities best exploit their research and provide the pharmaceutical industry with more mature drug leads that allow easier investment decisions. There are now 75 active projects in this Scheme, 5 portfolios with Universities, resulting in 38 potential therapeutics under study and 7 new diagnostic approaches.
- Increased research training awards for clinicians and translational research.
- Led on global health research, currently investing £40 million per year, and driving the 'Global Alliance for Chronic Diseases' which has been created to support priorities for a coordinated research effort that will address the growing health crisis in the developing world.
- Increased support for experimental medicine that has led to more than 3000 patients being brought into early phase studies.
- Demonstrated continued commitment to methodology research by awarding £16 million to establish a national network of seven hubs to develop new and improved methods to design, conduct, analyse and report clinical trials.
- Invested heavily in UK infrastructure, including £220 million for a new building for the LMB, and a major contribution to the planned UKCMRI in London.

¹¹ Academy of Medical Science and Royal Society (2006). *Response to the review of UK health research*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Cookseyr.pdf>

¹² Further information is available from <http://www.mrc.ac.uk/Achievementsimpact/index.htm>

¹³ Medical Research Council (2009). *MRC annual report and accounts*. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC006563>

The UK already leads the world in key fields of basic research, such as genetics and structural biology, and we now have the chance to grow new and existing areas such as the fundamental biology of ageing and the neuroscience of addiction.^{14,15} The time is right to capitalise on the excellence of our universities, hospitals and research institutes, and their distinguished record of discovery and innovation. Many recent UK scientific advances are now on the cusp of translation into benefits for patients and society. Important opportunities include:

- Delivering more effective treatments to the right groups of patients through stratified (personalised) medicines.¹⁶
- Molecular diagnostic tools to improve the diagnosis of disease and detect markers of its severity, and genome-wide association studies to offer novel insights into the genetics of common diseases, such as type II diabetes and depression.^{17,18}
- Medical devices for unmet needs, such as robotic surgery, medical implants and prostheses.¹⁹
- Regenerative medicines such as alternatives to blood, cell-based therapies and interventions to restore vision and motor function.

The opportunities presented by the NHS, together with the world-class status of our researchers, medical science industries, charities, universities and research funders, offer the UK unparalleled advantages for health and wealth creation. We cannot, however, be complacent. The UK's competitors have already begun to realise the huge economic potential of medical science and are implementing active industrial policies and investment to grow this crucial sector:

- The USA has committed \$10.4 billion additional funding for medical research to the US National Institutes of Health as part of its recent fiscal stimulus.²⁰
- China increased R&D spending by more than 20% year-on-year between 1999 and 2005.²¹
- In 2004 alone, China produced 6.5 million undergraduates and 500,000 postgraduates in science, medicine and engineering.²²
- The French government announced a \$50.5 billion package in late 2009 to boost the country's economic competitiveness that included around \$11.5 billion for research and around \$15.9 billion for higher education.²³

¹⁴ Academy of Medical Sciences (2009). *Rejuvenating ageing research*. <http://www.acmedsci.ac.uk/p47prid62.html>

¹⁵ Academy of Medical Sciences (2008). *Brain science, addiction and drugs*.

<http://www.acmedsci.ac.uk/p48prid47.html>

¹⁶ Academy of Medical Sciences FORUM (2007). *Optimising stratified medicines R&D: addressing scientific and economic issues*. <http://www.acmedsci.ac.uk/p50evid79.html>

¹⁷ House of Lords Science and Technology Committee (2009). *Genomic medicine*.

<http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf>

¹⁸ Academy of Medical Sciences FORUM (2009). *Genome wide association studies: understanding the genetics of common disease*. <http://www.acmedsci.ac.uk/p114.html>

¹⁹ Academy of Medical Sciences (2009). *Submission to DIUS regarding strategic priorities for research*. Academy of Medical Sciences, London.

²⁰ Further information is available from <http://www.researchresearch.com/> and

<http://www.hhs.gov/recovery/programs/nih/index.html>

²¹ Leadbeater C & Wilsdon J (2007). *Atlas of ideas: how Asian innovation can benefit us all*.

http://www.demos.co.uk/files/Overview_Final1.pdf?1240939425

²² Wilsdon J & Keeley J (2006). *China: the next science superpower?*

http://www.demos.co.uk/files/China_Final.pdf?1240939425

²³ Butler D (2009). *French research wins huge cash boost*. Nature **462**, 838.

- Singapore is now one of the fastest growing bioscience clusters in the world after recent government investment of over \$2 billion.²⁴
- Between 2000 and 2006 there was a 379% increase in the number of registered clinical investigators in China and Russia.²⁵

The increasingly competitive international research environment is illustrated by the fact that the proportion of the world's clinical trials conducted in the UK has already fallen from 6% in 2000 to 2% in 2006, with much going to our European competitors.^{26,27} We can and should reverse this decline. Medical research is by its nature a long-term endeavour and large, one-off injections of funding can sometimes be detrimental. The most important feature of any additional investment in medical science is therefore that it is sustainable (see Section 4).

Our vision

This paper sets out the Academy of Medical Sciences' vision for medical science that, if realised, will revitalise the UK economy and alleviate the burden of ill-health on patients and our public services. Supported by the right policies, UK medical science can deliver exceptional health, economic and social benefits. A new UK Government must unite researchers from across academia, the NHS, industry and charities, and engage with patients and the public, so that within the next five years the UK will be on track to achieve:

- Integration of medical innovation into the fabric of the NHS and public services offering better, more cost-effective healthcare and public health services, along with improved opportunities for collaborative R&D with industry.
- A national system of electronic health records that will allow researchers access to data from one of the world's largest single healthcare systems to improve the safety of medicines, to understand the causes of disease, to identify research participants and to locate patients who would benefit most from targeted health interventions.
- A fertile research environment created by better regulation and financial incentives that enables the medical science industries to flourish, generating public revenue and high-value jobs.
- Cost-effective international development measures and stronger international health research capacity to enable poorer countries to address their own health needs and reduce health and security threats to the UK.
- A world-class pool of biomedical science professionals to undertake the research needed to tackle major diseases.

²⁴ The Economist (2004). *Singapore's man with a plan*. <http://www.economist.com/node/3084417>

²⁵ Kaitin K (2008). *Offshoring: cost-effective clinical research*. http://www.pharmafocusasia.com/clinical_trials/offshoring_cost_effective_clinical_research.htm

²⁶ Bioscience Innovation Growth Team (2009). *The review and refresh of bioscience 2015*. <http://www.berr.gov.uk/files/file49805.pdf>

²⁷ Office of Life Sciences (2009). *Life science blueprint*. http://www.dius.gov.uk/innovation/business_support/~/_/media/publications/O/ols-blueprint

Challenges for the next Government

The recent financial crisis offers an opportunity for the UK to rebalance its economy towards a medical science sector that can drive economic growth and meet future health challenges. To reap the rewards from recent generous support for medical science, the UK must tackle the following seven important challenges, detailed in subsequent sections of this document:

1. To benefit patients the NHS must become a willing participant in health research.
2. The regulatory environment is driving medical science abroad.
3. Innovative incentives must firmly root the medical science industries in the UK.
4. Publicly funded health research needs further coordination.
5. Public health challenges must become cross-Departmental priorities.
6. Health research should be used as a driver of foreign policy and international development.
7. The UK must sustain and grow its world-class biomedical workforce for our knowledge economy.

This paper contains the recommendations of a working group established by the Academy of Medical Sciences to provide independent strategic advice on medical science policy to inform a new Government (see Annex 1). The Academy is the independent UK body that represents the spectrum of medical science from the laboratory to the clinic.²⁸ Our 944 elected Fellows are the UK's leading medical scientists from academia, hospitals, general practice, industry and public service.

²⁸ Further information is available from: <http://www.acmedsci.ac.uk/p29.html>

1. To benefit patients the NHS must become a willing participant in health research

As one of the largest single healthcare systems in the world, with millions of patients and healthcare staff, the NHS offers the UK a unique strategic advantage as a partner for medical research. Research provides the medicines that allow people to live longer and healthier lives, and helps to mitigate the economic cost of ill-health to the UK taxpayer. Unemployment and sickness absence alone is estimated to cost the UK over £100 billion every year, which is approximately the current annual budget of the NHS.²⁹ Research and innovation encompass clinical practice and service design that are integral to the NHS and have the potential to make it more efficient and cost-effective.³⁰ For example, UK scientists helped to show that more rapid treatment of stroke can save brain tissue and so significantly reduce the future burden of disability on the individual and society.

Previously, research in the NHS suffered through the diversion of money intended for research and infrastructure support into direct patient care. NHS managers are subject to intense pressures to deliver immediate healthcare targets, and understandably afford a low priority to research. As a result, the NHS was often perceived by the academic and commercial community to be a challenging and inconsistent research partner.

Over the past four years, several initiatives have sought to increase the standing of the NHS as a health research collaborator. The most significant improvements have resulted from the establishment of the NHS National Institute for Health Research (NIHR) with its ring fenced budget (see Box 2 for NIHR initiatives to strengthen UK health research) and the formation of the Office for the Strategic Coordination of Health Research (OSCHR). OSCHR has promoted coordination of the strategies of the MRC (see Box 1), NIHR and health research in the Devolved Administrations, and driven greater coherence across the spectrum of UK health research.

Several important collaborative entities have also recently been established. The NIHR has formed Biomedical Research Centres and Units with medical schools. The Academic Health Science Centres (AHSCs), Collaborations for Leadership in Applied Health Research and Care (CLARHCs) and Health Innovation and Education Clusters (HIECs) have generated collaborations with the wider NHS and sectors such as academia and industry.

This focus on research has been signalled in the new NHS Constitution, recent NHS Operating Frameworks and the Government's recent five year plan to reshape the NHS, which all state requirements for the NHS to promote and conduct research.^{31,32,33,34}

²⁹ Black C (2008). *Working for a healthier tomorrow*. <http://www.workingforhealth.gov.uk/documents/working-for-a-healthier-tomorrow-tagged.pdf>

³⁰ Darzi A (2008). *High quality care for all: NHS next stage review final report*.

http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825

³¹ Further information is available from: <http://www.dh.gov.uk/en/Healthcare/NHSConstitution/index.htm>

³² Department of Health (2008). *The NHS in England: the operating framework for 2009/10*.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyandGuidance/DH_091445

³³ Department of Health (2009). *The NHS in England: the operating framework for 2010/11*.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110107

³⁴ Department of Health (2009). *NHS 2010-2015: from good to great. Preventative, people-centred, productive*.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/@sta/@perf/documents/digitalasset/dh_109887.pdf

Box 2 NHS National Institute for Health Research (NIHR)

The NHS National Institute for Health Research (NIHR) was established in 2006. Its budget falls within the health research ring fence and its research is coordinated by OSCHR alongside that of the MRC. Its goal is to create a health research system in which the NHS supports outstanding individual researchers, working in world-class facilities, conducting leading-edge research focused on the needs of NHS patients and the public.

As part of its activities to strengthen UK health research, the NIHR has:^{35,36}

- Formed Biomedical Research Centres and Units as collaborations between the NHS and medical schools.
- Set up Clinical Research Networks to ensure that patients and clinicians can share the benefits of participating in clinical research.
- Provided programme grants for applied health research that will be worth up to £75 million per year when fully established.
- Established the NIHR Faculty for all professionals who carry out people and patient-based applied health research and who are funded by the NIHR or the Department of Health Policy Research Programme.
- Made research training awards available to all professionals with an interest in people and patient-based applied health research, in order to build a leading NHS Research Faculty, and develop research careers, research leaders and collaborators.
- Expanded the successful Health Technology Assessment (HTA) programme that produces independent research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS.
- Set up the Public Health Research Programme to evaluate the effectiveness, cost-effectiveness and broader impact of public health interventions.

We welcome these initiatives, which will undoubtedly increase the role of the NHS in UK health research as they progress and develop. However, a radical step-change is needed to embed a culture of enquiry and innovation throughout the NHS, and create a sense of ownership of the research agenda by NHS management and staff. Unless this happens, the NHS will not be regarded as a willing participant in health research by the academic and commercial communities and its research potential will not be realised.

Research must be at the core of the next NHS Operating Framework and incentivised at all levels from senior management to individual healthcare practitioners. High quality research should be included among the outcome measures upon which the success of the NHS is evaluated. Patients are at the heart of the NHS and must be actively engaged and encouraged to participate in research that improves both their health and that of others in the future. Appropriate training is also vital in inspiring the next generation of NHS clinicians and other healthcare professionals about research (see Section 7). In short, research must be at the heart of UK healthcare.

³⁵ Department of Health (2008). *Transforming health research. The first two years. National Institute for Health Progress report 2006-2008.* <http://www.nihr.ac.uk/files/pdfs/NIHR%20Progress%20Report%202006-2008.pdf>

³⁶ Department of Health (2009). *Delivering health research. National Institute for Health Research Progress report 2008/09.* http://www.nihr.ac.uk/files/Publications/296542_DeliveringHealthResearchReport_acc3.pdf

We recommend that high-quality research should be an integral component of the next NHS Operating Framework and be part of the outcomes on which NHS Trust performance is measured.

A key lever in unleashing the research and innovation power of the NHS lies in the use of electronic health records (see also Box 4). Countless lives have been saved or improved by medical research using health information.³⁷ Studies of patient databases have shown that statins reduce the risk of heart attack and stroke in a much wider range of high-risk people than previously thought, thus saving lives and making healthcare more cost-effective.³⁸ Applications such as QFlu offer immediate benefit from patient data by using anonymised electronic patient records to monitor influenza and support the response to this threat.³⁹

Information held by the NHS offers an unparalleled resource to:

- Monitor and improve the safety of medicines – a major near-term benefit.
- Identify potential research participants.
- Locate patients who would benefit most from targeted health interventions.
- Better understand the causes of disease.

The strength of a system of NHS electronic health records lies in the unique combination of the sheer size and diversity of the population covered, along with the opportunities for follow-up. Although the health systems of other countries share some of these properties few have them all. Harnessing electronic patient records for research is an achievable goal that offers huge benefits. Initiatives to develop General Practice Research databases are already well established in the UK and internationally recognised as a major strategic advantage.⁴⁰ The Scottish health records system provides a useful model for the rest of the UK: each patient has a unique identifier that has the potential to record every episode of healthcare, allowing researchers to establish customised databases for particular conditions such as cancer, diabetes or obesity.

Society has legitimate concerns about the protection of medical records, but a balance must be struck between these concerns and the many benefits offered by medical research using electronic records. If in the future patients have greater control over access to their electronic patient records then systems must be put in place to encourage and facilitate the use of this information for research for the benefit of patients and society.

The Research Capability Programme established under NHS Connecting for Health is an important platform to develop the UK's capability in e-health, regardless of whether a centralised or localised system of NHS patient records is eventually established. Vital components for success will include:

- Inter-operability between records systems.

³⁷ Academy of Medical Sciences (2006). *Patient data for public good*. <http://www.acmedsci.ac.uk/p48prid5.html>

³⁸ Heart Protection Study (2002). *MRC/BHF Heart Protection Study of cholesterol lowering simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial*. *Lancet* **360**, 7–22.

³⁹ Further information is available from <http://www.qresearch.org/public/qflu.aspx>

⁴⁰ Academy of Medical Sciences (2009). *Research in general practice: bringing innovation into patient care*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/12569153801.pdf>

- A strategic framework through which healthcare providers, universities and research funders can work in partnership.
- Commercial involvement.
- Political leadership that champions the importance of electronic health records in improving patients' health and healthcare.

The opportunities offered by NHS data are attractive to industry and will drive future commercial investment, as well as improving health. Significant scaling back of the systems that allow the use of electronic records for research is therefore likely to be a false economy. The facilitation of research must be a central goal of any NHS system for electronic health records and incentives should be created to encourage health service providers to allow access to records for research.

We recommend making research a central goal of any NHS system for electronic health records, allowing researchers access to data to improve the safety of medicines, to better understand the causes of disease, to identify research participants and to locate patients who would benefit most from targeted health interventions.

2. The regulatory environment is driving medical science abroad

The UK must develop a rational and proportionate regulatory framework for medical research.⁴¹ The combined regulatory requirements of the EU Clinical Trials Directive, European Medicines Evaluation Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), NHS ethics committees, R&D offices in NHS Trusts, the National Information Governance Board and other agencies are stifling UK R&D in both the private and public sectors. Ultimately, this reduces the rate at which innovative new medicines and other interventions are brought to market for the benefit of patients.

Burdensome regulation is driving pharmaceutical companies abroad in what is an increasingly global scientific market.⁴² Compared to its European competitors, the UK is now slower to initiate clinical trials, slower to recruit patients, and trials in the UK are more expensive to run.⁴³ In 2002, 46% of EU products in clinical trials development were in the UK; by 2007 this had fallen to 24%.⁴⁴ Good governance is needed to protect patients, but excessive regulation can cause net harm to patients by denying them access to new medicines. Efforts to improve and simplify the regulatory burden offer an opportunity to significantly boost UK medical research without the need for major financial investment or compromising safety.

We welcome recent initiatives to reduce the regulatory burden on researchers, such as the Integrated Research Application System (IRAS) and the NIHR Coordinated System for gaining NHS Permissions (CSR).⁴⁵ However, there is considerable variation in the time taken to set up trials between centres, with one study of non-commercial trials indicating that it took over six months to activate trials in over half of centres investigated.⁴⁶ We remain concerned about issues including:

- The impact of the EU Clinical Trials Directive, which is increasing the cost and duration of trials, particularly non-commercial and academic trials (see Box 3).
- The delay created by the requirement for individual NHS R&D governance approval and contracts in multicentre studies.
- The interfaces between different national regulatory systems that are hindering multinational trials.
- Continued difficulties and uncertainty around appropriate research access to health datasets that are impeding large-scale population studies (see Box 4).

⁴¹ Medical Research Council and Wellcome Trust (2008). *Regulation and biomedical research*. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC005613>

⁴² Katlin K (2008). *Offshoring: cost-effective clinical research*. http://www.pharmafocusasia.com/clinical_trials/offshoring_cost_effective_clinical_research.htm

⁴³ Further information is available from http://www.ukcrn.org.uk/index/library/presentations/mainColumnParagraphs/01/document/Lynne_Abley.ppt

⁴⁴ Bioscience Innovation Growth Team (2009). *Review and refresh of bioscience 2015*. <http://www.berr.gov.uk/files/file49805.pdf>

⁴⁵ UK Clinical Research Collaboration (2009). *The changing regulatory and governance environment for health research for the UK. A guide for researchers*. UK Clinical Research Collaboration, London.

⁴⁶ Hackshaw A, et al. (2008). *Setting up non-commercial clinical trials takes too long in the UK; findings from a prospective study*. *Journal of the Royal Society of Medicine* **101**, 299–304.

Box 3 European Clinical Trials Directive (ECTD)

Clinical trials are an indispensable component of clinical research and are required for the development of innovative new medicines. The ECTD was introduced in 2001 to:

- Protect the health and safety of clinical trials participants.
- Ensure the ethical soundness of clinical trials.
- Ensure clinical trials produce reliable and robust data.
- Simplify and harmonise the governance of clinical trials to allow for cost-effective clinical research.

While the Academy supports the principles underpinning the ECTD, its implementation, particularly in the UK, has been inconsistent, disproportionate and has stifled medical innovation. For example, the Impact on Clinical Research of European Legislation (ICREL) study, sponsored by the EU Framework Programme, found non-commercial and academic costs had increased by 90% as a result of the ECTD.⁴⁷

In response to a recent consultation from the European Commission, the Academy has recommended that the Directive should be reviewed and amended to introduce a risk-based approach to regulation of clinical trials.⁴⁸

There are real opportunities to improve existing regulatory systems. Speeding up initiation of trials and studies and improving patient recruitment are essential to the UK's status as a cost-effective environment for commercial and non-commercial research.

The risk profiles of research protocols vary considerably. In the case of clinical trials the risk for the participant varies depending on factors including:

- The extent of prior knowledge about the product being investigated.
- The population of patients involved.
- Whether the medicine is being assessed for approved indications or other therapeutic uses.⁴⁹

Too often regulation adopts a 'one-size-fits all' approach, meaning that low-risk trials using marketed drugs often bear the same regulatory burden as large trials of new drugs. New approaches to medical research regulation need to adopt a more proportionate risk-based approach.

There is an urgent need for a comprehensive overhaul of medical research regulation, informed by an independent review, to ensure the UK can safely, quickly and cost-effectively realise the benefits of health research. This will also ensure that the UK is a globally competitive location for commercial and non-commercial medical research. Any changes to governance should involve consultation with representative groups of patients, not simply those who choose to get involved.

⁴⁷ Further information is available from <http://www.efgcp.be/icrel/>

⁴⁸ Academy of Medical Sciences (2010). *Response to the European Commission consultation on the assessment of the functioning of 'Clinical Trials Directive 2001/20/EC'*. <http://www.acmedsci.ac.uk/publications>

⁴⁹ European Commission (2009). *Assessment of the functioning of the clinical trials directive 2001/20/EC. Public consultation paper*. http://ec.europa.eu/enterprise/pharmaceuticals/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf

We recommend that the UK should lead the world in creating a proportionate, risk-based regulatory framework for medical research involving patients, which is fit for purpose and informed by an independent review of existing regulations.

Box 4 Personal data for public good

Medical research using patient data has had a long and successful history of providing vital knowledge on the causes of disease and the effectiveness of treatments. The unique features of the NHS, recent technological developments and the advent of large patient databases present unparalleled opportunities for enhancing such research. However, advances are increasingly inhibited by unnecessary constraints on the use of patient data. These include confusing legislation and professional guidance, bureaucracy of process and a lack of engagement between patients, data controllers and researchers. A particular challenge is 'consent for consent' whereby researchers are required to seek consent from patients to contact them, in order to subsequently seek consent to use their data.

Medical confidentiality and appropriate consent are important patient entitlements that must be protected by an ethically sound regulatory framework. However, evidence of public attitudes towards the use of health information in research is largely absent, forcing regulatory and advisory bodies to make assumptions about what the public might find acceptable. These factors have created a conservative culture of governance, where disproportionate constraints are imposed on research that can compromise its quality and validity. The difficulties of the current situation are a significant disincentive for researchers to undertake work in this field and are detrimental to research aimed at improving public health.

In 2006 the Academy of Medical Sciences published a report '*Patient data for public good*' that considered the use of patients' data in medical research, further details of which can be found at <http://www.acmedsci.ac.uk/p48prid5.html>. Many of the conclusions and recommendations remain valid but have yet to be fully implemented.

Alongside clinical research, the UK has an outstanding record of preclinical biomedical research. Experiments conducted in the UK involving research animals or cellular material make invaluable contributions throughout the development of treatments, from basic investigative research to preclinical testing of new drugs and devices.

The UK system of oversight for animal research is widely respected and includes an ongoing commitment to the '3Rs' (Replacement, Reduction, and Refinement of animal use). Proportionate and effective regulation of the use of animals in scientific research must be maintained in the UK. It is imperative that EU-wide legislation, such as the current revision of '*EU Animals Directive on the protection of animals used for scientific purposes*', promotes consistency of research practices and movement of skilled researchers within Europe.⁵⁰ Equally, this new legislation must not compromise or unduly restrict the UK's ability to undertake animal research, including that involving non-human primates, in academic or industrial sectors.

⁵⁰ Further information is available from: http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

3. Innovative incentives must firmly root the medical science industries in the UK

The UK has historically enjoyed a strong pharmaceutical and biotechnology sector that is the largest in Europe and second in size only to the USA.⁵¹ In 2007 the sector accounted for the largest share of total industrial R&D spend.^{52,53} The UK is the home of two of the world's largest pharmaceutical companies, GlaxoSmithKline and AstraZeneca, and nearly 800 medical biotechnology companies with a combined turnover of £4.2 billion.^{54,55} Representatives of the pharmaceutical and biotechnology sectors stress that one of the UK's major strengths is the quality of its academic research base. We *must* continue to invest in our universities and Research Councils to develop the scientific and entrepreneurial leaders of the future and to encourage UK talent to return from overseas (see also Sections 4 and 7).

A thriving pharmaceutical and biotechnology sector is crucial to the UK's ability to turn scientific discoveries into new treatments, diagnostics, devices and interventions that will improve health and generate public revenue. In the long-term, there is a trend for societies to spend more on health, so medical science will be one of the growth industries of the future.⁵⁶ The medical science industries are also a significant employer of highly skilled staff and support over 250,000 UK-based high-value jobs.⁵⁷ The influential US National Academies of Science report '*Rising above the gathering storm*' argued that, without high-quality, knowledge-intensive jobs such as these, the US economy would suffer from the increasing competition caused by economic globalisation.⁵⁸ A similar challenge faces the UK: we now have the opportunity to create more jobs in the medical sciences to both replace jobs lost in the economic downturn and to tackle competition from abroad.

To generate a flourishing bioscience sector we need to foster an environment where global companies invest in the UK and where entrepreneurs are encouraged to establish new companies. Several recent reports, including '*Review and refresh of biosciences 2015*' from the Bioscience Innovation Growth Team, Lord Darzi's '*NHS next stage review*' and the Office for Life Sciences' '*Life sciences blueprint*' set out a package of measures that could transform the ability of the NHS to attract commercial investment to the UK and drive improvements in the quality and efficiency of our healthcare.^{59,60,61} We will not

⁵¹ Office of Life Sciences (2009). *Life science blueprint*.

http://www.dius.gov.uk/innovation/business_support/~media/publications/O/ols-blueprint

⁵² *Ibid* 51

⁵³ Further information on UK R&D investment can be found at: http://www.innovation.gov.uk/rd_scoreboard/?p=11

⁵⁴ Association of the British Pharmaceutical Industry (2007). *Facts & statistics from the pharmaceutical industry*.

<http://www.abpi.org.uk/statistics/section.asp?sect=1>

⁵⁵ UK Trade and Investment (2009). *Strength and opportunity*. <http://www.berr.gov.uk/files/file53947.pdf>

⁵⁶ Fogel R (2009). *Forecasting the cost of US healthcare*.

<http://www.american.com/archive/2009/september/forecasting-the-cost-of-u-s-healthcare>

⁵⁷ Association of the British Pharmaceutical Industry (2009). *Prescription for innovation*.

<http://www.abpi.org.uk/Details.asp?ProductID=350>

⁵⁸ National Academies of Science (2006). *Rising above the gathering storm: energising and employing America in a brighter economic future*. http://www.nap.edu/catalog.php?record_id=11463

⁵⁹ Bioscience Innovation Growth Team (2009). *Review and refresh of bioscience 2015*.

<http://www.berr.gov.uk/files/file49805.pdf>

⁶⁰ Darzi A (2008). *High quality care for all: NHS next stage review final report*.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

⁶¹ *Ibid* 51

rehearse the arguments set out in these reports here, save to emphasise some key incentives that will allow the UK to compete effectively for new commercial investment in medical research:

- Adopting an approach to drug pricing and reimbursement through National Institute for Clinical Excellence (NICE) appraisal that balances the need to deliver value for money for the NHS with the need to support and nurture innovation.⁶²
- A tax regime that provides incentives for international pharmaceutical companies to invest in the UK by providing a fiscal environment that can compete with countries, such as Ireland and Singapore, which are attracting significant investment in the life sciences.
- Mechanisms to improve the uptake of innovative medicines and technologies, such as rapid approval of genuinely new drugs using innovation 'passes' or conditional licensing.⁶³
- Direct government investment to stimulate and increase the demand for R&D, similar to the successful Small Business Innovation Research (SBIR) programme.⁶⁴
- Encouraging academic researchers to engage in effective exploitation of their research through incentives such as reinvestment of all income on royalties from MRC Technology into medical research.⁶⁵

We recommend using a range of instruments to drive investment and stimulate the development of novel therapeutics, diagnostics and devices, including flexible pricing, public procurement strategies, tax incentives and new pathways to support uptake and access to medicines.

The medical science industries are undergoing a set of important challenges linked to a lack of risk capital and declining return on investment.⁶⁶ However, this period of uncertainty in the sector occurs during a highly productive phase in non-commercial research and there are now many opportunities involving different therapeutic targets and in areas of significant unmet medical need. To capitalise on these opportunities and boost innovation and productivity, larger pharmaceutical companies are increasingly outsourcing R&D, which presents exciting possibilities for small and medium-sized enterprises (SMEs) and for the academic community. The UK is already home to several impressive examples of industry-academia collaborations that can take advantage of these new opportunities and we encourage such alliances. Examples include:

- Pfizer and the University College London Institute of Ophthalmology have developed a collaboration to advance the development of stem cell based therapies.⁶⁷
- AstraZeneca and the University of Manchester have developed a collaboration to deliver safe and effective medicines to patients.⁶⁸

⁶² Academy of Medical Sciences FORUM (2007). *Optimising stratified medicines R&D: addressing scientific and economic issues*. <http://www.acmedsci.ac.uk/p50evid79.html>

⁶³ Office of Life Sciences (2009). *Life science blueprint*. http://www.dius.gov.uk/innovation/business_support/~/_/media/publications/O/ols-blueprint

⁶⁴ Further information is available from http://grants.nih.gov/grants/Funding/sbirstr_programs.htm

⁶⁵ Further information is available from <http://www.mrc.ac.uk/Newspublications/News/MRC004293>

⁶⁶ Bioscience Innovation Growth Team (2009). *The review and refresh of bioscience 2015*. <http://www.berr.gov.uk/files/file49805.pdf>

⁶⁷ Further information is available from <http://www.ucl.ac.uk/iao/news090424.php>

⁶⁸ Further information is available from <http://www.manchester.ac.uk/business/working/astrazeneca/>

- GlaxoSmithKline, Imperial College London and the MRC have established a Clinical Imaging Centre.⁶⁹
- The Division of Signal Transduction Therapy (DSTT) is a collaboration between scientists in the MRC Protein Phosphorylation Unit and the College of Life Sciences at the University of Dundee and AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Merck-Serono and Pfizer.⁷⁰

Partnerships across the sectors – industry, academia, charities, the NHS and patients – are being forged and strengthened to translate medical research for patient benefit. The planned UK Centre for Medical Research and Innovation (UKCMRI) is a prime example of a partnership between these groups (see Box 5). Such projects can leverage substantial support from industry and allow the UK to capture industrial investment as companies externalise more of their R&D (see Section 4).^{71,72}

Box 5 Cross sector partnerships: the UK's Centre for Medical Research and Innovation (UKCMRI)

The plans for a unique £500 million medical research partnership to create UKCMI - a world-class centre for medical research in London highlight the potential of cross-sector partnerships.⁷³ The MRC, Cancer Research UK, the Wellcome Trust and University College London are funding the new Centre, and partnerships with the NHS will enable translation of groundbreaking scientific discoveries into new treatments for a range of diseases.

Funders are increasingly working together to maximise the impacts of their skills, resources and expenditure. In particular the UK Clinical Research Collaboration (UKCRC) has brought together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia in a UK-wide environment to tackle long-standing problems such as research regulation and to coordinate funding. In addition, the Academy's FORUM, an active network of scientists from industry, academia and the public sector, plays an important role in facilitating, promoting and informing relationships between these groups.⁷⁴

In the longer term, however, more effort is needed to foster a collaborative research and innovation culture. Despite recent progress that has brought extensive collaboration between the NIHR and industry, the rest of the NHS still does not fully engage with the medical science industries, although the recommendations outlined in Section 1 should help to address this challenge. The mobility of researchers is also an important part of this agenda: exchanging skills, forging opportunities and promoting mutual awareness (see Section 7).

⁶⁹ Further information is available from <http://cic.gsk.co.uk/>

⁷⁰ Further information is available from <http://www.lifesci.dundee.ac.uk/dstt/>

⁷¹ Alzheimer's Research Trust (2009). *Forward together. Complementarity of public and charitable research with respect to private research spending.* <http://www.alzheimers-research.org.uk/assets/docs/20090917162138ForwardTogetherSep2009.pdf>

⁷² Academy of Medical Sciences (2008). *The UK pharmaceutical industry: what does the future hold?* <http://www.acmedsci.ac.uk/p50evid90.html>

⁷³ Further information is available from <http://www.ukcmri.ac.uk/>

⁷⁴ Further information is available from <http://www.acmedsci.ac.uk/p23.html>

We recommend encouraging alliances between the NHS, universities and industry to share the risk and reward associated with generating more cost-effective and novel therapeutics, diagnostics and devices.

4. Publicly funded health research needs further coordination

Medical research offers substantial health, economic and social rewards. A 2008 report commissioned by the Academy of Medical Sciences, Wellcome Trust and MRC demonstrated that every £1.00 invested in public or charitable research into cardiovascular diseases in the UK between 1975 and 1992 produced a stream of health and economic benefits equivalent to earning £0.39 per year in perpetuity.⁷⁵ Public investment in medical research must be sustained and delivered in a coordinated fashion to ensure maximum impact and to continue to leverage many times its value in funding from industry (see Box 6) and charities.

Box 6 Leveraging private investment

Public and charitable investment in medical science stimulates additional private investment. A recent report commissioned by the Alzheimer's Research Trust found that every £1 of public or philanthropic spending on basic research can lead to an increase of £8 in private investment over the following eight years. The same report found that every £1 *increase* in public spending on medical research stimulates investment of £2 to £5 in research by the pharmaceutical industry.⁷⁶

Medical research has benefited from the recent uplift in public sector investment in health science, which is now around £1.6 billion per year.⁷⁷ To tackle rising public debt and the budget deficit, decision makers in the UK are looking to the fiscal consolidation policies applied by countries, such as Sweden and Canada, during their recessions in the 1990s. The next UK Government must consider the potential impact of the approaches taken by these countries on the short and long-term health of the science base, particularly given the role that medical science can play in reinvigorating the UK economy and making the NHS and public services more cost-effective, efficient and productive.

To create the best environment for future research and to help resolve major global health challenges, sustained science funding is required to support our universities, foster a pool of talented medical scientists and generate the ideas for commercialisation and improvement of health. Medical science is a long-term endeavour so major reductions in funding will cause significant harm. Areas of research that are cancelled before they can deliver represent wasted investment. Moreover, subsequent loss of staff and expertise mean that projects and research areas cannot easily be resumed if funding subsequently becomes available.

In promoting coordination of the strategies of the MRC and NIHR, OSCHR has made substantial progress towards improving the cost effectiveness of funding and making UK

⁷⁵ Health Economics Research Group at Brunel University, Office of Health Economics and RAND Europe (2008). *Medical research: what's it worth?* <http://www.acmedsci.ac.uk/index.php?pid=99&puid=137>

⁷⁶ Alzheimer's Research Trust (2009). *Forward together. Complementarity of public and charitable research with respect to private spending.* <http://www.alzheimers-research.org.uk/assets/docs/20090917162138ForwardTogetherSep2009.pdf>

⁷⁷ Further information is available from <http://www.publications.parliament.uk/pa/cm200910/cmhansrd/cm091201/text/91201w0019.htm>

health research more coherent.⁷⁸ Crucially the ring fence around the health research budget coordinated by OSCHR has been vital in safeguarding the research agenda from the healthcare pressures in the NHS and providing confidence in the UK's commitment to health research.⁷⁹

We recommend maintaining a ring fence around the budgets held by the MRC and NIHR.

It is possible that in the near future a reorganisation of science funding will be considered in an attempt to provide improved value for money from the science budget. This will present an opportunity to consider different structures for the delivery of the health research budget that can further facilitate rapid translation of research findings into health and economic benefits. The experiences of other countries will be important when considering how best to integrate research into healthcare systems.

The strengthened relationship between the MRC and NIHR created through OSCHR has transformed the UK health research landscape, and the gains made in coherence across health research must be protected.⁸⁰ Any reorganisation of research funding **must** avoid any further separation of the MRC and NIHR or distance them from the NHS. The research functions of the health services in the Devolved Administrations must form an integral part of a single coherent UK health research strategy. Also important are the relationships between the MRC and the other Research Councils, as many contemporary medical science challenges require interdisciplinary collaboration with the biological, physical, mathematical, engineering and social sciences. Links between publicly funded health research and research conducted by industry and charities are also vital to ensure scientific advances are translated into patient benefit.

Despite the major improvements since the formation of OSCHR there are still significant discontinuities to overcome, particularly in the area of public health where difficulties in defining remits and multiple government departmental and agency responsibilities have hampered progress (see Section 5). Further co-ordination and integration in the way funding is organised would promote the iterative cycle of ideas that should exist between the laboratory, clinical and population sciences rather than perpetuating the false dichotomy between 'basic' and 'applied' research.

We recommend protecting and building on the successes of OSCHR, to ensure basic biomedical and translational science are managed in a coordinated fashion. The UK should further strengthen health research by maintaining and enhancing coordination of the MRC and NIHR, in close collaboration with the NHS. The relationship with other scientific disciplines, industry, charities and the Devolved Administrations are crucial determinants of a successful health research agenda.

⁷⁸ Office for the Strategic Coordination of Health Research (2008). *Chairman's first progress report*. http://www.nihr.ac.uk/files/pdfs/OSCHR_Progress_Report_18.11.08.pdf

⁷⁹ Department of Health (2006). *Best research for best health: a new national health research strategy* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127127

⁸⁰ *Ibid* 78

5. Public health challenges must become cross-Departmental priorities

The UK faces major health challenges in the future, such as the ageing population, pandemics and obesity. Many of these threats can only be fully addressed through public health measures that improve the health and well-being of the population as a whole and prevent disease before it reaches the clinic. The focus of the NHS needs to shift from one that treats acute disease to a health service that encompasses prevention and management of chronic conditions.⁸¹ Public health policies that focus on increasing healthy life expectancy must be enacted across government to tackle the wider causes of disease.⁸²

The social and economic conditions in which people live contribute substantially to their health.⁸³ Indeed, life expectancy falls by around one year for every station travelled eastwards on the Jubilee underground line in London from Westminster to more deprived Canning Town.⁸⁴ Research will help us understand the complex web of health determinants and much greater efforts are urgently needed to develop suitable public health interventions. Of particular importance is research into preventive measures, interventions that can change health behaviours, health inequalities and genomic medicine, which will help us to understand, prevent and tackle disease before it becomes clinically manifest. This will in turn make both collective public health policies and individual actions more effective, thereby reducing the burden of ill-health on public services. Modest investment *now* can prevent much more costly disease in the future.

Frequently, public health policies offer additional benefits beyond health as they often converge with the policies needed to tackle other government priorities such as promoting the aspirations of young people and poverty reduction. Conversely the policies needed to tackle other government priorities can also benefit public health. An example is given in Box 7 that considers the health co-benefits of tackling climate change.

The many causes of disease and corresponding opportunities for intervention mean that responsibilities in public health issues cut across nearly every government department. Effective co-ordination between departments can ensure the co-benefits of individual policies are maximised and that policies to improve public health are not undermined by those introduced in other parts of government. However, the UK has yet to achieve sufficient coordination of government policies and investment to harness fully the potential of public health research and delivery (see Section 4).

⁸¹ Wanless D (2004). *Securing good health for the whole population*. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4074426

⁸² Academy of Medical Sciences (2009). *Rejuvenating ageing research*. <http://www.acmedsci.ac.uk/p99.html>

⁸³ *Ibid* 82

⁸⁴ Marmot M (2009). *Overview of the review of health inequalities in England post 2010*. <http://www.ucl.ac.uk/gheg/marmotreview/overview>

Box 7 The health co-benefits of tackling climate change

Climate change is a serious global threat that requires an urgent global response.⁸⁵ There is now emerging evidence that the measures needed to tackle climate change might also offer health benefits, adding force to the already compelling arguments to reduce emissions.⁸⁶

More detailed consideration of the health benefits of climate change mitigation is given in a series of articles of which the Academy of Medical Sciences was a sponsor; specific examples include the following:

- Replacing car journeys with walking and cycling in urban areas would increase physical activity, thus improving cardiovascular health and reducing cerebrovascular disease, depression, dementia and diabetes.⁸⁷
- Falls in livestock production as part of wider efforts to curb emissions could reduce consumption of saturated fat from animal products and could in turn reduce the burden of ischaemic heart disease in the UK by around 15%.⁸⁸
- Low-emission stoves in developing world countries, such as India, would reduce childhood respiratory infection and adult heart and lung disease.⁸⁹
- Changing modes of electricity generation, particularly in the developing world, would reduce levels of particulates that cause cardio-respiratory disease and lung cancer.⁹⁰

Ensuring that the health co-benefits of mitigation of climate change are realised will involve co-ordinated action by many government departments, such as the Department of Transport; the Department of the Environment, Food and Rural Affairs; the Department of Energy and Climate Change; the Department of Health; the Department of Children Schools and Families; and the Devolved Administrations.

Political support is required at the highest level to coordinate, facilitate and incentivise cross-departmental working along with appropriate inter-departmental structures and funding. Proposals from the Cabinet Secretary to create single budgets for cross-departmental challenges, such as obesity and Alzheimer's disease, and to make Ministers responsible for delivery across government could incentivise more effective coordination.⁹¹ Even the creation of a Department of Public Health, suggested by some, would not preclude the need for improved coordination across Government.

⁸⁵ Academy of Medical Sciences (2009). *Mitigating climate change: improving global health*. <http://www.acmedsci.ac.uk/index.php?pid=99&puid=168>

⁸⁶ Haines A, et al. (2009). *Public health benefits of strategies to reduce greenhouse-gas emissions: overview and implications for policy makers*. *Lancet* **374 (9707)**, 2104-2114.

⁸⁷ Woodcock I, et al. (2009). *Impact on public health effects of strategies to reduce greenhouse gas emissions: urban land transport*. *Lancet* **374 (9707)**, 1930-1943.

⁸⁸ Friel S, et al. (2009). *Impact on public health strategies to reduce greenhouse gas emissions: food and agriculture*. *Lancet* **374 (9707)**, 2016-2025.

⁸⁹ Wilkinson P, et al. (2009). *Impact on public health strategies to reduce greenhouse gas emissions: household energy*. *Lancet* **374 (9707)**, 1917-1929.

⁹⁰ Markandya A, et al. (2009). *Impact on public health of strategic to reduce greenhouse gas emissions: low carbon electricity generation*. *Lancet* **374 (9707)**, 2006-2015.

⁹¹ Sherman J (2009). *Sir Gus O'Donnell warns of sweeping cuts in public services*. <http://www.timesonline.co.uk/tol/news/politics/article6715497.ece>

The ageing population, rising public expectations and the chronic diseases associated with unhealthy lifestyles are likely to increase the cost of healthcare in the future. New technologies and knowledge enable us to evaluate the cost-effectiveness of health interventions in a different way. An integrated public health agenda founded on a thriving research base and strong NHS could make the economics and success of treatment far superior in the future.

We recommend establishing budgets and strategies for specific public health priorities that fund research and service delivery across Government departments.

Policy-makers often have to make public health decisions rapidly using existing research evidence rather than waiting for further research to be generated and completed.⁹² It is therefore necessary to integrate vigorous piloting into the implementation of new public health policies and practice, which may mean a new policy is modified or reconsidered. Natural experiments, such as differences in the way that individual NHS Trusts have tackled particular health challenges, offer another opportunity to understand better which policies are most effective.

Since even well-evidenced policy changes may not bring about expected benefits, it is crucial that changes be introduced in a manner that allows rigorous evaluation, and that funds are provided for such evaluation. Although scientific evidence is not the only factor that must be considered when making public health policy, scientists do have a vital role to play in providing and interpreting evidence. Policy-makers should, however, be transparent about the extent to which public health policies are based on scientific considerations.⁹³

We recommend ensuring that all new public health policies are supported by evidence-based decision-making, robust piloting and rigorous evaluation throughout implementation.

⁹² Academy of Medical Sciences (2007). *Identifying the environmental causes of disease: how do we know what to believe and when to take action?* <http://www.acmedsci.ac.uk/p99puid115.html>

⁹³ House of Commons Science and Technology Select Committee (2006). *Scientific advice, risk and evidence based policy making*. <http://www.publications.parliament.uk/pa/cm200506/cmselect/cmsctech/900/900-i.pdf>

6. Health research should be used as a driver of foreign policy and international development

The next UK government must seize the opportunities offered by medical science to tackle the major international threats to UK health and alleviate the disproportionate burden of disease experienced by the world's poorest people. Our increasingly interdependent world means that many health issues, such as pandemic influenza and drug-resistant tuberculosis, present just as much danger to the UK as anywhere else. The moral case for research into the health issues that affect poorer countries is strong. Average life expectancy in the UK at birth is currently around 80 years, whereas in some African countries it is under 50.^{94,95} Improving health in poorer countries through research offers wider benefits too. The Global Peace Index, for example, shows the importance of health services and higher life expectancy in bringing peace, which can in turn improve international security.⁹⁶

At the heart of international efforts to meet the needs of the world's poor are the eight Millennium Development Goals (MDGs); three of which directly concern health and would benefit particularly from health research:⁹⁷

- MDG 4: reduce childhood mortality.
- MDG 5: improve maternal health.
- MDG 6: combat HIV/AIDS, malaria and other diseases.

Chronic non-communicable diseases, such as heart disease, cancer and diabetes, also present an increasing development challenge; they already account for around 60% of all deaths worldwide and their incidence in low and middle-income countries is growing.⁹⁸

Given its fundamental importance, health research should clearly be at the heart of UK foreign and international development policy. Despite recent efforts, however, the full potential of medical science has not been brought to bear on the health problems of the developing world. Currently only around 10% of worldwide expenditure on health research and development is devoted to problems that affect 90% of the world's population, and 31 richer countries account for the overwhelming majority of the world's most highly cited publications in science and engineering.^{99,100}

Recently there has been much debate about the effectiveness of aid and international development.¹⁰¹ Discussion has been further focused by the global economic downturn, which is likely to make funding increasingly scarce. All UK funded programmes to tackle

⁹⁴ World Health Organisation (2008). *Closing the gap in a generation*. http://whqlibdoc.who.int/publications/2008/9789241563703_eng.pdf

⁹⁵ Office of National Statistics (2009). *Life expectancy at birth and at age 65 by local areas in the United Kingdom*. <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=8841>

⁹⁶ Further information is available from <http://www.visionofhumanity.org/index.php>

⁹⁷ Institute of Medicine (2008). *The US commitment to global health: recommendations for a new administration*. <http://www.iom.edu/Reports/2008/The-US-Commitment-to-Global-Health-Recommendations-for-the-New-Administration.aspx>

⁹⁸ Daar AS, et al. (2007). *Grand challenges in chronic non-communicable disease*. *Nature* **450**, 494–496.

⁹⁹ Global Health Forum (2004). *10:90 Report*. Global Health Forum, Geneva, Switzerland.

¹⁰⁰ King DA (2004). The scientific impact of nations. *What different nations get for their research spending*. *Nature* **430**, 311–316.

¹⁰¹ Easterly W (2006). *The white man's burden: why the West's efforts to aid the rest have done so much ill and so little good*. Barns and Noble, New York.

disease in resource-poor settings should be rigorously evaluated to ensure that scarce resources are used cost-effectively.

We recommend that health research should be central to UK foreign policy and should underpin all efforts to tackle disease in resource-poor countries.

Medical scientists are an invaluable national and international resource, yet many poorer countries have too few researchers to address their particular health challenges. All too often the brightest and best scientists move from their home countries, depleting already scarce local expertise. A strong medical research workforce offers the opportunity to tackle specific local health problems, with an understanding of indigenous societal and cultural considerations, that may be neglected by scientists from elsewhere. Medical research professionals strengthen local health and public services, can help drive economic growth, and can advise national governments and decision-makers on appropriate policy. They also facilitate participation in fruitful international scientific collaborations, such as mapping the human genome or large clinical trials of vaccines. Without indigenous research capacity and infrastructure, poorer countries will find it difficult to address their own health needs in the long-term, so will continue to require assistance from richer countries.

Despite its importance, indigenous capacity building in medical research is often not prioritised by international research funders, or it is undertaken in ways that are not sustainable over the longer-term. Initiatives to develop a critical mass of people, intellect and resources are required in low and middle-income countries, along with a satisfactory career structure and a clear strategic vision.¹⁰² To be effective, efforts to build research capacity need to be accompanied by capacity building in areas such as education and health services. Capacity building in research should concern the whole spectrum of laboratory, clinical and population sciences.¹⁰³ Partnerships between institutions in the global 'North' and global 'South' can be valuable in building capacity but must be both sustainable and equitable.¹⁰⁴ We welcome the Wellcome Trust's African Institutions Initiative that aims to strengthen research capacity in Africa, and look forward to the findings of the rigorous evaluation of its outcomes; we encourage other research funders to support similar sustainable capacity-building measures.¹⁰⁵

We recommend that greater efforts are made by the UK Government to support indigenous research capacity in resource-poor countries.

¹⁰² Academy of Medical Sciences (2009). *Global health perspectives*.

<http://www.acmedsci.ac.uk/index.php?pid=98&puid=167>

¹⁰³ Academy of Medical Sciences (2009). *Research in general practice: bringing innovation into patient care*.

<http://www.acmedsci.ac.uk/p20.html>

¹⁰⁴ Weatherall D, *et al.* (2005). *A case for developing North-South Partnerships for research in sickle cell disease*. *Blood* **105**, 921–923.

¹⁰⁵ Further information is available from <http://www.wellcome.ac.uk/Funding/Biomedical-science/Grants/Other-initiatives/WTD028338.htm>

7. The UK must build a world-class biomedical workforce for our knowledge economy

The capacity and composition of the UK's medical research workforce is central to maximising the potential of the UK's rich bioscience base and ensuring research is translated into benefits for patients and society. We must nurture and develop a pool of talented bioscience professionals – across the academic and private sectors – who are equipped with the full range of skills needed to advance understanding and develop novel interventions and diagnostics for major diseases.

Innovative medical research and the delivery of mainstream clinical medical services depend on:

- Discoveries and innovations by researchers working within the NHS, Higher Education (HE) institutions, research institutes, primary care and industry.
- Excellence in teaching and education that inspires the next generation.
- Medical management and administration of healthcare delivery.
- Clinicians involved in public service roles, developing policies at the national and local level.
- Activities and outreach to encourage public engagement in medical science and align research with society's needs.

The UK must promote and sustain this range of expertise, to achieve excellence in all aspects of research and medical practice.

Interdisciplinary working is increasingly required for innovative medical research. Cross-fertilisation of traditional clinical academic disciplines from a wider range of relevant basic and clinical research areas must be encouraged (see Box 8).

As previously highlighted, the excellence of the UK's HE system is a key factor in attracting medical science businesses to the UK and retaining them. We are therefore concerned by the recent announcement of a £398 million cut to the annual funding of English universities that will impact on teaching and capital expenditure.¹⁰⁶ Pre-dating these cuts, a succession of inquiries had raised concerns about the supply of the skills needed by UK pharmaceutical and biotechnology companies. A survey of pharmaceutical companies by the Association of British Pharmaceutical Industry (ABPI) identified current skill shortages predominantly in the *in vivo* science disciplines (e.g. physiology, pharmacology and clinical pharmacology, toxicology and pathology) and chemistry.¹⁰⁷ Skills gaps in the drug development pipeline need to be addressed, and recent steps to encourage partnership between the HE sector and industry in addressing capacity and competency should be encouraged.

¹⁰⁶ Mandelson P (2009). *Higher education funding 2010-11*.

<http://www.hefce.ac.uk/news/hefce/2009/grant1011/letter.htm>

¹⁰⁷ Association of British Pharmaceutical Industry (2008). *Skills needs for biomedical research. Creating the pools of talent to win the innovation race*. <http://www.abpi.org.uk/publications/pdfs/2008-10STEMSkillsReviewReportFINALamended2.pdf>

Box 8 Promoting interdisciplinary working

Many of the challenges currently facing medical science today, such as ageing or inflammation, require close collaboration and interactions between disciplines that have traditionally operated within different university departments, schools and faculties. Although the promotion of interdisciplinary working should not detract from excellent research in single disciplines, there has long been recognition of the value of such interdisciplinary collaboration. The successful sharing of a common research agenda, however, remains the exception rather than the rule.

The development of talented interdisciplinary researchers and clinicians can be achieved by:¹⁰⁸

- Creating funding opportunities that combine more conventional biomedical and clinical disciplines with 'technology platforms' in the biological sciences (e.g. genetics, genomics and proteomics), advances in engineering science (e.g. in imaging, computing, medical device technology and robotics), and advances in chemistry, in statistical mathematics and in the social sciences.
- Generic training positions that allow suitable individuals to be supported on an opportunistic basis and provide a broad range of training possibilities outside the conventional boundaries of their specialty.
- Informal 'osmosis' of ideas through physical co-location and shared infrastructure that encourages scientists from different disciplines to spend time together.
- Multi-level networking to encourage senior academics from different departments who have the initial visions for interdisciplinary projects to interact more easily with the junior academics who take them forward.
- Proactive management of integrated working through strong leadership, clear shared goals, and mutual understanding of methods of working and definitions of success.
- Capitalising on mid- and late-career researchers by encouraging established academics to work in different fields.
- High-level support from the home institution, with commitment of funds to posts and infrastructure.

Efforts to build research capacity need to be coordinated to provide the most effective support for critical research areas. There is a need for a skills strategy that identifies current gaps and future needs, and embraces private and public research to underpin the complex processes of translating research into health and economic benefits. In addition to the current gaps outlined above, capacity in areas such as ageing, bioinformatics, clinical pharmacology, molecular pathology, quantitative sciences, modelling, genetic epidemiology, systems biology and clinical epidemiology will be crucial in the future.^{109,110,111}

¹⁰⁸ Academy of Medical Sciences and the Royal Academy of Engineering (2006). *Systems biology: a vision for engineering and medicine*. <http://www.acmedsci.ac.uk/p48prid4.html>

¹⁰⁹ Academy of Medical Sciences (2009). *Rejuvenating ageing research*. <http://www.acmedsci.ac.uk/p47prid62.html>

¹¹⁰ *Ibid* 107

¹¹¹ Academy of Medical Sciences FORUM (2009). *Genome-wide association studies: understanding the genetics of common diseases*. <http://www.acmedsci.ac.uk/p48.html>

We recommend better coordination of efforts to build UK biomedical research capacity, focusing on developing interdisciplinary researchers and workers in key areas of current and future need, including quantitative science and bioinformatics, systems biology, ageing, physiology and pharmacology.

To flourish, the NHS requires a clinical workforce and leadership trained to use research and innovation for patient benefit. As discussed in Section 1, academic values and the spirit of enquiry must pervade the NHS. A thriving research and training environment is vital to attract and sustain a first-class workforce, and a culture of research and scholarship should be integral to all medical schools. Clinical academics should be given sufficient time to undertake research, teaching and health service delivery, all of which are of enormous value to the health of the nation.¹¹²

A major achievement of the NIHR has been to promote innovative partnerships between the NHS and research institutions through several schemes and programmes. This approach is helping to reassert academic endeavour as a vital role of clinicians and to promote a better understanding of the contributions clinical academics make to the NHS.

A key priority is to promote the mobility of researchers between industry, academia and the NHS – to exchange skills, to forge opportunities for cross-sector working, and to promote mutual awareness.¹¹³ We welcome the proposals from the Higher Education Funding Council for England (HEFCE) to put greater value on mobility between the academic, commercial and health service sectors, as part of the new Research Excellence Framework.¹¹⁴ However we are concerned that current proposals for revalidation (the relicensing and recertification of doctors on the GP or specialist register to ensure they remain fit to practice) might have serious unintended consequences in limiting the scope, flexibility and mobility of the academic medical workforce. Unless the revalidation process recognises the important roles played by clinicians in research, industry, education, management and policy (and allows them to be revalidated equitably) the UK's ability to deliver high quality clinical research and excellent patient care will be hindered.¹¹⁵

We recommend promoting and supporting biomedical research training for doctors and other healthcare professionals in the NHS, and incentivising the mobility of researchers across academic, industry and healthcare sectors.

¹¹² British Medical Association (2009). *Standing up for doctors. Standing up for health. The BMA manifesto*. BMA, London.

¹¹³ Academy of Medical Sciences (2007). *Careers for biomedical scientists and clinicians in industry*. <http://www.acmedsci.ac.uk/p48prid56.html>

¹¹⁴ Academy of Medical Sciences (2009). *Response to the first HEFCE consultation on the Research Excellence Framework*. <http://www.acmedsci.ac.uk/p100.html>

¹¹⁵ Academy of Medical Sciences (2009). *Position paper on revalidation*. <http://www.acmedsci.ac.uk/p99puid160.html>

Conclusion

We call on the next UK Government to harness the rich opportunities offered by the medical sciences to improve health and wealth for the benefit of patients and society. Medical research will create new jobs, catalyse sustained economic growth and help to restore public finances by improving health and making the NHS and public services more cost-effective and productive. Generous donations to medical research charities and enthusiastic backing of the NHS indicate strong UK public support for medical science. The next UK Government must respond to this chorus of public approval by placing medical science at the heart of its agenda.

Annex I Working group membership

Sir David Cooksey GBE FMedSci (Chair)
Chairman, UK Financial Investments

Professor Fran Balkwill OBE FMedSci
Professor of Cancer Biology and Centre Lead for Translational Oncology, Centre for Cancer and Inflammation at Barts and the London, Queen Mary's School of Medicine and Dentistry

Professor Sir John Bell FRS HonFREng PMedSci
Regius Professor of Medicine, University of Oxford

Professor Carol Dezateux CBE FMedSci
Director of the MRC Centre of Epidemiology for Child Health, Institute for Child Health, University College London

Professor Sir Andrew Haines FMedSci
Director, London School of Hygiene and Tropical Medicine

Professor Ron Laskey FRS FMedSci
Honorary Co-Director of the MRC Cancer Cell Unit, University of Cambridge

Dr Melanie Lee FMedSci
Director, Think10

Professor Sir Alex Markham FMedSci
Professor of Medicine, University of Leeds

Professor Patrick Maxwell FMedSci
Head of the Division of Medicine, University College London

Professor Terence Rabbitts FRS FMedSci
Director of the Leeds Institute of Molecular Medicine, University of Leeds

Professor Jonathan Seckl FRSE FMedSci
Director of Research at the College of Medicine and Veterinary Medicine, University of Edinburgh

Professor Stephen Smith FMedSci
Chief Executive of Imperial College Healthcare NHS Trust and Principal of the Faculty of Medicine, Imperial College London

Professor Patrick Vallance FMedSci
Senior Vice-President for Drug Discovery, GlaxoSmithKline

Observers

Sue Middleton
Director of Corporate Government Affairs, GlaxoSmithKline

Dr Helen Munn
Executive Director, Academy of Medical Sciences

Secretariat

Laurie Smith
Medical Science Policy Manager, Academy of Medical Sciences

Dr Robert Frost
FORUM Manager, Academy of Medical Sciences

Dr Rachel Quinn
Director of Policy, Academy of Medical Sciences



Academy of Medical Sciences
10 Carlton House Terrace
London, SW1Y 5AH

+44(0)20 7969 5288
info@acmedsci.ac.uk
www.acmedsci.ac.uk

Registered Charity No. 1070618
Registered Company No. 3520281