

We are a coalition of charities and organisations who fund and support health research in the UK. We share an interest in the changes proposed by the health and social care bill and the overarching reforms to the NHS and public health system.

We welcome the increased focus on research and innovation that followed the government's listening exercise, which provided a clear signal that the government wishes to foster a culture of research and innovation throughout the NHS and public health system. Further work is needed to define and realise these commitments within the new structures, ensuring effective partnership with existing and newly created bodies.

Our key messages:

The environment across the NHS and public health system must facilitate and strengthen research for the benefit of patients now and in the future. The government should:

1. Give further detail of how the commitments to promote research and innovation will be delivered
2. Develop effective mechanisms to deliver research locally
3. Establish streamlined and robust regulation and governance of health research
4. Integrate meaningful patient and public involvement in research
5. Enable the safe and secure use of patient data for research
6. Develop the health research workforce
7. Support innovation in the NHS

This briefing proposes how this can be achieved through the Health and Social Care Bill and via additional measures that can be taken forward as the health and public health systems are reformed.

Introduction

- Investing in research in the NHS and in public health is vital to improve all aspects of patient care, including prevention, diagnosis and treatment, and ultimately patient outcomes. Research also facilitates the introduction of new innovations and approaches that can in turn save the NHS money. A vibrant research environment in the NHS brings broader societal benefits including employment and investment from the pharmaceutical industry as it makes the UK a more attractive location for research.
- The government is committed to research as a core role of the health system and there is considerable public support for this.
 - The NHS constitution affirms the NHS's 'commitment to innovation and to the promotion and conduct of research to improve the current and future health and care of the population'.
 - The public overwhelmingly believe the NHS should support research into new treatments – 93% believe their local NHS should be encouraged or required to support research.¹
 - The health white paper *Equity and Excellence: Liberating the NHS*, outlined the government's commitment to the promotion and conduct of research as a core role of the NHS.
- In 2009-10, public funders invested almost £3 billion in health research in the UK, with over £1 billion coming from medical research charities. In the same year, over 3,000 clinical studies were conducted in the NHS; 37% were funded by Association of Medical Research Charities (AMRC) member charities.

¹ Ipsos MORI, 2011. *Public support for research in the NHS*. AMRC: London

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- We welcome the government's increased focus on research and innovation. Following the listening exercise, the government has made commitments to:
 - Deliver a new duty within the Health and Social Care Bill for the secretary of state to promote research
 - Deliver a new duty for clinical commissioning groups to promote research and innovation and the use of research evidence, in line with the current duty on the NHS Commissioning Board
 - Ensure that a culture of research and innovation is embedded in the arrangements for both the board and Public Health England
 - Make sure that clinical commissioning groups and the NHS Commissioning Board ensure that treatment costs for patients who are taking part in research funded by government and research charity partner organisations are funded through normal arrangements for commissioning patient care, as set out in existing guidance
 - Establish Public Health England as an executive agency of the Department of Health, ensuring that expert and scientific advice is independent, while at the same time integrating policy and action to allow a more joined-up approach to health protection and emergency planning
 - Include a new duty for the secretary of state to maintain a system for professional education and training.

1. Give further detail of how the commitments to promote research and innovation will be delivered

Issue: To conduct research effectively and efficiently, there needs to be a culture of promoting and undertaking research throughout the NHS and public health system.

*Best Research for Best Health*² heralded significant improvement in the clinical research environment in the UK, taken forward by the work of the National Institute of Health Research (NIHR). However parts of the NHS currently do not successfully engage with research. The government's increased focus on research and innovation provides an ideal opportunity to build on successes, working in partnership with organisations such as NIHR, to create a research-friendly environment throughout the NHS and public health system.

Changes to organisational structures and culture will be needed to support research. This needs the engagement of staff at all levels. Leadership and high-level recognition of the value of research will be particularly important. The new duty on the secretary of state to promote research reflects the core role of research in the NHS and is an important step towards this. However further details are needed on what this duty will mean in practice.

It is essential that the changes to structures and culture needed to promote research and innovation are built into the new health system as it is developed. We are concerned that there is a lack of focus on research and innovation across ongoing developments in the NHS which may reflect a lack of leadership on this issue.

Case study: Initial plans for the NHS Commissioning Board make little mention of research and innovation

The government committed to ensuring that a culture of research and innovation is embedded in the arrangements for the NHS Commissioning Board. On 8 July, the Department of Health published its initial thinking on how the new commissioning system could work and the board's role within this system.² This blueprint contains little reference to research and innovation. For the commissioning board to meet its duty to promote research and innovation and the use of research evidence, these endeavours must be placed at the heart of its foundations.

² Department of Health, 2006. *Best Research for Best Health: A new national health research strategy*. Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127127 [Accessed 6 October 2011]

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Recommendations:

- Clearly define the duty on the secretary of state to promote research to ensure it leads to pro-active, top-down leadership and initiatives to embed research across the system as it is developed and in its long-term operation.
- Develop clear and measurable benchmarks to monitor the conduct of research in the NHS and the performance of those bodies with a duty to promote research.
- The NHS Commissioning Board and Public Health England must provide clear leadership in research and innovation and should have access to health research expertise. Public Health England should be accountable to an autonomous board ensuring the independence of its scientific evidence and advice.

2. Develop effective mechanisms to deliver research locally

Issue: The move to clinical commissioning groups and the greater responsibility for health improvements placed on local authorities needs to be accompanied by efforts to ensure that both these groups are supported and engaged within a positive research culture.

The government is introducing a duty through the Health and Social Care Bill for clinical commissioning groups to promote research and innovation and the use of research evidence, bringing them in line with the research duties placed on other NHS structures and the secretary of state. We welcome this, but are concerned that as clinical commissioning groups are created they should receive the necessary support to establish, coordinate and develop expertise that allows them to engage meaningfully with research.

The bill gives local authorities new public health functions, but does not place a comparable duty on them in relation to research. Research and evidence are a key part of public health, informing effective policies and practice and enabling us to critically evaluate how effective these are. Action must be taken to ensure that they are embedded in public health practice.

Case study: Public health policy and practice can only be effective if informed by research and evidence

Research plays a key role in developing public health policy and practice. Findings from studies on the health effects of high salt intake have led to a reduction in the salt content of processed foods; and research has guided the introduction of new immunisation programmes, such as the meningitis C vaccine that has been extremely successful in controlling the disease. Research is also critical to evaluate whether public health policies and practice are effective. Studies have shown that the number of hospital admissions for heart attacks has reduced since the introduction of the ban on smoking in public places.

Recommendations:

- Ensure support is developed for clinical commissioning groups to establish, coordinate and develop expertise, and engage meaningfully with research, to ensure that this duty does not simply result in a tick box exercise. Provide more detail about how the NHS Commissioning Board will work alongside clinical commissioning groups to embody this role.
- Require and support all bodies with a public health function to engage meaningfully with relevant research. We understand that it may be difficult to place a research duty on local authorities, however it would be valuable to explore how more specific duties and support could be developed, to ensure that local authorities do not become a barrier to public health research.
- Ensure support is maintained for established research collaborations between clinical research networks and NHS organisations throughout this transition period, to ensure that existing research is not impacted negatively and that new links can be forged.

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3. Establish streamlined and robust regulation and governance of health research

Issue: The UK's many strengths in health research are undermined by an overly complex regulatory and governance environment. This is evidenced by a fall in the UK's global share of the number of patients in clinical trials, and by the increase in cost and time to navigate the complex research approval processes.

Case study: Time taken to navigate complex research approval processes

A recent analysis from Cancer Research UK showed that after its funding for a study has been agreed, it now takes an average of 621 days to recruit the first patient.³

The recent Academy of Medical Sciences' review of the regulation of health research in the UK set a vision for a streamlined regulatory pathway with a 'single research regulator'. This received strong support from across the research community. As funders of health research, our priority is to ensure that the regulation of health research in the UK is improved.

The government set out a number of commitments to address this in the *Plan for Growth*, published alongside the 2011 budget. We welcome the legislation that has been introduced to establish a single regulator of health research, the Health Research Authority (HRA), as a special health authority. This will provide a home for the National Research and Ethics Service (NRES). NRES previously sat within the National Patient Safety Agency that is due to be abolished. This government has committed to establishing the HRA in primary legislation in due course, currently planned for the next session of parliament.

The HRA needs to oversee a streamlined pathway for the approval of research studies. It should provide a one-stop shop for ethics and specialist approvals. The HRA must also ensure improvements across NHS R&D permissions and clinical trials authorisation and inspection. It is essential that the government considers the regulation and governance pathway as a whole to avoid further piecemeal reforms that have created many of the difficulties present in the current system. While we welcome the government's intention to undertake these reforms, it is not yet clear whether the proposals will go far enough to resolve the serious barriers identified in the Academy's review.

Recommendations:

- The government must provide a clear and comprehensive vision of the future functions of the HRA and its role in providing coordination and oversight across a single regulatory and governance pathway.
- Provide a clear timetable outlining the further development of the HRA and how this will be aligned with associated improvements across NHS R&D permissions and clinical trials authorisation and inspection.
- Consult on the roles and operation of the HRA to ensure it addresses identified barriers and operates for the good of patients and the public.

4. Integrate meaningful patient and public involvement in research

Issue: Involving patients and the public in research helps deliver high quality, more relevant research. Public involvement can bring invaluable insights that help design better projects, ensure studies are relevant and people-focused and improve recruitment rates.

The NHS constitution undertakes to ensure that patients are notified of opportunities to join in relevant research and are free to choose whether they wish to do so.

Polling shows that people value these opportunities:

- 72% would like to be offered opportunities to be involved in trials of new medicines or treatments if they have a health condition that affects their day-to-day life.

³ Average time from 25 studies approved by Cancer Research UK's Clinical Trials Awards and Advisory Committee during the period November 2006 to July 2007.

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- 80% would like to consider allowing a researcher confidential access to their medical records.
- 88% would be happy to be asked to talk to researchers about their family history or give a sample of their blood to be tested in a laboratory.

Public funders involve patients and the public in decisions over the research they are going to fund. Initiatives such as the UK Database of Uncertainties about the Effects of Treatments (UK DUETs) work with patients, carers and clinicians to identify where more research needs to be done into the effects of treatments. The NHS workforce needs support and leadership to successfully roll out this good practice and meaningfully involve patients and the public in research.

The Future Forum is currently considering support for patient and public involvement as part of its workstream on education and training.

We welcome the ambition of ‘no decision about me without me’ and the focus on the best interests of patients. The moves made by the government to strengthen accountability and public involvement, including a director-level role with responsibility for patient and public engagement on the NHS Commissioning Board, are welcome.

Case study: Patients value opportunities to be involved with research since it helps to improve their outcomes for the future.

‘It should be called the National Health *and* Research Service – not just health.’

AMRC and INVOLVE, 2010. *Patient perspectives on the regulation and governance of medical research.*

Case study: Dementia research

The government has identified dementia research as a priority. To progress in dementia research there is a need to understand early symptoms and test new treatments throughout disease progression. Being able to do this research depends on patients being given the opportunity to participate in research studies at all stages of disease. This could, for example involve giving a small blood donation or taking part in clinical trials. This can only be achieved if patients and the public are offered real opportunities for involvement in all aspects of their care.

However, we are anxious to ensure that the philosophy of patient and public engagement is integrated ‘at all levels of the health and wellbeing system’ and includes research as a core component of that system.

Many research funding applications now require evidence of patient and public involvement in the design and recruitment to the project. This is a valuable step building involvement in research into the system but support is needed to ensure this is meaningful engagement rather than more tokenistic involvement.

Case study: NIHR research funding applications require patient involvement and influence on the research protocols

The recent NIHR-wide call for dementia research proposals asked for patient involvement and influence on the research protocols, how the research outcomes will be disseminated and implemented, and how patients and the public will engage with these activities. Many researchers do not have experience in responding to these questions and need support to do this.

Recommendations:

- Ensure that patient and public involvement in research is embedded throughout the health and public health system.
- Ensure health and public health services with responsibility for patient and public engagement are supported to develop and share best practice, building a culture of involvement throughout the system.
- Ensure professionals across the healthcare workforce will be supported to understand and utilise research so that they can engage with patients and the public effectively about research projects.

5. Enable the safe and secure use of patient data for research

Issue: The information contained in NHS patient records is a rich resource for medical research. Patient data are essential for the delivery of healthcare services and for the recruitment of patients to clinical trials, research to understand disease, and the development of new treatments. A clear framework that enables the safe use of this information for research, while protecting both patients and researchers is vital.

Following ongoing work across the scientific community to improve the environment for using patient data, the *Plan for Growth* published alongside the 2011 budget included an undertaking to publish clearer proposals in autumn 2011.⁴ When revising the bill, the government undertook to 'amend the bill to protect patient confidentiality in a way that supports our plans to drive quality improvement through greater access to information; and to promote high quality research.'

The Future Forum is now leading a workstream focused on how to ensure information improves health, care and wellbeing which will report to the government later this year.

We support the government's ambition to amend the bill to enable greater access to information for research while protecting patient confidentiality. We will participate in the Future Forum's workstream on information and will support work to explore options under consideration by the Department of Health.

The solution must enable the use of both anonymous and identifiable patient information for research. Some research – such as the case study below – could not be conducted without access to potentially identifiable patient information. Although researchers may need to access this data at an individual level, they do not usually want to know the actual identity of the individual.

Case study: The value of research studies requiring the use of identifiable patient information – power lines and the risk of childhood leukaemia

Cancer registries were used to identify 33,000 children with cancer, aged up to 14 years. The study showed that, compared with children who lived greater than 600m from a line at birth, those who lived within 200m had an increased risk of leukaemia (relative risk: 1.69).

This study involved information that a child of a particular age lives in a specific postcode. These two pieces of information alone could enable the identification of an individual child. However, it would not have been feasible – or proportionate – to seek individual consent from all 33,000 children health policies and practice are effective.

Case study: The value of patient data for research to improve healthcare – the Million Women Study

The Million Women Study is a national study of women's health involving more than 1 million UK women aged 50 and over. Information gathered through women self-reporting when recruited and follow-up questionnaires, combined with record linkage with the NHS Breast Screening Programme, cancer registries and the Office of National Statistics, has enabled this study to look at a broad range of health issues. These include hormone replacement therapy (HRT). The study has shown the full health effects of HRT on a range of different diseases which has been of great value to women, enabling more informed choices about the use of such treatment.

Recommendation:

- The government must develop safe and secure systems and governance arrangements that enable researchers to access both anonymous and identifiable patient information for important research, while protecting patients and researchers.

⁴ Academy of Medical Sciences, 2010. Recommendation 10 in 'A new pathway for the regulation and governance of health research'.

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6. Develop the health research workforce

Issue: With the promotion and conduct of research at the heart of the NHS, we need a workforce and leadership trained to demand, understand and utilise research and innovation to improve patient care. Without this, we cannot successfully embed a culture of research and innovation across the health system.

We share the government's desire to develop a world-class, responsive workforce within the health service and welcome the new duty for the secretary of state to maintain a system for professional education and training.

We look forward to contributing to the development of an effective system of workforce planning, education and training and to the publication of further detail in the autumn.

Higher education institutions (HEIs) play a major role in developing the NHS workforce. Effective partnerships between academia and the NHS are already delivering research and innovation. Greater mobility across academic and clinical practice would support efforts to equip the healthcare workforce to utilise the latest knowledge and research to deliver first class patient care.

Recommendations:

- Ensure an effective system of education and training is in place throughout the health and public health reforms.
- Develop a strategy to create an organisation that enables individuals from across the NHS – not just consultants and academics, but also nurses, midwives and therapists – to engage in both research and clinical practice.
- Focus not only on training the next generation of healthcare professionals, but also on developing the 1.3 million healthcare professionals comprising the current workforce.
- Establish Health Education England to strategically coordinate all health education and training across England as soon as possible.
- Develop the new system on the basis of effective piloting and evaluation
- Involve HEIs in workforce planning, education and training, promoting career pathways that offer mobility across academic and clinical practice.

7. Support innovation in the NHS

Issue: Innovation in the NHS – the creation and adoption of new ideas, technologies and processes – is essential for improving patient care. As one of the largest single healthcare systems in the world, the NHS should offer the UK a unique strategic advantage as a resource for medical research and innovation. However in practice the adoption and spread of new innovations within the NHS is often very slow and sometimes even the best of them fail to achieve widespread use. Integrating innovation into the fabric of the NHS would allow the best care to be quickly provided to patients, deliver more cost-effective health services and attract commercial investment and R&D into the UK.

Recognising these difficulties, the NHS chief executive is currently leading a review of innovation in the NHS.

This is a valuable opportunity to review innovation in the NHS and to build the findings into the system as it develops. Steps to foster a culture of innovation, ensure new interventions are evaluated and commissioned in a timely manner and that we have a flexible, skilled health research workforce that can engage with these new interventions will ensure that new research is translated into benefits for patients.

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Case study: Brain tumour treatment which experienced considerable delays coming to market

Temozolomide is an important treatment for glioblastoma – an aggressive form of brain tumour and the most common primary brain tumour in adults. The use of temozolomide both during radiotherapy and for six months post radiotherapy is now the gold standard treatment for most cases of glioblastoma. Temozolomide was developed in the UK, with work originally starting in the late 1970s at Aston University in Birmingham, where Professor Malcolm Stevens led a team of Cancer Research UK-funded pharmaceutical scientists. There were considerable delays bringing this treatment to market in the UK. Since its introduction, the drug has achieved sales of over \$1 billion.

Recommendations:

- A culture of innovation must be embedded into the new NHS structures, including the approach taken by the NHS Commissioning Board and clinical commissioning groups. Initiatives focused on supporting innovation should not be viewed separately from the overarching changes to the NHS and public health system.
- A focus on adopting new ideas and technologies must not be at the cost of nurturing early stage research throughout the system.

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Supporting organisations:

