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Professor Steve Field
Chair, NHS Future Forum
NHS Modernisation Listening Exercise
Room 605, Richmond House
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31 May 2011

Dear Professor Field,

RE: Building research into the structure of the NHS – submission to the NHS Future Forum

The Health & Social Care Bill proposes extensive changes to the structure of the health system in the UK. This will have a significant impact on health research in the UK and our ability to improve patient care for the future.

The Government outlined in their White Paper Equity and Excellence: Liberating the NHS their commitment to the promotion and conduct of research as a core role of the NHS.

A coalition of charities and organisations sharing an interest in health research – including the Association of Medical Research Charities, the Wellcome Trust, Cancer Research UK, British Heart Foundation and the Academy of Medical Sciences – have come together to ensure the proposals in the Health & Social Care Bill deliver this commitment.

We enclose a briefing identifying the key issues for health research raised by the bill and proposing solutions to create an environment in the health system that facilitates and builds research for the benefit of current and future patients.

Our key messages to embed and support research throughout the NHS and public health system are:

- A duty to promote research must be embedded throughout the system
- Mechanisms must be developed to mitigate the impacts of localisation on research
- The payment of excess treatment costs must be clarified in the new commissioning structures
- Incentives must be created for research
- Independent advice to government must be maintained
- The system must support and strengthen meaningful patient and public involvement in research.

Becky Purvis is acting as lead contact for the coalition and can be contacted on 020 7685 2626 or b.purvis@amrc.org.uk.

Yours sincerely,

Lord Willis
chair
Association of Medical Research Charities

The Academy of Medical Sciences

Alzheimer's Research UK
Defeating Dementia

Support • Leadership • Influence

Building research into the health system:

Embed and support research throughout the NHS and public health system

We are a coalition of charities and organisations funding and conducting health research in the UK who share an interest in the changes proposed by the Health and Social Care Bill.

The Health and Social Care Bill proposes extensive changes to the structure of the health system in the UK. This will have a significant impact on our ability to conduct health research and bring about innovation, which are essential to improve patient care in the future.

The health reforms present an opportunity to improve health in the UK; research and the use of evidence are key to achieving this goal.

This briefing identifies issues for health research raised by the bill and proposes solutions to create an environment in the NHS and public health system that facilitates and builds research for the benefit of current and future patients.

Together, these recommendations will ensure we embed and support research throughout the NHS and public health system.

Embed a duty to promote research throughout the system

Issue: **To conduct research well, there needs to be a culture of promoting and conducting research throughout the NHS and the public health system. Currently, a lack of engagement at just one level can result in delays, increased bureaucracy and potentially act as a barrier to research.**

Case study 1.1: ***Role of GPs in informing patients about research***
GPs should be a key contact between patients and the public and researchers. 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. To help deliver this commitment, GPs must be engaged and informed about research.

The many pressures that GPs face can make it difficult to engage with research as a key component of good patient care in the doctors' surgery. At present, therefore, GPs can be a barrier to research leading to difficulties in recruiting patients to trials, impacts on accessing patient data for research and can halt research projects. These problems could be exacerbated as GPs take greater responsibility for commissioning in the new system.

Recent research, funded by the UK Clinical Research Collaboration (UKCRC) Public Awareness Sub-Group on Patient Data and led by AMRC, explored patient and GP understanding and acceptance of the use of patient data in research. This highlighted significant obstacles at GP level to facilitating data-sharing.

Case study 1.2: ***Difficulties in getting NHS R&D permissions across multiple individual NHS trusts***
NHS trusts review and assess every research application before deciding whether to grant R&D permissions to allow it to go ahead. Each NHS organisation is a separate legal entity and has a legal duty of care for its patients. A research project spanning multiple NHS sites needs R&D permissions to be granted separately by each of these sites. However individual trusts vary significantly in their research activities. Many take a risk-averse approach to research when granting permissions. Until permissions are granted by all sites involved, research projects can be delayed or stopped.

››Recommendations:

High-level recognition of the value of research will lead organisational change from the top, underpinning pan-organisational engagement with research.

- The bill places a duty on the secretary of state to take such steps as they consider appropriate for the purpose of protecting the public from disease or other dangers to health. Although these steps can include research, the secretary of state does not have a specific duty towards research. To reflect the core role of research in the NHS, we therefore recommend that there should be a direct duty on the secretary of state to promote research.

Building research into the health system

A culture which values and utilises research must be fostered across the NHS and public health system, including the NHS Commissioning Board, commissioning consortiums, Public Health England and local authorities. Legislative and policy development steps to support this include:

- A senior 'research champion' should sit on the NHS Commissioning Board to ensure that research is promoted within the NHS.
- The secretary of state's mandate to the NHS Commissioning Board should include research within its remit.
- The NHS Commissioning Board should include members with expertise or experience in health research, and these members should act together as a sub-committee dedicated to research.
- The bill currently gives commissioning consortiums a power to conduct research or assist any person to conduct research. A duty should be placed on consortiums to assist and support the NHS Commissioning Board in relation to research and provide a specific power to promote and take part in research and education. The power in the bill allowing consortiums to group together in the exercise of their functions and establish pooled funds would protect against individual consortiums struggling to meet this duty and support collaboration and partnership in delivering research objectives. This would also introduce consistency to the research duties placed across NHS structures by the bill.
- At least one member of each consortium should have special responsibility to promote research.
- Public Health England and local authorities should have duties to promote research and the use of evidence in public health services.

Mitigate the impacts of localisation on research

Issue: **The move to GP commissioning and the greater responsibility for health improvements placed on local authorities means that there are likely to be many more commissioners and bodies involved in research projects. This requires coordination of funding streams and permissions across a greater number of bodies, increasing the likelihood of costly delays to research projects.**

››Recommendations:

The system must be designed to recognise the value of research. As policy is developed, processes will need to be established to streamline and co-ordinate different bodies nationally. Effective links must be established across all health providers, including the devolved administrations, championing research at all levels. However, there are opportunities in the bill to establish groundwork to underpin the value of research.

- The bill currently gives local authorities a power to conduct research or assist any person to conduct research. We recommend that the forum consider strengthening this to a duty to ensure that all local authorities engage with research and evidence when carrying out their public health functions.
- Proposed increased localisation may present difficulties to the secure use of data, as they may become fragmented across multiple bodies. This could raise questions over data ownership and introduce delays in coordinating research projects. We recommend that the anticipated information revolution includes measures to manage this.

Building research into the health system

Clarify payment of excess treatment costs associated with research in the new commissioning structure

Issue: **The cost of treating someone involved in a research project may differ from the cost of treating them with existing medicines; they may need extra diagnostics, therapeutics or procedures as part of the testing of the new treatment which can increase the cost. Any increased cost is currently covered by primary care trusts' (PCT) commissioning budgets. However there is a lack of clarity over how trusts can recover these costs resulting in a perceived increased cost of doing research as resources must be invested to resolve them. Together with the delays this introduces, this can act as a disincentive to research.**

Case study 3.1: ***Confusion over who pays excess treatment costs impacts on clinical research***
In 2010, a researcher received a £1.5 million grant from the National Institute of Health Research's (NIHR) Health Technology Assessment programme to look at the health-economic impact of the different methods of giving insulin to children and young adults (insulin pumps vs multiple injections). All the research costs were paid by NIHR, but the costs of providing insulin pumps was classed as an 'excess treatment cost', and so a responsibility for the NHS commissioners. The researcher spent the next 12 months negotiating with ten different PCTs to ensure that the study could go ahead. This represented a waste of their time, and of the money committed to the project which could not begin until all excess treatment costs were funded.

Case study 3.2: ***Difficulties in recovering excess treatment costs across multiple clinical study sites***
A research study to find out whether a drug, donepezil, if given in the early stages of Parkinson's disease improves the long term outcomes for patients secured funding in early 2010 to be conducted across multiple sites in the UK.

Funding was through the NIHR Health Technology Assessment programme, with the dementia research study group of DeNDRoN covering the service support costs of the study. But a difficulty arose because treatment with donepezil is more expensive "up front" – approximately £48k for each site conducting the study – than the treatment which is currently given to these patients (they may normally receive donepezil as part of their clinical care but will not normally pay the whole cost up front).

NHS trusts receive money to cover these excess treatment costs, however there is little clarity over how they recover this. To go ahead, the trial needs commitment from each site and their local trust that they are willing to cover these excess treatment costs up front. Currently one or two trusts have agreed, but in the absence of clarity over payment and a lead individual to resolve the issue, a year after funding was confirmed, no patients have been recruited to this study.

››Recommendations:

- We recommend that the opportunity created by the reorganisation of NHS structures is used to clarify the payment of excess treatment costs, so they are no longer a disincentive to research.

Create incentives for research

Issue: **In a cash-strapped, busy NHS, activities such as research could easily slip down the list of priorities unless performance is being measured and reported. There is also a need for strategic oversight of the changing NHS to ensure that any detrimental impacts for research are identified and remedied.**

››Recommendations:

The collection of comprehensive research performance metrics and national review of these would ensure research performance is valued and any difficulties are identified and mitigated efficiently.

- The bill places a duty on Monitor such that, in exercising its functions it must have regard to the need to promote research into matters relevant to the NHS by persons who provide health care services for the purpose of the NHS. To ensure Monitor's scrutiny of research reflects the core role of research in the NHS, we recommend the forum consider strengthening this to a duty on Monitor to have regard to the need to not just promote but conduct research.

- The bill states that commissioning consortiums must provide information required by the secretary of state. This should include research performance metrics.
- A 'research champion' on the NHS Commissioning Board could monitor research through national collection of research performance metrics to ensure the board can make informed decisions in the exercise of its power to promote and conduct research. We recommend that the forum consider placing a duty on the NHS Commissioning Board to review and report on these metrics as part of the board's mandate.

Maintain independent expert advice to government

Issue: **Arm's length bodies conduct their functions independently of government. The planned abolition of some of these bodies and reorganisation of their functions may lead to a loss of independence for some important functions.**

The bill plans to abolish the arm's length body, the Health Protection Agency (HPA), and transfer these functions to the Department of Health. These functions include research and providing evidence and advice on public health. This loss of independence would seriously undermine these functions because a government department is not in a position to provide independent advice to itself, or other parts of government.

››Recommendations:

- The functions currently performed by the HPA must retain independence from the Department of Health, for example as part of an NHS special health authority or executive agency.

Patient and public involvement

Issue: **Patient and public involvement in research is essential to delivering high quality, relevant research. The concept of 'no decision about me without me' and a focus on the best interests of patients underpins the changes proposed in the bill. This concept must extend to research appropriately by developing a robust system which supports and strengthens meaningful patient and public involvement in designing the research agenda and conducting research.**

Case study 6.1: ***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/INVOLVE, Patient perspectives on the regulation and governance of medical research, 2010

Case study 6.2: ***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.

››Recommendations:

- A duty towards patient and public involvement must extend to research to give patients and researchers greater opportunities to choose to participate in and conduct research. This must reflect the commitment made in the NHS Constitution that patients should be notified of opportunities to join in relevant research and are free to choose whether they wish to do so.
- Patient and public involvement should be captured within health service performance metrics to allow strategic oversight.

- The NHS Commissioning Board's mandate should include the development of guidance on patient and public involvement, in consultation with those, such as third sector organisations, who have expertise in delivering patient and public involvement.
- HealthWatch should have the authority to reach across all engagement mechanisms relating to commissioning, scrutiny and accountability. We recommend the forum consider whether HealthWatch or the local Health and Wellbeing boards should have a duty towards research.

Maintain robust regulation and governance

Issue: **Separate to the bill are plans to establish a Health Research Regulatory Authority, initially as a special health authority with the National Research Ethics Service as its core. The authority will be established as a non-departmental public body in primary legislation through the next parliamentary session's Health and Social Care Bill.**

It is important for researchers, patients and the public to have confidence in the quality and robustness of our regulation and governance of health research.

The bill contains provisions to abolish certain public bodies involved in regulation and governance including the National Patient Safety Agency – which currently houses the National Research Ethics Service – and the National Information Governance Board.

The research community is broadly supportive of the proposals, but we recognise the importance of ensuring that confidence in the regulatory system is maintained as these changes take place. The process and timescale should enable expertise to be maintained and ensure that essential services are not disrupted.

››Recommendations:

- We recommend that steps are taken to communicate the process of change and measures being taken to ensure continuity and maintain efficiency and expertise.

Enable the safe and secure use of patient data for research

Issue: **The wealth of information retained by the NHS in patients' records provides an unrivalled resource for medical research. However a clear framework protecting both patients and researchers and enabling the safe use of this information is vital. Progress is being made towards this framework and the *Plan for Growth* published alongside the Budget 2011 included an undertaking to publish clearer proposals in the autumn.**

The bill plans to abolish the National Information and Governance Board (NIGB) which currently governs the use of patient data for medical research.

››Recommendations:

- Clarity is needed over the new governance processes to ensure researchers can confidently and securely conduct research projects using patient data.
- Work must continue to develop a clear framework for a secure data service protecting both patients and researchers by the autumn as outlined in the plan for growth.

For further information please contact Becky Purvis, head of policy, Association of Medical Research Charities, b.purvis@amrc.org.uk, 0207 685 2626.