

Summary

- Health research underpins the prevention and treatment of ill health and brings benefits across the UK population. We welcome the creation of Health Education England (HEE), the Local Education and Training Boards (LETBs) and the Health Research Authority (HRA), in primary legislation. This Bill provides the opportunity to ensure that the UK has a workforce that can undertake and reap the benefits of this research and a proportionate regulatory and governance framework to underpin it.
- Research training and experience should be seen as a key component of education and training. We welcome the clause that places a duty on HEE and LETBs 'to have regard to the need to promote research', although we, along with other respondents to the Department of Health's consultation on the Bill, would like to see this duty strengthened to simply 'promote research'. We are pleased to see that the need for effective reporting arrangements is acknowledged in the draft clauses. These reporting arrangements must ensure that HEE is held to account for its performance in delivering its duty towards research.
- We welcome the focus of the HRA on promoting the co-ordination and standardisation of the regulation of health and social care research in the United Kingdom and in seeking to ensure that such regulation is proportionate. We have identified a number of areas that should be addressed to ensure that the HRA can be effective in achieving these aims.
- Delay and duplications inherent in obtaining research permissions from NHS Trusts are regarded as causing the greatest inefficiencies in health research in England. It would be helpful if the HRA's role in facilitating NHS research governance (which we regard as a priority) could be explicitly mentioned in the Bill.
- Monitoring performance across the health research pathway, engaging with stakeholders (including patients and researchers), and early knowledge of future challenges and opportunities for the regulation of research will all be essential if the HRA is to fulfil its roles and responsibilities. We would like these to be reflected in the wording of the Bill.
- We see significant risks and minimal benefit in disbanding the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). We support retaining both the HFEA and the HTA providing that they work closely with the HRA and other regulators to further streamline the regulation, inspection and governance process for patient and public benefit.

Introduction

The Academy of Medical Sciences welcomes the opportunity to contribute to this scrutiny of the draft Care and Support Bill. The Academy promotes advances in medical science and campaigns to ensure these are translated 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. Health research provides patients with early access to new and innovative treatments, it improves the quality and efficiency of health services for the wider public and it attracts investment and jobs into the UK. To undertake, and realise the benefits of, this research requires a workforce that is appropriately trained and a regulatory and governance framework for research that is fit for

purpose. Our response to this consultation therefore focuses on the Committee's questions about the establishment of Health Education England (HEE) and the Health Research Authority (HRA) in primary legislation and the future of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) (Questions 26-31). The Academy responded to the Department of Health's (DH) consultation on this Bill and this response is an updated version of that submission.¹

General

Question 26: What is your view of Part II of the draft Bill (health)? In your view, are there any omissions in this part of the Bill?

We welcome the moves to establish HEE, LETBs and the HRA in primary legislation. This is an important step to securing the future of these bodies and of education, training and research in the NHS.

Health Education England

Question 27: Are the powers envisaged in the draft Bill for Health Education England sufficient, especially in relation to long-term workforce planning? Does the draft Bill set out HEE's powers clearly, along with its relationships with other bodies, especially the Local Education and Training Boards?

We agree with the Government that principles such as security of supply and responsiveness should be central to any system of workforce planning and development.² To respond to changing healthcare demands, now and in the future, it is imperative that the workforce has appropriate educational foundations, is well trained, and is practically and intellectually flexible. Research and innovation are central to delivering these ambitions. Academic values and a spirit of enquiry should be pervasive throughout the health service. The Academy regards it as essential that all staff be provided with a diverse education and exposure to research.

Research duties

We welcome the inclusion of a duty on HEE to 'have regard to the need to promote research' in clause 57. We have previously welcomed the Government's commitments towards medical research and the life sciences, including the introduction of duties throughout all levels of the reformed NHS to promote research, innovation and the use of evidence.³ The education and training reforms represent an excellent opportunity to develop appropriate arrangements to deliver these commitments. The duty towards research must therefore be placed at the forefront of the planning and implementation of education and training. With research firmly established as a core role of the NHS, training in, and experience of, this endeavour must be a key component of education and training across the workforce.

¹ <http://www.acmedsci.ac.uk/p100puid256.html>

² Department of Health (2010). *Liberating the NHS: developing the healthcare workforce.*

www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122933.pdf

³ For example: Coalition of funders and supports of health researchers in the UK (2011). *Joint briefing: Embedding research in the NHS.* www.acmedsci.ac.uk/download.php?file=/images/project/Jointbri.pdf

However, we would go further than this. There are particular issues with academic training that we have highlighted previously, such as the importance of ensuring flexibility and providing long-term career pathways, which we see as fundamental to developing a research culture within the NHS. We believe that HEE can and should play an important role in championing research within the new education and training system. We would therefore suggest that this duty should be strengthened to require HEE to 'promote research'. This would reinforce the statements and commitments made by government recently that have recognised the vital role played by education and training in promoting research and development in the NHS. For example, the recent NHS innovation strategy noted that 'creating an innovative culture starts with basic training, education and induction and continues throughout an employee's career through personal and Continuing Professional Development'.⁴ The Department of Health reported that many respondents to its consultation on the Bill agreed that the duty should be strengthened and we would encourage the Committee to consider recommending this.⁵

In our conversations with individuals from DH, we were reassured to learn that the research duty placed on HEE will follow through to the LETBs, as committees of HEE. We think that the community would value explicit clarification that this duty also applies to LETBs.

Academic-health partnerships

The Government has made strong commitments towards strengthening the relationship between academia and the NHS, for example its 'Strategy for UK life sciences' endorsed academic-health partnerships as an essential component of our economic recovery.⁶ To maximise the value and success of these alliances, they must be reflected in the workforce reforms. Workforce planning, education and training provide an ideal context for fostering such partnerships.

The Academy has stressed the importance of ensuring that education providers, including higher education institutions (HEIs), play a core role in the new arrangements for workforce planning, education and training.⁷ We welcome steps to require HEE to receive representation from education providers (clause 60). It is vital that this represents a genuine opportunity for education providers, including HEIs, to use their expertise to support and advise HEE. We look forward to seeing further detail on how this relationship will work in practice.

We also welcome the entitlement of education providers to serve on the governing boards of LETBs, as outlined in clause 62. We were pleased to see that the LETB Authorisation Framework outlined the importance of working in partnership with education providers and encouraged LETB governing boards to take on a diverse membership, up to a third of which could be drawn from outside of healthcare providers.⁸ We have argued that neither education providers, nor health service providers, can be truly independent commissioners of education and training. We believe that to enable co-development of appropriate educational provision that is both service sensitive and academically and professionally informed, LETBs should be closely aligned with academic health alliances, such as the Academic Health Science Networks (AHSNs) as they come on stream. We would like to see this clause edited to reflect the diversity in membership encouraged by the

⁴ Department of Health (2011). *Innovation, health and wealth: Accelerating adoption and diffusion in the NHS*. www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131784.pdf

⁵ <https://www.wp.dh.gov.uk/publications/files/2012/12/Summary-of-consultation-responses-CS-Bill.pdf>

⁶ Department for Business, Innovation and Skills (2011). Strategy for UK Life Sciences.

www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences

⁷ Academy of Medical Sciences (2011). Response to the consultation 'Liberating the NHS: Developing the Healthcare Workforce'. www.acmedsci.ac.uk/download.php?file=/images/project/132075187126.pdf

⁸ Health Education England (2012). *Local Education and Training Board: Authorisation Framework (10 September 2012)*. www.wp.dh.gov.uk/healtheducationengland/files/2012/09/LETB-Authorisation-Framework-10-September-final-approved-version.pdf

Authorisation Framework. We would also welcome it being further strengthened so as to secure close alignment between the LETBs and AHSNs.

Question 28: Are the proposed arrangements for the governance and accountability of HEE and the LETBs robust enough?

We are pleased to see that the need for effective reporting arrangements is acknowledged in the draft clauses. We look forward to seeing more detail on how this will function in practice. We understand that within clause 58, the Secretary of State will set out an Education Outcomes Framework as well as annual objectives for HEE. We welcome this proposal. These reporting arrangements must ensure that HEE is held to account for its performance in delivering its duty towards research. We also understand that HEE will develop annual priorities for the system, based on those documents; priorities that will in turn be managed by the LETBs. We would again stress that these must outline to LETBs how they are expected to deliver on the research duty.

Establishment of the Health Research Authority (HRA)

Question 30a Will the powers envisaged for the Health Research Authority be effective?

There is evidence that the UK's strengths in health research are being undermined by an overly complex regulatory and governance environment. We have therefore been supportive of the work that the HRA has been carrying out since its creation as a Special Health Authority. The establishment of the HRA as a non-departmental public body will fulfil one of the key recommendations made by the Academy in its 2011 report on the regulation and governance of health research.⁹ We welcome the clarification of its role, as articulated in the Bill, of promoting the co-ordination and standardisation of the regulation of health and social care research in the United Kingdom and, most importantly, to 'seek to ensure that such regulation is proportionate' (Clause 68 (3)). We are pleased to see that, to promote a harmonised approach to regulation and governance across the UK, the HRA can exercise the health research regulatory functions of the devolved administrations (Schedule 7, Part 2). There are a number of areas that would benefit from consideration by the Committee when considering whether the HRA can effectively deliver its role. We outline these below.

The role of the HRA in facilitating NHS research governance

When the Academy carried out its review of regulation and governance in 2010, the delay and duplications inherent in obtaining research permissions from NHS Trusts were highlighted as the greatest inefficiency in the research process in England by those consulted. Government did not take forward our recommendation to create a National Research Governance Service to centralise study-wide research governance checks as part of the HRA, instead focusing on a bottom-up approach. Currently the HRA's responsibility for NHS R&D is only implicit in the Bill (i.e. by definition 'health and social care research' will include the part of the process undertaken in the NHS) and, although there is a duty of co-operation between the HRA and bodies such as the MHRA and the Care Quality Commission (clause 68), there is no equivalent duty of co-operation with those responsible for research governance in the NHS.

We have welcomed the HRA's recent announcement of a feasibility project that will explore whether it can support NHS Trusts by providing them with a simplified, streamlined and quality

⁹ Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. www.acmedsci.ac.uk/p47prid88.html

assured assessment for all research in the NHS.¹⁰ This provides reassurance of the HRA's commitment to facilitating improvements in this part of the regulatory pathway and, if successfully implemented, would address one of the major recommendations of our report.¹¹ However, given the importance of the NHS research governance processes for those in academia, industry and the charity sector who carry out research, we think it would be helpful for this part of the HRA's role to be formalised by explicit mention in the Bill, as it is in Factsheet 8 that accompanies the Bill. We note that this view is shared by other organisations that responded to the DH's consultation on the Bill.¹²

Other aspects of the Academy's vision for the HRA

In our 2011 report on the regulation and governance of health research, the Academy set out a vision for the HRA. We highlighted the need for the HRA to be able to respond to the regulatory needs of emerging areas of health and to take advantage of new (e.g. statistical) techniques that could improve the monitoring of clinical trials. This is acknowledged in the draft Bill in Clause 68 (5) where it states that the '*HRA must keep under review matters relating to the ethics of health or social care research and matters relating to the regulation of such research*'. To do this it will need its own horizon scanning capacity (as the HFEA has) or access to that of others.

Two areas within the Academy's vision for the HRA are not included within the Bill's list of its roles or functions. We would like these to be considered by the Committee for inclusion.

- **Measuring performance.** We would like to see the HRA have a role in developing metrics and indicators for the regulation and governance pathway as a whole, and monitoring these to ensure that improvements are being made. It will be important to ensure that the timeline is not being manipulated (e.g. by 'stopping the clock' more often) and that the introduction of new benchmarks for Trust's research performance does not discourage them from undertaking certain types of research (e.g. on rare diseases). In the HRA's annual report (specified in Schedule 7, Part 3) we would expect to see metrics demonstrating how its own performance has contributed to decreases in the time taken to get regulatory approval and progress towards creating a single portal for applications for health research.
- **Communication and engagement.** In fulfilling its roles and functions, the HRA will need to engage with a wide range of stakeholders. This will include patients and the wider public as the HRA seeks to protect and promote their interests, and researchers in academia, industry and charities to gain feedback on whether it is being successful in its work to co-ordinate and standardise research and increase the proportionality of regulation. We are aware that the HRA has been in dialogue with patients and their representatives since its establishment. For example we welcome the establishment of the HRA's Collaboration and Development group, on which the Academy is represented. However, we note that there is no formal commitment to this type of engagement by the HRA in the Bill.

Question 30b Is there a risk of conflict between transparency in the publication of research results and patient confidentiality?

The transfer of responsibility for the research use of confidential patient information to the HRA (Clause 74) provides a good opportunity to reduce complexity in this area of regulation and

¹⁰ <http://www.hra.nhs.uk/hra-news-and-announcements/hra-given-go-ahead-for-feasibility-study-hra-assessment-for-approval-of-research-in-the-nhs/>

¹¹ Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.* www.acmedsci.ac.uk/p47prid88.html

¹² <https://www.wp.dh.gov.uk/publications/files/2012/12/Summary-of-consultation-responses-CS-Bill.pdf>

governance that has led to conflicting interpretations of it by researchers, Trusts, patients and other stakeholders. The provision of clear and authoritative guidance in this area by the HRA will be particularly crucial. It will be important to consider the relationship between the HRA and the Information Commissioner who also has a responsibility to issue guidance around access and use of personal data.

The HRA's new responsibilities for patient data and its links with associated stakeholders will assist it in contributing to the wider debate around transparency in the publication of research results. We welcome the fact that the HRA has already announced plans to take steps to follow up the commitments that researchers make to research ethics committees relating to the publication of summary trial data. We are supportive of mechanisms to make clinical trial data available to inform research for the benefit of patients. This is subject to appropriate safeguards of confidentiality of participants (many mechanisms already exist to ensure this) and of course assuming that the research is scientifically sound. There are a number of issues around the publication of clinical trial data that need to be considered. These include the development of mechanisms to enable the release of data in a form that is both accessible and useful and avoids being misleading. We hope that the HRA will contribute to the debate about how these mechanisms should be developed. It is not as simple as just publishing raw data – it must be analysed in informed and validated ways to avoid spurious conclusions being drawn that can cause unnecessary concerns about particular drugs or screening programmes.

We will be considering these issues in more detail in our forthcoming response to the House of Commons Science and Technology Committee inquiry on clinical trials.

Human Fertilisation and Embryology Authority and Human Tissue Authority

Question 31 What are the risks and benefits of the provisions in the draft Bill on the Human Fertilisation and Embryology Authority and the Human Tissue Authority?

The Academy responded to the consultation held by the Department of Health about the future of the HFEA and the HTA.¹³ There is a great deal of support among our community for the HFEA and the HTA; both are perceived as having developed the experience to respond in a balanced, practical way to the changing landscape that reflects the evolving risks and benefits of research. The relatively small savings to be made through disbanding the HFEA and the HTA need to be balanced against the inevitable period of disruption and uncertainty, and any potential risk of loss of expertise, efficiency, effectiveness and coherence that could hinder research and practice and result in the loss of public and professional confidence. (Our submission to DH expands on these significant risks and the minimal benefit in more detail.) In addition, these areas of regulation and governance are not perceived to present the greatest barriers to research by our community and the two regulators do not deal with a large number of research applications. We therefore support retaining both the HFEA and the HTA, providing they work closely with the HRA and other regulators to further streamline the regulation, inspection and governance process for patient and public benefit.

In this early stage of the HRA's work we would prefer that it is able to give priority to its work in supporting the NIHR in its efforts to improve research governance in the NHS and to successfully taking on the data functions of the National Information Governance Board for Health and Social

¹³ <http://www.acmedsci.ac.uk/p100puid254.html>

Care (NIGB). These areas of regulation and governance present greater challenges to the research community than those covered by the HFEA and HTA. However, should the Government decide to disband the HFEA or the HTA we would recommend that their functions are transferred to the HRA rather than the Care Quality Commission.

This response was approved by the President of the Academy of Medical Sciences. For further information, please contact Dr Rachel Quinn (rachel.quinn@acmedsci.ac.uk; +44(0)20 3176 2163).

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.

Academy of Medical Sciences
41 Portland Place
London, W1B 1QH
+44(0)20 3176 2150

info@acmedsci.ac.uk
www.acmedsci.ac.uk

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