

Joint Committee on the draft Care and Support Bill: Call for written evidence

Response by the Wellcome Trust

January 2013

Key Points

- We welcome the proposals to establish Health Education England and the Health Research Authority as non-departmental public bodies to secure their independence.
- Health Education England's research duty must be strengthened to "promote" research and the use of research evidence.
- It is vital that higher education institutes are closely integrated in the role of Health Education England and its Local Education and Training Boards. While the need for some integration is reflected in the Bill, this should be strengthened.
- We welcome the proposed duties of the HRA, which are important to ensure that the HRA fulfils its envisioned role of promoting proportionate and consistent regulation in the UK, and providing effective guidance to researchers and other stakeholders.
- It will be important that all stakeholders share an understanding of the HRA's role in a National System of Research Governance, to ensure that the HRA has the authority to take the steps needed to improve the NHS R&D permissions process.
- We welcome the provisions to transfer the function of approval for processing confidential patient information for research to the HRA.

INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to provide written evidence to the Joint Committee on the Draft Care and Support Bill. Our response focuses on those parts of the Bill concerning the establishment of the Health Research Authority and Health Education England¹, and summarises our position taken in our response to the recent consultation on the future of the Human Fertilisation and Embryology Authority and Human Tissue Authority.²

¹ We also previously responded to the Department of Health's consultation on the draft Bill, in which we made similar points:

http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTP040657.pdf

² Full response available at:

http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm056499.pdf

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?

Establishment of HEE as a non-departmental public body

2. We welcome the proposal to establish Health Education England as a non-departmental public body as this will secure its independence and provide a secure foundation for the future of education and training of the healthcare workforce (clause 54(1)).

Research duty

3. We consider the duty for HEE to “have regard to the need to promote” research and the use of research evidence (clause 57(2)) to be far too weak. As drafted this duty is too ambiguous and fails to commit HEE to action, therefore this duty must be strengthened simply to “promote”. This change would recognise the important role that HEE must play in championing research within the new education and training system. To build a strong and modern workforce it is essential that HEE oversees a system that provides the education and training needed for the workforce to conduct and appreciate the value of research.
4. The NHS Chief Executive's Review, *Innovation: Health and Wealth* said that “innovation is central to the future of the NHS”³ and recognised the importance of the workforce in realising this ambition. We support this view. In order to ensure that new technologies such as genomics and stratified medicines are deployed effectively in the NHS, it is essential that healthcare professionals are given the education, training, time and resources needed to support research and innovation. HEE must ensure that this is the case and also needs to increase the flexibility in the training pathway of clinicians to ensure that they develop a fully rounded set of skills and are able to devote time to activities away from the bedside, such as research.
5. A duty to “promote” research would also be consistent with the wording of the duties on the Secretary of State, National Commissioning Board and the Clinical Commissioning Groups, as enshrined in the Health and Social Care Act, ensuring clarity throughout the system.
6. We understand that the research duty on HEE will also apply to Local Education and Training Boards (LETBs), as committees of HEE. It will be important to make this responsibility of LETBs clear to ensure that it is implemented. We look forward to hearing more about how HEE and LETBs will report against this duty, for example against the requirements set out in clause 58.

³http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131299

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

7. We are pleased to see that persons who provide education and training are included in the list of persons from whom HEE must seek advice (clause 60(2)(f)).

Relationship between HEE and the academic sector

8. It is absolutely crucial that universities play a central role in the delivery of education and training, to maintain links both to the academic research environment and to ensure seamless provision of undergraduate medical education. We therefore consider that education and training are delivered most effectively by partnerships between local higher education institutions (HEI) and healthcare providers. We are pleased that this is acknowledged in clause 62(3), which makes it clear that persons who provide education and training are entitled to serve as members of the governing board of an LETB. We welcome the approach of the LETB Authorisation Framework that notes that LETB boards “should include representatives from the education sector”.⁴ Clause 62(3) should be strengthened to mandate the inclusion of persons who provide education and training on an LETB governing body. This would better reflect the vital role of HEIs education and training that is recognised in the LETB Authorisation Framework.
9. Academic Health Sciences Networks (AHSNs), proposed in *Innovation: Health and Wealth*, provide an exciting opportunity to link education and training with research and innovation, building on strong partnerships between centres of academic excellence and healthcare providers across England. We are pleased that the LETB Authorisation Framework promotes “cross board representation” between LETBs, AHSNs and Academic Health Sciences Centres to ensure that their activities are closely aligned.
10. We support the appointment of an independent chair to the governing body of an LETB (clause 62(7)). We also welcome the approach of establishing the governing body of an LETBs as a committee of HEE (clause 62(10)) as this ensures that LETBs are accountable to HEE and empowers HEE to provide national coordination for the education and training system.
11. Set up in this way, with HEI representation and building on existing relationships, we consider that LETBs will be well-placed to play a key role in connecting healthcare provision with research and innovation, therefore strengthening the global competitiveness of the NHS. Furthermore, these partnerships would enable UK institutions to compete for the best international talent, ensuring a steady income stream for the partners and, crucially, improving service provision for patients.

⁴ <https://www.wp.dh.gov.uk/healtheducationengland/files/2012/09/LETB-Authorisation-Framework-10-September-final-approved-version.pdf>

HEALTH RESEARCH AUTHORITY

Question 30: Will the powers envisaged for the Health Research Authority be effective, and is there a risk of conflict between transparency in the publication of research results and patient confidentiality?

Functions and role of the HRA

12. We welcome the proposal to establish the Health Research Authority as a non-departmental public body, as we consider this a vital step towards streamlining and simplifying the approvals process for research projects and providing advice and guidance for researchers while securing the HRA's independence. We also welcome the HRA's work to date in establishing its role and its effective stakeholder engagement.
13. We also welcome the establishment of the main functions and objectives of the HRA; it is critical that the research regulatory and governance framework achieves an appropriate balance between promoting research in the public interest while protecting the interests of patients and research participants. The HRA will play a central role in this, and the aims set out in the draft Bill will enable it to fulfil this duty. However, in communication and engagement activities it will be important to be clear that the HRA's role in improving the research environment in the UK does not mean that the safety of participants and potential participants will be compromised. It is also important to strike the necessary balance between maximising research transparency and protecting patient safety and confidentiality.

Co-ordinating and promoting regulatory practice

14. We welcome the requirement for the HRA to have a duty of cooperation with the bodies and stakeholders listed in clause 68(1), in order to effectively coordinate and promote good practice.
15. The Academy of Medical Sciences' review of research regulation and governance⁵ identified the process of obtaining NHS R&D permission as the most significant barrier to health research in the UK. We therefore welcome the statement in the factsheet accompanying the draft Bill⁶ that the "HRA would continue to have a role as part of a national system of research governance, promoting a proportionate approach among all those involved in research, including for example, NHS providers". We also welcome the recent announcement of a feasibility study to be conducted by the HRA of the potential benefits of a single research review.
16. We welcome the duties detailed in clause 68(3), (4) and (6). These measures will be essential in ensuring that the HRA fulfils its envisioned role of promoting proportionate and consistent regulation in the UK, and providing effective guidance to researchers and other stakeholders. We also welcome the provision in Schedule 7 for the HRA to

⁵ Academy of Medical Sciences (2011). 'A new pathway for the regulation and governance of health research' www.acmedsci.ac.uk/p47prid88.html

⁶ <http://www.dh.gov.uk/health/files/2012/07/Care-and-Support-Bill-Factsheet-8-Health-Research-Authority.pdf>

exercise functions on behalf of the devolved administrations as part of a standardised and consistent approach across the UK.

17. We also welcome the provision for the HRA to “keep under review matters relating to the ethics of health or social care research and matters relating to the regulation of such research” (clause 68(5)). We hope that in due course this will also include a dedicated public engagement and communications function to enable the HRA to take a leading role in the public and policy discussions around such developments, in order to review its own processes effectively.

Policy and guidance

18. We further welcome the setting out of the HRA’s policy on research ethics committees, as detailed in clause 69, and its duty to publish guidance as detailed in clause 70. These provisions are consistent with our view that the HRA should be a focal point for research approvals and the provision of advice and guidance on research regulation.

Functions relating to patient information

19. Patient information is a valuable resource for health research, yet the complexity of the UK regulation and governance framework for the use of such information has contributed to a risk-averse culture among those sharing and using data, and is a significant barrier for research. The 2008 Data Sharing Review identified the high degree of complexity and confusion around the legal framework that governs data sharing, and concluded that “many practitioners who make decisions on a daily basis about whether or not to share personal information do so in a climate of considerable uncertainty.”⁷
20. We consider that the HRA can have a particularly valuable role in reducing complexity and creating greater cohesion around regulation and guidance on the use of patient information in research. We therefore welcome the provisions in clause 74 to transfer the function of approval for processing confidential patient information for research to the HRA as an important first step towards providing a transparent, consistent and streamlined process for decision-making. We also welcome the recent announcement that the HRA will host transparent expert advice to support decisions on access to personal information.
21. In order to reduce complexity in the landscape for the use of patient data in research, it will be vital for the HRA to produce clear and authoritative guidance. We consider this to be a priority area for the HRA to fulfil its duty to publish guidance on principles of good practice and requirements in the conduct of health and social care research (clause 68(6)). This will assist the HRA in producing definitive guidance on the use of personal data in research and enable best practice to be embedded in the approvals process.

Research transparency

22. On the issue of transparency, we consider that transparency in the publication of research results is a vital part of the research pathway. While we do not envisage an immediate role for the HRA with regard to research transparency, it will be important to

⁷ Richard Thomas and Mark Walport (2008). ‘Data Sharing Review Report’
<http://www.justice.gov.uk/reviews/datasharing-intro.htm>

embed this principle throughout the regulatory pathway; numerous bodies have a role to play in this, including the Research Ethics Committees overseen by the HRA, as well as research funders and sponsors, and so it will be important that dialogue continues on this subject between the relevant stakeholders. Any release of data will have to take account of a number of issues, including the need to balance transparency with the protection of patient safety and confidentiality.

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?

23. In the Trust's response to the recent Department of Health consultation on the future of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA), we outlined what we consider to be the risks of transferring the powers of the HFEA and HTA elsewhere, as proposed under Options 1 and 2. These are as follows:

- Transferring functions away from the HFEA and HTA would present a significant risk for loss of specialised expertise and specialist function within the HFEA and HTA, and potential corresponding impacts on researcher and public confidence in the regulatory system. Furthermore, we considered the proposal to split the HFEA's functions by transferring its research functions to HRA, and the rest of its functions to the CQC, carried a risk of losing cohesion between the HFEA's clinical and research functions and diminishing its ability to keep pace with emerging treatments and techniques.
- We were concerned that the proposal to transfer functions from the HFEA and the HTA to the Care Quality Commission (CQC), in light of concerns about the CQC's performance and governance, would risk damaging public confidence
- We also felt that splitting the functions of the HTA across several other bodies, as proposed under Option 2, would increase the regulatory burden for sites storing tissue for multiple scheduled purposes.

24. In light of these concerns, we broadly supported Option 3 in which the HFEA and HTA would retain existing functions but deliver further efficiencies. We proposed an enhanced version of this option that seeks to further streamline the regulatory pathway and has the potential for significant cost savings in the future.⁸ We therefore consider that the provisions in clause 75 to allow for the abolition of the HFEA and HTA should be deleted.

⁸http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm056499.pdf

that the provisions in clause 75 to allow for the abolition of the HFEA and HTA should be deleted.

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.

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