




An Audience with the HRA

May 2013



Academy of Medical Sciences

The Academy of Medical Sciences is the independent body in the UK representing the diversity of medical science. Our mission is to promote medical science and its translation into benefits for society. The Academy's elected Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service. We work with them to promote excellence, influence policy to improve health and wealth, nurture the next generation of medical researchers, link academia, industry and the NHS, seize international opportunities and encourage dialogue about the medical sciences.

Contents

Summary	4
Presentations	5
Question and answer session	7

Summary

The Academy of Medical Sciences welcomed the creation of the Health Research Authority (HRA) - catalysed by the Academy's report on health research governance - and supported its current work on streamlining ethics and R&D approval for research in the NHS.

Dr Janet Wisely and Professor Jonathan Montgomery summarised the history, vision and role of the HRA. They highlighted past achievements in streamlining research ethics, and current projects to develop this further and streamline research governance. Their vision is to make the UK a great place to do research. As a small organisation with a wide remit they would work through leadership and consensus building. They have the complementary objectives of promoting and protecting the interests of patients and the public in research - considered within the wider context of ensuring that the UK is an attractive place to carry out research. They believe that research is in the best interests of patients and the public, but they have a primary duty to promote the interests of patients in research. They aim to understand and amplify the public's concerns via public consultation and dialogue. They are keen to act early, and use their findings to reflect on and review their strategy. A key current project is a feasibility study on streamlining of R&D approval within NHS Trusts.

The Q&A discussion ranged across the principles of governance (namely consent and governance of sharing research), processes of approval (including delays to R&D approval caused by some Trusts - related to inefficiency, inconsistency and a risk-averse culture) and the nature and limits of the HRA's role (in relation to promotion of research and obstacles to research beyond the regulation and governance process). Attendees welcomed the HRA's commitment to improving and streamlining regulation and governance across the whole research pathway, particularly within NHS Trusts. Complex issues in relation to consent were outlined. HRA's underpinning principles for resolving these would be proportionate response, consensus building with key partners and public consultation. In terms of its remit beyond research regulation and governance, the HRA would aim to work with partners in a leadership role, build consensus and leverage the new duty on NHS England to promote research. It was clear that the meeting had been a constructive opportunity for dialogue between the HRA leadership and Academy Fellows and it was agreed that it would be helpful to meet again in a year's time to review progress.

Presentations

Introduction

Sir John Tooke PMedSci highlighted the 2011 Academy of Medical Sciences report, 'A new pathway for the regulation and governance of health research'¹, which recommended the creation of a single research regulator. This paved the way for the creation of the Health Research Authority (HRA). The President also highlighted the Academy's response to the parliamentary scrutiny committee², examining the Bill that would establish the HRA in primary legislation, which argued that the HRA should oversee NHS R&D approval. He welcomed the feasibility study on central assessments by the HRA for NHS Trust R&D approvals.

The HRA's vision, history, role and plans

Professor Jonathan Montgomery (HRA Chair)

Professor Montgomery focused on three key areas:

1. The HRA being charged with promoting and protecting the interests of patients and the public in research. It sees these as complementary objectives rather than in conflict with each other. He believed that it was in the interest of patients and the public for good research to be done, so that care was evidence-based, and that the public needed to have the opportunity to be informed about research and wanted the chance to participate in it. This important focus on promoting and protecting public's interests also needed to be considered within the wider context of ensuring that the UK is a good place to carry out research.
2. The HRA as a small organisation with a big agenda: he explained that the HRA is working collaboratively with others and using the leverage of other organisations for common effectiveness. It is having an on-going dialogue with patients and the public.
3. The HRA wanting to act not just talk: he was keen for the HRA to continue to get things done where feasible, and then reflect on where this initial work leads onto in terms of the overall objectives of the organisation.

Dr Janet Wisely (HRA Chief Executive)

Dr Wisely talked about the HRA's vision, history and roles. Her slides are in Appendix 1. She said that the ambition of the HRA was to make the UK a great place to do research, and that this would require the HRA to tackle governance across the whole research journey. The HRA would achieve its aims through leadership and by consensus. She highlighted her past successes with the National Research Ethics Services (and the Integrated Research Application System or IRAS), which rationalised the ethical approval process and improved its efficiency. The HRA would continue to develop this service (e.g. by renewing its IT platform and seeking user feedback). Other highlighted HRA projects included:

¹ <http://www.acmedsci.ac.uk/p47prid88.html>

² <http://www.acmedsci.ac.uk/p100puid264.html>

- The development of an online resource for advice and guidance (a decision aid tool for researchers)
- The launch of a new website to facilitate public dialogue and engagement
- Transfer of responsibility for Section 251 (governing access to identifiable patient data) to the Confidentiality Advisory Group (CAG) convened by HRA in terms of advice (for all data uses) and approval (for use of data in research).
- Transfer of responsibility to the HRA of 'The Over Volunteering Prevention Scheme' or TOPS.
- A leadership role in relation to the transparency agenda (the HRA issued a position statement on this in May/2013³).
- The creation of an HRA Collaboration & Development Programme; overseen by a Collaboration and Development Steering Group⁴ that is a UK wide steering group for a set of projects that will enable the implementation of a unified approval process and will support the HRA in promoting proportionate standards for compliance and inspection; specifically where implementation will be required not just by the HRA but by others as well to improve the research journey in the UK. The Academy is a member of this Steering Group.

Dr Wisely expanded on one of the projects under the umbrella of the Collaboration and Development Programme: 'The HRA assessment for the approval of research in the NHS'. This is a feasibility study to test the potential benefits of a simplified and streamlined HRA assessment for all research in the NHS (which employs a single application package for both ethics and R&D approval). It aims to decrease duplication and inefficiency in the current system. It would be overseen by HRA, but quality-approved by an R&D manager. The ultimate aim would be to redefine the role of R&D staff in Trusts away from approval of research and towards supporting delivery of research at the local level. Dr Wisely raised a number of issues that need to be addressed to make this successful, including improving the quality of applications submitted by researchers; a review of risk assessment and proportionate response (whereby risks for complex, but well-established studies, are regarded as lower than those for studies that are less complex but push the boundaries of research methodologies) and a change of culture within R&D departments.

Response by Sir Michael Rawlins FMedSci

Sir Michael again reflected on the Academy's 2011 report on research governance, which identified fundamental failings in relation to the multiplicity of research governance or approval bodies in the UK, and the research governance processes within individual NHS Trusts. He welcomed the HRA's feasibility study on streamlining approvals across ethics and R&D.

³ <http://www.hra.nhs.uk/hra-news-and-announcements/transparent-research/>

⁴ <http://www.hra.nhs.uk/hra-publications/?entryid85=147929>

Question and answer session

There was a wide-ranging and lively discussion, chaired by Sir Patrick Sissons FMedSci, on a number of issues that can be grouped under three broad headings:

1. Principles underpinning HRA's work
2. Governance processes for HRA and its partners
3. The role of HRA and its limits

Principles underpinning HRA's work

The issues raised here included principles of consent in complex contexts and governance of sharing research results and data.

Consent for future research

There was a discussion on consent for future research (e.g. in longitudinal studies where patients have consented to future projects, but not to the specific (potentially unforeseen) particulars of a proposed project). Some Fellows highlighted the problem of 'shifting goalposts' by approval bodies, where initially acceptable consent is re-defined over time. The HRA responded that some of these problems could be avoided by careful planning of future consent, in consultation with ethics committees. Where there is ambiguity, the principle of proportionate response would apply.

Consent by minors

There was a discussion on consent given by parents on behalf of minors (e.g. for paediatric neuro-imaging data; which may be made available to the international research community), and whether continued use of this data once the minors reach adulthood requires re-consent. Discussion between the HRA and some Research Ethics Committees (RECs) identified that re-consent is something that RECs expect to be considered, but they do recognise challenges and the National Research Ethics Advisory Panel is exploring if guidance is needed in this area.

In general, the HRA would like to use the principle of competence-based rather than age-based consent. Competence-based consent is the standard practice, although this is not the case for clinical trials of investigational medicinal products (CTIMP) in Europe.

Consent for consent

Fellows raised the problem of being unable to access identifiable data to identify participants for research studies without the patient's prior consent (so-called 'consent-for-consent'). Reliance on a member of the narrowly defined care team (e.g. a GP) to identify and approach suitable participants is especially problematic in primary care and in non-research active hospital settings where clinicians may lack the time or incentives to approach patients for research. Dr Wisely and Professor Montgomery are keen to encourage a distinction between identifiable data that remains within the NHS (e.g. is accessed by a research nurse for recruitment to studies) versus access by others (with the data potentially leaving the NHS). They thought there was a need for: (a) a proportionate response (b) a broad-enough definition of the 'clinical care team' in

consultation with CAG and (c) a public consultation - to identify and amplify people's concerns and their attitude to the use of data to contribute to research for evidence-based medicine.

Sharing research results and data

Finally, there was a discussion on the changing nature of research, with the development of huge datasets (e.g. in genetic research) that are shared internationally to optimise their use for discovery and patient benefit. The HRA acknowledged the need to identify different consent solutions for different research problems. In this particular example, they would seek to build consensus with the CAG and the ICO (Information Commissioner's Office). Once again, the views of the public will be important in informing HRA policies. It was noted that the streamlining of R&D approvals would help facilitate research using these large datasets.

Governance processes: the HRA and its partners

Timely consent in emergencies

Fellows working in infectious disease research raised the problem of gaining timely approval in the context of emerging infections (e.g. novel coronavirus) or epidemics; where research may need to be carried out at short notice across the UK. They gave the example of the recent influenza virus outbreak, where some researchers were unable to carry out research in the first wave of the epidemic due to delays in the approval process. The ideal situation would be one where any Trust in the UK could receive patients, and timely research could be carried out nationally. The HRA explained that they had procedures in place for accelerated approval in emergencies (within 24 hours where necessary). They are working with partners in the CAG to develop a process for timely approval from all relevant bodies. They would advise researchers to discuss potential emergencies as early as possible with approval bodies. In some situations there may be scope for a two-stage approval process (e.g. accelerated approval for collecting and storing samples, and later approval for use of these samples in research). The Fellows highlighted the importance of dialogue between Public Health England and the HRA on research of public health importance.

Caldicott guardians and R&D approval

There was much discussion on the role of Caldicott Guardians and the R&D approval process. The predominant view among the audience was that these bodies had a risk-averse culture, with an undue emphasis on the protection of patients' rights to confidentiality and an insufficient emphasis on the potential benefits of research. There was concern about the duplication of approval, inconsistencies between Research Ethics Committees and R&D decisions, and the lack of research expertise among some R&D staff. The HRA hoped that the current feasibility study on streamlining ethical and R&D approval would address many of these concerns. The Health and Social Care Act 2012 places a new duty on NHS bodies to promote research, and the HRA hoped that this would shift the culture of Caldicott Guardians and R&D bodies towards one where research was actively promoted and facilitated. The HRA would aim to have conversations with and support Caldicott Guardians to help them fulfil this new duty.

Some Fellows were concerned about the difficulty in identifying Caldicott Guardians for population-level research or research in primary care. They also noted the differences between the treatment of 'portfolio' and 'non-portfolio' studies ('Portfolio studies' are studies that are eligible for support by the Clinical Research Network, and which have been added to one of the four Portfolio database held by the devolved UK Health Administrations). Dr Wisely noted that the HRA aims to streamline approval for all NHS research in England regardless of setting, nature and populations.

The role of HRA and its limits

Role of HRA in promoting research

There was an interesting discussion on the role of HRA in promoting research. Some Fellows asked for a clear commitment by the HRA to promoting research. The HRA made a distinction between 'promoting patient interest in research' and 'promoting research'. They explained that whilst their overall view is that research is in the best interest of patients and the public, their primary responsibility is to promote patient interest in research. If it becomes clear from public consultation that more information is needed or wanted about the benefits of research in informing treatment and prevention then they would have a legitimate role in providing this. However there is always a role for the Academy and others to play in demonstrating the importance of medical research.

Role of HRA in use on non-health data

There was a query on what the role of the HRA was in relation to non-health datasets. This was of particular relevance to population health and epidemiology researchers, who may combine health, social and educational data in their research. In these cases, there are multiple approval bodies beyond the NHS (e.g. the Office for National Statistics, government departments) further complicating governance. The HRA explained that they have a current role in non-research use of health data (S521 advisory role) but not in the use of non-health data. However, they envisage that this will develop over time, in a leadership role and in collaboration with partners (e.g. the Nuffield Council on Bioethics).

Role of HRA in broader challenges to research implementation

There was a discussion on the role of HRA on issues that clearly fall outside its remit and control, but which nonetheless impact on the ability of researchers to carry out their research in a timely and efficient manner. This included funding blocks, payment for excess treatment costs, and obstacles placed by local Trusts on the implementation of research despite ethics and R&D approval. The HRA explained that they would not take on responsibility for these broader issues, but that they have a leadership role to play in building consensus with all partners involved in research. They would use leverage from the new duty to promote research that has been placed on NHS England; facilitate discussions between researchers and Trusts; highlight good practice; set benchmarks and develop metrics to enable Trusts to measure their performance against recommended best practice.



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