



Discussion with the Health Research Authority

October 2014



Academy of Medical Sciences

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Disclaimer

This document reflects the views of participants expressed at the meeting and does not necessarily represent the views of all participants or of the Academy of Medical Sciences. For Further information, please contact Dr Rachel Quinn, Director of Medical Science Policy (rachel.quinn@acmedsci.ac.uk, (0)20 3176 2163).

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Contents

Summary	3
Presentations	4
Question and answer session	6
Annex I: Agenda	9
Annex II: Attendees	10

Summary

The Health Research Authority (HRA) was created following a recommendation in the Academy's 2011 report on the regulation and governance of health research. This was the second opportunity for Fellows and invited guests to hear about the HRA's work plan and to provide feedback on the current opportunities and challenges in the regulation and governance pathway.

Professor Jonathan Montgomery (HRA Chair) and Dr Janet Wisely (HRA Chief Executive) summarised the progress made by the HRA since the last meeting with Fellows and outlined future directions. The HRA intends to standardise the regulation of both health and social care research. It aims to promote and protect the interests of patients and the public in health research and wants to be viewed as a trusted and transparent organisation by all stakeholders. The HRA Approval Programme has been designed to be compatible across the UK and, crucially, will involve only one application, one assessment and one approval for research being carried out in the NHS in England. A team of interim application managers within the HRA are in place to support applications that are disadvantaged by the current processes (such as rare diseases) and where there is high public need for the research. A team is coordinating the first phases of provision of single technical assurances, such as pharmacy, using expertise from the NHS. These will be incorporated into HRA Approval. A revised system for management of amendments will include presumed approval by Trusts after 35 days. The Approval Programme will be rolled out by study type by the end of 2015, and will be used as a platform for the European Union Clinical Trials Regulation which is expected in 2017.

The presentations were followed by a Q&A session which covered the practicalities of making the transition to the HRA Approval Programme in more detail. The HRA will be putting external change managers in place to help aid the transition. It is currently collecting comments on draft guidance on seeking informed patient consent in simple pragmatic trials. Both Fellows and the HRA were in agreement that public and patient trust and understanding with regards to health research is essential, particularly in the areas of safety and patient data. Data was a key area of discussion, including the management of multi-centre trial data, the proposed European Data Protection Regulation, and the associated ethics, such as ownership. It was suggested by Professor Montgomery and Dr Wisely that legitimate use of data is a more important issue than ownership and that consistent messages to the public about the use of data in research will be helpful. The HRA is already working with both public and patient groups to identify and address areas of concern.

There was strong support from attendees for the development of the HRA Approval Programme and confidence in the progress of the organisation to date. It was made clear that once the HRA Approval Programme has been rolled out, researchers will have an important role in ensuring its implementation by dealing with the HRA rather than engaging in dialogue with Trusts about the regulation and governance of their research. The Academy will examine the progress of the HRA again in 12-18 months as part of the five-year follow up of its report.

Presentations

Introduction

This meeting, held at the Academy of Medical Sciences on 15 October 2014, was the second opportunity for Fellows and invited guests to hear about the HRA's work plan and to provide feedback on the current opportunities and challenges in the regulation and governance pathway. The agenda and attendees are listed in Annex I and Annex II respectively. Sir Michael Rawlins FMedSci chaired the event. He reflected on the progress made since the 2011 Academy of Medical Sciences report, 'A new pathway for the regulation and governance of health research' which he chaired.¹ The report recommended the creation of a single research regulator and paved the way for the creation of the HRA. Sir Michael noted that the wider impact of the Academy's report, that also included consideration of the impact of the EU Clinical Trials Regulation, will be assessed next year.

The HRA's successes, challenges and future directions

The slides and supporting documents that accompanied the presentations can be accessed at <http://www.acmedsci.ac.uk/policy/policy-projects/discussion-with-the-health-research-authority/>

Professor Jonathan Montgomery (HRA Chair)

Professor Montgomery gave an update on the progress of the HRA which focused on several key areas:

- He reiterated that the HRA aims to both promote and protect the interests of patients and the public in health and social care research and that he believes that these are complementary, rather than contradictory, objectives. Ensuring more patients take part in research is crucial.
- The establishment of the HRA as a non-departmental public body in the Care Act 2014 will provide stability and longevity for the changes that it introduces to streamline the processes of regulation and governance, introduce proportionality and reduce duplication. It also places obligations on others (e.g. NHS Trusts) to have regard for the HRA's guidance.
- The HRA must be viewed as a trusted and transparent organisation by all stakeholders. He again stressed the importance of the actions of the HRA being informed by public discussion. Their public and patient dialogue suggested that, whilst participants saw their safety being protected through participation in the process, the public saw the involvement of experts as crucial. There was also concern from these groups about commercial involvement.
- He concluded that increased transparency and reduced bureaucracy would maximise the value of health research.

¹The Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*.
<http://www.acmedsci.ac.uk/download.php?f=file&i=13646>

Dr Janet Wisely (HRA Chief Executive)

Dr Wisely gave an update on the HRA Approval Programme.

- Importantly, whilst an England-only programme, HRA Approval will be compatible across the UK and will involve one application, one assessment and one approval for research in the NHS in England. There will be opportunities for refinement during the phased roll out of HRA approval, which will be done by study type with the ambition to complete by the end of 2015.
- The role of the NHS will be to determine feasibility, select sites and ensure sites are ready to deliver following HRA Approval. Technical assurance, for example pharmacy assurance and radiation assurance, will be provided by the NHS but co-ordinated by the HRA. A team of interim application managers within the HRA are in place to support applications that are disadvantaged by the current processes (such as rare diseases) and where there is high public need for the research.
- In order to effectively manage amendments to clinical trial protocols—a problem highlighted by Fellows at the previous meeting—a new proportionate system of categorising amendments according to whether they need to be reviewed, and by whom, will be introduced by the end of the year. The system includes presumed approval by Trusts after 35 days if regulatory approvals are in place.
- The project to replace the Research Ethics Database with a new database—the HRA Assessment and Review Portal (HARP)—has been completed on time and within budget. This system will be developed further as the platform for HRA Approval.

Question and answer session

There was a wide-ranging discussion, chaired by Sir Michael Rawlins FMedSci, on a number of issues including implementation of the new HRA Approval Programme, data management and how to achieve public trust and understanding.

Implementation of the HRA Approval Programme

Adapting to HRA Approval in Trusts

Questions were raised about whether the necessary culture change in Trusts would occur to facilitate HRA Approval. Dr Wisely highlighted the network of external change managers that will ease the transition and explained that sufficient Trusts were signed up to lead the change and demonstrate its benefits. Once the Trusts are no longer undertaking unnecessary checks they will be able to focus on planning and delivering research. It was stressed that researchers can play an important role in implementation by notifying the HRA of any unnecessary requests from Trusts, rather than simply complying. The HRA would like to hear about any regulatory or governance barriers experienced by Fellows and other researchers in order to address these promptly and diffuse good practice.

HRA Approval application form

Following a question about the length and detail required for HRA Approval via the Integrated Research Application System (IRAS), Dr Wisely stressed that the application form is dynamic and the length depends on the nature of the study. The HRA is hoping to introduce the option for a supervisor to submit one application to cover a group of related student projects. It was noted that 'Class approval' for different research projects using the same database is not supported by ethics committees as a generic approach but defined and managed examples, such as databases and tissue banks, have worked well.

Patient consent

The issue of the requirement for written patient consent was raised. It was suggested that it would be desirable to develop means of capturing consent electronically so it can be shared amongst organisations. There was also a question about whether, following the new EU Clinical Trials Regulation, simplified consent in trials using children would be introduced. Dr Hugh Davis, National Ethics Advisor, is examining this issue. The HRA is currently seeking comments on their draft guidance on 'Seeking informed consent for simple and efficient trials in the NHS' and would welcome feedback from Fellows.²

² The Health Research Authority (2014). *Seeking informed consent for simple and efficient trials in the NHS Draft guidance: For comment*
<http://www.hra.nhs.uk/documents/2014/10/seeking-informed-consent-simple-efficient-trials-nhs-draft-guidance-comment.pdf>

Data

Ownership of data

There was a discussion regarding the ownership of data and whether, as in Boston, a contract could be developed whereby the NHS owns the data and it can therefore be used for research and to underpin decisions on healthcare delivery. Professor Montgomery suggested that this could be a difficult debate to have at the moment given the public resistance to care.data. He thought it should be made clear that patient data is essential for good care to be delivered and that patients own their data but professionals analyse it in a legitimate way. Finally, he identified the need to avoid fragmented conversations about patient data and the importance of trusted voices delivering consistent messages. Concerns were raised about the implications that the proposed European Data Protection Regulation would have on the ability to use patient data. Further discussion focussed on the amount of data that was now available to participants in trials and whether a clinician's duty of care extended to what they did with this data. The importance of linking patients to counselling and advice is key, as well as awareness that genetic information has implications for relatives. The sharing of information between trial participants on social media presents challenges and had led to one trial being unblinded.

Caldicott Guardians

Inconsistencies in approaches taken by Caldicott Guardians in different Trusts were highlighted as a problem at last year's meeting. Attendees heard that not all Trusts use Caldicott Guardians for decisions about research and there is clearly room for improvement.

Accessing data without consent

The HRA's Confidentiality Advisory Group (CAG) considers requests to access confidential data without consent under Section 251 of the NHS Act. CAG now meets monthly and has an active improvement programme.

Real world data

Fellows discussed the use of 'real world data' as well as the possible impact of patient-led research via social media. The HRA reminded Fellows that some types of research, such as data collected outwith the NHS, do not fall under its remit and can therefore be used without approval.

The quality of trial data

There was some concern about the quality of the reported data in multi-centre trials (e.g. in stem cell research). Dr Wisely thought that it was beyond the remit of the research ethics committee (REC) to set and manage data quality standards for research.

Patient trust and understanding

Patient trust in research, particularly around the increasing amounts of data that are being collected, was highlighted as a key area by Fellows and the HRA. It was acknowledged that workshops with the public had identified that the public was initially

concerned about lay people being on ethics committees as they expected professional assurance. However, on being given further information on the regulatory process and roles of the members, this was no longer a concern.

It was noted that there needs to be a conversation with the public to ensure they are aware that research is as safe as possible. Ideally, the HRA want to identify the 'perceived risk'—areas that are of concern to the public—and present evidence illustrating the management of these areas of concern. Work with public and patient groups suggests they are in favour of health research as long as it is sufficiently regulated. The HRA is also assessing whether protocol breaches have presented a risk to patient safety or not. Further information is available on the HRA website.³

Other issues highlighted

Legacy studies

It was brought to the HRA's attention that there could be problems declaring the end of a study and consequently being without ethics approval despite non-interventional aspects of a trial continuing. It was advised that there are now simple solutions to this, and the HRA Director of Operations, Joan Kirkbride can be contacted for further information (joan.kirkbride@nhs.net).

Controlled drugs

It was suggested by a Fellow that regulations relating to work with controlled drugs (for example medical cannabis and MDMA) are restrictive and costly and are limiting medical innovation. At present the HRA is focussing on addressing other priorities but offered to help with this issue on a case-by-case basis.

Concluding remarks

The President of the Academy of Medical Sciences, Professor Sir John Tooke, brought the meeting to a close. He recognised the confidence that the Academy Fellows have in the current work of the HRA and noted that it was apparent that pragmatic solutions are being implemented by the HRA to address many of the practical issues raised during the discussion. Dialogue between the Academy of Medical Sciences and the HRA will continue as the Academy undertakes a comprehensive review to assess the impact of its report on health research governance.

³ <http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/replacing-research-governance-framework/risk-research-serious-breach-notifications-safety-reporting/>

Annex I: Agenda

Wednesday 15th October 2014, The Wolfson Conference Suite, Academy of Medical Sciences, 41 Portland Place, London W1B 1QH

- 17.15-17.45 **Registration and Refreshments**
- 17.45 **Welcome & Introduction**
Professor Sir Michael Rawlins FMedSci, Chair of AMS
Working Group on Regulation and Governance of Health
Research
- HRA Presentation**
Professor Jonathan Montgomery, HRA Chair & **Dr**
Janet Wisely, HRA Chief Executive
- Q & A Session**
- Closing comments and thanks**
Professor Sir John Tooke PMedSci, President of the
Academy of Medical Sciences
- 19.00 **Refreshments**
- 19.30 Close

Annex II: Attendees

Professor Deborah Ashby OBE FMedSci Co-Director of Clinical Trials Unit	Imperial College London
Professor Carol Brayne FMedSci Professor of Public Health Medicine	University of Cambridge
Sir Alasdair Breckenridge CBE FRSE FMedSci Former Chair of the MHRA	Academy of Medical Sciences Fellow
Hollie Chandler Policy Adviser	Cancer Research UK
Dr Claire Cope Policy Officer	Academy of Medical Sciences
Professor David Edwards FMedSci Professor of Paediatrics and Neonatal Medicine	King's College London
Dr Russell Hamilton CBE Director of Research & Development	Department of Health
Dr Sabine Irtan Clinical Research Associate	University College London
Professor Peter Jones FMedSci Professor of Psychiatry	University of Cambridge
Professor Roger Jones FMedSci Emeritus Professor of General Practice	King's College London
Professor Alejandro Madrigal FMedSci Professor of Haematology UCL; Scientific Director	Anthony Nolan Research Institute
Professor Jonathan Montgomery Chair	Health Research Authority
Professor David Nutt FMedSci The Edmond J Safra Chair	Imperial College London
Sir Mark Pepys FRS FMedSci Director of Wolfson Drug Discovery Unit	University College London
Sir Dennis Pereira Gray OBE FMedSci	Academy of Medical Sciences Fellow
Professor Kathryn Pritchard-Jones FMedSci Professor of Paediatric Oncology; UCL Programme Director, Cancer	University College London
Dr Rachel Quinn Director of Medical Science Policy	Academy of Medical Sciences
Sir Michael Rawlins FMedSci Chair, Academy of Medical Sciences Working Group on Regulation and Governance of Health Research	Academy of Medical Sciences Fellow
Professor Elio Riboli FMedSci Professor in Cancer Epidemiology and Prevention; Director	Imperial School of Public Health
Dr Duncan Richards VP, Clinical Head of the Academic Discovery Performance Unit	GlaxoSmithKline

Dr Rachel Richardson Policy Intern	Academy of Medical Sciences
Professor Paul Stewart FMedSci Dean of Medicine	University of Leeds
Professor Sir John Tooke PMedSci President	Academy of Medical Sciences
Professor Sir Nicholas Wald FRS FMedSci Director, Wolfson Institute of Preventive Medicine	Barts and The London School of Medicine and Dentistry
Professor Lucy Wedderburn Professor of Paediatric Rheumatology	University College London
Professor Sir Simon Wessely Professor of Psychological Medicine	King's College London
Professor Roger Williams CBE FMedSci Director, Foundation of Liver Research	Foundation of Liver Research
Dr Janet Wisely Chief Executive	Health Research Authority
Professor Patricia Woo CBE FMedSci Emeritus Professor of Paediatric Rheumatology	University College London
Dr Naho Yamazaki Head of Medical Science Policy	Academy of Medical Sciences



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