

Transforming the regulation and governance of health research in the UK

May 2012



About the meeting organisers

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.

Cancer Research UK is the largest independent funder of cancer research in Europe. Over half of all cancer research in the UK is carried out by our doctors and scientists. Cancer Research UK's research is entirely funded by the public. In 2010/11 we spent £332 million on research, supporting the work of more than 4,000 scientists, doctors and nurses. We fund research into all aspects of cancer from exploratory biology to clinical trials of novel and existing drugs, as well as epidemiological studies and prevention research. Our scientists and doctors have contributed to most of the world's top cancer drugs.

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.

Disclaimer

The views expressed in this document were as a result of an open discussion between many individuals and do not necessarily represent the views of the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust.

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Introduction

In March 2010 the Academy of Medical Sciences was asked by Government to undertake an independent review of the regulation and governance of health research. The review was commissioned due to 'widespread and increasing concern that the process of medical research is being jeopardised by a regulatory and governance framework that has become unnecessarily complex and burdensome.'

A new pathway for the regulation and governance of health research, was published in January 2011 and contained a series of recommendations to transform the regulation and governance of health research in the UK. These recommendations were based around key principles ensuring that the protection of participants was paramount.

The Government responded with a series of commitments in its *Plan for Growth*, and were swift to act on these by establishing a new Health Research Authority (HRA) in December 2011. These developments occurred alongside proposals to reform the NHS and a series of reports focusing on harnessing the potential of the NHS and a thriving life sciences sector. The Prime Minister articulated the Government's commitment to realise the health and wealth benefits of the UK's life sciences sector at the launch of the Life Sciences Strategy and the NHS Chief Executive's report on innovation on 5th December 2011.

Health research is a complex process, involving a range of partners. How we regulate and govern this research is changing. It is essential that stakeholders form part of a continuous and inclusive dialogue to inform and shape these changes as they are taken forward. Therefore, in February 2012 the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust brought together leading figures from across the health research sector including: funders, industry, Government, regulators, patient representatives, academics and NHS organisations.

The meeting was held across four sessions focusing on specific elements of the regulation and governance pathway. Following short presentations by invited speakers there was open discussion among delegates. This report documents these discussions, concluding with the delegates' reflections of how far the landscape has evolved, and what more is needed to truly transform the environment in the UK.

Streamlining regulation through the Health Research Authority

Introduction

The formation of a single body overseeing research regulation and governance was a key recommendation from the Academy of Medical Sciences' review. The review proposed that a single body (incorporating ethics approvals and NHS R&D permissions, and with formal links with the Medicines and Healthcare products Regulatory Agency) could provide a single point of access and contact for researchers throughout the approvals process.

The Government responded to this recommendation by announcing that it would create the HRA, which was formed in December 2011. A non-executive board will be established to confer a degree of independence on the organisation. Further legislation is also planned to make the HRA a non-departmental public body.

In Brief: The Health Research Authority

The HRA has been created to protect and promote public and patient interests and so improve confidence in research regulation. It aims to reduce the regulatory burden with more timely decisions and it has specific new functions: to combine and streamline approvals for research in a unified process and promote consistent, proportionate standards for compliance and inspection. It will operate as part of a national research governance system for health and social care and will work with partners, including:

Devolved Administrations; Care Quality Commission; Medicines and Healthcare products Regulatory Agency; National Information Governance Board; Administration of Radioactive Substances Advisory Committee; Human Tissue Authority; Human Fertilisation and Embryology Authority; National Institute for Health Research.

The HRA has taken on the functions of the National Research Ethics Service (NRES) and the Integrated Research Application System (IRAS).

Alongside exercising these existing functions, the HRA is focused on establishing an effective national role to fulfil its new functions. To do this it is looking at remit, behaviours, systems and processes across the complete lifetime of a research 'event'. This will identify key points in the progress of a research project application and examine quality, waste and duplication.

A Chief Executive, Chair and two non-executive Directors will be appointed in Summer 2012.

Discussion

One-stop-shop

Many delegates wanted further information on how far the HRA was planning to implement the Academy's recommendation to provide one single body for regulation and governance of research. The quick establishment of the HRA and its current work was warmly welcomed, but a question remains as to whether the body could take more of a role in providing leadership on and a national solution to difficulties in research governance processes in the NHS. It was stated that there had been a clear message from the evidence presented in the Academy's review that navigating the NHS governance processes led to the biggest delays in study set up.

Department of Health (DH) and HRA representatives emphasised that the new body would have a role in championing research to NHS organisations and promoting a proportionate approach. Its role as a trusted grantor of regulatory approvals will hopefully instil confidence in NHS organisations, meaning they are less likely to replicate approvals already given by regulators. This theme was picked up further in the session on research governance.

Many delegates wanted further detail on how the new HRA would work with existing bodies that would continue to have a regulatory role, such as the Medicines and Healthcare products Regulatory Agency (MHRA). It was clear that some confusion remains as to exactly where certain approvals will be based going forward, and therefore how researchers would navigate the system.

The Integrated Research Application System was seen as key in creating a single 'front door' for research approvals and longer-term developments could be made to ensure that a single application delivers a single response. The expected establishment of the HRA in primary legislation, on which the Government had stated its intention to publish draft clauses during the next parliamentary session, was seen as a further opportunity to provide clarity as to the exact regulatory functions that it would take on.

Engaging patients and the public

The discussion highlighted the essential role that patient and public engagement should take early on in the development of the HRA. For example, a scoping project is being led by the HRA with support from the Association of Medical Research Charities and INVOLVE to look at how patients and the public could be involved, which many agreed was essential.

It was acknowledged that the HRA was being formed at a time when the NHS was undergoing significant changes and that it was the role of the research community at large to ensure that research remained a priority for the NHS and Government. Engaging with patients to enable them to become advocates for research was seen as vital while major changes are being made to NHS structures and roles. For example, patients could create a local voice that encourages clinical commissioning groups to provide opportunities to engage in research.

The appointment of a non-executive board to build public confidence in the independence of the body, especially in upholding its key role in promoting public and patient interests, was highlighted as being crucial to its future.

Conclusion

There was widespread acknowledgement that the Government's speed in setting up the Health Research Authority has been important in demonstrating its commitment to support the life sciences sector in the UK.

It was clear that there remains a strong need for the HRA to build on dialogue with the research community, patients and the public as it is established. There should be continued consideration of the functions that the body could take forward to create a truly unified and risk proportionate approval process, including an oversight role in research governance.

Regulating clinical trials of investigational medicinal products

Introduction

The focus of this session was the work to adopt a more proportionate approach to the regulatory framework for clinical trials of investigational medicinal products. This included looking at the impact of the EU Clinical Trials Directive, including inspection of study sites, together with initiatives such as earlier access to drugs recently announced in the Government's Life Sciences Strategy.

In Brief: Regulating clinical trials

The EU Clinical Trials Directive came into force through UK regulations in 2004. Since its introduction, there has been widespread acceptance that it has not delivered the EU-wide harmonisation desired.

The European Commission has been consulting on how to revise the Clinical Trials Directive since January 2010, and its draft legislative proposal is expected in late summer 2012.

Following commitment in the 2011 Plan for Growth, the MHRA has been piloting risk-adapted approaches to regulation. Work in this area is in early stages, but the MHRA is taking the lessons learnt from this initiative into discussions with the European Commission to inform revision of the Directive.

The MHRA has also been considering a scheme for earlier access to medicines, which would allow patients to have drugs for unmet needs before a full market licence is issued. The concept of earlier access to drugs was announced in the Government's *Life Science Strategy* as a means to benefit patients and incentivise industry to locate trials in the UK. A full consultation on the MHRA's Early Access Scheme is currently expected in May 2012, and work is ongoing to explore additional options to provide earlier access to medicines pre-licence.

Discussion

European Clinical Trials Directive

It was clear that many delegates felt that the MHRA had made significant progress in exploring risk-adapted approaches to regulation. However, the majority still saw the revision of the EU Clinical Trials Directive as the main route to enshrine a risk-based approach in legislation and create a proportionate European regulatory system. There was concern expressed that the revision timetable was slipping slightly, and also that the UK was not being given much detail on the Commission's plans for revisions. On a more positive note, many attending felt encouraged that the Commission was keen to learn from the MHRA pilots of a risk-adapted approach.

The current lack of harmonisation across the regulatory framework was regarded as presenting a significant barrier to the increasing number of multinational trials. There was consensus among delegates that a mechanism must be adopted to ensure consistent approvals for multinational trials, for example through a centralised or coordinated assessment procedure within the revised Directive.

Inspections

There was a strong agreement from delegates and the panel that the MHRA approach to inspections had dramatically improved over the last 12 months. It was reported that inspections had been performed in a more proportionate, consistent and constructive manner. The engagement of the inspectors in the development of proportionate regulatory processes was felt to be a very positive step. The MHRA outlined that work was ongoing to improve the quality of inspections through building in an increased knowledge of new research and manufacturing practises.

Earlier Access to Drugs

The proposed introduction of an Early Access Scheme for drugs was discussed. Many delegates were not clear on the rationale behind the scheme, and had therefore not considered whether there may be an impact on the conduct of research studies. There was a sense that the proposals may not be as transformative as some delegates desired, and that additional initiatives such as adaptive licensing should therefore be considered alongside early access. It was recognised that the scheme to enable earlier access would add most value if it generated real world data on the drugs involved.

Conclusion

There was general agreement that significant progress had been made by the MHRA in their approach to inspections and their pilot of risk-adapted approaches to clinical trial regulation was welcomed. It was recognised that the revised EU Clinical Trials Directive would be a key mechanism for transforming the regulatory landscape. Adopting a unified position and approach from the UK medical research community was seen as important to ensure the greatest gains were made in negotiating the changes.

NHS governance of health research

Introduction

Following publication of the Academy's review there was widespread agreement that the most significant barrier to setting up studies was the processes for seeking R&D permissions from NHS organisations. This session looked at the measures set out in the *Plan for Growth* to improve NHS governance of research. This included support through the NIHR Research Support Services Framework and accountability through the 70 day benchmark to recruit first patients for trials, which is tied to NIHR funding. It also explored what change was needed to embed a culture of research in the NHS and the role of the NIHR Clinical Research Network.

In Brief: National system for research governance

Funding from NIHR to NHS organisations will, in part, be conditional on meeting benchmarks, including a 70 day benchmark to recruit first patients for all trials they participate in from 2013. This 70 day benchmark measures time between receipt of a valid research application to recruitment of the first patient at that site. This is designed to ensure that providers of NHS services play their part in a national system of research governance, by delivering permissions for clinical trials and planning trial start-up, in a timely and professional manner.

NHS organisations are supported in improving performance through the NIHR Research Support Services (RSS) Framework for local health research management. The RSS framework sets out good practice and standard procedures to risk assess studies and streamline the management and governance of these in the NHS. The framework does not specify who should undertake specific roles within local health research management, but identifies those activities for which the organisation is accountable.

Discussion

R&D permissions

Much of the discussion during this session focused on how the various initiatives fitted together, and where the responsibility for improving R&D processes lay. Key problems delegates discussed included NHS Trusts duplicating study-wide R&D checks that only need to happen once for a study, as well as approvals that have already been undertaken by other regulators. Significant concerns were also raised that the 70 day target is not measuring the right parameters and may not lead to improvements in the overall time taken to set up clinical studies.

There was some concern raised that NHS research governance, and transforming the process for R&D permissions, were not described as a key role for the HRA. Many delegates expressed their desire for the HRA to take on a holistic approach to transforming regulation and governance. Some participants were reassured to learn that the NIHR Clinical Research Network Coordinating Centre is contributing to the HRA's work on proportionate standards and the creation of a unified approval process that will bring together NHS and HRA systems for research applications.

A strong message from the DH and the NIHR Clinical Research Network was that only NHS Trusts can assess local feasibility and take actions to ensure a provider can deliver a study. However, work is being undertaken by some Trusts to move from the status quo where each Trust undertakes separate checks, to a model of mutual recognition of each others' sign-off processes for checks that are needed only once for a study. Initiatives being taken by NHS Trusts to find regional solutions to the governance processes were welcomed, however caution was expressed that this could lead to several different models that researchers had to navigate across the country. The consensus was that if initiatives can be found that work at the regional level, then the HRA could have a role in showcasing best practice, to help disseminate and embed a national system of governance.

Culture of research in the NHS

The focus of the discussion here was the opportunity provided by the NHS reforms to truly embed research into new structures and roles. Although some delegates focused on the significant threat that research would be seen as less of a priority, many clearly felt that the research community had a key role to play in championing research.

There was discussion as to who needed to be influenced in the new structures. NHS Trust management, commissioning groups at the national and regional level, and healthcare professionals all emerged as key audiences. Delegates also highlighted the importance of patient views in championing research in the NHS, and how this could be done in a meaningful way.

An important message throughout was that the inclusion of research duties in the Health and Social Care Act was a welcomed first step, but now action must be taken by Government at a national level to reflect this commitment. While it is important that the commitment to research should be formalised at all levels during this period of change for the service, especially as the mandate for the Commissioning Board is developed and Clinical Commissioning Groups develop their constitution and are authorised, this should not be a substitute for progress towards a culture change towards research in the NHS.

Conclusion

There was a certain lack of clarity as to who was responsible for developing a national system for research governance, combined with a concern that changes are not being aligned with the rest of the regulation and governance pathway. All delegates were clearly committed to ensuring a step change in the time taken to set up studies in the UK, and therefore intended to closely monitor progress. There was strong agreement that all stakeholders in research had a key role to play in championing research at all levels, to maximise the opportunity to embed research as the NHS undergoes transition.

Ensuring secure use of patient data in health research

Introduction

The ability of researchers to access patient data and use it to improve standards of care is a cornerstone of a modern healthcare system. The AMS review identified significant issues that restricted UK researchers' ability to use patient data. It is widely acknowledged that creating a more proportionate and efficient data regime would significantly benefit clinical research and medical advances in the UK.

In Brief: Use of patient data in health research

The Clinical Practice Research Datalink (CPRD) will enable health researchers to have better access to anonymised NHS data from patients. The CPRD combines the Research Capability Programme and the General Practice Research Database, to provide a secure portal for researchers to access and link data held within the NHS. It will be operated by the MHRA.

The CPRD, along with all use of patient data in health research, operates within a complex regulatory framework in the UK, one of the main components of which is the Data Protection Act. The EU Data Protection Directive lays out the requirements that are put in place through the Data Protection Act, and the European legislation is currently being revised.

The NHS Constitution sets out what patients can expect from their NHS, including opportunities to be informed of research opportunities. There will be a consultation later in 2012 on amending the NHS Constitution so that "whilst protecting the right of an individual to opt out, there is a default assumption that data collected as part of NHS care can be used for: approved research, with appropriate protection for patient confidentiality; and patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved."

Discussion

Clinical Practice Research Datalink

Delegates welcomed the development of the CPRD as a secure mechanism for researchers to access anonymised patient data. There was a clear interest in learning more about how this new service would operate, what datasets would be included, and how it would link up with other initiatives. It was recognised that more communication could be done about how the service would benefit academics and medical research charities, as well as the pharmaceutical industry.

Regulation of use of patient data

It was clear from the discussion that there is still a significant lack of understanding about the complex regulatory and governance framework through which patient data are accessed for use in research. Some delegates expressed frustration that it is difficult to unpick the framework and truly identify where barriers lay, and that dialogue with patients on this issue was challenging. Delegates agreed with speakers that there was an opportunity with the development of the new EU Data Protection Regulation to provide clarity on the UK regulatory framework.

NHS Constitution

Many delegates found this session useful in providing clarity about the plans for the NHS Constitution, for example that a position could be adopted where an individual's data are made available for use in research studies unless they opt-out. There was a discussion on the role of the research community in assuring the public that data are being used safely, securely and effectively. It was noted that the UK Clinical Research Collaboration leaflets on use of data in research are an effective tool for informing the public about how their data are used. There was consensus that the consultation on changes to the NHS Constitution later this year would provide a significant opportunity to undertake a programme of engagement with patients and the public about the importance of patient data in research.

In addition to engaging patients, delegates raised the need to engage healthcare professionals. This was first voiced in the session on embedding research in the NHS and was built on in discussions about patient data. Given that patient data underpins so many research studies it was felt that this was a specific issue the community should be championing.

Conclusion

Speakers and panellists emphasised that there is still untapped potential in NHS patient data that we need to unlock to deliver better healthcare benefits for our patients. A significant effort is needed to inform patients, the public and healthcare professionals about the value of patient data for research. The UK also needs to present a clear negotiating position on the EU Data Protection Regulation, to ensure we clarify our complex data regulation framework.

Conclusions

Bringing together stakeholders to discuss progress is essential in shaping the direction for developments in the regulation and governance of health research. One of the most important messages to come from delegates at the meeting was that the dialogue should not stop now, the research community needs to remain engaged, and it is the responsibility of everyone to champion health research in the NHS.

It was clear from the discussions at the meeting that to streamline the regulation and governance pathway, stakeholders would need to work together to take forward the following cross-cutting priorities:

- A **holistic approach** is needed. All stakeholders have the best intentions, wanting high quality research to happen whilst ensuring the safety of participants is protected. The regulation and governance of research needs a pathway-wide approach in order for a transformational change to take place. The research community is still looking for leadership here, and there remains an opportunity for the Health Research Authority to take a greater role in streamlining the whole pathway.
- **Patient and public involvement** is essential. As a community we have not yet found a platform that ensures patient and public involvement is integrated throughout the health research process, including both research design and regulation and governance processes.
- **Championing research** is the role of all stakeholders, and should be taken forward at all levels within the NHS. The NHS is going through a significant period of change and so we should use this opportunity to highlight the important role of research in delivering health and wealth benefits. There is a need to communicate the strength of UK health research at an international level.
- **Effective monitoring and dialogue** will ensure that the research community can assess progress and performance in new systems. Regulation and governance processes are constantly evolving, as are the types of research being undertaken. We need to develop better data as a community to understand how much, and what types of, health research we are undertaking, and how quickly we are getting studies set up compared with our international counterparts.

There has clearly been a significant effort made to introduce initiatives to streamline the regulation and governance of health research. The creation of the Health Research Authority has sent a clear signal to stakeholders that the Government is genuinely committed to substantial reform in this area. All stakeholders now have to take responsibility for ensuring that change is delivered. We should be optimistic that we can transform the landscape for health research in the UK to ensure we reap both the health and wealth benefits.

Key resources

Publications

Department of Business Innovation and Skills: Innovation and Research Strategy for Growth (2011)

Department of Health: Innovation health and wealth: Accelerating adoption and diffusion in the NHS (2011)

HM Government: Strategy for UK Life Sciences (2011)

HM Treasury: Plan for Growth (2011)

Academy of Medical Sciences: A new pathway for the regulation and governance of health research (2011)

Websites

Clinical Practice Research Datalink: <http://www.cprd.com/intro.asp>

European Medicines Agency: <http://www.ema.europa.eu/>

The Health Research Authority: <http://www.hra.nhs.uk>

The Health Research Authority Statutory Instruments: <http://www.legislation.gov.uk/>

INVOLVE: <http://www.invo.org.uk/>

Medicines and Healthcare products Regulatory Agency: <http://www.mhra.gov.uk/>

We would be happy to provide any further information as required. Please contact Emma Greenwood on emma.greenwood@cancer.org.uk or telephone 020 3469 8358.

Slide presentations and the agenda for the day can be found on the Cancer Research UK website: <http://info.cancerresearchuk.org/publicpolicy/ourpolicypositions/researchpolicy/NHS-research/>

Delegates

Dr Christiane Abouzeid	BioIndustry Association
Dr Shannon Amoils	British Heart Foundation
David Ardron	NCRI Consumer Liaison Group
Professor Deborah Ashby OBE	National Institute of Health Research
Dr Mary Baker MBE	European Federation of Neurological Associations
Dr Richard Barker	Oxford Centre for Accelerating Medical Innovations
Simone Bayes	Department of Health
Professor Sir John Bell FRS HonFREng FMedSci	Life Science Champion
Dr Helen Bodmer	Department for Business, Innovation & Skills
Rachael Brannan	NCIN and NCRI and London SHA
Professor Sir Alasdair Breckenridge CBE FMedSci	Medicines and Healthcare products Regulatory Agency
Daniel Bridge	Cancer Research UK
Professor Peter Brocklehurst	University College London
Sophie Broster-James	Medical Research Council
Sarah Buckland	INVOLVE
Professor Paul Burton	University of Leicester
Dr Helen Campbell	NIHR
Joseph Clift	British Heart Foundation
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Professor Finbarr Cotter	Royal College of Pathologists
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Simon Denegri	NIHR and INVOLVE
Dr Sarah Dickson	Medical Research Council
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Dr Rob Frost	GSK
Dr David Gillen Bsc MD FFPM	Celgene
Nicky Gower	UCL Cancer Centre
Professor Malcolm Grant	NHS Commissioning Board
Emma Greenwood	Cancer Research UK
Dr Shaun Griffin	Human Tissue Authority
Dr David Griffiths-Johnson	Department for Business, Innovation & Skills
Louise Haines	NISCHR Welsh Government
Dr Julie Hearn	Cancer Research UK
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Professor Jonathan Ledermann	University College London
Dr Louise Leong	ABPI
Dr David Lynn	Wellcome Trust
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Candy Morris CBE	Department of Health
Alan Morrison	Amgen
Sharmila Nebhrajani	Association of Medical Research Charities
Alex Newberry	NISCHR Welsh Government
Sara Osborne	Cancer Research UK
Dr John Parkinson	Medicines and Healthcare products Regulatory Agency
Sir Nick Partridge OBE	Terrence Higgins Trust
Nicola Perrin	Wellcome Trust
Becky Purvis	Association of Medical Research Charities
Dr Rachel Quinn	Academy of Medical Sciences
Sir Michael Rawlins FMedSci	National Institute for Clinical Excellence
Tony Rees	Clinical Contract Research Association
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Mia Rosenblatt	Breast Cancer Campaign
Dr Jonathan Sheffield	National Institute of Health Research
Professor Sir Patrick Sissons	University of Cambridge
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Carys Thomas	NISCHR Welsh Government
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Lord Leslie Turnberg FMedSci	House of Lords
Sir Mark Walport	Wellcome Trust
Dr Martyn Ward	Medicines and Healthcare products Regulatory Agency
Professor David Webb FMedSci	University of Edinburgh
Professor Peter Weissberg FMedSci	British Heart Foundation
Professor Simon Wessely FMedSci	King's College London
Maggie Wilcox	Independent Cancer Patients' Voice
Dr John Williams	Wellcome Trust
Dr Janet Wisely	Health Research Authority
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