The Academy of Medical Sciences

NHS Health Research Authority

The HRA at ten: progress to date and future gazing

Summary of a joint Academy of Medical Sciences and Health Research Authority workshop held on 17 February 2022

The 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.

The Health Research Authority
The Health Research Authority is an independent arm's length body of the Department of Health and Social Care. We were set up in 2011 with a mission to protect NHS patients, your tissue and your data when you are involved in research.

We have more than 250 staff in England including offices in London, Bristol, Newcastle, Manchester and Nottingham. They're supported by our community of around 850 people who volunteer their time generously to help us to deliver our services, and members of the public who advise us on our work. The HRA's Board leads the organisation and makes decisions that affect our work.

To make it easy to do research that people can trust, the HRA:

- works with people to understand what you want research to look like and acts on this so that you can trust research
- makes sure that people taking part in research are treated ethically and fairly, by reviewing and approving health and social care research studies that involve people, their tissue or their data before they can start
- champions research transparency, so that you can always see when research is taking place, or the results of that research if it has finished
- works with other organisations across the UK to make sure that, wherever you are, research studies can be set up smoothly and are always subject to the same scrutiny before they start
- is one of the gatekeepers of patient data, making sure that your information is protected if it's used for research

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences or its Fellows, or the Health Research Authority.

All web references were accessed in June 2022.

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Executive summary

In 2011, the Academy of Medical Sciences published a landmark report on the state of health research regulation and governance in the UK. The report, produced following an extensive review led by Professor Sir Michael Rawlins GBE FMedSci, concluded that the current system was overly bureaucratic and stifling research without significantly benefiting patients. It also recognised that patients could be harmed if unduly onerous and cumbersome governance procedures held back research. The overarching recommendation of the report was that research oversight systems should be redesigned so that they are proportionate, taking into account the degree of risk associated with each study.

The report led to significant changes in health and social care research regulation, including the establishment of the **Health Research Authority (HRA)**. The HRA was charged with developing and implementing governance frameworks that protect human research participants and promote the interests of both participants and the public by creating an environment in which health and social care research can thrive.

Over the past decade, the HRA has introduced new ways of reviewing research that have had a major impact on health and social care research. These new mechanisms have cut the time taken for studies to start and increased levels of public and patient involvement in both regulation and research, all while maintaining the highest standards of patient safety.

To mark the tenth anniversary of the founding of the HRA, in February 2022 the Academy of Medical Sciences and the HRA jointly organised a virtual workshop to discuss progress to date, likely future research trends, and how the HRA might need to adapt to meet the needs of these trends. The workshop was co-chaired by **Jennifer Bostock**, public representative, Co-Chair of a Global Research Ethics Committee (REC) for Save the Children UK, former HRA NHS REC Vice Chair and Ethics Lead for National Institute for Health and Care Research (NIHR) Research Design Service London; and **Professor Chris Butler FMedSci**, Professor of Primary Care and Director of the Primary Care Clinical Trials Unit at the University of Oxford. The meeting was attended by researchers, patients, members of the public and policymakers, and representatives from the HRA and other regulatory authorities, funders, charities and industry.

Discussions at the workshop highlighted how the HRA has significantly enhanced the environment for health and social care research in the UK, through streamlining review processes, reducing the need for duplicating applications, and ensuring ethics reviews are timely and proportionate. This has been effectively balanced with the need to protect the interests of research participants, service users and the public, through promoting public involvement in research and regulation and improving transparency around clinical trials and

research results, all with the effect of promoting public trust in research. The adaptability and agility of the HRA was also commended. This was demonstrated during the COVID-19 pandemic, where the organisation played a critical role in ensuring rigorous ethical oversight of studies despite highly contracted timeframes.

The discussions also highlighted a range of priorities for the HRA over the next decade. These included:

- Working with others to **embed research** into everyday practice across an integrated health and care system.
- Embedding **patient and public involvement** at all stages of research from idea to impact.
- Improving **equality, diversity and inclusion** in research and regulation.
- Building **regulatory innovations from the COVID-19 pandemic** into business-as-usual practices.
- Supporting researchers to consider the **ethical implications** of their studies during research design and planning.
- Adapting to a more **complex data environment**, including new sources of data and new technologies for integrating and analysing data, and mitigating the impact of the 'digital divide'.
- Enabling, identifying, and responding to **innovative research approaches**.
- Being clear that the remit of the HRA extends far **beyond clinical trials** for medicines.
- Improving regulation across the **whole research and innovation pathway** from end to end, through **dialogue and collaboration** with other stakeholder organisations and regulatory bodies.
- Building on **engagement and coordination with international regulators**.
- **Communicating** actively and widely to improve transparency, build trust, and increase the impact of health and social care research.

The HRA and other regulators face a challenging balancing act. On the one hand, they need to protect research participants and ensure that research is driven by the needs of patients and the public. On the other hand, they are required to provide an environment that facilitates research and makes the UK an attractive place in which to conduct health and social care research.

Over the past decade, participants felt that the HRA has generally achieved this balance well. It has brought together different parts of the health and social care research ecosystem, such as researchers, service users, carers, members of the public, industry, funders, other regulatory authorities, and charities. By continuing to place patients at the heart of its activities and strategy, the HRA now has the opportunity to build on this solid foundation to address emerging challenges and exploit new opportunities to accelerate the development of innovations that truly meet patient needs.

Introduction

In the early 2000s, there was growing frustration with the regulatory requirements faced by scientists planning research involving human participants. The system was felt to be fragmented, with separate permissions required for each site involved in a research study, and burdensome, adding to both the cost and time of research projects.

In response, the Government invited the **Academy of Medical Sciences** ('the Academy') to perform a review of existing practices and to make recommendations for the future oversight of health research. The review was led by Professor Sir Michael Rawlins GBE FMedSci, then head of the National Institute for Health and Care Excellence (NICE). This landmark study, published in 2011, concluded that current practices were stifling research without significantly benefiting patients.[1] It highlighted two key principles: that governance should be proportionate, taking into account the degree of risk faced by research participants, and that it should be 'symmetrical' – it should recognise the potential harms to patients associated with not carrying out research due to an overemphasis on risk mitigation.

The Academy's report led to the establishment of the **Health Research Authority (HRA)** in 2011. The HRA was charged with developing and implementing governance frameworks that protect human research participants and promote the interests of both participants and the public by creating an environment in which health and social care research can thrive. It formed part of a wider vision of all patients having the opportunity to take part in research.

In 2016, the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust convened a workshop to reflect on the role and remit of the HRA and discuss progress that had been made in its first five years.[2] The workshop acknowledged improvements in the simplification and coordination of NHS research governance driven through the establishment of the HRA and HRA approval processes, including a reduction in timelines for NHS permissions and study set up.

With 2021/22 representing the tenth anniversary of the founding of the HRA, the Academy and the HRA jointly convened a virtual workshop to:

- Reflect on the progress made since the establishment of the HRA, identifying key successes, learnings and areas for improvement.
- Consider the research trends that will emerge over the coming decade and identify how the HRA could best meet the future needs of the research ecosystem and facilitate high-quality research and innovation while effectively protecting and promoting the interests of patients, health and social care research participants, and the public.

Attendees at the meeting included researchers, patients, members of the public and policymakers, and representatives from the HRA and other regulatory authorities, funders, charities and industry. It was chaired by **Jennifer Bostock,** a public representative, Co-Chair of

a Global Research Ethics Committee (REC) for Save the Children UK, former HRA NHS Research Ethics Committee Vice-Chair and Ethics Lead for the National Institute for Health and Care Research (NIHR) Research Design Service, London, and **Professor Chris Butler FMedSci**, Professor of Primary Care and Director of the Primary Care Clinical Trials Unit at the University of Oxford.

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Progress to date

Dr Matt Westmore, Chief Executive Officer of the HRA, and Nicola Perrin, Chief Executive Officer of the Association of Medical Research Charities, provided context within which to think about the progress made over the last decade by highlighting some of the difficulties faced by health and social care researchers before the establishment of the HRA.

In 2011, the average time from funding approval to the start of a clinical trial was 621 days.[3,i] Experiences such as the need to obtain approvals for 117 different sites for a single multicentre study, and three-year PhD projects where the first two and a half years were spent securing approvals, were commonplace. This slowed research and cost money that could be used more productively.

Ms Perrin argued that a mark of the HRA's success was the absence of these kinds of stories today. While it was noted that there is a fine balance to be struck between protecting patients and promoting research, it was generally considered by participants that the HRA has got this balance right. Other key successes of the HRA over the past decade were mentioned throughout the workshop **(Box 1)**. The HRA was particularly commended for its agility, as demonstrated during the COVID-19 pandemic. This adaptability will be important for the HRA as it addresses future challenges.

Box 1 – Key accomplishments of the HRA over the past decade

Reduced duplication: More than 50% of applications to the HRA are for research that will take place at more than one site.[4] Duplication has been reduced through the Integrated Research Application System,[5] the integration of the Health and Care Research Wales and the HRA approval processes,[6] technical assurances,[7] and model agreements.[8] One result is increased cost-effectiveness, an important measure of success for medical research charities in particular.

[i] The 621 days is the time from decision to support the study to first patient entered at the first site. This is the average time from 25 studies approved by Cancer Research UK's Clinical Trials Awards and Advisory Committee during the period of November 2006 to July 2007.

Working in partnership: The HRA works closely with the Medicines and Healthcare products Regulatory Agency (MHRA), NICE and funders to connect the end-to-end system, and regulators across England, Scotland, Wales and Northern Ireland, to make it easier to do research all over the UK.

Streamlining applications across the research and development pathway: As of 1 January 2022, all applications for Clinical Trials of Investigational Medicinal Products (CTIMPs) must be made by combined review with the MHRA through the Integrated Research Application System (IRAS).[5] Combined review is on average twice as quick as the two separate systems were, cutting the time between application to recruiting a first patient by 40 days,[ii] and improving the UK's global competitiveness for commercial research.

Timely ethics reviews: 99% of ethics approvals of CTIMPs are completed within 60 days, with the median time being 25 days.[4,iii]

Encouraging public involvement in research and regulation: The proportion of research applications with public involvement has increased from 19% in 2010 to 74% in 2019.[4]

Increasing transparency: From January 2022, the HRA is automatically registering CTIMPs and will ask researchers at the end of study if they have published their results and communicated these to their participants. This is just one commitment the HRA has made as part of its Make It Public strategy.[9]

World-leading response to COVID-19: The HRA approved 1357 COVID-19 studies between April 2020 and September 2021, and the fast-track approvals service for the most urgent COVID-19 research reduced the average research review timelines by 90% to 5 days.[4]

Contributing to a system that builds public trust in health and care research: A 2020 review found that 73% of people would be interested in taking part in health research.[10]

[ii] This performance data is taken from timelines for CTIMPs going through separate and combined review from 2018 to present (February 2022).
[iii] Figures refer to non-combined CTIMPs, January to October 2021

Box 2 – The UK Government perspective

Providing a recorded message, George Freeman MP, Minister for Science, Research and Innovation, outlined the UK Government vision for the future of health and social care research.

The Minister noted that creation of the HRA was part of a wider initiative, outlined in the Government's Life Sciences Strategy,[11] to create a world-leading UK clinical research environment that is more efficient, more effective and more resilient, with research delivery embedded across the NHS, as articulated in our vision for clinical research. Part of the emphasis has been on ensuring the health and care system is configured to support research and that industry is facilitated to make use of this research infrastructure.

This model remains at the heart of the UK clinical research Recovery Resilience and Growth programme and the Life Science Vision of 2021, which has a focus on research to address the key conditions affecting health at the population level.[12]

The Minister congratulated the HRA on the progress it has made, in areas such as patient involvement, fast-track ethics review, contract review processes, unified applications and transparency. He also noted that the speed of technological change was accelerating, creating new challenges but also offering many new opportunities.

He concluded by noting how the RECOVERY trial, by far the largest COVID-19 therapeutics trial globally, was rapidly set up and delivered vital findings, and provides an illustration of what can be accomplished. The NHS and NIHR offer a unique infrastructure to support research, while the Our Future Health initiative[13] foresees a world in which people are more able to access and contribute to research through digitally enabled devices. Bringing these twin aspects together will create a world-leading engine for research-based medicine from which all could benefit.

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Future gazing: The next ten years

Through short presentations, panel discussions and breakout groups, participants discussed emerging challenges and trends and how the HRA could address and respond to them. Several key themes emerged:

Working with others to embed research into everyday practice across an integrated health and care system

The formation of the HRA was part of a wider drive to ensure that every NHS patient and service user has the opportunity to take part in research. Despite much progress, research is still not as embedded in the NHS as, say, teaching. The governance and resourcing of research should be a normal part of NHS care. The barriers to participation in research need to be lowered, and everyone, across all levels of management in the NHS, must be committed to delivering research as a key aspect of care.

Participants noted that the vision of "every patient a research patient" has yet to be fully realised, even though patients have a growing expectation to be involved in research. To address this situation, **Dr Louise Wood** CBE, Director of Science, Research and Evidence at the Department of Health and Social Care, noted the progress that has been made through the UK vision for the Future of Clinical Research Delivery through the Recovery Resilience and Growth (RRG) programme.[14] The vision, which has patient and public involvement at its heart, was developed with input from key stakeholders, including the NHS, charities, industry and regulators. It sets out a future for clinical research that is people-centred, digitally enabled, and creates a pro-innovation environment. It encompasses mechanisms for fast-track ethics review and coordination across agencies such as the HRA and MHRA.

Dr Wood noted that more than a million people in the UK had volunteered to take part in COVID-19-related research and take up of COVID-19 interventions had been high. On the other hand, she reflected on the negative impact of the pandemic on non-COVID-19 research studies, calling on the system to ensure that the pre-pandemic portfolio of research is regained. There is an opportunity to take advantage of the increased public interest and trust in science, with a key challenge remaining around how we make participation in research as easy as possible.

Discussions touched upon the need for common protocols and common contracts for multisite studies. Although it was acknowledged that progress was being made, the contracting processes can still be a significant barrier. However, there are moves towards harmonisation – the COVID-19 RECOVERY trial, for example, was based on a single contract at all participating sites.

Embedding patient and public involvement at all stages of research from idea to impact

The sudden drop in public involvement in the development and implementation of research early in the COVID-19 pandemic suggests that it is not as embedded as was assumed. There is a need to continue pushing for earlier and wider involvement, with the HRA acting as a facilitator as well as an enforcer, helping to build capacity for public involvement and focusing on quality as well as quantity.

The HRA responded rapidly to the drop in public involvement in research early in the COVID-19 pandemic. Participants praised the HRA's leadership of a collaborative effort to emphasise the importance of designing research with people with lived experience and its creation of a UK COVID-19 public involvement matching service, helping applicants meaningfully involve the public in their projects. This work reinforced the HRA's expectation that patients and the public should be routinely involved in research and that it is possible to do so, even in a pandemic.

Dr Kristina Staley, Director, TwoCan Associates, suggested that public involvement has become increasingly mainstream over the past decade. She commended the HRA for showing strong leadership in this area, particularly by encouraging different approaches to involving people depending on the purpose of involvement.

Nevertheless, she argued that there were opportunities to be more radical. Her work with the James Lind Alliance, which brings together patients, carers and clinicians to identify research priorities, suggests that these prioritisation exercises are not yet having a major impact on research agendas (although it was noted that some medical research charities were acting on the Alliance's recommendations).

Dr Staley also noted that researchers tend to focus on assessing the impacts of single interventions while patients are more concerned with how to achieve their desired outcomes. Truly patient-centric research would focus more holistically on how treatments(s), self-management and lifestyle changes can in combination maximise the chances for improvement in people's health, rather than focusing on whether single clinical interventions 'work'.

Dr Simon Stones, medical writer and health advocate, provided a wide-ranging patient's perspective of current practice and future trends. He opened with a passionate endorsement of public involvement, suggesting that "research was the best treatment I ever had" and that taking part in research can enable patients to better manage their health conditions.

Dr Stones argued that this is the era of the empowered patient, who (along with families and carers) should be considered partners in research – experts on account of lived experience. To reflect this shift, relationships with researchers should be deep and collaborative, avoiding tokenism. Dr Stones' highlighted several characteristics of good people-centred research **(Box 3)**.

In discussions, participants noted that the quality of public involvement was variable, not always well planned or undertaken at early stages of research planning, and in some cases verging more on the side of engagement rather than true involvement. It was suggested that lay members of research ethics committees could play a key role in assessing the quality of

Box 3 – Key characteristics of people-centred research

- Authentic involvement as part of the research team
- Transparency
- Strategic focus on patient-relevant outcomes and experiences
- Long-term partnerships with patient advocacy organisations, patient advocates and opinion leaders to build better relationships and avoid tokenism
- Increased diversity of research participants by removing and alleviating barriers to participation (see below)
- Research and data sharing embedded as part of routine health and social care
- Interdisciplinary research, including qualitative research
- Monitoring and evaluation procedures embedded and acted upon
- Patient feedback incorporated throughout
- Awareness of short- and long-term impact on patient communities and how to increase this impact
- Proactive communication at all stages
- Patient involvement in dissemination strategies and publication planning activities
- Multimedia approaches to communication, appealing to as wide an audience as possible
- Patients given roles as authors and presenters
- Public kept informed through plain language summaries, infographics, podcasts and social media posts

public involvement, and that the HRA could encourage groups such as funders and academic journals to treat public involvement as an essential component of study design and the publication of findings. It was noted that some funders already have high expectations of public involvement, and will reject grants on the basis of inadequate involvement. However, public involvement is not currently a prerequisite for most grant applications, and it was acknowledged that funders should do more to ensure researchers have the time, money and resources they need to meaningfully involve the public. Similar points were raised at an Academy FORUM workshop on 'Public involvement and engagement in research during the COVID-19 pandemic', where participants stressed the need for all stakeholders across the research ecosystem to commit to promoting public involvement, especially research funders.[15]

However, the issue of variable quality of public involvement raises the question of how 'quality' can be assessed, and the impact of public involvement evaluated. There is much anecdotal evidence of impact, in terms of improving the quality of research conducted, but some participants felt that this evidence had not been systematically assembled in ways that would help researchers appreciate the value of involvement and how best to carry it out. Another suggestion was that a better understanding of the elements and applications of public involvement that really benefit both research and patients is needed to improve the quality of

public involvement. Other participants suggested that public involvement was essential on an ethical basis, and evidence of impact was not needed as a justification. However, it was pointed out that some researchers still see HRA processes as a hurdle rather than an opportunity to improve their research practices and the impact of their research, and systematically assembled evidence relating to public involvement could potentially shift their mindset.

A further issue raised was how best to facilitate public-led community research. It was suggested that a 'partnership of equals' was the best approach, with researchers using their methodological skills to facilitate and support the activities prioritised by patients.

Dr Staley explained that there is a need to be responsive at both 'macro' and 'micro' levels, with one example of a 'micro' issue being patient information sheets, which can be extremely long. Participants noted a sense that the key purpose of some information sheets was not to inform patients but to provide a legal defence should problems arise. Patients could be involved more in the development of these resources, and alternative approaches could be considered, such as summary versions with the option to receive detailed information on request. It was also noted that complex patient information sheets could deter people from taking part in research.

In relation to public involvement in the regulation of research, participants commended the activities of the HRA's Public Involvement Network, but noted that, with 91 members, there was an opportunity to grow this network. Questions were also raised about the process of ethics reviews. For example: How do we democratise the process? How do we ensure diverse and representative voices feed into research reviews? How does the HRA, as a national body, ensure that research reviews are conducted with regional place-based needs in mind?

'It's time to eliminate the inherent, unconscious biases in research which regard patients and caregivers as inferior to those in positions of authority and power' – Dr Simon Stones

Improving equality, diversity and inclusion in research and regulation

Health inequalities are prevalent in the UK and may be exacerbated by failing to include certain groups of people in research. Working with other bodies, the HRA needs to identify and address the barriers that make it difficult for people from groups currently underserved by research to take part in research, regulation, and the activities that shape research priorities and methodologies.

Participants identified a need for equality, diversity, and inclusion to be addressed to ensure more equitable participation in research. As Dr Stones emphasised, realising this will require a more inclusive culture, active collaboration with underserved groups of people, and an awareness of power relationships between clinicians and patients.

There are many reasons why particular people with lived experience of health and social care issues are not included in research and regulation. This includes not being given information about opportunities to take part, being made to feel that it is 'not-for-them', or not having sufficient time or money required to take part (e.g. for travel). Many different approaches will be needed to support more people with lived experience to become involved in research. These

might include making more resources available to reduce financial barriers to participation.

It was suggested that funders and trial sponsors should consider the geographic scope of recruitment as a fundamental ethical and equity issue. Digitally enabled and remote participation could help to address geographic inequities, where patients living a long way from existing centres of research excellence have fewer opportunities to participate in research. However, it is important to acknowledge that while digital and remote participation may improve access to research for some groups, the 'digital divide' means it also has the potential to exclude others, namely those who do not have access to or the capability to use digital technologies.

Building regulatory innovations from the COVID-19 pandemic into business-as-usual practices

The HRA's approach to the COVID-19 pandemic was regarded as gold-standard, pragmatic, agile, and something that can be built on.

Dr Westmore noted that the COVID-19 pandemic has been the catalyst for multiple innovations in regulatory practice, given the urgent need for research on this novel threat to health, without sacrificing participant safety. These included online decision-making, a fast-track ethics review service (which has halved the time it takes to review and approve research proposals from 28 days to 14[16,iv]), and close liaison with bodies in the devolved nations. Processes have been streamlined, particularly through joint review with the MHRA, and efforts are being made to further strengthen public involvement.

Dr Westmore noted that it was now necessary to make these innovations a routine aspect of the HRA's work. While the nature of research is changing rapidly, the HRA's core mission remains unchanged – to ensure that researchers carry out research that people can trust.

Providing the perspective of a clinical researcher and end-user of HRA services, **Professor Christopher Chiu**, Professor of Infectious Diseases at Imperial College London, agreed with this point of view, noting that the agility and support exhibited by the HRA was a key enabler of his own research studies during the pandemic. Dr Chiu suggested that this experience of COVID-19 should not only be used to inform business-as-usual processes, but also to ensure that the HRA is able to fulfil its critical role in pandemic preparedness and general resilience to future health challenges.

Supporting researchers to consider the ethical implications of their studies during research design and planning

Researchers should be supported to consider the ethical implications of their projects at earlier stages. This means reviewing and mitigating against ethical

[iv] Median approval time for full REC in 2021 (Jan to October) is 28 days, for Fast track REC this is 14 days.

issues before applying for research funding, ensuring that the safety and interests of patients are put at the heart of research design, and the research is not delayed at later stages during ethics review.

Professor Christopher Chiu suggested that ethical review processes are now so streamlined that they are rarely the rate-limiting step in the initiation of research studies.

Professor Chiu leads research programmes in the ethically complex area of human challenge studies, where volunteers are deliberately infected with infectious micro-organisms, under highly controlled conditions. He suggested that independent ethical scrutiny is absolutely essential in this area.

He has led the world's first SARS-CoV-2 human challenge studies and praised the HRA's oversight, which included the convening and training of a special research ethics committee. This has enabled the UK to be a world leader in the field of SARS-CoV-2 human challenge studies, attracting considerable international interest, while still protecting the interests of study volunteers and maintaining public confidence.

Despite these clear advances over the last decade, there is still work to do to ensure that ethical issues are considered from the outset. It was suggested that ethicists and philosophers could be more routinely involved in grant writing, and even act as co-applicants. Although this may seem unorthodox, until recently qualitative research input was also seen as unusual, yet its value is now widely recognised.

Adapting to a more complex data environment, including new sources of data and new technologies for integrating and analysing data, and mitigating the impact of the 'digital divide'

Data sharing has long been a thorny issue in health and social care research, with technical, regulatory and operational challenges. Finding better and proportionate ways to ensure smooth, timely data sharing will be a key future priority. Central to this will be earning public trust and approval and encouraging patients to be advocates for the sharing of data. Beyond data sharing, real-world evidence and data harvested from everyday activities have enormous potential to provide insights into impact on patients.

Discussions highlighted the role that electronic health records could play in facilitating the sharing of health and social care data, but also the many obstacles that currently inhibit data sharing. While greater use of digital technology could provide new opportunities for participation in research, the need to consider the 'digital divide' was also raised, given the potential to exclude people without access to or the capability to use digital tools.

Other innovations with potential implications for research include 'blockchain', which is a system used in cryptocurrency systems for recoding information in a way that means it is difficult to change, and Trusted Research Environments. These technologies may offer new opportunities

to manage and safely curate data and could enable patients to retain greater control over use of their data.[17,18] It was suggested that standardisation of terminology (for example, what is meant by 'anonymised' data) would also be helpful.

It was noted that there is need for an authority to be a voice on public interest in the use of data, and it was suggested that the HRA could take on this role. However, there would be a need to consider the reputational risk to the HRA if it were to lead in this area.

Enabling, identifying, and responding to innovative research approaches

The HRA's processes must be able to adapt to new research techniques and applications - both those that we are aware of, and unknown innovations of the future.

Clinical trial design is becoming more innovative, with, for example, adaptive and platform trials. In addition, there are more opportunities for self-testing and remote data gathering from participants at home. These trends could make it easier for people to take part in health and care research but raise a host of issues that the HRA will need to consider.

Professor Ruth Plummer FMedSci, Professor of Experimental Cancer Medicine at Newcastle University, discussed recent innovations in trial design, particularly the growing use of 'adaptive trials' that evolve as findings emerge. 'Basket' trials focus on evaluation of therapeutics targeting specific molecular abnormalities in a wide range of tumour/patient types, while 'umbrella' trials compare multiple different treatments in the same study. Platforms are being set up so that patients can be profiled and then connected to the appropriate ongoing study depending on the specific characteristics of their condition.

These advances are opening up trials to more patients and decentralising trials, making it easier to recruit patients from all regions of the UK and, in some cases, internationally. This is, however, dependent on the digitalisation and sharing of health records, as well as digital consent and remote data collection from participants, all of which need to be improved. Furthermore, the use of remote testing and reporting has the potential to exclude those who are not confident using digital technology, raising further issues for equality, diversity and inclusion in trials. As with health and social care more generally, the HRA should act to ensure that all patients are able to benefit from these new innovations in trial methodologies, while mitigating against any unintended negative consequences.

In addition to being able to adapt to new clinical trial methods and the increasingly complex data environment, there are a host of other emerging fields and research trends that will require slightly different approaches to the current standard of regulatory practice. Some mentioned during the workshop were artificial intelligence **(Box 4)**, precision medicine, personalised medicine, and research to study health inequalities.

In addition to these 'known unknowns', there is also a need for the HRA to consider how it will identify and respond to the 'unknown unknowns' of future research practice. Horizon scanning was noted as a key priority to build resilience in the regulatory system and permit the translation of new innovations into benefits for patients in a timely manner.

Box 4 – AI in healthcare

Artificial intelligence (AI) could have a major impact on patient care, yet its application in medicine will raise new regulatory challenges.

Dr Usman Munir, AI Research Programme Manager at Microsoft Research, argued that, despite the potential of AI, many AI applications fail in practice, because often the focus is to find healthcare problems to apply AI solutions to without due consideration given to the local context such as clinical workflows, patient needs, trust, safety and ethical implications.

Dr Munir suggested that AI amplifies and augments, rather than replaces, human intelligence. When building AI systems in healthcare, it is key to not replace the important elements of the human interaction in medicine but to focus it and improve the efficiency and effectiveness of that interaction. AI innovations in healthcare will come through an in-depth, human-centred understanding of the complexity of patient journeys and care pathways.

As an example, he discussed the InnerEye project collaboration with oncologists in Cambridge. Extensive liaison with clinicians, involving social researchers, helped to map out the daily life of oncologists, and identified the extensive time spent planning radiological treatments to avoid irradiation of healthy tissue as a key opportunity for AI and automation. The resulting application helped to cut preparation time by 90%.[19] The AI model is freely available as an open-source toolkit and has potential to be applied in other areas of medical imaging.[20]

Being clear that the remit of the HRA extends far beyond clinical trials for medicines

Health and social care research spans a wide range of disciplines and methods. In addition to clinical trials for medicines, research in social care and public health, trials on preventative interventions and technologies, qualitative research, economic evaluations, longitudinal cohort studies, secondary data analyses and meta-analyses are also part of the HRA's remit. These all contribute to a rich, diverse and progressive health and social care research landscape, and each area presents the HRA with a different set of challenges.

Action to support best practice need to be applicable across the health and social care research landscape and the HRA needs to ensure its regulatory processes support different research areas and methodologies, including multidisciplinary approaches. Although the HRA does work across all areas of health and social care research, there is a recognition that the organisation could strengthen the way it communicates about its work and remit.

Improving regulation across the whole research and innovation pathway from end to end, through dialogue and collaboration with other stakeholder organisations and regulatory bodies

For patients to benefit from safe medical innovations as rapidly as possible, an end-to-end perspective of the research and development (R&D) pathway is needed. This will ensure there are no unnecessary 'roadblocks' and that activities at one step mesh smoothly with those at the next. The HRA needs to continue examining not just its own practices but also its interactions with other bodies, to help create an ecosystem that supports the speedy development, evaluation and implementation of medical innovations while protecting research participants.

Dr Jennifer Harris, Director of Research Policy, the Association of the British Pharmaceutical Industry, noted that, from an industry perspective, the HRA has been successful in driving a transparent, open and people-centred approach to clinical research approvals, helping to ensure studies conducted in the UK are ethical and of a high-standard.

Dr Harris emphasised the need for the HRA and other UK regulators to be sustainably resourced to ensure innovative processes and learnings from the COVID-19 pandemic are taken forward and embedded across the agency. She also highlighted the importance of taking an end-to-end perspective to clinical research approval and delivery, to ensure that there are no unnecessary roadblocks and that transitions between stages occur smoothly.

It was noted that the key shift since the creation of the HRA is the focus that has been placed on symmetry – the recognition that the potential harms of not doing research might match the risk associated with research. However, it was emphasised that this view is not reflected across all players in the system, particularly university sponsors and contractors, and so the HRA could play a role in influencing other entities to take a similar approach.

Building on engagement and coordination with international regulators

For the UK to remain an attractive place for commercial R&D, the HRA must keep a close eye on the evolving global landscape, ensuring it has a 'seat at the table', with the aim of achieving international harmonisation in regulatory practice.

Dr Harris noted that the response of the HRA and MHRA during the COVID-19 pandemic had been globally recognised, with pragmatic and innovative regulatory thinking. However, she also emphasised the importance of global dialogue to promote harmonisation in regulatory practice, facilitating cross-border studies.

Communicating actively and widely to improve transparency, build trust, and increase the impact of health and social care research

Delegates stressed that communication needs to be at the heart of the HRA's work – with the public to encourage participation and promote the benefits of research, with researchers to promote greater public involvement and consideration of ethical issues, and with stakeholders to ensure more joined up approaches. The HRA is also well placed to act as a facilitator of communication between different parts of the system.

The HRA has a role to play in ensuring the transparent dissemination of research findings, supporting researchers to think earlier and more creatively about how to disseminate their findings to maximise the impact of their work. As well as feeding back the outcomes of their research to participants, this might also include working with participants to act as 'champions' of research findings.

While the HRA's 'Make it Public: transparency and openness in health and social care research' strategy was welcomed, it was noted that there is a long way to go to achieve fully open practices and transparent reporting of results, beyond just clinical trials. Collaboration with funders and publishers to communicate examples of best practice was highlighted as one way to achieve this.

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Conclusion

When it was established, the HRA was charged with both protecting research participants and promoting the interests of the public by creating an environment in which health and social care research can thrive. This includes coordinating and standardising regulation and ensuring that this is proportionate, as well as promoting transparency in research.

Delegates felt that the HRA has achieved this balance well, maintaining trust in research and ensuring good take up of medical innovations, even given the challenges presented by the COVID-19 pandemic. Attitudes are shifting, but there is still more to do, as evidenced by the discussions at this meeting. Gaining ethics approval for research is still seen by some as a burdensome hurdle, rather than a welcome step in which expert input improves the quality of research, maximises patient and participant safety and protects researchers by providing assurance that their research is legal and ethical. More work is also needed to ensure that everyone is included in health and social care research so that everyone can benefit from its outputs, and to enable research findings to improve care faster by making the UK the easiest place in the world to do innovative research that people can trust.

The HRA's response to the COVID-19 pandemic illustrated its ability to respond flexibly and adapt to changing circumstances, while maintaining its core function of protecting the interests of research participants. The coming decade is likely to test the HRA's adaptability further, but by continuing to work with patients, carers, the public, researchers and other stakeholders, the HRA can build on the solid foundation it has created to address emerging challenges and exploit new opportunities to accelerate the development of innovations that truly meet patient needs.

Since the workshop was held, the HRA has published its strategy for 2022-2025 'Making it easy to do research people can trust', which takes forward many of the issues raised at the workshop.[21]

References

21. Health Research Authority (2022). *We make it easy to do research that people can trust. Strategy 2022-25.* https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/HRA_Strategy_2022-25.pdf

Annex 1: Agenda

13.30	Meeting starts
13.30-13.40	**Welcome and introduction** **Professor Chris Butler FMedSci**, Professor of Primary Care, University of Oxford **Jennifer Bostock**, public representative, Co-Chair of a Global Research Ethics Committee (REC) for Save the Children UK, former HRA NHS REC Vice Chair and Ethics Lead for NIHR Research Design Service London
13.40-13.50	**10 years of the Health Research Authority and shaping its future** **Matt Westmore**, CEO, will give an introductory talk outlining the HRA's progress over the past 10 years and looking to the future.
13.50-14.35	**Panel session: Progress to date – key successes, lessons learned and areas for improvement** This session will include brief remarks from each of the panellists, followed by a Q&A session. Panellists: • Dr Louise Wood CBE, Director of Science, Research and Evidence, Department of Health and Social Care • Dr Jennifer Harris, Director of Research Policy, The Association of the British Pharmaceutical Industry • Nicola Perrin, CEO, Association of Medical Research Charities • Dr Kristina Staley, Director, TwoCan Associates • Professor Christopher Chiu, Professor of Infectious Diseases, Imperial College London
14.35-14.40	**Break**
14.40-14.50	**A note from the Minister for Science, Research & Innovation** **George Freeman MP**, Minister for Science, Research & Innovation, will detail his ambitions for health and social care research for the next decade in a pre-recorded message.
14.50-15.30	**Looking ahead to the next decade** This session will include 5-minute talks from representatives on the future trends in research, followed by a Q&A session. Speakers: • Dr Usman Munir, AI Research Program Manager, Microsoft Research – *AI and machine learning* • Professor Ruth Plummer FMedSci, Professor of Experimental Cancer Medicine at Newcastle University – *novel trial methods for personalised medicine.* • Dr Simon Stones, Medical Writer and health advocate – *innovative patient-centred research*
15.30-15.40	**Break**
15.40-16.20	**Break-out sessions** Participants will be allocated to breakout rooms to discuss the following questions in relation to the future needs of the biomedical and health and social care research ecosystem:

	• What are the upcoming trends and advances in health and social care research? • What should the HRA be doing to respond to these upcoming trends and advances? • What should the HRA be doing to meet the needs of research participants, patients and the public over the next decade?
16.20-16.50	**Feedback session** Breakout group facilitators will be invited to share key points from their group's discussions, followed by an open discussion.
16.50-17.00	**Closing remarks** Professor Chris Butler FMedSci and Jennifer Bostock
17.00	**Meeting ends**

Annex 2: Attendees

Co-Chairs

Jennifer Bostock, public representative; Global Research Ethics Committee (REC) Co-Chair, Save the Children UK; former NHS REC Vice Chair, HRA; Ethics Lead, National Institute for Health Research (NIHR) Research Design Service London
Professor Chris Butler FMedSci, Professor of Primary Care and Clinical Director of the Primary Care Clinical Trials Unit, University of Oxford

Participants

Dr Virginia Acha, Associate Vice President, Global Regulatory Policy, MSD
Christopher Albertyn, Research Portfolio Lead, Kings College London
Professor Parveen Ali, Professor of Nursing, University of Sheffield
Dr Rasha Al-Lamee, Clinical Senior Lecturer, Imperial College London
Professor Deborah Ashby OBE FMedSci, Director of the School of Public Health and Professor of Medical Statistics and Clinical Trials, Imperial College London
Dr Janice Bailie, Assistant Director, Public Health Agency Northern Ireland Research and Development (R&D) Division
Dr Kate Blake, Director of R&D Strategy, NIHR Guy's and St Thomas'/Kings College London Biomedical Research Centre, Guy's and St Thomas' NHS Foundation Trust
Catherine Blewett, Senior Development Manager, HRA
Dr Helen Bodmer, Head of Health Systems Partnerships, Medical Research Council
Dr Laura Boothman, Deputy Director – Policy and Engagement, The Institute of Cancer Research
Oliver Buckley-Mellor, Policy Advisor, Cancer Research UK
Professor Christopher Chiu, Professor of Infectious Diseases, Imperial College London
Professor Sir Rory Collins FRS FMedSci, Head of Nuffield Department of Population Health and BHF Professor of Medicine and Epidemiology, University of Oxford
Dr Elizabeth Coulthard, Associate Professor in Dementia Neurology, University of Bristol
Katherine Cowan, Senior Advisor, James Lind Alliance; Consultant
Professor Mary Dixon-Woods FMedSci, Director, THIS Institute; The Health Foundation Professor of Healthcare Improvement Studies, University of Cambridge
Dr Jim Elliott, Head of Public Involvement, HRA
Anne Ferrett, HRA Public Involvement Network member
Professor Andrew George, Non-Executive Director, HRA, Health Education England and Surrey and Borders Partnership NHS Foundation Trust; Chair, Imperial College Health Partners; Director and Consultant, AJTG Ltd
James Green, Department for Business, Energy and Industrial Strategy
Kate Greenwood, Senior Improvement Delivery Manager, HRA
Dr Jennifer Harris, Director of Research Policy, The Association of the British Pharmaceutical Industry
Clare Hedwat, Senior Strategy Advisor, Office for Life Sciences

Professor Kerry Hood, Professor of Trials and Director of the Centre for Trials Research, Cardiff University
Professor John Iredale FRSE FMedSci, Interim Executive Chair, Medical Research Charity
Dr Erika Kennington, Head of Research and Innovation, Asthma UK and British Lung Foundation
Dr Alison Knight, Data/AI Policy Secondment, HRA
Lynn Laidlaw, HRA Public Involvement Network member; patient researcher
Dr Mohamed Lockhat, Medical Director of Infectious Diseases and Vaccines, J&J - Janssen UK
Emma Lowe, Head of Research Policy, Clinical Research and Growth, Department of Health and Social Care (DHSC)
Dr Helen Macdonald, Research Integrity Editor, BMJ
John Maingay, Director of Policy and Influencing Healthcare Innovation, British Heart Foundation
Elaine Manna, public and patient representative
Dr Janet Messer, Director of the Approvals Service, HRA
Edel McNamara, Data Protection and Information Governance Lead (Global), Health Data Research UK
Professor Sir Jonathan Montgomery FMedSci, Professor of Healthcare Law, University College London; Chair, Oxford University Hospitals NHS Foundation Trust; Former Chair, HRA; Former Chair, Nuffield Council on Bioethics
Dr Katherine Morley, Senior Research Leader, RAND Europe
Dr Usman Munir, AI Research Program Manager, Microsoft Research
Alastair Nicholson, Head of Coordination and Standardisation, HRA
Dr Martin O'Kane, Head of Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Maria Palmer, Director, NHS R&D Forum
Nicola Perrin MBE, Chief Executive Officer, Association of Medical Research Charities
Professor Ruth Plummer FMedSci, Professor of Experimental Cancer Medicine, Newcastle University; Honorary Consultant Medical Oncologist, Newcastle Hospitals NHS Foundation Trust
Becky Purvis, Deputy Director of Policy and Partnerships, HRA
Anna Quigley, Director of Health Research, Ipsos MORI
Professor Sir Michael Rawlins GBE FMedSci, Honorary Professor, London School of Hygiene and Tropical Medicine; Emeritus Professor, University of Newcastle upon Tyne
Mandy Rudczenko, public and patient carer representative
Dr Shiphali Shetty, Senior Manager, Clinical Operations, Bristol Myers-Squibb
Dr Tim Sprosen, Director, Early Phase Clinical Trials, University of Sheffield; Chair, Yorkshire and the Humber - Sheffield REC
Dr Kristina Staley, Director, TwoCan Associates
Professor Sir Terence Stephenson, Chair, HRA
Dr Simon Stones, Medical Writer, Engage Scientific Solutions; Health Advocate
Dr Kenji Takeda, Director of Academic Health and AI Partnerships, Microsoft Research
Juliet Tizzard, Director of Policy and Partnerships, HRA
Dr Andrew Toft, Senior Research Policy Manager, Chief Scientist Office, Scottish Government
John Turner, public and patient representative; Diabetes UK Grants Advisory Panel
Dr William van't Hoff, Chief Executive Officer, NIHR CRN
Daniel Wake, Research and Innovation Lead, Universities UK

Dr Lynne Webster, Head of Research Office, University of Manchester NHS Foundation Trust
Professor Matthew Westmore, Chief Executive, HRA
Karen Williams, Deputy Chief Executive and Director of Finance, Procurement and Estates, HRA
Roger Wilson, HRA Public Involvement Network member
Dr Louise Wood CBE, Director, Science, Research and Evidence, DHSC
Katharine Wright, Assistant Director, Nuffield Council on Bioethics
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