Written Evidence Submitted by the Health Research Authority (HRA) (C190096)

Introduction

1. The Health Research Authority (HRA) welcomes this opportunity to submit evidence to the Science and Technology Committee (Commons) inquiry into UK Science, Research and Technology Capability and Influence in Global Disease Outbreaks.

2. The HRA is a non-departmental public body of the Department of Health and Social Care. We have a remit to protect and promote the interests of patients and the public in health and social care research, and we do this by working with partners across the UK.

3. We provide expert advice and guidance to researchers and review research studies through 64 Research Ethics Committees (RECs) in England and the Confidentiality Advisory Group (CAG), and we provide specialist review and assurance of research on behalf of NHS organisations.

4. We review around 6,000 new research studies each year, ranging from observational studies in care settings, tissue banks and research databases, to large, multi-centre clinical trials of new medicines and advanced therapeutics. In addition, we review around 18,000 amendments to research studies each year.

5. We also manage the national health and social care research approval technology platforms, on behalf of partners across the UK. These enable researchers to apply for research approvals from a number of different regulators and review bodies and provide a system for review by UK committees and reviewers.

6. Our submission responds specifically to a section of number 3 and number 6 of the Inquiry Terms of Reference.

3. The flexibility and agility of institutions, Government departments and public bodies, and processes to respond appropriately during the crisis including the optimal functioning of regulatory and ethical processes

Fast-track review of applications

1. The HRA was able to introduce fast-track review of COVID-19 research applications, co-ordinated across the four nations, overnight because we already had:
    - an agreed process for managing research approval applications in public health emergencies (section 9 of Standard Operating Procedures for Research Ethics Committees)
    - a staff structure and work processes designed to be able to flex to circumstances
    - a programme of work to transition RECs to meet virtually rather than face to face
    - established remote working approaches for staff.

2. The fast-track service offers approval timelines which are much shorter than normal. The speed of turnaround depends on study type as shown below:
    - urgent public health COVID-19 research – 24 hours
    - vaccine, treatment or diagnostic research – 36 hours
    - general understanding (immune response, prevalence of transmission) – 72 hours
    - others which include the following – 1-2 weeks
        - study of the wider impact of COVID-19 (including on mental health)
        - study to enhance general understanding of COVID-19 (e.g. in specific patient populations)
        - retrospective analysis of existing data

3. We have approved 364 new COVID-19 studies and 260 amendments to existing studies to add a COVID-19 element through fast-track review (as of 18.07.2020). The median approval timeline for standard review is 80 days, whilst that for COVID-19 fast-track review is 7 days, representing a 90% reduction in average timelines.

4. This has been made possible by:
    - enhancements to approvals processes, staff roles and technology over the past few years
    - a 30% reduction in applications for new studies and amendments to existing studies
    - stopping review of master's student studies after consultation with partners in the devolved administrations
    - staff continuing to work through lockdown, enabled by technology, with some working evenings and weekends

- many staff being diverted from other work to support COVID-19 research approvals, public involvement and transparency, with much of project activities postponed
- all REC meetings taking place via videoconference
- over 150 volunteer REC members taking part in expedited reviews, being co-opted to other RECs to help provide additional expertise, and making themselves available to join ad hoc committees at short notice
- introduction of an out of hours telephone service supported by expert advice
- researchers responding quickly to requests for information

5. We were also able to capitalise on existing collaborative relationships with other regulators, established for instance through a joint programme to pilot combined review of clinical trials of medicine (CWoW) with the MHRA, which was already delivering a 40% reduction in approval timelines before the pandemic hit. Maintaining strong working relationships and effective information exchange with other regulators, at all levels, will be crucial for a swift and effective response to future waves of the pandemic.

Patient and public involvement

6. We have demonstrated that we can go fast and maintain standards of ethical research in the face of public health emergency. Right at the start of this pandemic, we wrote to researchers about the importance of seeking ethical review for their research, stressing its importance but also reassuring them that we can review applications quickly without compromising standards.

7. We have, however, noted applicants failing to meet some aspects of best practice such as patient involvement in study development. At the end of March, we analysed the first 40 applications through our fast-track review process to see what public involvement had taken place. We found that 20% of applicants for research approval said they had or planned to involve patients and the public in their study. This represents a quarter of what we would normally see.

8. Where applicants said they haven't involved patients in the study, we asked them why. Many appeared to have assumed that they didn't have the time available to them to involve patients. We were, however, also hearing from public contributors and public involvement practitioners that patients were available to help and were prepared to do so at short notice and quickly. They were involved in existing networks and groups but also a few new COVID-specific groups.

9. In response, we have led the establishment of a 'UK COVID-19 public involvement in research database'. We are using this to match researchers planning COVID-19 studies with the most appropriate public involvement groups, networks, or individuals listed on this platform. Hosted on the FutureNHS Collaboration Platform, this growing platform will help ensure that future development of COVID-19

research can have full patient and public involvement without compromising the need for speed. We will also explore with stakeholders to see if similar platforms could be developed for other types of research.

Future model of research approval

10. In the coming months, we will undertake a review of what our research approval model should look like in the future. Applicants and stakeholders, who have praised the HRA for our great service in response to the pandemic, are asking whether it is possible for us to maintain the current speed of review for a broader range of research. The current operating model for COVID-19 research, however, is only sustainable for the short term and offers no resilience. What is working in a pandemic (staff and volunteers going the extra mile, a clear, national focus and energy, applicants being receptive) is unlikely to work when paused research restarts. This review will help us decide what we want to retain of the current incident response ways of working, what we should stop doing – both from the current and pre-COVID-19 ways of working - for good, and what we want to do differently or introduce in the future.

11. Through this review, we aim to agree and implement an evolved model for research approval which is more proportionate, streamlined and user friendly for researchers and research sponsors, meets the needs of study reviewers (ethics service and other regulatory checks) and supports good practice in research.

6. The mechanisms for communication of scientific evidence internationally, within national governments and with the public including the handling of conflicting scientific opinions

1. The HRA saw the full diversity of COVID-19 research from the start of this pandemic – from interventional studies to data and tissue research to surveys of health and social care staff – reflecting our role as the 'final common pathway' for all research involving patients and healthy volunteers.

2. To help promote transparency, we established a process where we publish the summary of all COVID-19 research within three days of approval. The aim is to support researchers, sponsors and funders to identify studies already taking place across the UK in order to:
    - facilitate collaboration and avoid unnecessary duplication and reduce research waste.
    - assist in the ongoing commissioning, funding and design of COVID-19 studies

3. Another aim is to provide the public, healthcare professionals and policy makers insight into research that is already taking place in the UK. We have started, and plan to continue, enhancing the lay summaries of some of the studies we have published on our website. In addition, we are exploring ways to add information on the findings from approved COVID-19 research in a way that is accessible and easy to understand to a wide range of audience to support the use of evidence and uptake of innovation.

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