House of Commons

Science and Technology Committee

Research integrity: clinical trials transparency: Health Research Authority Response to the Committee's Tenth Report

Tenth Special Report of Session 2017–19

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Science and Technology Committee

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The current staff of the Committee are: Danielle Nash (Clerk), Zoë Grünewald (Second Clerk), Dr Harry Beeson (Committee Specialist), Dr Elizabeth Rough (Committee Specialist), Martin Smith (Committee Specialist), Sonia Draper (Senior Committee Assistant), Julie Storey (Committee Assistant), and Joe Williams (Media Officer).

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Tenth Special Report

On 30 October 2018 the Committee published its Tenth Report of Session 2017–19, *Research integrity: clinical trials transparency* [HC 1480]. On 5 February 2019 we received the Health Research Authority's Response to the Report, which is appended below.

Appendix: Health Research Authority's Response

Introduction

One of the key principles in our UK Policy Framework for Health and Social Care Research is that 'research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency'. That means registering research studies, making results public, giving access to data and tissue, and feeding back the findings of the study to participants. Without this openness about individual studies, research funding is not used effectively and participants' time and commitment is wasted.

As the regulator of all health and social care research in the UK, through agreement with the devolved administrations, the Health Research Authority (HRA) has two statutory objectives:

- to protect research participants and the public by encouraging research that is safe and ethical; and
- to promote the interests of those participants and the public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research).

Transparency is essential so that participants are protected from unnecessary research, and patients benefit from improved outcomes and care informed by high quality studies.

As an organisation, we have always taken research transparency seriously. We are a signatory to the AllTrials campaign and, since 2013, make it a condition of a favourable ethics opinion that all clinical trials are registered before recruitment to the study begins. We also convene the Transparency Forum, which brings together funders, sponsors, research ethicists, clinical research organisations and publishers to enhance research transparency across the health and care research landscape.

Since our oral evidence session to the Committee in January 2018, we have allocated more staff time and focus in this area of work through the appointment of a Director of Policy and a reshaped team, focussing on understanding the obstacles to compliance with research transparency requirements, and making it easier for researchers to meet those requirements.

Now the Committee has set us a challenge to step up our work: to move away from encouraging best practice and instead to drive improvements. We accept that challenge and understand that if we are to see significant improvements in registration and publication rates, we need to change our approach.

The Committee has recommended that we develop a detailed strategy for achieving full clinical trials transparency. We accept that recommendation and will consult on that strategy. In the meantime, we will continue our work to be clear about our expectations, to make compliance easy and to work with partners to ensure expectations of researchers are aligned.

Our work to address the Committee's recommendations forms part of a wider initiative to increase transparency in health and social care research as a whole. The report focusses on clinical trials, which makes sense given that our condition of ethical approval to register applies to clinical trials (of medicines, devices and surgery). However, the overarching transparency principle in the UK Policy Framework applies to all health and social care research. As part of the strategy development, we will consider the scope of requirements and what steps we take to enforce compliance with them, taking into account risk, ethics and proportionality.

We are also committed to enhancing patient and public involvement in research. Besides publishing the findings of research for the benefit of other researchers and funders, it is crucial that researchers also tell study participants about their results in a way that they will understand. If we are to retain the public's interest in and support for medical research, we must see patients and the public as partners in research, rather than mere subjects. We will also seek to address this area of research transparency in our strategy development.

The broader context of this work is Brexit. It is vital that the UK continues to have a strong life science sector and remains an attractive destination for multi-national clinical trials. At the same time, we need to retain – and grow – our reputation for high quality research. The example of commercially-sponsored clinical trials in relation to transparency shows that this is possible. As the Committee observes in the report, the pharmaceutical industry has improved its transparency performance significantly over recent years, now outperforming non-commercial research. This shows that we can indeed make quality improvements to research whilst maintaining an active research environment.

Response to recommendations

Auditing compliance

Recommendation: We recommend that the Health Research Authority (HRA) should be provided with funding to establish a national audit programme of clinical trials transparency, including the publication of a single official list of which UK trials (trial by trial) have published results and those which are due to but have not. In the first instance this should focus on providing information on whether any results have been published in an academic journal following global best practice, building on the automated methods already developed by others. We recognise that there are other dissemination routes for clinical trials results beyond academic journals that automated methods might not capture. Where alternative means have been used to publish information the HRA can use this process to prompt lead investigators to provide details of where the results have been posted so that the entry for that trial can be corrected as necessary.

We accept the recommendation to monitor more actively compliance with research transparency requirements for clinical trials. We have carried out audits of compliance

with registration requirements on samples of studies and following up any missing records has had the effect of increasing registration. However, achieving meaningful improvements in registration and making results publicly available will require routine follow-up to check whether researchers have in fact done what they told us they would do.

We have already written to NHS Trusts which are non-compliant with the requirement to post summary results, to ensure that they are aware and are taking steps to address this. We will be taking the same approach with other sponsors over the next few months.

As the Committee observes, we will require additional funding to address this recommendation. We have costed one possible model and are in discussions with DHSC. If funding is made available to us, we will implement the most cost-effective way of gathering registration and publication information. It may be that enforcing reporting requirements, rather than searching for information ourselves, is a better method of checking compliance. This may involve working directly with third parties.

Funding

Recommendation: We recommend that the HRA undertake further work to determine an accurate figure for the cost of such an audit and prepare a funding proposal for the Government to consider.

We accept this recommendation and have costed a possible model.

Publishing information about individual trials

Recommendation: The Government should direct the HRA to publish information on trials that have received ethical approval but are not registered in a publicly-accessible register, on a trial-by-trial basis.

We agree that we should publish more information about individual trials than we currently do in our research summaries tool. We plan to redevelop that tool (assuming we are able to fund this) as part of the redevelopment of IRAS, the UK research applications portal which we manage. The new version of the research summaries tool will include more information about each approved study, including links to registration and publication details.

Although publishing more information in this way is the right thing to do, we are not yet sure whether this is the most effective way of increasing compliance. The 'name and shame' approach can be effective, but it relies upon drawing attention to the information on an ongoing basis in such a way as to drive good behaviour. Given that we have a regulatory relationship with study applicants, we will also pilot more direct, and potentially more effective, methods of improving compliance through the development of our strategy.

Sanctions

Recommendation: We recommend that the HRA introduce a system of sanctions to drive improvements in clinical trials transparency, such as withdrawing favourable ethical opinion or preventing further trials from taking place. The Government should consult specifically on whether to provide the HRA with the statutory power to fine sponsors for non-compliance.

We accept the need to make better use of our powers under existing legislation to tackle non-compliance around clinical trials registration and publication. We are committed to taking steps to address poor performance.

Following receipt of the Committee's report, we have already sought legal advice on the extent of those powers and the steps we could take to enforce requirements, including whether the powers extend to the HRA (as opposed to research ethics committees) and their scope beyond England to the devolved nations. We will seek views on how we should use those powers as part of the development of our strategy.

Transparency strategy

Recommendation: We recommend that the Government ask the HRA to publish, by December 2019, a detailed strategy for achieving full clinical trials transparency, with a clear deadline and milestones for achieving this.

We also recommend that the Government write to the HRA to clarify that it should interpret the Care Act 2014 to mean that it is responsible for driving improvements in clinical trials transparency—as opposed to 'promoting' transparency as a virtue. The performance of the HRA should then be explicitly measured on this basis through its annual report, including through specific measurable performance indicators. If further financial resource for the HRA is required to tackle clinical trials transparency then the Government should consider favourably such requests.

We accept the recommendation to develop a research transparency strategy. We are forming an expert group, drawn from a range of interests, to help us shape this strategy and we will consult on it during 2019. Ahead of the publication of the strategy, the HRA will raise awareness of transparency requirements and will engage with individual sponsors to improve compliance.

Compliance with research transparency requirements is ultimately the responsibility of sponsoring organisations and individual researchers. HRA will agree performance indicators with DHSC and will build these into the annual report.

Powers

Recommendation: We recommend that the Government consult further with the HRA on whether it is capable of delivering the improvements to clinical trials transparency needed within its current remit. If necessary its remit should be extended through introducing legislation which amends the provisions of the Care Act 2014.

We have sought legal advice on the extent of our powers, including whether any change to legislation might be necessary. Ultimately, this is a decision for the Government.

In the interim, we will work with members of the Transparency Forum, which includes publishers, funders, charities, researchers and ethics experts, to implement changes at every stage of the research pipeline from funding approval to reporting. The larger public funders have recently introduced grant conditions with increased requirements around research transparency and the Transparency Forum will examine the impact of these changes over the coming year.