Research Transparency Strategy Group

Minutes

21 October 2019, 2-5pm, Skipton House, 80 London Road, London SE1 6LH

Attendees

Expert group members

Alex Newberry	Head of NHS Research Governance and Informatics, Welsh Government	In Attendance
Derek Stewart	Public contributor/patient engagement expert	In Attendance
Dr Cham Herath	Director of Healthcare and Medical Affairs UK, AstraZeneca	In Attendance
Dr Julie McCarroll	Northern Ireland Public Health Agency	In Attendance-Teleconference
Dr Marina Parry	Senior Research Associate, UCL Cancer Institute	Apologies
Dr Matt Westmore	Operations Director, NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)	In Attendance
Dr Simon Kolstoe	University of Portsmouth and Research Ethics Committee chair	In Attendance
Marise Bucukoglu	Head of Research Governance, University of Edinburgh	In Attendance
Nisha Tailor	Head of Policy and Public Affairs, Association of Medical Research Charities	Apologies
Professor Andrew George	HRA non-executive director (Chair)	In Attendance
Professor David Edwards	Professor of Neonatology, St Thomas' Hospital London	In Attendance
Professor Sir Stephen O'Rahilly	Professor of Clinical Biochemistry and Director, MRC Metabolic Diseases Unit, University of Cambridge	Apologies
Sile Lane	Head of Campaigns, AllTrials	Apologies

HRA staff

Clive Collett	Ethics Policy Manager	In Attendance
Eve Hart	Head of Communications	Apologies
Juliet Tizzard	Director of Policy	In Attendance
Naho Yamazaki	Head of Policy & Engagement	In Attendance
Nicola Gilzeane	Engagement Officer	In Attendance
Teagan Allen	Policy Officer	In Attendance

1. Welcome and Introductions

Professor Andrew George welcomed everyone to the Research Transparency Strategy Group meeting and noted apologies.

2. Findings of the Make it Public consultation

HRA secretariat presented a report on the findings of the Make it Public consultation. The report detailed the findings of responses given in the online survey, open workshops, patient and public focus group, research ethics committee member webinar and HRA staff workshops.

Scope

The Group was informed that across workshops and the survey there was general support for the scope of the strategy and the proposal that the strategy should focus on three of the four pillars of research transparency: registration, reporting and feeding back to participants. There was agreement that although making data available for future research (pillar four) is important there are others better placed to champion this area of research transparency. Overall there was support for the initial focus of implementation to be on clinical trials although some, particularly attendees at the open workshops, felt that the strategy should apply to all research. There was however general agreement that a phased approach would be acceptable allowing all research to be addressed in time.

Registration

The results of the consultation showed overall the most support was for the HRA becoming a registry, with strong support voiced in the workshops for everything to be in one place. However, it was acknowledged by respondents that this would take a lot of resources to achieve. There was also support from the workshops and survey for the two alternative suggestions in the draft strategy: requiring registration to occur prior to approval being granted or the HRA registering on behalf of studies. The Group discussed the need to ensure, whatever decision is made to address registration, that it is futureproofed to allow for the inclusion of all research in time.

Reporting

The consultation gathered views on the HRA's plans to be clear that a final report must be submitted to the HRA within 12 months of the study end date and that there will be prompts for these reports. The HRA also proposed to publish information received on a public website or link to a publication. The Group were informed that there was a strong feeling from the consultation that these measures will improve the reporting of results. In addition to the measures proposed in the strategy responders to the consultation placed emphasis on the need to work with others across the system to improve reporting, funders in particular were believed to have a key role.

Feedback to participants

The Group was informed that during the consultation respondents gave suggestions on how feedback to participants could be improved. Practical suggestions were offered, such as the creation of a central facility for feedback and producing templates for researchers. Respondents also felt that feedback can be improved by researchers asking participants how they want feedback and involving patients in drafting research summaries and good practice guidance. It was noted in two of the workshops that there could be a danger of being too transparent as this could lead to false hope. The Group felt that any information we publish, that will be accessed by patients, should be framed in such a way to make it clear where the information is from, what it means and availability of any interventions. The Group went further by suggesting the creation of a information about how to understand research findings. They added that there is a need for clarity to be

provided on how to feedback appropriately in specific contexts such as end of life research. If research is published ahead of peer review, this should be made clear.

Implementation priorities

Respondents to the online survey and attendees at the open workshops were asked to comment on the importance of changes the HRA has already decided to make to support good practice and make compliance easier. The HRA informed the Group that the four changes that were believed to be most important were:

- Being clearer what we expect of sponsors and researchers
- Making it clear what information from applicants we will make public and what we will share with others
- Introducing automated reminders for researchers/sponsors to submit transparency data and to view the status of their studies
- Flagging up individual studies where transparency information is overdue

The Group agreed that making things clear and simple would be an impactful step to improve research transparency. They discussed the need to be clear on requirements and expectations but also processes. The Group highlighted the importance of ensuring guidance takes into consideration all of the audiences that would require clarity and noted that it is important to include those working on the 'frontline'. There was a feeling that guidance should have sections for each audience and that it is important to state principles, be clear what is and is not expected. The Group also felt guidance should be clear on expectations of what will happen for participants.

Sanctions

The consultation explored the appropriateness of introducing sanctions, including:

- League tables
- Taking transparency past performance into consideration at ethical review
- Fines

In the online survey there was support for the introduction of league tables to display transparency performance (69% considered this appropriate or highly appropriate) and considering past performance as part of the ethical review for future studies (75% considered this appropriate or highly appropriate). In both instances there was stronger support from patients and the public than research professionals. There was also support for these measures across the workshops, although caution was raised that a negative ranking on a league table could deter people from taking part in research at certain institutions. There was also a feeling that league tables could lead to game playing. In the workshops there was split opinion on whether it should be the sponsor or the researcher who have their past transparency performance consider during ethical approval.

In the online survey fines received the least support, with 39% of respondents considering this would be appropriate or highly appropriate. Again, more patients and public were in support than research professionals. Across the workshops there was a feeling that providing support and improving processes must be done before taking punitive measures. There was also concern that commercial organisations could be fined with little impact whereas a non-commercial organisation could be badly impacted by a fine. There was a general feeling that sanctions that impacted on reputation and future ability to conduct research would have more effect than fines. In the patient and public focus group there was support for league tables and withholding ethical approval but not fines.

3. Taking action in the case of non-compliance

The HRA secretariat advised the Group that the findings from the consultation provided information on the appetite for sanctions as a whole and the individual measures proposed. It is for the Group and the HRA to consider the practicalities and feasibility. As a public body the HRA must consider whether a sanction is going to work and if it is proportionate.

It is important to ensure that right policies and conditions are in place. The HRA needs to establish whether new requirements are needed or just the strengthening of existing requirements. The HRA must have the ability to effectively monitor compliance before action can be taken on non-compliance. This monitoring must be based on a reliable measure collected by the HRA and not that of a third party. The Group agreed that the existing HRA 'final report' should be used as the basis for performance reporting and monitoring.

There was discussion over what information should be gathered through final reports. The Group made the distinction between information *about* the study and information *from* the study and emphasised that care should be taken about how and when each type of information is used. There was agreement that information about the study was most appropriate, for example, if the study finished on time, and whether participants received feedback.

The HRA asked the Group whether they recommend the introduction of the proposed sanctions.

League tables

The Group discussed whether they would recommend the introduction of league tables as a sanction. The Group felt that there was merit to making information public to highlight poor performance and encourage behaviour change. However, the Group was concerned that a 'league table' could actually normalise poor performance. It felt that an alphabetical list, rather than a ranked table, might be more appropriate. The HRA need to ensure there are the resources to be able to be fair, robust and allow people to know what will be published about them.

Taking account of past performance

The Group agreed that past transparency performance should be taken into account for new research applications. They felt it would be appropriate for the HRA 'final report' to also be used to determine past transparency compliance that could be considered as part of ethical review. However, there were split opinions on whether this should be applied against the individual researcher or the sponsor. Similarly, the Group were undecided on whether the review should sit with the Research Ethics Committee or whether this should be done at desk level by HRA staff. There was a feeling that the application of the sanction would be more consistent if it were applied by HRA staff. However it was noted that as transparency is an ethical issue it may be more appropriate for the ethics committee to apply it. The Group came to the consensus that a working group should be brought together to consider the practicalities of this measure.

Fines

There was agreement among all attendees that fines should not be introduced as a sanction. The Group felt that removing money from research is ethically problematic, especially when the effectiveness of fines on increasing transparency compliance is unclear. Similarly, the Group noted that the impact of this sanction is likely to vary significantly between commercial and non-commercial organisations and so sanctions which will have more equal impact are preferable. The Group was also concerned that fines could result in the wrong person being punished (the institution rather than the researcher or sponsor. There was also a feeling that imposing fines, although may be effective to some degree, would have the potential to deter some from conducting research in

the UK. It was agreed that withholding approval was more likely to work as a sanction rather than a fine on a study that is already completed or in progress.

4. Make it Public strategy

The Group discussed the draft of the final strategy and agreed that the focus on making compliance easy was right. The Group highlighted that where the HRA wish to make things clearer the aim should be for simplification and cutting out bureaucracy. They agreed that it is important to ensure the strategy is directed at all parties in the system - not just researchers and sponsors - and to acknowledge how many people are involved in the process. There needs to be an understanding of who is responsible, but also who will be carrying out the requirements. There was also a feeling that the strategy should make it clear how improving transparency compliance will contribute to the UK being a great place to do research. The importance of making sure the strategy is accessible and written in plain language was highlighted.

Action

HRA to update the draft of the final strategy and circulate it to the Group for final comments

5. Next steps

The Group were informed that the final strategy will be present to the HRA Board 10 December. From January onwards working parties will be formed to assist taking the strategy forward.

Professor Andrew George thanked the Group for their contribution to creating the research transparency strategy.