## Research transparency: next steps

1. **Background**
   1. Research has a crucial role to play in improving the health and wellbeing of the population: developing new and better medical treatments and services and promoting good health and preventing ill health. But carrying out research is not enough on its own. Researchers must share their findings so that others can learn from their experience and understand what does and does not work. So, transparency is central to good quality research.
   2. Transparency in research includes:

* registering research
* publishing and disseminating findings and conclusions
* providing access to data on which finding and conclusions are based
* providing information at the end of research to participants
* providing access to tissue used in research, for use in future research
  1. Registering research is important because other researchers can see that research is underway and avoid duplicating effort. Registration also provides a record against which to expect to see a publication. Providing access to data allows asserted findings and conclusions to be verified or challenged and, like access to tissue, can allow future research without additional subjects, avoiding any risks to participants. A lack of transparency wastes research funding, research findings and research effort, distorts the evidence base and is a betrayal of patients and participants, ultimately risking public confidence in research.
  2. However, health research in the UK has a patchy record of transparency. Although clinical trial registration and publication has improved over recent years, there is still room for improvement in these types of studies. Beyond clinical trials, dissemination of results is relatively low, with university-led studies having a particularly poor track record. Recent developments, such as the House of Commons Science and Technology Committee’s current inquiry on research integrity and campaigning from opinion leaders such as Dr Ben Goldacre, have put this lack of research transparency in the spotlight.
  3. This paper sets out our continued work on improving research transparency to protect and promote patients’ and the public interest in research. Rooted in our duty in the Care Act 2014 to promote research transparency, our strategic aims commit us to championing transparency in research and improving registration and dissemination rates. With increased capacity in our policy function and the forthcoming redevelopment of the Integrated Research Application System (IRAS), the 2018/19 business year offers an opportunity to make real inroads into this issue.

1. **Existing expectations and requirements**
   1. The UK Policy Framework for Health and Social Care Research sets out our expectations around transparency. We expect that research projects are registered, the data and tissue they collect are made available for future analysis and research findings are published and summarised for those who took part in them. The following principles apply:

* **Integrity, quality and transparency** – Research is designed, reviewed, managed and undertaken to ensure integrity, quality and transparency.
* **Information about the research** – In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed).
* **Accessible findings** – Other than research for educational purposes and early phase trials, findings are made accessible in a timely manner after they have finished. Information about the findings of the research is available, in a suitable format and timely manner, to participants.
  1. The framework also sets out the responsibilities of different research stakeholders:
* **Sponsors** are responsible for ensuring appropriate arrangements are made for meeting the expectations in the policy framework.
* **Chief investigators** are responsible for adhering to the agreed arrangements.
* **Employers** of chief investigators and other researchers are expected to encourage a high-quality research culture, including ensuring employees are supported in and held to account for conducting research in a professional manner. They are also expected to take proportionate, effective action in the event of breaches.
* **Funders** are responsible for using contracts and conditions of funding to promote compliance with the policy framework.
  1. We have specific requirements in place to ensure compliance with the principles and responsibilities in the policy framework. We also take a number of steps ourselves to promote transparency. The following table sets out those requirements, with current levels of compliance and effectiveness.

| **Transparency area** | **Current position** | **Compliance/Effectiveness** |
| --- | --- | --- |
| Research summaries | A plain English summary of all research proposals reviewed by RECs, along with the REC’s decision. Applicants may ask for publication of the summary to be deferred. | The research summaries database could be made more visible and easier to search. |
| Registration | Registration is a condition of REC approval for clinical trials. Registration must happen before the first participant is recruited, though registration can be deferred on reasonable grounds, e.g. if immediate registration would compromise commercial interests. We have agreed standards for appropriate registration of clinical trials: registration is in a register that is public, that elicits the key information about a trial and that meets journals’ expectations. | Although all phase 2+ drug trials are registered automatically as part of the EU regulatory authorization process, our audits have shown two thirds’ compliance among other clinical trials (phase I drug trials 87%; device trials 67%; other clinical trials 64%). |
| Plans for publication and dissemination | REC applicants have to state in their application their intended arrangements for publishing and disseminating their findings. | Our audits suggest that this stated intention is achieved in as little as 9% of studies. We have commissioned the Equator Network to review with stakeholders how IRAS could ask better questions about applicants’ plans for publications and dissemination, in order to elicit more meaningful assurances and encourage best practice. |
| Summary results | Summary results for all phase 2+ drug trials should be published automatically as part of the EU regulatory reporting process. | Our search of the EU Clinical Trials Register suggests only 40% have results posted. |
| Feedback to participants | REC applicants are expected to feed back a summary of their findings to participants in line with guidance we have published. | We do not yet have any data on compliance with this. |
| Final reports | REC applicants should send a summary of the final research report within 12 months of the end of the study. There is no standard format for final reports but the applicant should say whether the study achieved its objectives, the main findings and arrangements for publication or dissemination of the research, including any feedback to participants. | Requirement to send a final report: 30% compliance  Requirement to include the arrangements for publication and dissemination: 44%  Only 29% of final reports include arrangements for publication and dissemination that match the intended arrangements in the application. |

1. **Understanding poor transparency**

*Poor performers*

* 1. Lower levels of transparency appear concentrated in research that is not drug trials and research that is not funded by the Medical Research Council or National Institute for Health Research (the strongest performers) or the pharmaceutical industry (also a strong performer). Between 95% and 99% of publicly funded health research (i.e. funded by MRC or NIHR) is registered and between 95% and 99% of registered MRC- and NIHR-funded research is published. 99% of trials related to drugs licensed in 2011 were disclosed by January 2013.
  2. Data from OpenTrials indicate that universities are the poorest performers in terms of publication of registered trials. Academic clinical trials account for over a quarter of all clinical trials submitted for research ethics committee (REC) review.

*Obstacles to good performance*

* 1. Our audits suggest that the main obstacles to compliance in clinical trials registration are poor awareness, prioritization and culture: 38% of investigators/sponsors contacted did not respond to the auditor; of those who did, 39% registered as a direct result of the auditor simply enquiring whether they had, while 8% claimed their study was not a clinical trial – with some stating they would have chosen a different (non-clinical trial) IRAS study category if they had known they would be expected to register. For research other than clinical trials, awareness both of the value of registration and of the registers available appears low anecdotally.
  2. Obstacles to publication are manifold. The more commonly cited examples include:
* journals favouring positive results
* running out of time/motivation after not getting accepted by journals on the first few attempts
* university employers expecting academics to demonstrate ‘real world’ impact of their research (potentially skewing publication effort towards research with positive results)
* scientists prioritizing doing research and applying for research funding over writing papers about the research they have done
* withholding unfavourable findings.
  1. We do not have any robust data on feedback of results to participants, but anecdotally researchers do not appear to do this as often as they could. We have an opportunity to seek further information about this as part of a related project being undertaken by the University of Aberdeen.

1. **Next steps: what we can do to increase transparency**
   1. It is worth noting that publication of research results is important, but it is not the only way of making results public and, where publication does happen, it does not necessarily achieve transparency. There are legitimate reasons why publication in medical journals is not achieved. There are also cases where a trial does have a publication, but the publication does not tell the whole story – some publications report on entirely different outcomes from those intended at the outset of the research, or report on positive findings while other trials of the same treatment with neutral or negative findings go unpublished.
   2. Research findings should be made public, but publication in medical journals is just one way of achieving that others should be pursued where they are appropriate and successful. For example, NIHR expects the findings of all the research it funds to be published and it provides UKPMC, an open-access system for doing so, whether or not the research is published in a journal, and the new NETSCC contracts will use the term “make public” instead of “publish”.

*Increasing compliance with existing requirements*

* 1. Our activity so far shows that engaging with the research community increases the registration rate, so we will be working in 2018/19 to set out our expectations more clearly (e.g. by simply rewording the REC approval letter) and to introduce automated measures to prompt transparency at the appropriate point. We anticipate that this will then enable us to explore making approvals contingent on researchers’ or sponsors’ track record of being transparent about clinical trials and other research.
  2. In 2018/19, we will be redeveloping the Integrated Research Application System (IRAS). We intend to take this opportunity to:
* enable applicants to make public any components of their application for REC approval or HRA Approval
* track whether the full results of the research have been published, either by ensuring new IRAS enables us to do so or by using other means following discussion with partners and other experts
* standardize the format for final reports and automatically extract relevant information to publish the summary of findings alongside the research summaries, aligning with the transparency information that will be in the new EU Clinical Trials Database under the forthcoming EU Clinical Trials Regulation and with WHO criteria for registers, and to compare the actual publication/dissemination with the intention stated in the original REC application
* introduce an electronic declaration of compliance referencing a number of integrity standards and obtain an electronic signature from the Chief Investigator which will be published alongside the research summary when a study has been approved.
  1. We will run a workshop with the Transparency Forum to test plans for IRAS pro-transparency functionality and assess the wider implications of this. We will examine the pros and cons of different standards (e.g. HRA standard is registration before recruitment unless deferral agreed; ABPI standard is registration within 21 days of recruitment) and work with the Collaboration and Development Forum to explore adoption of common pro-transparency conditions across partners’ contracts. We will work with MHRA to understand the apparent compliance rate of posting results for the trials they regulate.
  2. We will plan a communications campaign with partners to raise awareness of the importance and benefits of transparency. We will also be clearer about our expectations to applicants and those with HRA approval, so that those running studies understand their responsibilities and are reminded to meet them.
  3. Beyond these measure, we could use information about who has and has not registered, published and or fed back to participants as a prompt to do so, working with universities to encourage these transparency actions. We may even wish to publish ‘poor performers’ in transparency, though this would rely on clear identification of roles and responsibilities of the different parties (investigators, sponsors and employers).
  4. We are taking forward work to review our guidance on conflicts of interest to ensure our approach learns from recent work on this topic done by the Academy of Medical Sciences, which is now being followed up by Sense about Science.
  5. Our success measures will include:
* 100% of REC applications have a research summary (or deferral)
* 100% of research summaries (for clinical trials) include WHO-compatible registration details
* 100% of research summaries (for clinical trials) link to an online journal publication or uploaded summary of results at 12 months after end of study
* 100% of REC-approved projects have a standard format final report at 12 months after end of study that includes information about publication/dissemination and/or feedback to participants
  1. Some of this work – if it involves audit, follow-up and analysis by HRA staff – is likely to require additional resources. However, some automated follow-up and analysis of compliance can be built into the new IRAS. Once we are clearer about what is possible in this area, we can identify what additional staff resource we might need.

*Potential additional requirements*

* 1. Going beyond seeking better compliance with our existing requirements, we propose to explore a number of other measures to promote transparency:
* registration as a precondition of site agreement to recruit
* registration as a condition of model agreement(s) (mCTA only or mCTA et al)
* HRA Approval contingent on prospective track record in relation to registration and/or publication and/or feedback to participants from a publicized future date (e.g. 1st Apr 2019)
* registration details as standard content of Participant Information Sheets in order to mobilize patient/participant demand for high standards
* publishing researchers’ commitments to transparency (i.e. their stated intentions in the IRAS application and the actual action reported in the final report).

1. **Recommendations**
   1. The board is asked to discuss and agree plans for work in this area for 2018/19.

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