Addressing barriers to sharing results with trial participants

Introduction

While most trial participants want to find out the results of the studies they have taken part in, most[1] never get to find them out. When study teams do share results, this is often done is a passive way (expecting participants to seek out results for themselves), and the information provided is often written for clinical or scientific audiences, rather than lay audiences. Funders have received feedback from their patient communities that participants are unhappy about not being offered study results. The forthcoming Clinical Trial Regulations in the UK will introduce a legislative requirement that trial findings are shared with participants in a suitable format (although this legislation will only apply to Clinical Trials of Investigational Medicinal Products (CTIMPs), rather than all trials).

During a workshop for UK trial funders, hosted by the MRC CTU at UCL in June 2024, participants discussed some of the barriers to sharing results with trial participants, and approaches that may help address these barriers. This document summarises this discussion, and signposts relevant resources and guidance. We plan to update the guidance as new resources become available. If you have any suggestions on resources to include, please contact a.south@ucl.ac.uk

[1] 90% of clinical studies had not shared results with participants according to the 2021 HRA Research Transparency Report.

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Barriers to sharing results with trial participants

Priorities

Not all research funders currently have explicit requirements for researchers to share results with trial participants. In this context, busy research teams may prioritise other activities which are explicitly mandated.

Some researchers (including site staff) may be unaware of the importance of receiving results to trial participants, in part because some participants are reluctant to ask for them because they do not want to 'bother' busy nurses and doctors.

Site staff may not see this activity as a priority for trial Sponsors, if Sponsors are not checking that this is done in the same way they do for other trial activities (e.g. through logs). This means that, even if Sponsors provide results summaries for participants to sites for distribution, the summaries may not get to all participants who want them.

Recommendations for funders

- Funders should consider mandating sharing of results with participants as part of funding calls, and including clear dissemination plans as part of assessment criteria.
- Funders should consider requiring researchers to report on sharing of trial results with participants in final reports and reporting platforms, such as ResearchFish.

Recommendations for trialists

- If sites are expected to share results with participants, Trial Sponsors/CTUs should include sharing results with participants as part of agreements with sites
- Trial Sponsors/CTUs should follow-up with sites to ensure this activity is carried out (e.g. through requiring logs to be kept) before the study is closed at the site, as they do for other trial activities.

Recommendations for PPI representatives and trial participants

- Patient representatives and trial participants should ask researchers how they plan to share results with participants, and let researchers know if they think this is important.

Recommendations for scientific journals

- Some journals (e.g. BMJ) have introduced the requirement that authors state how results have/will be shared with participants, and, if there are no plans to

do this, to justify why. This may help raise researchers' awareness of the importance of sharing results with participants. Other journals should consider introducing similar requirements.

Challenges communicating complex science to lay audiences

Communicating trial results to participants may require specialist skills that not all researchers have, such as writing in plain language or graphic design. Without access to the necessary skills, researchers may find it hard to produce communication materials that are easy for participants to access, understand and use. Patient and Public Involvement (PPI) is vital to ensuring results summaries are clear and understandable.

Recommendations for funders

- Funders could compile and signpost researchers to good templates that have been developed for sharing results with participants, good examples from previous trials and relevant plain language glossaries and guidance (see Guidance, toolkits & further information for researchers).
- Where funders employ patient information specialists, researchers should be encouraged to seek their feedback on drafts of summaries for participants, if the team have capacity for this.
- Where funders have patient involvement communities, they could link researchers up with patients with capacity to provide input into communication plans.

Recommendations for trialists

- Researchers should plan ahead to ensure they have access to the necessary specialist skills for sharing results with participants, identifying individuals within the research team, wider institution or partner organisations who can provide this input, or budgeting to use external specialists.
- Researchers should include PPI input on sharing of results in their PPI plans. This should include getting comments on the language of draft results summaries as well as how the results are shared.
- AI tools like ChatGPT may help with drafting/editing of results summaries to ensure they are written in plain language (although these summaries will need to be checked by PPI representatives and trial staff for accuracy, sensitivity and sense).

Resources

Sharing results with participants requires resources to develop and distribute appropriate summaries of the results. It may require input from communications

experts. It also requires input from patient partners. Depending on how the results are distributed, it may require time from site staff. If resources for this are not included in the funding for the trial, this can be a major barrier to sharing results with participants.

An addition challenge in terms of resourcing this activity is the timing of it, which may be after the grant funding the trial has ended, or teams have been reallocated to other projects.

Recommendations for funders

- Funders should consider explicitly asking applicants, in their budget guidance notes, to include resources for sharing results with participants in grant applications.
- Funders could consider setting up a small grant scheme where trials which have not included resources for this activity in their application, or where it cannot take place until after the trial grant has finished, could apply for these dissemination costs.

Recommendations for trialists

- Researchers should consider the resources required for sharing results with participants at the planning stage of the trial, and include in grant applications.

Challenges communicating results in tricky situations

There may be particular reluctance to communicate results in tricky situations, such as results from ‘negative’ trials (where the intervention is not superior to the control). Trialists may be concerned about upsetting participants, or leaving the impression that the trial was a waste of time. In Show RESPECT, which communicated the results of a trial which found no benefit from the two interventions tested, participants were still glad to receive the results, despite around 17% of them finding the results upsetting to some degree. Participants interviewed as part of Show RESPECT understood that the trial was still worthwhile, even though it did not find a benefit from the interventions.

Another situation where there may be concerns about sharing results is in trials for conditions with a poor prognosis. Show RESPECT was carried out within the context of an ovarian cancer trial, and again, most participants wanted to know the results and were glad to receive them. However, little research has been conducted around sharing results with loved ones of those who die during a trial. What research has been done, in the context of neonatal and paediatric intensive care trials, suggests that some bereaved parents highly valued receiving the overall trial results.

Recommendations for trialists

- Patient and public involvement is important for helping researchers think through the likely impact of results on participants, and how difficult results can be shared sensitively with participants, and, if appropriate, their loved ones.
- If the trial is in a condition where some participants are likely to die during the trial, thought should be given to whether and how to share results with next of kin. If results will be offered to loved ones of those who die during the trial, this should be included in discussions early on in the trial, to ask the preferences of participants and their loved ones, seek their consent and contact details.

Misconception about the need for ethics approval

Some researchers have the misconception that the summary of results for participants requires ethics approval. The UK HRA ethics application form includes questions about how results will be shared with participants. As long as the results summary and how it is shared with participants is consistent with what was written in the Participant Information Sheet and the ethics application, the results summary does not need to be reviewed by an ethics committee in the UK. This highlights of the importance of forward planning for the dissemination of results.

If the plan for sharing results subsequently changes, or the initial ethics application did not contain information on how results would be shared, this would need to be submitted to the ethics committee as an amendment.

Recommendations for trialists

- Researchers should check the latest HRA guidance on sharing results with participants to see what current requirements are
- Trialists need to think about how they will share results with participants when putting together their ethics application

Risk of reinforcing inequalities

There is growing awareness that clinical trials need to do more to improve the diversity of trial participants, so trials truly reflect the patient population they wish to serve. The way in which results are shared with trial participants has the potential to reinforce these inequalities, and lack of trust in research, if not done well. This may further exacerbate inequalities in future trial participation. For example, if results are only provided by electronic means (e.g. websites or email), this may mean participants who are not computer literate, or who do not have access to the internet are excluded from receiving the results, which may discourage future trial participation. Office for National Statistics research shows that women, older people, people with disabilities, people on long-term sick leave, and those from households

with lower incomes are most likely to be internet non-users. This overlaps with some of the groups who are not currently well represented in clinical trials.

Another example of how the way in which trial results are shared may reinforce existing inequalities is if what is shared is not tailored to lay audiences. Research by Schroter et al found that 40% of researchers who had shared results with clinical trial participants had shared documents or presentations prepared for clinical or academic audiences. This may mean that people with less than university-level education may find it difficult to understand the results.

Recommendations for trialists

- Involve patients and the public in planning how results are shared with participants, and making sure results summaries are understandable, considering both digital and health literacy.
- When planning how to share results with participants, researchers should consider the needs of the full range of participants in their study. If patient information sheets were available in several languages or accessible formats, the results should also be made available in these languages and formats.

Guidance, toolkits & further information for researchers

Importance of sharing results with trial participants

- This podcast episode focuses on the importance of sharing trial results with participants

Planning how to share results with participants

- The SHOW RESPECT adaptable framework of considerations for planning how to share trial results with participants can help researchers think through how to share results with participants. There is a paper describing the framework, and an editable template.
- Parkinson's UK Staying Connected Toolkit: this toolkit covers principles and timelines for communicating with participants throughout their research journey, simple tools and templates researchers can use to communicate with participants, and information on how to plan communications.

Communicating complex science to lay audiences

- Health Research Authority guidance on writing in plain language summaries of research findings
- NIHR guidance on plain language summaries

- The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard have developed a Clinical Research Glossary which offers easy to understand clinical research definitions that have been developed in partnership with patient advocates.
- Envision Pharma have developed a Plain language summaries toolkit, which includes a quality control checklist
- The RECAP project developed a plain language summary template for sharing results with trial participants.
- The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard developed a toolkit for sharing aggregate trial results with participants, including a template, a checklist for reviewers and guidance on language

Examples of results summaries

- Cancer Research UK's 'Find a Trial' database, which contains plain-language summaries of trial results (not specifically aimed at participants)
- Posted printed summary and enhanced webpage used in the Show RESPECT study which shared the results of an ovarian cancer treatment trial
- Poster co-developed with young people living with HIV, sharing the results of the CHAPAS-4 paediatric HIV treatment trial (shared with participants at face-to-face results meetings)

Costing sharing results with participants

- This paper from the Show RESPECT study provides detailed information about the costs of sharing trial results with participants via posted printed summaries, webpages and email list, both to the clinical trials unit and to sites
- This letter shares costs of sharing trial results with participants via a webinar

Sharing tricky trial results

- This paper summarises the patient results of the Show RESPECT study, which looked at communicating trial results where no benefit was found from the interventions, to participants in an ovarian cancer treatment trial
- The BRACELET study on death, bereavement and randomised controlled trials included research exploring sharing trial results to parents of babies who died during a trial

Ethics requirements

- The HRA have produced guidance on communicating results to participants

Evidence gaps

Workshop participants agreed that, while there are evidence gaps, lack of evidence should not prevent action on sharing results with participants, as it is the ethically correct thing to do. However, it would be good to expand the evidence base as we share results with trial participants.

Key questions:

- How should trial results be shared with participants in different trial contexts, populations, diseases and results scenarios?
- How should offering trial results to loved ones of participants who have died during a trial be approached?
- Can we quantify the tangible benefits of offering trial participants the results of trials they have taken part in?

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