Briefing Paper
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The SHOW RESPECT adaptable framework for planning how to share results with trial participants

The problem

Sharing results with participants is a complex issue, with trialists facing considerable challenges including practical and resource barriers and concerns about the emotional impact of sharing results. It is important that it is done well, as there is potential for harm.

It is likely that there is no one-size-fits-all approach to sharing results. Trial teams need to think about the participants and context of their own trial when planning how to share results with participants. This briefing paper presents an adaptable framework of factors for trialists to consider, based on qualitative insights from data collected from site staff and patients who took part in the Show RESPECT study.

Key points

- Sharing results with trial participants is an important, but often neglected, aspect of the ethical conduct of trials
- There is unlikely to be a one-size-fits-all approach to it
- The SHOW RESPECT adaptable framework can help trial teams think through the different considerations when planning how to share results with their participants

The SHOW RESPECT framework

This framework provides a list of considerations and prompts to help trial teams think through how overall trial results should be shared with participants. It is helpful to work through this framework at an early stage in the trial development process to ensure that sufficient resources are budgeted and that appropriate information is included in the participant information sheet. However, not all the relevant information will be available at this point (e.g. what the results show, any special considerations that emerge during the trial). This means the framework should be revisited at a later point, when results are known, to see if the approach originally planned is still appropriate.

It is good to include team members from a variety of roles in these discussions, including, but not limited to, trial operational staff (e.g. trial manager), clinicians and research nurses who have been involved in caring for trial participants, and patient representatives.

The Show RESPECT study

The Show RESPECT study took place within the ICON8 ovarian cancer treatment trial. Different hospitals that were part of ICON8 were randomised to share the ICON8 results in different ways, using either a basic or enhanced webpage; sending a printed summary by post or not; and inviting participants to sign up to an email list or not inviting them to join the email list. We then asked participants and site staff for feedback on how the results were shared.

The primary outcome of Show RESPECT was participants' reported satisfaction with how the results were shared. 180 women and 65 site staff from 43 UK hospitals took part in the study. We also carried out qualitative interviews with both participants (13) and site staff (11) involved in sharing results.

The SHOW RESPECT adaptable framework

	Considerations	Additional prompts
S	Supporting and preparing trial participants to receive results	• How will you prepare participants for receiving results? » What did your Patient Information Sheet say about how and when results will be shared? » How will you inform participants that the results are available? • Will you use an opt-in or opt-out approach? » Are most of your participants likely to want to know the results (if so, an opt-out approach may be best)? » How and when will you give participants the choice of whether to receive results? • How will you provide support to patients who have additional questions or concerns about the results? » Are participants still in follow-up? Can they still access support from their research nurse/doctor? » What other support is available to them to help understand and process the results?
HO	HOw will the communication tool(s) reach participants?	• Which communication channels are likely to be accessible to your participants? • How can you make sure the results are accessible to all your participants? • Where will participants receive results? » Will participants prefer to receive results at the clinic, where support may be immediately available, or in the privacy of their own homes, where they can process it in their own time?
W	Who are the trial participants?	• What are the demographic characteristics of your trial participants? » What is their: age, socio-economic status, education level, health literacy, computer literacy, access to the internet? • How well are your participants likely to be? » How is their health at the time of receiving results? » How was their health and experience of adverse events or side-effects during the trial? • What expectations do your participants have around receiving trial results? » What did you put in your Patient Information Sheet about whether/when results would be available? » Do you need to get ethics approval for any changes to how you plan to share results? • What will participants want to do with the results? » Will participants want to keep results for future reference? » Will participants want to share results with others?
RE	REsults – what do they show?	• What do your trial results show? » Will it be seen as good / bad / neutral news by some/all participants? • How complex are your results? » Are your trial results complex (e.g. there is important heterogeneity between sub-groups, or do different outcomes go in different directions)? • Will the results have implications for the participants' or their families' future health or care?
S	Special considerations	• Have things happened over the course of the trial that need to be taken into account? For example: » Were there changes to the trial over the course of the trial that need to be explained? » Are there results from other trials that need to be taken into account when communicating the results of this trial? » Has the trial closed early for efficacy, for safety or for accrual issues? » Has the trial received negative publicity?

P	Provider – who will provide the results to participants?	• How close are relationships between site staff and participants likely to be? » How long were participants in the trial for? » Was follow-up done face-to-face? If face-to-face, was it in person or virtual? » Which organisation or individual was their main point of contact for the trial? » Are the staff members who were their main point of contact still working on the trial? » Does the communication need to be personalised to respect the relationship between site staff and participants? • How many participants do sites have? » Will sites with large numbers of participants have sufficient resources to share results individually? Or must other communication approaches be considered?
E	Expertise and resources – what expertise and resources do you have access to for sharing results?	• What budget do you have for sharing results with participants? » Have you budgeted for costs such as printing and postage, filmmaking, web development etc? • What expertise around developing patient-facing communications tools do you have? » Do you have access to expertise on this within the team, through partners or paying for specialist support? • Is this activity seen as a priority for CTU and/or Sponsor staff? » Is sharing results with participants incorporated in CTU Standard Operating Procedures and trial protocols? (If not, can it be?) • Has sharing results been included in agreements with sites? » Do sites know this is a trial activity they are expected to do (if you are planning for the results to be shared by site staff)?
C	Communication tools – which ones will you use?	• What will participants want to know? » Can participants who want different levels of information/detail find out what they want to (providing layered information)? • What language will your participants understand? » In what languages was the Patient Information Sheet available? » Do you know how to write in plain language? » How will you get feedback from PPI contributors about your draft results summaries? • How will you make your information product accessible, welcoming, and easy to follow and use? » Do you have the skills to do this in-house? » Do you have good templates to base it on? » Do you have the budget to pay for a designer? • Can you give participants a choice of communication tools? • Which communication tools will you use for sharing results?
T	Timing – when should results be communicated?	• How urgently do results need to be shared? » Are your results likely to receive media coverage? If so, how can you make sure participants don't first find out results via the media? » Do your results have implications for the future treatment of your participants? » Are participants still in follow-up? If so, is it feasible to integrate sharing results with routine clinic visits or do they need to reach participants sooner? • Are you sufficiently confident that your key messages are unlikely to change substantively, to share them with participants prior to publication?

Conclusion

Trialists must consider how results will be shared with participants from the planning stage of trials, to ensure that adequate resources are budgeted for and included in agreements with sites. Relevant information about how results will be shared should be included in the Patient Information Sheet.

When deciding how to share results with participants, trialists should consider the following factors: how to support and prepare participants to receive results, including whether to use an opt-in or opt-out approach and who will be available to answer participant questions; how the results will reach participants; the characteristics and expectations of participants in relation to the results; what the results show and how they are likely to be perceived by participants; special considerations; who will provide the results to participants; the expertise and resources available for sharing results; the communication tool(s) to be used; and the timing of results communication.

Patient and public involvement is essential for planning how to share results with participants, identifying the outcomes and study results that are important and relevant to participants, and developing the content of results summaries to ensure they are written in a clear and sensitive manner.

Further information

An editable version of the template is available from https://osf.io/rndmc?view_only=1fed4585370e4f0a9d43a79d4940cf97

South, A., Snowdon, C., Burnett, E. et al. The SHOW RESPECT adaptable framework of considerations for planning how to share trial results with participants, based on qualitative findings from trial participants and site staff. *Trials* 25, 467 (2024).

South A, Joharatnam-Hogan N, Purvis C, James EC, Diaz-Montana C, Cragg WJ, et al. Testing approaches to sharing trial results with participants: The Show RESPECT cluster randomised, factorial, mixed methods trial. *PLoS Medicine.* 2021;18(10).

South A, Bailey J, Bierer BE, Burnett E, Cragg WJ, Diaz-Montana C, et al. Site staff perspectives on communicating trial results to participants: Cost and feasibility results from the Show RESPECT cluster randomised, factorial, mixed-methods trial. *Clinical Trials.* 2023:17407745231186088.

Podcast episodes available from https://soundcloud.com/trial-talk-podcast:

1. Part 1: why sharing results with participants is important
2. Part 2: what are the best ways of communication results to participants?

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