

Plain English Summary of Findings

What was the METHODICAL study?

Patients and members of the public are increasingly involved in the design and delivery of clinical trials. For example patient and public involvement (sometimes called PPI) might involve helping to identify which topics should be prioritised for research, or helping to write trial information materials, such as leaflets and posters. However, we do not know the best ways to involve patients and members of the public in trials and what impact this involvement has on clinical research.

In the METHODICAL study we wanted to help resolve uncertainties and improve how we do PPI in clinical trials by identifying the most important topics for future research. To do this we organised a survey which ran between October 2015 and March 2016.

What did we do?

We used something called a Delphi survey, which is a type of survey used to find people's opinions on important topics and seek agreement on topics across groups of people who might have different views. Our Delphi involved two online surveys followed by a face to face meeting.

Who took part in METHODICAL?

People with at least one year's experience of working within PPI in clinical trials were invited to take part in the survey. We identified seven different groups of people working in PPI:

PPI Contributors	Patient representatives, members of the public and research partners in clinical trials
Lay Reviewers	Members of the public sitting on clinical trial funding boards or Research Ethics Committees (RECs)
PPI Coordinators	Roles within a Clinical Trial Unit (CTU) or research network to coordinate PPI activity, PPI contributors and research partners in trials
PPI Advisors	Roles offering advise on how to design and delivering PPI activity within trials. This includes member of the National Institute for Health Research (NIHR) Research Design Service (RDS)
PPI Planners	Chief Investigators, trial managers and other researchers/staff who plan or oversee PPI in individual trials
PPI Researchers	People who conduct research into PPI in clinical trials and authors of PPI guidance documents
Non-lay Reviewers	Professional members of clinical trial funding boards or Research Ethics Committees (RECs)

What happened in the online survey?

The research team created a list of 36 possible research topics that they wanted to ask each group about. This list was written after looking at research papers, speaking to experts who are part of the METHODICAL study team and testing it with people who were likely to take part in the survey.

Everyone was asked to score the importance of each research topic on a scale of 1-9:

- 1, 2 or 3 = Topic was not important
- 4, 5 or 6 = Topic was important but not critical
- 7, 8 or 9 = Topic was of critical importance.

Participants could choose not to score a topic and could also suggest new topics that they felt were missing.

237 people visited the website of which 219 (92%) completed the initial survey (which we refer to as the Round 1 survey).

Everyone who completed the round one survey was sent the survey again a few weeks later (Round 2 survey). However, this time they were shown graphs of the scores for each of the seven groups who took part in round one. Participants were asked if, after reviewing the scores of those in their own group and other groups, they wanted to keep or change their score from round one. Participants were also asked to score the six new topics that were suggested in round one.

187 people completed the second round of the survey.

What happened in the meeting?

Twenty five people went to the meeting. 8 people were members of the METHODICAL study team and 17 were people who completed the online survey. Nearly half of the people at the meeting were patients or members of the public involved in designing and running trials.

The face to face meeting gave people the chance to see the results from round 2 scores and discuss each topic. They were then invited to vote for a final time about the topic. Electronic voting handsets were used so individual scores could not be identified. At the end of the meeting we ordered the topics based on the number of people scoring a topic as critically important (scores 7-9).

What did the METHODICAL study find?

The study identified the top ten priorities for improving PPI in clinical trials. Three topics came equal first:

- Developing strong and productive working relationships between researchers and PPI contributors
- PPI practices in selecting trial outcomes of importance to patients
- A systematic review of PPI activity in improving the accessibility and usefulness of trial leaflets and information sheets for clinical trial participants

The full list of topics can be viewed at www.methodicalstudy.uk

What will happen next?

The results of the study will help us to know what research is important to help improve PPI. As part of this we are helping connect people who are interested in starting research projects for each topic. To find out more about the working groups visit www.methodicalstudy.uk or email k.woolfall@liv.ac.uk.