

Methods for Patient and Public Involvement (PPI) in Clinical Trials: A Research Priority and Agenda Setting Exercise

End of Project Report – N62

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1) Summary of the original objectives

To identify PPI methodology research priorities to inform the targeting of research efforts to coordinate and improve the design of future PPI in trials and avoid unnecessary duplication of research. We aimed to achieve this through a modified Delphi priority setting exercise involving key PPI stakeholders. We also proposed to bring together PPI stakeholders to discuss the potential for setting up a working group to assist the delivery of project recommendations.

2) What was achieved?

Study set up (including literature review and Delphi topic list)

- We established a working group of 17 members to oversee the study. The 'METHODICAL team' included representation from all seven pre-defined PPI stakeholder groups: 1) PPI contributors; 2) lay reviewers; 3) Non-lay reviewers; 4) PPI coordinators, 5) PPI Planners (e.g. Chief Investigators and Trial managers), 6) PPI advisors (e.g. Research Design Service members) and 7) PPI researchers.
- We used literature that systematically evaluated the scope and impact of PPI within health research to develop broad list of potential methodological research topics for round 1 of the Delphi. This was supplemented by a review of recent publications assessing PPI specifically within clinical trials for each topic; accompanying descriptive text was developed to help explain these.
- The study team reviewed the list of topics and descriptions to ensure they were distinct and covered known uncertainties and challenges associated with PPI in clinical trials.

- The list of topics was then piloted with a small group of lay (n=2) and non-lay (n=3) PPI stakeholders to check clarity and understanding. Feedback from the pilot was used to refine the list of topics and descriptive text.

Two round online survey

An overview of the Delphi process is shown in Figure 1 (see page 4).

- We used snowball sampling to invite PPI stakeholders from across the UK to take part in the online Delphi.
- In total, 237 people registered of whom 219 (92%) completed the first round. 187 of 219 (85%) completed the second; all key stakeholder groups were represented in the survey.
- The survey sample size was relatively large and included high levels of participation from lay stakeholders compared to other Delphi studies.
- The attrition rate was low, with those taking part in round 1 likely to complete round 2.
- Round 1 of the survey comprised 36 methodological research topics. Round 2 of the survey comprised 42 methodological research topics, including the six new topics created from participant suggestions.

Consensus meeting

- A consensus meeting was held in Liverpool on the 21st of March 2016.
- 25 stakeholders attended. All stakeholder groups were represented at the meeting.
- During the meeting all 42 topics were discussed and voting was undertaken on all except two- which were subsumed within other topics. Changes were made to three topic titles and nine help texts after group discussion in order to clarify the topic before voting.
- A ranked list of prioritised research topics was achieved.
- Sixteen topics achieved consensus with greater than 70% of participants scoring them 7-9 (critically important) and less than 15% scoring them 1-3 (not critical or low importance)
- Meeting attendees were virtually unanimous about the most important PPI research priorities, with the top six all achieving over 92% consensus.

Summary of what was achieved

Through a consensus building process we have identified priority topics for methodological research to inform PPI in clinical trials. The number and range of topics considered by more than 70% of meeting participants to be critically important indicates the high level of uncertainty and lack of evidence to inform PPI in clinical trials. This research agenda will help improve the design of future

research on PPI in trials and avoid unnecessary research waste. Working groups have been established to take this work forward with a focus on the top 10 prioritised topics (further details are outlined below).

3) Next steps

- A paper is in final draft and will be submitted to BMJ Open in September 2016.
- We will submit an abstract to the 4th International Clinical Trials Methodology Conference, Liverpool , 2017.
- Consensus meeting attendees signed up to working groups to take this work forward. We have developed a website to help facilitate working groups. Once the paper is published the website will go live. We will then publicise the working groups and website to enable any interested stakeholders who were not at the meeting to register their interest in joining a group. Each group will have a lead who has agreed to organise the first working group teleconference.
- A short (lay summary) of the study findings has been drafted and will be widely disseminated to the PPI community once the paper has been published. A link to the paper will be included along with an acknowledgment that this work was funded by the MRC HTMR network.

Fig 1. Overview of the Delphi process



