The impact of patient and public involvement (PPI) in the dissemination of clinical trial results to participants

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Introduction

The results of clinical studies are often disseminated to participants through direct postal or electronic leaflets/infographics, social media and via patient groups. Patient and Public Involvement (PPI) groups are sometimes consulted for opinions on these dissemination materials before they are distributed to patients. However, the impact of consulting PPI groups at this stage of a clinical study is rarely reported. **We aimed to investigate the contributions that PPI groups can make when they are included in the dissemination of results to clinical study participants.**

Methods

We circulated a short questionnaire via email to Trial Managers/Coordinators within the Bristol Trials Centre (N=27). We asked for responses from those who had experience disseminating study results to participants. The following questions were included and all answers were provided in a free text format.

- Name of study/trial?
- What was the format of the dissemination materials for participants (leaflet/video/poster)?
- Where and how were the results shared (postal/ email/social media)?
- Was PPI input sought for the study dissemination materials?
- Was any feedback sought for the dissemination materials that was not from a PPI group?

If PPI input was sought, Trial Managers were asked to provide a summary of the PPI group's comments and whether the dissemination materials were updated in line.

Responses were reviewed independently by both authors to identify themes in the type of changes requested by PPI members when reviewing dissemination materials. The changes requested for each study were grouped into the identified themes.

Results

We received seven responses referring to seven different randomised controlled trials. One of the seven respondents did not seek PPI input on their dissemination materials for participants, another did but was unable to provide a summary of the PPI group's comments. Therefore, these two responses are not included in this analysis. See Table 1 for a summary of the studies included in this analysis, all of whom sought PPI feedback on their dissemination materials.

Study name	Clinical speciality	Study design	Format of results	Method of dissemination	Feedback sought outside of PPI?
VICI	Ophthalmology	RCT*	Leaflet	Post	TMG*
ComFluCOV	Vaccinology	RCT*	Leaflet	Email	TMG* & sponsor
Harvest	Cardiac surgery	RCT*	Leaflet	Post	None
INVITE	Cardiac surgery	RCT*	Infographic poster	Not yet disseminated	TMG*
ROMIO	Upper GI* surgery	RCT*	Infographic poster	Not yet disseminated	TMG*

Table 1: *Summary of studies included in this investigation and their approaches to drafting dissemination materials for study participants.*
**GI = Gastrointestinal, RCT = Randomised Controlled Trial, TMG = Trial Management Group*

Changes to dissemination materials requested by PPI groups

A total of 32 requests for changes were identified across the PPI consultation summaries from the five studies. This ranged from 1 to 11 changes requested per study.

Four themes were identified which encompassed all of the requested changes:

1. Reprioritising content
2. Addition or removal of content
3. Formatting changes
4. Clarifications or wording changes

Addition or removal of content was requested in 5/5 studies.

Reprioritisation of content, formatting changes and clarifications or wording changes were all requested in 3/5 studies.

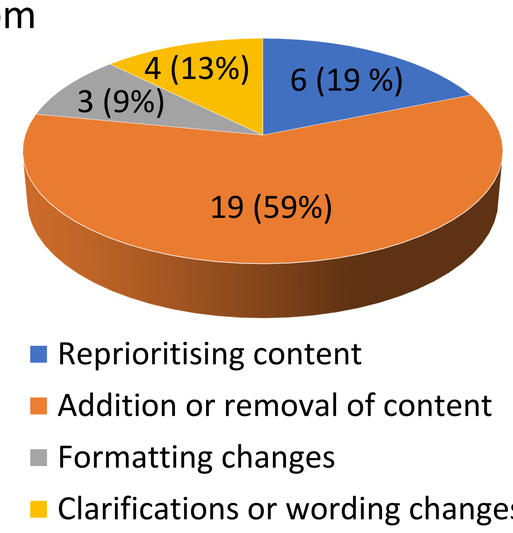

Figure 1: *Number of changes requested by the PPI groups which were categorised into each of the identified themes.*

Examples of notable comments received from PPI groups

The VICI PPI group noted that the result of one of the secondary outcomes was more important to them than the primary outcome.

The ComFluCOV PPI group requested the definition of the placebo used to be added to the results leaflet.

The INVITE PPI group suggested inserting a quote to personalise the results more.

Discussion

This work demonstrates the value of consulting PPI groups when designing materials to disseminate study results to participants. The PPI groups made suggestions for the main content of the materials more often than they suggested simple formatting or wording changes. This work has also demonstrated that PPI groups may prioritise certain outcomes/results differently to the researchers running the study. PPI groups requesting additional content or reprioritising outcomes may not only inform the dissemination materials for patients, but also the materials and design of future trials in that patient population. We therefore recommend including PPI groups at the end of a clinical study to ensure results are presented in a meaningful way to participants. We also recommend discussing preferences for results circulation methods in early PPI meetings as this may be constrained later by consent for certain types of contact.

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