Reviewer's report

Title: What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership – The PRioRiTy II (Prioritising Retention in Randomised Trials) Study

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Reviewer: Ruth Simms-Ellis

Reviewer's report:

I enjoyed reading this interesting paper which describes findings from a James Lind Alliance Priority Setting Partnership to determine the most important unanswered research questions in trial retention. The retention field has been dominated by trying to determine 'what strategies work', but this has failed to yield reliable evidence for researchers, despite a number of systematic reviews. I believe this paper makes a significant contribution by seeking to regenerate the stagnated field by proposing a paradigm shift towards 'what unanswered questions should we prioritise?'

A further contribution of this paper is that it draws upon patients' voices/experiences of being in trials, which have been neglected in the retention literature to date. JLA research priority settings have typically targeted clinical research priorities, where patients contribute their personal experience of, for example, dementia (Kelly et al, 2015) or inflammatory bowel disease (Hart et al, 2016). Involving patients in methodological priority setting is novel and progressive of the authors. However, compared to researchers, the lay-person is likely to find contributing to methodological research far more challenging. I feel that the paper would be enhanced by the authors describing more clearly the extent to which patients were able to contribute as "stakeholders" in this process, and steps that were taken to support them. To help with this, please find below some queries and suggestions for improvement.

Introduction

Line 132: The authors state that within this study they expanded on their previous approach by adding more patient partners who were new to research methodology. It would be useful to include a sentence briefly explaining what learning led to this decision.

Methods

Line 138: Can the 'back-translation' process be explained here when first mentioned rather than later.
Line 147: The 'patient or member of the public' category is quite diverse and mixes quite different experiences. Those taking part in a trial, parents/carers of participants are likely to have a different perspective/experience and be less conversant with research per se than those
contributing to designing/delivering trials. It would be useful to separate the latter out from participants/parents/carers so the reader could determine the ratio.

Line 161: Can the authors provide details of the size of the steering group, how members were recruited and its composition (i.e. how many patients who were not socialised in designing/delivering trials).

Line 177: It is unclear what the text in brackets refers to (see methods section) - as it is within the methods section.

Appendix 1: The Initial survey - I felt these questions were particularly challenging to understand and respond to as a lay-person. The language was technical in places and asking a lay person to generalise from their individual experience is difficult, e.g. item 2 "Based on your experience, what questions or comments do you have (if any) about the planning of study data collection?"

Line 183: States that the initial survey questions above were piloted (n=6) - could the authors include who piloted these and what piloting involved. This would reassure the reader that lay-people had been involved (rather than being tested by people familiar with research terminology).

Line 216: The El Feky et al (2018) paper cited as one of the three evidence sources checked is a protocol paper only - not the full review. I understand the team involved in this paper is also involved in that review, therefore would have had the information/knowledge available. However at this point the full review is not in the public domain, therefore hard to corroborate independently. Could the team briefly state their role in this paper - it would make more sense to the reader how they were able to draw on such information.

Line 227: Who were these Stakeholders and how were they approached?

Line 256: Did different stakeholder groups have different rankings for the importance of the 27 questions presented? It would be interesting to know if patients had different perspectives on what was important compared to researchers, in light of evidence that researchers' perceptions of why patients remain in a study may differ from patients' own accounts (Mein et al, 2012).

Methods

Line 290: Table 2 - Of all the "Stakeholders" it appears that 72% are researchers, PIs or trial methodologists, and 5% were members of the public who contributed to designing/running trials. Just 17% of the sample had been invited to take part in a trial/parent or carer, which seems rather low. Was it difficult to recruit these stakeholders?

Line 321: Table 3 - Can the 'patient or public member' (n=174) entry be separated out - so it is clear how many of these are (1) A participant; (2) Parent/carer of a participant; (3) contributor to design/delivery. This would also be consistent with Table 2, and easier to see how many lay-people were involved (i.e. (1) & (2)).
Line 321: Can the authors specify the make-up of the 12 'patients' in the consensus group (i.e. were these participants, carers/parents or contributors to trials).
Line 328: I am unclear how key research questions 2 and 3 differ. Is Q2 - making better use of routine care - also about reducing burden in the same way as Q3? Could an example be provided?

References


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