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Title: Patient and public involvement in pragmatic trials: online survey of corresponding authors of published trials
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Reviewer 1: Lawrence Richer
Institution: Faculty of Medicine & Dentistry, Pediatrics, University of Alberta
General comments (author response in bold)

31 Abstract: Clarification needed: it may be helpful to report if there was more than one respondent per trial or how many distinct trials were represented in the survey sample (i.e., was there only one respondent per trial - which should be true based on the methods and invitation to the corresponding author, but clarification in the abstract would be helpful)
There was only one respondent per trial. We have changed the sentence to "Of 3,163 authors invited, 2585 invitations were delivered and 710 (27.5%) *reported on 710 unique trials and* completed the survey…" (p. 3)

32 Introduction: It's a minor point, but to many, the acronym PPI refers to a proton pump inhibitor; many have become accustomed to the term 'patient engagement' and SPOR has defined a patient engagement framework (https://cihr-irsc.gc.ca/e/48413.html); I appreciate that the authors have defined PPI for this manuscript but wanted to raise this point for consideration.
We considered using the term "patient engagement," but believed that PPI would be more suitable for the international sampling frame of our questionnaire. To maintain consistency with the language used in the questionnaire, we opted to use "PPI" terminology in this manuscript.

33 Conclusion: The opening line of the conclusion should be clarified; see "Given that PPI aligns with the intention of pragmatic trials to produce patient-relevant evidence,[7,8] our finding that trials self-identifying as pragmatic had a higher prevalence of reported PPI in the survey is not surprising." - higher than what? Other studies not identifying as pragmatic; or higher than what is reported in the manuscripts of the reviewed pragmatic trials?
Thank you for this comment. We have changed this sentence to: "Given that PPI aligns with the intention of pragmatic trials to produce patient-relevant evidence,[7,8] our finding that trials self-identifying as pragmatic *(i.e., trials in which authors were so confident about the degree of pragmatism in their trial that they were willing to explicitly claim the label in the report)* had a higher prevalence of reported PPI *than those not using this label*, is not surprising." (p. 16)

34 Conclusion: I'm not sure I agree that the authors can assert a causal association between funding in the UK, like the National Institute of Health and Care Research INVOLVE and Be Part of Research, as the cause for higher reporting of PPI among UK-led pragmatic trials based on the data presented in this manuscript - data on the history of funding for patient engagement in the respondent's countries was not presented.
We have modified this sentence: "It is also not surprising to find that researchers in the United Kingdom conducted PPI much more frequently than those in other

countries, *which may be related to* the longstanding promotion of PPI by the National Institute for Health and Care Research INVOLVE and Be Part of Research…" (p. 16)

35 Tables: I would recommend incorporating some categories of Appendix 5 with Table 1; comparing respondents to non-respondents is very illustrative and assures the reader how similar/dissimilar the respondents were from non-respondents; it is less likely to be accessed as an appendix; possibly a subset of the categories from Appendix 5 could be incorporated in Table 1 and then keep Appendix 5 for the complete list?
Thank you for this suggestion. We agree that presenting information about respondents vs. non-respondents is important. Unfortunately, we do not have the data presented in Table 1 for non-respondents. Furthermore, data presented in Table 1 were sourced from the survey responses, whereas data from Appendix 5 are from MEDLINE or extracted from manual review of the published articles as part of previous projects, so merging these tables would not be feasible.

Reviewer 2: Paul Fairie
Institution: Community Health Sciences, University of Calgary Cumming School of Medicine
General comments (author response in bold)

36 Introduction: My only thought is about using a Canadian definition of PPI for a study of international uses of PPI – would alternative definitions reflecting different approaches to the engagement of the public and community in health research projects change the result?
Thank you for this point. Our definition of PPI is consistent with the Canadian definition, but draws upon international definitions presented by Hoddinott et al., which we have cited in the Introduction section. We have also noted in the limitations section: "It is possible that some respondents did not have the same understanding of PPI as ours, which may have led to misclassification. We attempted to limit this risk by providing a clear definition of PPI and requiring authors to confirm that they had read and understood our definition." (p. 17)

37 Results: I do think the result around underreporting PPI practices is very interesting and consistent with other studies– does it suggest that journals are not providing enough space, that project teams do not consider this type of activity part of the necessary scientific reporting, or something else altogether?
We have modified the following in the Conclusion paragraph: "*Journal requirements and ample space for* trialists to describe their approach to PPI, even if they elect not to pursue it, may allow for greater transparency about gaps in PPI uptake and identify opportunities for guidance. *Future qualitative work exploring these and other reasons why authors do not describe PPI in trial manuscripts may help inform strategies to improve reporting.*" (p. 18)

38 Interpretation: The response rate is good, and does not concern me, though I do wonder specifically about the nature of the selection bias here. As reported in the paper and in Appendix 5, respondents vs. non-respondents reported PPI at different rates (12% v 8%), both of which were much lower than survey respondents (47%). While the under-reporting is not surprising, I would not be surprised if there was a selection bias related to the under-reporting – respondents who want to report (for good reasons!) their PPI in a survey might be especially motivated to reply, whereas PIs who did not report

PPI in their manuscript and did not have any PPI to report otherwise might have been especially non-motivated to complete the survey. This does not significantly change the paper in any way but might be a reasonable mechanism whereby the underreporting is significant among the ⅓ of those motivated to respond, but less so among the ⅔ who did not.

Thank you for this insightful comment. We have modified our limitations paragraph: "We assessed the risk of selection bias by comparing trial characteristics of respondents and non-respondents, and we were unable to identify substantial differences, *except that respondents were more likely to have reported PPI in their trial. Self-selection* bias in favour of those more likely to report PPI or who had experience with PPI, however, cannot be ruled out, as *the prevalence of reported PPI was relatively high and* only 7% of respondents reported <1 year of experience with PPI." (p. 17)