Reviewer's report

Title: The management of dental caries in primary teeth - involving service providers and users in the design of a trial

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Reviewer: Bridget Young

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This paper reports on a qualitative study of stakeholder (staff, parent and child) perceptions of participation in a pilot trial of primary care dental treatment for children with caries. Few if any previous studies of this sort have been conducted to investigate the views of stakeholders within the dental care context. Therefore this study addresses an original question and has potential to provide useful information for those planning similar trials.

Major compulsory revisions

1. The results section of the abstract is presented as a list of themes which tells the reader little of the study's findings. This should be revised so that it outlines the key findings from the study. Similarly, the conclusion section of the abstract should indicate the key recommendations from the study. The background section of the abstract could be shortened as necessary to accommodate these changes.

2. In the background section in the main paper (page 4), it would be helpful if the authors could outline what they anticipate to be the specific difficulties involved in running clinical trials in primary dental care and involving child patients. Has recruitment to such trials been a difficulty in the past? This would help to strengthen the justification of this study.

3. My main concern about this study regards the adequacy of the sampling. The omission of some information about the sampling has hampered my judgement of this and a more comprehensive description of the sampling is needed before a judgement can be reached:
   a) How many practices and dentists participated in the pilot trial and how were they selected? The authors mention that purposive sampling was used but do not state what criteria informed this.
   b) What strategy was used to sample dental staff for the qualitative study? How many practices were represented in the qualitative study?
   c) Of those approached to participate in the qualitative study (both staff and family members) how many went on to participate in it? The overall number of staff participants in the qualitative study should be indicated (i.e. did any dentists participate in both an individual interview and the group interview?). If the number of participants was a relatively small proportion of those approached for either staff or family members or from few practices, then the authors need to note this
limitation and outline the implications in the discussion.

d) I have concerns regarding the claim that theoretical saturation was achieved for participating staff. Just 4 individual interviews were conducted with dentists which is a very small number of interviews, even for a qualitative study. While the “informal meeting” with 17 dental team members may have gone some way to supplementing the individual interviews, the extent to which such a meeting provides a basis for claiming saturation is open to question. Would all participants in the meeting have had an opportunity to express their views in such a large meeting? Given the diversity of staff present would they all have felt comfortable expressing divergent views (e.g. receptionists may not feel comfortable airing views that contradict those of more senior staff)? It would be helpful if the authors could provide a fuller account of this meeting, including its purpose (incidentally the meeting is described as a “group interview” in the abstract but elsewhere it is called an “informal meeting”), the numbers of receptionists, dentists etc present and how many practices were represented. What steps were taken to help ensure individual participants were given adequate opportunity to voice their perspectives during the meeting and how successful were these (did any staff members remain silent during the meeting).

4. In the discussion the authors should identify any further limitations that emerge from the fuller descriptions of their sampling and consider the implications for the conclusions reached. For example, on page 16 it is stated that in contrast to dentists’ perceptions, parents did not mind not knowing which arm their child was allocated to. However, this contrast could potentially be an artefact of the sampling of staff and families or both.

Minor essential revisions

1. The first sentence on page 4 should perhaps read "Contemporary approaches advocate user involvement in research”

2. Page 6, should "despite an 80% update rate" instead read "despite an 80% uptake rate”?

3. There are some problems with the use of apostrophes. E.g. page 4, paragraph 2, line 5 should read "professionals' “; page 10, heading 1.3 should read “Parents' involvement in the trial”; page 12, heading 2.2 should read "Parents’ perspectives on recruitment”. Please note that I've not listed these problems exhaustively.

4. Page 18, paragraph 4, there are two instances where the use of the term "less” appears grammatically incorrect and should be replaced with “fewer”.

Discretionary revisions

1. The analysis process is generally well described. However, it would be helpful if the authors could indicate what steps they took to avoid the fragmentation that can result from a focus on short sections in qualitative analysis. Did the analysis link to longer sections/whole transcripts as well as to shorter sections?

2. In the context of an academic paper some of the family member pseudonyms
seemed rather bizarre. While the study team’s aim in offering participants the opportunity to select their own pseudonym is well intentioned, I wondered if their use in an academic paper is potentially distracting and could even contribute to the trivialisation of qualitative research? The authors might consider replacing the pseudonyms with participant ID numbers for family member and staff participants alike.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests