Reviewer's report

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

**Version:** 1 **Date:** 22 February 2012

**Reviewer:** Martin Tickle

Reviewer's report:

The aim of this study was to describe service providers’ and users’ perspectives on the FiCTION pilot trial to improve the design and conduct of the FiCTION main trial. This paper reports on these perspectives and the resultant changes to the FiCTION main trial.

Major compulsory revisions

My main comments relate to wider application of the findings of this study to other trials and user involvement in research in general. The aim is very specific, involving the collection of data to support the design and conduct of a larger trial. However the introduction talks about the need to deepen our understanding of how to involve patients and service users in research. Although the feedback particularly from the dentists will be helpful in refining the design and conduct of the FiCTION main trial I think the team could have in addition to the trial specific questions asked more broader questions about user involvement in research; what are the barriers and are the inducement offered by bodies like NIHR sufficient to overcome the barriers. Also the notion of user researchers could have been explored and what support would be required for members of the public to take on a more hands on role in research.

My other main concern is the sampling and the numbers of users involved in the study. Only 4 children and parents agreed to participate all of whom were participating in the trial. I think it would have been very helpful to obtain the views of parents and children who refused to participate in the trial about the reasons why they declined to participate and to talk to parents and children not approached to participate in the trial to talk about the wider issues I mention above.

Another concern is that parents and children were interviewed together rather than separately. There are a number of methodologies that can be employed to collect qualitative data from young children, see

And
Epstein I, Stevens B, McKeever P, Baruchel S, Jones H.

To make a significant contribution to the literature on user involvement and children and parents' participation in trials the team may wish to consider collecting more data.

Minor Essential Revisions
More information is required about the sampling strategy and a reference for framework analysis is required.

Discretionary Revisions
The authors may wish to include a statement on reflexivity in the manuscript.

**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 have no competing interests