Reviewer's report

Title: Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial

Version: 1 Date: 31 October 2013

Reviewer: Alan R Tait

Reviewer's report:

This study examined parents’ responses to having their child randomized to the control arm of an RCT of early BCG vaccination. While I think this is an interesting study, the findings are not entirely surprising.

1. This is a study wherein both the safety and efficacy of the experimental arm (BCG) are well-established and furthermore there is the potential for additional benefits with respect to reducing other infectious diseases in the first years of life. The risks appear minimal. As such, I am not surprised that some parents were disappointed at being allocated to the control group. Although the authors allude to this in the limitations, it would have perhaps been more compelling to have done this study following an RCT that offered greater equipoise.

2. I also wonder why the authors did not interview subjects who received the experimental treatment. I imagine that they would be uniformly satisfied but it is also possible that some had regret. Interviewing the experimental arm group would have given you a better feel for any differences in the ways in which these 2 groups viewed their participation.

3. Feelings of satisfaction and disappointment are often a function of expectations. As such, it would be interesting to know exactly what subjects were told regarding the randomization process and the risks and benefits of each arm of the study. Perhaps the authors could include a copy of the consent document that dealt with these issues as an appendix.

4. Did the fact that the focus group and telephone interview questions differ affect the identification of themes?

5. For readers that are unfamiliar with qualitative research, it may be helpful to describe how thematic saturation was achieved.

6. Results: It would be helpful to provide numbers. Terms such as “most” and “few” tell the reader very little.

7. The use of a tool to examine subjects’ attitudes towards research participation in an RCT is intriguing. Suggest further development and testing.

Level of interest: An article of limited interest
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