Reviewer’s report

Title: Factors influencing access of pregnant women and their infants to their local healthcare system: a prospective, multi-centre, observational study

Version: 0 Date: 24 Jul 2017

Reviewer: Patricia Bailey

Reviewer's report:

This manuscript is well written and adds to the literature on how to improve recruitment and retention in clinical trials. However, barriers to the utilization of maternal and infant health services are of interest to a wider readership than those conducting clinical trials and the authors might explicitly recognize that a greater understanding of predictors of access to services have programmatic implications that extend beyond the implementation of clinical trials.

Observations for consideration

1. It would be helpful to the reader to know what the proposed schedule for the GBS vaccine is: Is it a series of vaccines? When during pregnancy and/or postpartum does a woman have the vaccine? If the scheduling of the vaccine is not yet determined or not yet public, then the authors might say that.

2. Under the study limitations, the authors list variables that were not included for consideration in this study but that perhaps should have been. Another variable to consider might be mode of delivery or whether the woman experienced a complicated delivery, both of which might predict a woman's likelihood of returning for a follow-up visit. Furthermore, the quality of the antenatal experience or the birthing experience - whether it was traumatic or supportive - might also affect her likelihood to return.

3. The conclusion "While heterogeneities were observed at site level, mode, duration and cost of transportation were significant factors influencing whether women returned to study site for delivery or follow-up visits" is stated under Results of the abstract and under Conclusions of the paper. However, it does not present the direction of this influence and therefore might be considered misleading or less than transparent, especially since some of the findings were surprising.

4. The unexpected findings, of which there are at least two [(1) as cost of transport increased, so did the likelihood of a woman returning to the study site, and (2) a higher return to study site rate if a woman had other children], are less than satisfactorily handled. Further attempts to explain these findings would be helpful. Similarly, what implications they might have for
preparing for phase 3 trials might be in line, though I can't think of how the first finding would have much effect on study design or implementation. Investigators might rest a little easier that cost wouldn't be expected to undermine study participation.

Need for greater clarification

* Why was Mozambique included as the only semi-rural site? Because of its known infrastructure as a clinical trial site, to represent semi-rural sites?

* To determine if childcare for other children was a deterrent for women to return to the study site, wouldn't a better comparison group have been women who had children and who did not have alternative childcare? Was this group not used because of its very small size? Also, page 11, lines 249-251 - "Since alternative childcare was very high, we were confident that we were comparing women with and without other children." This statement isn't clear. Why would your confidence have been in question?

* Page 13, line 316, you might consider specifying how you think education is a factor in younger women being at greater risk of GBS than older women.

Minor editing suggestions

* "Data" page 5, line 113, should be followed by a verb in the plural - "data were"

* Page 7, line 165, add the word 'who' to "The proportion of women who withdrew …"

* Page 9, line 211. Readers may be more familiar with the term "holding variables constant" or "controlling for other variables" rather than "fixing variables".

* Page 12, line 271, consider replacing the word "defining" with "identifying"

* Page 12, line 274, perhaps the word "fail screening" and "screening failure rates" might be replaced with the concept of ineligibility

* Page 12, line 282, the correct preposition in this case is "among" rather than "between"

* Page 12, line 284, "difficult" might be replaced with "less available"

* Page 14, line 326. Replace the comma with a period before the start of the sentence "While heterogeneities…"
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
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