Reviewer's report

Title: BabyGel Pilot: a pilot cluster randomised trial of the provision of alcohol handgel to postpartum mothers to prevent neonatal and young infant Infection-related morbidity in the community

Version: 1 Date: 08 Apr 2018

Reviewer: Pavani Ram

Reviewer's report:

Sincere thanks for the opportunity to review this paper on an interesting study. There is a substantial need to identify effective interventions to prevent neonatal and young infant sepsis that can be applied among health workers and family members. Increasing convenience of hand hygiene via a waterless hand cleansing option is an important potential approach to strengthening hygiene in the newborn period. Please see below a number of major and minor comments. I hope that they are helpful to the authors.

Major comments:

1. Methods
   
a. Outcomes
   
i. How was feasibility defined?
   
ii. How was mother-reported infection defined?

   b. Intervention
   
i. Is the theory of change for the behavior intervention detailed elsewhere? If not, please explain here.
   
ii. In addition, please describe the behavior communication strategy more fully. What was the behavior change communication (BCC) strategy? How frequent was the interaction for BCC with the women and when did the BCC interaction(s) occur? Who provided the BCC.
   
iii. Were expert children encouraged to use the ABHR themselves or did they serve principally as reminders? Might they not have been important vectors of pathogens, given their exposure to primary school environments?
   
iv. Is the ABHR available commercially? Were refills from pharmacies to be given free or did participants have to pay for them? If the latter, what was the cost of the refill?
v. The manuscript is not clear about the inclusion of ABHR for cord cleansing, in addition to hand hygiene. What is the available evidence regarding the benefits of applying alcohol (and not chlorhexidine or vs. dry cord care) to the cord stump? It is surprising that there were no feasibility objectives linked to adherence to cord application of the ABHR. Also, the results suggest that some facilities were distributing chlorhexidine in the area. How common is this, what is the national policy regarding chlorhexidine for cord care, and why does it make sense to introduce an alternative to chlorhexidine (namely ABHR)?

c. Site Selection

i. Provide any available information regarding NMR or proportion of newborn deaths attributable to infection from the study area or a higher level of administrative unit.

d. Participant selection

i. Were only those women attending the ANC days eligible for participation? What is the risk of excluding women who don't attend ANC, and who might be at concomitant risk for adverse birth outcomes (such as preterm birth or low birthweight or unskilled birth attendance) that place newborns at risk for infection?

ii. What's the coverage of ANC attendance in this area?

iii. How was the sample size distributed across the 10 health facilities?

iv. Why did it take a full year to recruit just 100 participants from 10 facilities?

e. Intervention

i. Are there any sociocultural barriers to hand hygiene behavior in / near the study area during the newborn period? If so, please explain what they are. Are there any barriers to women asking their family members, especially other adults, to improve their hand hygiene?

f. Sample size

i. No sample size estimations are actually provided. Did any analytic objectives related to feasibility assessment drive sample size calculations or was this driven solely by budgetary and logistical constraints?

g. Analytic methods

i. The feasibility-related measures of interest should be detailed.
ii. How was adherence to the ABHR regimen defined and measured? Was this solely through self-report, which carries a substantial risk of bias?

iii. The decision not to account for clustering in the analysis should be explained and justified in the analytic methods section.

iv. The composite measure of infection should be defined here.

2. Results

a. Which proportion of women were identified within the first 24 hours after delivery?

b. What were the mean number of refills obtained?

c. Primary outcome: page 16, line 12: is this an error? This says 29% but the n/N reads 4/48.

3. Discussion

a. Which data supports the efficacy of the expert child? This seems a foregone conclusion as presented on page 18, lines 0-0.

b. The confirmation of only a few blood-culture confirmed infections is hardly surprising. The methods for blood specimen collection and culture were not described in the methods. Also, isn't such a finding consistent with other assessments of pathogen identification from blood cultures among newborns with PSBI / suspected infection?

c. Page 18, line 51: how have the investigators determined that there is a training deficit in improving infection identification?

d. Page 19, line 0: please clarify in what way women had "daily contact with the intervention".

e. The suggestion of the potential use of a placebo hand rub begs the question: is the anticipated study question for the larger trial one of the efficacy of ABHR for prevention of neonatal infection or is it about the broader implications of integrating hygiene promotion into antenatal / postnatal care?
4. Conclusions

a. The authors call attention to the small sample size as an explanation for not finding a significant difference in infection risk in intervention vs control newborns. However, this was not an objective of this pilot study, or at least this manuscript describing the feasibility of the implication. It seems important to focus the conclusions on the objectives of this particular paper rather than the overall pilot and feasibility study.

Minor comments:

1. Abstract

a. The final sentence does not make sense because neither the expert child nor the concept of the composite outcome have been introduced elsewhere in the abstract.

2. Background

a. There is an error in the first sentence. The under-five mortality count is far lower (closer to 6 million). Please see the latest IGME 2017 estimate or Liu et al from the Lancet 2015.

b. Reference 26 reports on an observational study but the description on page 7, line 1 suggests a confirmed causal relationship.

3. Site Selection

i. State eligibility criteria for communities up front, rather than forcing the reader to go to figure 1.

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