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: 2 Date: 03 Oct 2018

Reviewer: Helen Buxton

Reviewer's report:

I think this is a very interesting and relevant study, and community use of hand gel could be very significant in reduction of infections, so will be interested to see this trial progress.

A major comment, as expanded on below is that you do not detail how you measured ABHR use. As this is a key outcome, I think this needs to be made explicit.

I also do not think you present enough evidence in support of the effectiveness of expert children. I would suggest reframing this as an avenue you wish to explore further in trial design, unless there is evidence of effectiveness either from literature or from findings not presented here?

Minor comments:

I think the word 'infective' is used incorrectly throughout the paper - e.g. you say infective deaths - but that implies the death causes infection in others, rather than the death is caused by infection https://www.merriam-webster.com/dictionary/infective

Should be rephrased to infection-related death/ infection-related morbidity etc

Introduction

Pg 5 line 12 - which children? Children under 5? Over what time period?

Pg 5 line 24 - 37 - this paragraph jumps from late onset sepsis, to early onset, and back to late - I think it should be reordered, and the transition should be more explicit. As I understand it the intervention is specifically targeting late onset sepsis, and this should be made explicit. Especially as when deaths occur in the late neonatal period (7 - 28 days) almost half of these deaths are due to infection http://www.who.int/bulletin/volumes/93/1/14-139790/en/
Pg 5 line 45 - the Blencowe review is reported as finding a 'lack of quality evidence' which I think is misleading. More accurate to say the reported concluded there was limited evidence, or that evidence in support of effect was low quality - line 50 - state the 40% reduction estimate relates to newborn care practices at home.

Pg 6 line 15 - reference for ABHR suggested to increase compliance?

Methods:

Pg 8 - Confused about timeline - study period is 8 weeks? But recruited in Aug-Nov 2015 and followed up until May 2016? How does the 8 weeks fit it?

Pg 9 - Description of 3 moments is confusing and differs from that shown in the figure - e.g.

[1] before touching the baby (with whole body wipe within 4 hours of birth ),

[2] before clean or aseptic procedures (at the time of birth and application of the alcohol hand rub to the end of the cord three times a day until the cord falls off),

[3] and after body fluid exposure risk (after the mother or carer uses the toilet and after touching any surfaces)

1 - this is 2 different actions, and it reads as if the section in brackets is explaining the previous section - therefore it appears that the only action required is to wipe the baby, rather than positioning 'before touching' as an ongoing action

3 - include after exposure to child faeces in the explaining section in brackets. I suggest the description needs a bit of a reword

Pg 9 line 53 - women were instructed by who? it is not clear who actually delivered the intervention

Outcome measurements - No information given on how ABHR use was measured

Results - pg 14 - line 21 - Perhaps make explicit the IMCI questions which the VHWs were able to answer - I assume the 30% positive result is based only on first 4 Qu in the tool?
Pg 15 - line 11 - See methods, no information given on how ABHR use was measured. Also I don't think the 'expert child' system should go here - no data presented measures the effectiveness or acceptability of the expert child? Again from line 50 - is there any data in support of this change? (even if reported elsewhere?)

Discussion

Pg 16 - line 33 - as above, no data presented supports the effectiveness of the expert child, may need to present this as an idea supported by examples from literature (if there are some? I think this mechanism has been used to support ARV adherence, but I don't have exact references?

Pg 18 - line 4 - Needs greater clarity:

defined as any one or more of (i) diarrhoea, (ii) lower respiratory tract infections, (iii) omphalitis, (iv) IMCI danger sign(s) verified by health staff, (v) hospitalisation, and (vi) death

Are (i, ii, iii) mother reported? Or also verified by health staff?

Limitations - you rely heavily on self report for baseline hand washing figures, it would be worth mentioning limitations of this, similarly if hand rub use is measured by self report, this should be mentioned as limitation. Is there a limitation in only targeting mothers when other household members may be engaged in care of the new born also?

Conclusion - I don't think you have presented enough evidence to refer to the expert child in the conclusion

Thanks very much

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