Author’s response to reviews

Title: The CRADLE Vital Signs Alert: qualitative evaluation of a novel device designed for use in pregnancy by healthcare workers in low-resource settings

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Author’s response to reviews:
1. Overall, the study was carried out in primary and tertiary-level settings in four different countries. Please indicate why no data collection was carried out in secondary level settings. Was this an issue of deciding that CRADLE would not be useful in such settings or an issue of where the research could be carried out most efficiently or something else?

The data collected for the entire project, for which this is a subset, comprised of two separate studies. The CLIP Trial specifically evaluated community-level interventions for pre-eclampsia and for this reason, secondary and tertiary-level data collection was not undertaken. The study that took place in South Africa evaluated the use of the device in tertiary centres, where the rate of adverse outcomes including eclampsia and hysterectomy were high. This was a pragmatic decision to effectively evaluate the traffic light thresholds in a high-risk population. A mixed methods approach was used to determine the acceptability of the device under high-intensity use. Although the three South African centres provided tertiary-level care, women requiring only secondary-level care were also cared for at these centres.

This has been made clearer in the manuscript Methods section:

“This study took place in tertiary centres, where the rate of adverse outcomes including eclampsia and hysterectomy were high, to effectively evaluate the traffic light thresholds in a high-risk population. These centres cared for women requiring either secondary- or tertiary-level care.”

2. The Three Delays Model is used as one framework to understand the importance of the device. Please summarize what this model is and states, for readers who are not familiar with it.

The model has now been described in the text for readers not familiar with it:

“The model is a conceptual framework describing the three delays in receiving care that can result in avoidable maternal mortality and morbidity: (i) delays in the recognition of the maternal health problem and decision to seek care; (ii) delays in reaching the health facility; (iii) delays in the provision of adequate care.”

3. p. 5: the authors mention mHealth technology- can the data collected through the CRADLE device be easily transmitted to or through a cell phone? Cell phones are more ubiquitous throughout the world and it would be interesting to better understand the interface or possible interfaces between the device and phones.

The current model is not capable of mHealth technology but the manufacturer has confirmed that mHealth technology could be incorporated into future models (although this would impact on the low price).

“Although the current model of the CRADLE VSA does not have mHealth capabilities, incorporation of mHealth technology to future models of the CRADLE VSA is possible (i.e.
transmission of vital signs data from the device to mobile phones or directly to a central facility)."

4. Methods: were the same healthcare workers (HCWs) who were interviewed also included in the focus groups? How did the participants overlap (if at all)?

The following text has been added to the Methods of the manuscript:

“Participants were approached to participate in either a semi-structured interview or a focus group discussion, with no one participating in both.”

5. P8: what type of process or assessment was used to be able to state that "coding agreements between the researchers was high"?

More detail has been added to the manuscript Methods text:

“The NVivo software coding agreement function (Kappa coefficient) was used to assess agreement between coders. If coding agreement was less than 93%, coding disagreements were discussed during Skype meetings until the researcher group reached a consensus.”

6. P9: The authors state "A large sample size was needed..." What was the final sample size and how was this determined? Please indicate the separate "needed" sample sizes for interviews and focus groups, by country and compare to actual sample sizes. This would best be presented in a table.

We have altered the text accordingly and sample size figures are provided in Table 1. The final sample size easily achieved data saturation as anticipated. The numbers selected were standard sampling for this type of qualitative work. We have added the following:

“A large sample size was needed to understand the country context influence in community, primary and tertiary health centres and data saturation was achieved (sample size shown in Table 1).”

7. P11: minor spelling error, line 58-"...every ones BP" should be changed to "...everyone's BP..."

Thank you for highlighting this. The text has now been changed.

8. P14: the quote, lines 43-53: the authors use this quote to illustrate a negative view that HCWs have of the device, but the last line also denotes something very positive in terms
of the impact on care- the nurse now has time to "speak to the patient to find out how the patient is doing..." This is significant; how many other HCWs had the same observation? If this is not an isolated comment, this is certainly an important theme.

Although many HCWs reported that it was more time consuming to measure BP in this way, only this one HCW reported that having to stay with the patient during measurement enabled them to further assess the patient. We therefore did not expand upon the comment.

9. P16: findings seem to show that the device helps women and their families become more aware of the importance of vital signs and thus seems to increase their own involvement in their care (at least to a limited extent). This is a theme that I would suggest highlighting in the abstract and in the discussion. Any advancements that can be made in empowering patients with more information and deeper understanding of their own health and health care are indeed important. (p21, lines 1-8 refer to how the device can also address the first delay. This is an excellent and important finding.)

We are pleased you agree that this is an important theme and for this reason, we have already highlighted this in the abstract and the discussion.

Abstract:

“The traffic light early warning system gave women and their families a better understanding of the importance of vital signs in pregnancy and during the postpartum period. The device motivated women to attend primary care and encouraged them to accept treatment and referral.”

Discussion:

“The traffic lights also gave women a better understanding of their health and the need for vital signs monitoring. This led to the perception that more women chose to attend primary health centres and easier counselling of women who needed urgent treatment or referral.”

10. P17, line 1: slight spelling error, change "My husband like it.." to "My husband liked it..." DISCUSSION

The text has now been corrected

11. The authors point out that having two phases of data collection allowed for temporal variations to be explored. Temporal variations were not presented in the Results section. The authors either should add findings regarding such variation or delete this sentence from the Discussion.
Temporal themes were only apparent with regard to views of accuracy and change of perception over time.

In the Results section we have described this:

In women’s homes and primary health centres in Mozambique, India and Nigeria the CRADLE device was perceived to be accurate. This perception was strengthened over time, demonstrated through a greater proportion of references regarding accuracy in phase 2 compared to phase 1.

“As we are getting more experience we are liking this apparatus more. Now we know that to detect one case of hypertension we have to check everyone’s BP frequently. As days are passing our faith on machine and accuracy of recording BP has increased tremendously.” Interview, ANM, India.