Reviewer’s report

Title: Exploring the effect of implementation and context on a stepped wedge randomized-controlled trial of a vital sign triage device in routine maternity care in low-resource settings

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Reviewer: Felix Limbani

Reviewer’s report:

* This is an interesting paper of a vital signs triage devise used in routine maternity care in low resource settings. The authors conducted process evaluation to explore the effect of implementation and context on a stepped wedge randomised controlled trial. The authors present a novel approach of evaluating implementation alongside effectiveness. Despite being a research study, and despite showing no correlation between the primary outcomes and different process evaluation domains, the findings present contextual and implementation factors important to similar maternal health interventions in low resource settings. Below, I have made a few observations aimed at strengthening the paper and mainly focuses on clarifying the study questions, logic model, mechanisms of action and mediators of action.

* There is a clear statement of purpose for the evaluation in the Introduction - "to describe the implementation of the intervention and the local contexts in which it was delivered and to determine whether differences in the effect of the intervention on the primary outcome can be explained." However, the study questions are not clearly presented. There is an attempt to mention them in the first column of table 1 but are not well articulated. Please list your study questions explicitly in the text (Introduction or Methods) and they should tie directly to the statement of purpose and Results. Justify why you chose to focus on these questions.

* The MRC process evaluation guide recommends articulation of a programme theory (causal assumptions of complex interventions). There is no clear program theory constructed, tested, or refined. The authors have provided the logic model in the supplementary material. I recommend the authors to clearly articulate the programme theory in the actual paper (not as supplementary material - reflecting assumptions regarding the causes of the problem and how actions will produce change. Apart from the diagram, the authors should briefly explain (in a paragraph) the initial programme theory for the CRADLE-3 VSA intervention and explain how it was elicited i.e. existing literature or the feasibility study.

* Background: The health systems need to be described briefly or presented as a figure so that readers who are not familiar with the health systems in the Ten clusters, understand the provision of maternal health services (especially before the intervention) i.e. equipment used and the workforce employed. Later is the Results, it will be good to show
how differences in the health systems across the clusters affected implementation of the intervention

* Page 6, line 42 - for the benefit of diverse readers please describe what is meant by vital signs. Vital signs can be described differently in different setups.

* Data collection methods - A variety of data sources are used. The nature of how 'contextual data' is collected during baseline and throughout the intervention is not clear (e.g. no interview guides, or observation tool). In table 1, methods and tools for data collection are clear for the other domains and not 'context' - it only says "measurement of resources at baseline and throughout the trial". This could be described briefly in the text. There is no indication that additional data was collected to answer particular arising questions (during the iterative process of process evaluation).

* The evaluation identifies various contextual influences (resource availability, staff levels). These seem to be appropriate. However, other important contextual influences like infrastructure, weather and politics, are only mentioned in the data collection section (lines 40 - 47) but are not explained in the results how they affected implementation in the individual clusters.

* On several occasions, the manuscript has made reference to "Mechanisms of action" i.e. "The intervention and its implementation strategies were refined, and potential mechanisms of action explored (page 6 lines 19 - 24). The MRC process evaluation guide defines Mechanisms of action as 'how intervention activities, and participants' interactions with them, trigger change'. Mechanisms should be the causal pathway generating a particular outcome, and your results should focus on identifying these mechanisms and describing how context influenced them. Currently the results section is silent on Mechanisms. For instance, explore on how nurses got frustrated or motivated with the new VSA and how that affected outcomes, space restrictions and how it affected healthcare workers, relationships and it affected teamwork, interaction with women and the intervention.

* Qualitative data - there is a clear description of what qualitative data was collected and how they collected it. This has been well laid down in the Results section (qualitative analysis). However, this section runs short of useful direct quotes as is expected of qualitative research to substantiate our statements.

* Mediators of action - Table 1 has defined each of the domains in the results i.e. context as the setting for implementation for each cluster. However, there is no definition of what the evaluation refers to as 'mediators of action'. I recommend to the authors to define this. Other literature looks at this as 'intermediate processes which explain subsequent changes in outcomes'. It is therefore unusual for this evaluation to refer 'mediators of action' of such a complex intervention just as referrals of maternity visits. Please furthers explore what were mediators and how they influenced outcomes.
Page 10, line 43 - deliveries at home. Please explain what is meant by 'systematically collected'. How data on deliveries at home were collected in the seven clusters? You might need to explain this in the methods.

In view of the CRADLE VSA that went missing (23), those that got broken down (180), and clinics that were not using them six months post intervention; what is your comment on the sustainability of the equipment? Based on the reasons for missing or breaking down of the machines, and based on your experience in implementing the trial, will you be able to provide recommendations on how to prevent this? i.e. issues of maintenance and security?

The evaluation shown no correlation between process measures within domains and no correlation between individual domains and the primary outcome. However, there are other process outcomes that improved as a result of the intervention and these outcomes varied across the clusters. Such variations provides an opportunity to describe contextual and other influences on the process outcomes. I would like to see this focussed more on discussing the connections between context and mechanisms. You have the opportunity to not just to focus on correlation between the domains and primary outcomes - but to delve into which are most important contextual influences to influence (or not influence) process outcomes. This is the core of process evaluations - explains what works for whom and in what conditions.

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