Author’s response to reviews

Title: A Condom Uterine Balloon Package Among Referral Facilities in Dar Es Salaam: An Assessment of Perceptions, Barriers and Facilitators One Year After Implementation

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Author’s response to reviews:

Editor:

Comment 1: Please try to abstain from abbreviations in the abstract

Response: The Ujenzi ESM-UBT device is the FDA registration name thus we used “ESM-UBT in the abstract. Other abbreviations were removed.

Comment 2: Please add on evidence of the balloon tamponade

Response: Additional references were included in the introduction regarding the evidence surrounding the balloon tamponade device.

Comment 3: There are quite a bit of language errors and spelling mistakes, please get someone who can help, including wrong writing of figures e.g. 4,6072 deliveries. This should be 46,072?

Response: The paper was thoroughly re-examined and any grammatical, spelling, and/or language errors were corrected.

Comment 4: Could you add in a box the curriculum of the training and re-training?
Response: This was added to the manuscript.

Comment 5: Methods: why did you use research assistants who were employed at the hospital. Were the two trained in qualitative research?

Response: We (OA and MS) are physicians and at the time, employed by the Division of Global Health Innovation at Massachusetts General Hospital as part of a (post-residency) fellowship. Prior to conducting the interviews, we received training in qualitative research while obtaining our Masters in Public Health degree in addition to training from senior investigators in our division.

Comment 6: Why was verbal and not written consent taken?

Response: Both IRBs felt that for this qualitative research verbal consent was adequate and most appropriate. Of note, the verbal consents are on saved audio recording.”.

Comment 7: Please make clear what your research question was and how the interview guide was reflecting this.

Response: The research question was: “What are the facilitators and barriers to uptake and best practice of the ESM-UBT device in Tanzania?” The research question was reflected in the last line of the introduction. Additionally, the interview guide has been added to the appendix which demonstrates that the line of questioning was related directly to obtaining details regarding demographics of the participant, details about common use and facilitators and barriers to implementation.

Comment 8: Did the midwives use the device alone or only together with a clinician?

Response: The midwives are usually the main providers during labor so they were trained to use the device alone. Additionally, during the interviews the midwives described using the device by themselves as well as with other providers.

Comment 9: I’m not sure your analysis has a sufficient level of analysis; it is still very close to what has been mentioned, so that the question arises: so what? The discussion section has no references. While I agree that there might be no qualitative study on the device, there are plenty of studies indicating the limitation of new technologies and training, and such literature would need to be worked in. Such an analysis would also help to get the analysis on a sufficient level of abstraction so that clear messages can be spelled out
Response: Your point is well taken regarding the level of the analysis. The discussion section has now been revised to reference previously published papers regarding limitations and successes of implementation of new technologies and training in low resource settings.

Comment 10: Please add the interview guide to the submission as well as the codebook. Please add an overview of codes and themes in a table

Response: This has been added to the appendix.

Reviewer 1

Comment 1: The authors' effort to document experience of providers with UBT is appreciated. However, the study is not appropriately situated as a piece of research in two ways: there is a body of literature on clinical skills training and attainment of competence; also there is a body of literature on interventions for PPH in low resource settings and how contextual factors in the service might influence the applicability of a particular intervention alongside others such as NASG and tranexamic acid. Both these areas of knowledge are overlooked in the manuscript and references. The introduction and discussion are mostly about the benefits of UBT not about the issues of attaining and maintaining competency, or how UBT fits in to care amid the particular constraints of Dar hospitals. The authors could usefully revise the manuscript using the raw material they have, placing the work more appropriately so as to show relevant insights about skills training and about PPH management. They could even draw on some of their other papers that are cited but not really used in the discussion to illuminate the influence of context and service setting.

Response: The discussion was extensively revised to include a more broad review of literature regarding implementation of new technology in the clinical setting. However in regards to other interventions for postpartum hemorrhage, the purpose of the paper was not to evaluate the validity of other interventions but to discuss how UBT, a device that has been validated in other studies, could be effectively implemented in a low resource setting. Furthermore, neither NASG nor TXA were part of standard practice in the study sites and as such were not mentioned in our discussion.

Comment 2: An aspect that might be illuminated further is the 'fear of blame' identified in the interviews. In this reviewer's current practice setting there are deep reservations among colleagues about UBT owing to the non availability of rapid recourse to blood transfusion and hysterectomy should conservative steps such as UBT fail - whereas in other settings one is more comfortable to deploy UBT knowing that rapid access to surgery is available should it fail. Thus clinicians are likely to make their own judgements of what is 'blame worthy' based on their knowledge of the consequences for patients in their particular setting. This would be an interesting area to explore further.
Response: This is a very valid point. This was an interesting and novel 'barrier' we uncovered in our study and we look forward to digging deeper into some of these barriers along with our local partners to see how they might be modified. The purpose of our study was to gain a broad understanding of the drivers of implementation at our study sites and are potentially generalizable to similar settings.

Comment 3: The referencing is rather selective e.g. not including the Dumont study.

Response: Thank you for bringing the Dumont study to our attention. We understand that there are limitations to every literature review and unfortunately this study was not published during our initial manuscript drafting phase.

Comment 4: The abstract conclusion statement that "The ESM-UBT device is effective in arresting PPH" is unrelated to this work, which is not about the efficacy of UBT.

Response: The conclusion has been modified to reflect the purpose of this paper.

Comment 5: Women are not 'diagnosed with PPH', the diagnosis applies to the condition, eg 'a diagnosis of PPH was made in .... women'

Response: The manuscript has been extensively revised to improve phrasing and readability.

Reviewer 2

Comment 1: No tables?

Response: A table has been added to the manuscript explaining the curriculum. Additionally, there is a codebook and interview guide in the appendix.

Comment 2: No comparison among participants. There is a need to show point of view and differences (if any) of different categories of providers

Response: Any significant differences in opinion between cadres were included in the discussion.