Author's response to reviews

Title: Development and Preliminary Validation of a Post-Fistula Repair Reintegration Instrument among Ugandan Women

Authors:

Alison El Ayadi (Alison.ElAyadi@ucsf.edu)
Hadija Nalubwama (hnalubwama@yahoo.com)
Justus Barageine (barageinej@gmail.com)
Torsten Neilands (torsten.neilands@ucsf.edu)
Susan Obore (arsuob@yahoo.co.uk)
Josaphat Byamugisha (jbyamugisha@gmail.com)
Othman Kakaire (kakaireothman@gmail.com)
Haruna Mwanje (mwanjehm2000@yahoo.co.uk)
Abner Korn (abner.korn@ucsf.edu)
Felicia Lester (felicia.lester@ucsf.edu)
Suellen Miller (suellenmiller@gmail.com)

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Author’s response to reviews:

Dear Dr. Seijo and the Editorial Board at Reproductive Health Journal,

We greatly appreciate the Editor and Reviewer’s comments on our previously submitted manuscript, REPH-D-17-00123, entitled “Development and Preliminary Validation of a Post-Fistula Repair Reintegration Instrument among Ugandan Women”. We have considered each of the comments and have made clarifications and revisions to our manuscript to address them. Our point-by-point response to each of the comments is below, with responses italicized and all changes to the manuscript underlined.

Thank you for your continued consideration of our manuscript. Please do not hesitate to follow-up with me regarding any further questions you may have. We look forward to hearing from you.
Point-by-Point Response to Reviewer Comments

Reviewer #1:

1. This is a good manuscript on a relevant topic. I have one content related question. Many authors reported "sexuality" and "fertility" as important concerns that affects the mental health of women who suffer from fistula. Those dimensions have not been explicitly integrated in the "Initial standardised reintegration scale items". Why? Do you think that the item 14 for instance "In general, I am comfortable with my relationship with my husband/partner" is sufficient to represent those dimensions? Can you discuss how this "systematic" exclusion of these dimensions is a limitation (or not) of this tool?

We greatly appreciate reviewer #1 bringing up this important question. We had also anticipated that sexuality and fertility concerns would be featured as important within our qualitative work, and yet the interview and focus group data that we obtained did not support the inclusion of specific questions on these issues as primary reintegration concerns. However, as we have stated within our limitations section (pages 22-23, lines 544-561), our instrument development and validation work is preliminary, based on a small and specific sample, and we call for further exploration of the construct of reintegration following fistula repair and our measurement instrument among larger and culturally distinct populations.

Reviewer #2:

Dear Authors, Research topic of this manuscript is a public health concern. The manuscript is well written. However, the following points should be addressed before resubmitting:

1. Title: The title should use tools instead of instrument, because you are validating the measurement tool

Suggested title- "Development and Preliminary Validation of a Post-Fistula Repair Reintegration Measurement Tool among Ugandan Women"

Thank you for this suggestion; however, we prefer to maintain the title as is given the equivalence of these terms.
2. Abstract: Page 2, lines 41-42: Why importance only on Africa and Asia ".....mostly in sub-Saharan Africa and Asia"? Why focus is not on under-developed and developing countries?

In our statement, we highlight that this condition is global, yet that the majority of women affected are in sub-Saharan Africa and Asia, as follows: “Obstetric fistula is a debilitating and traumatic birth injury affecting 2-3 million women globally, mostly in sub-Saharan Africa and Asia.” (page 2, lines 40-41). This is consistent with the literature on prevalence and incidence of obstetric fistula [1, 2].

3. Abstract: Page 2, line 50: change "thematic analysis" to "thematic content analysis"

Thank you for this suggestion; however, we have maintained our current use of ‘thematic analysis’ as it is the appropriate term for our analysis given the distinctions between ‘thematic analysis’ and ‘content analysis’, as described in Marks and Yardley [3]. We have added the Marks and Yardley citation to the methods section as a reference to readers (page 8, line 201).

4. Abstract: You should limit the key words (around 5). You may delete some key words like- survey, measure, etc.

We appreciate this suggestion and have removed three of the key words: measurement tool, beyond repair, and survey. Seven essential key words remain: obstetric fistula, social reintegration, maternal morbidity, obstructed labor, measure, instrument, Uganda.

5. Background: More evidenced based literature around reintegration following obstetric fistula surgery need to be reviewed.

The state of the evidence around post-fistula surgery reintegration is limited, hence the need for our research project. At your suggestion we have added an additional sentence to highlight the importance of work in the reintegration process: “Further studies have highlighted the positive influence of returning to work and economic productivity in the reintegration process [30, 31]” (page 5, lines 137-138).

On page 5 (lines 128-138), we have a paragraph discussing the post-surgical reintegration literature, as follows: “Only recently have researchers begun longitudinal assessment of post-surgical recovery processes after fistula repair to better understand women’s experiences. General improvements in perceived quality of life, particularly among women with successful surgery, have been reported [4, 5]. However, multiple studies have documented challenges, including persistent post-repair fistula-related symptoms such as residual incontinence [6-8], pain and weakness [4, 9], and sexual and fertility complications [4, 10-13]. Women experiencing lingering physical problems such as these are less able to resume their previous roles and less likely to consider themselves recovered [4, 5, 14, 15]. These women are at greater risk of poor continued mental health [9, 16, 17]. For all women, anxieties around fistula recurrence have been
reported as contributors to low mental health status and as affecting women’s resumption of sexual activity and intimate relationships [4, 9, 12, 18, 19].”

6. **Background:** Is there any other measurement tool for evaluating women's post-surgical reintegration success?

To our knowledge, no other measurement instrument for evaluating women’s post-surgical reintegration success exists. We describe this on page 5, lines 144-145: “However, currently no standardized measurement tool exists to evaluate how successful a woman’s post-surgical reintegration has been.”

7. **Methods:** Why you do the survey in "one apex hospital" in the country; because there is possibility of less complication in post obstetric fistula surgery due to better facilities in the apex hospital. Sample should be taken randomly from various hospitals.

Our exploratory study was conducted at Mulago National Teaching and Referral Hospital, as this is the only hospital in Uganda that provides routine fistula care, given it is a highly specialized area. Fistula surgery is available at other facilities in Uganda, yet is limited to the surgical camp setting. We acknowledge the limitations to our findings imposed by our sample in our discussion section, as follows: “Finally, both our formative research for measure development and measure validation was conducted among women comprising the patient population for Mulago Hospital in Kampala, Uganda, and our results may not be generalizable to other cultural contexts. Further exploration of the construct of reintegration following fistula repair and the measurement instrument should be conducted in larger and culturally distinct populations.” (p22, lines 557-561), and hope to further explore differences and similarities across populations of women affected by fistula in future work.

8. **Methods:** Sample size is very less (particularly for quantitative analysis). Please give some explanation on methods section.

Our qualitative sample size was determined by achievement of data saturation. In our methods section we state, “Of the 45 eligible women contacted, most (44) provided verbal consent for participation. 33 ultimately participated; 11 did not participate due to achievement of data saturation.” (page 6, lines 166-168). Our quantitative sample size of 60 was selected taking into consideration feasibility within the context of our funding timeline, and we acknowledge that this is a smaller than desired sample size in our limitations section, as follows: “While this validation of our post-surgical reintegration measure is promising, it must be considered preliminary due to several limitations. First, our validation sample consisted of only 60 individuals; this sample size is low, particularly given the number of items included within our measure [20].” (page 22, lines 544-546). In response to the reviewer’s comment, we have added some additional text to the methods section: “A sample size of 60 was targeted based on feasibility.” (page 9, lines 238-239).
9. **Methods:** Page 7, Line 171-175: Along with other questions, history of still birth or fetal demise should have been asked. Since stillbirth is very common among such patients of obstructed labor with fistula ranging from 50-89% in the countries under consideration. Also the history of foot drop should have been asked. These histories should be asked since both of them have an impact on mental health of the women after delivery. They might affect mobility as well. Similarly history of repeat pregnancy after fistula operation is important in 6-24 months? I think it might exaggerate the situation.

We agree that women’s experience of stillbirth or fetal demise, and footdrop and other fistula-associated complications are likely to have an important impact on women’s reintegration success, and these experiences were explored within our qualitative work and captured in our longitudinal survey. The reviewer’s comment refers to the demographic survey conducted among the qualitative participants, which did include the outcome of the pregnancy that resulted in the fistula but did not include assessment of other fistula-related symptoms due to the need for brevity and the fact that we were conducting in-depth qualitative work with these participants. The proportion of infants that were live born and did not die shortly after birth was 30.3% among our qualitative participants and 28.3% among our longitudinal cohort; we have added this information to Table 1.

10. **Methods:** Line 238: Local research coordinators are from the same Hospital or you hired local researcher for this purpose.

The local research coordinator was hired full time to coordinate the study. She had not previously been affiliated with the Makerere College of Medicine. The local research team also comprised 5 medical doctors and researchers already affiliated with the Makerere University College of Medicine.

11. **Methods:** There should be focus on history of post-operative complication after surgery which might affect the overall change in mood, mobility or mental health.

Please see our response to question 9 above.

12. **Results:** Page 18: A summary paragraph at the end of qualitative analysis will help the reader to understand the list of issues in a bird-eye-at view.

The summary paragraph of relevance to the qualitative analysis begins on page 13, line 325. In response to the reviewer’s comment, we have adjusted the language to better mirror the themes. The paragraph reads as follows: “Themes that emerged as central to women’s experiences following achievement of continence, their perceptions of recovery from the fistula, and ultimately reintegrating included overcoming limited mobility and social participation, improving self-worth and reduction of internalized stigma, resuming work and reducing economic dependence, achieving the ability to meet other expected and desired roles, and changing their overall outlook to being able to consider their lives more broadly.”
13. Results: Page 18, line 451-452: you need to put comma (,) after factor loading and before thus (factor loadings, thus were excluded from all further analysis of the scale”.

Thank you for identifying this typographical error. We have made the change.

14. Results: The paragraph in page 19 is too big, is it possible to do two paragraphs

Thank you for the recommendation; unfortunately, we do are not able to identify an appropriate place to split the paragraph into two and have maintained the paragraph as is.

15. Discussion: It is important to discuss how many women generally seek surgery for obstetric fistula and what are the guidelines/ pathways of care for post-surgery of obstetric fistula at the hospital/ facility level.

The objective of this manuscript is to describe the development and validation process for a measurement instrument thus the focus of our discussion is around the instrument itself. Following your suggestions, we have inserted a sentence into the background that describes the number of women seeking surgery for obstetric fistula annually, as follows: “Approximately 23 thousand fistula surgeries occurred globally in 2014-2015 [16].” (page 4, lines 121-122).

16. Discussion: Page 21, line 523-525: Suggest to discuss the coping strategies in light of the qualitative data and socio-demographic profile of the women collected from the field along with evidence based literature.

We appreciate the reviewer’s suggestion, as coping strategies are quite important for women with fistula; however, given our manuscript objective, the qualitative data collected on coping strategies is not presented here. Instead, we plan to include coping strategies in another manuscript.

17. References: Should be arranged according to the journal requirement

The references are formatted using the BioMed Central format in Endnote, as specified by the journal.

References


