Author's response to reviews

Title: A Program Evaluation Report of a Rapid Scale-up of a High-Volume Medical Male Circumcision Site, KwaZulu-Natal, South Africa, 2010-2013

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Author's response to reviews: see over
Dear Reviewers:

Thank you for reviewing our manuscript entitled, “A Study of the Rapid Scale-up of a High-Volume Medical Male Circumcision Site, KwaZulu-Natal, South Africa, 2010-2013.” We appreciate receiving your thoughtful and comprehensive comments and edits. Our responses to each question are outlined below.

**Response to Reviewer 1 (Anne Thomas)**

**Major Compulsory Revisions:**

1. **There is no question or hypothesis addressed in the article. This is a program description. It describes a partnership, which supported training of VMMC providers and service delivery in which, over time, the number of clients coming for VMMC declined and funding for the program was eventually cut due to several reasons.**

We agree. This article provides a description and simple analyses on the monthly uptake of a VMMC program that was provided in KwaZulu-Natal, South Africa. We have altered the title so that it better reflects the descriptive nature of our analysis. The new title is: *A Program Evaluation Report of a Rapid Scale-up of a High-Volume Medical Male Circumcision Site, KwaZulu-Natal, South Africa, 2010-2013*

2. **A table of client demographics should be presented by year.**

We agree that a table of client demographics would improve understanding about the sample of individuals who received circumcision services at Asiphile. However, at this time only aggregate, programmatic data are available to the authors.

3. **On line 130, the authors state that there was a needs assessment done and that “Based on the results of a needs assessment, the male circumcision program was targeted to HIV sero-negative men aged 15-49 years in a catchment area near the clinic of 200,000 men.” It is unclear to me that the focusing of the program was made on the basis of a needs assessment; rather, this was likely due to the Ministry of Health prevention strategy. If there was more of an assessment done, it would enhance the paper to include the methods of the assessment and more of the findings than were presented here.**

We agree with the reviewer that the targeting of program was not based solely on the needs assessment. Rather, the target population was identified through Ministry of Health guidance and surveillance data. The needs assessment identified the physical space, staff, equipment, and supply chain needs that are needed to provide accessible high-volume medical male circumcision services to the target population. We have made changes in the manuscript. Unfortunately, the detailed results of the needs assessment are not available to the authors.
4. Please provide more details regarding the targeting sero-negative men. Was testing compulsory? Were clients able to get circumcised if they tested HIV positive yet were otherwise healthy? This may have contributed to the decline in clients over time. The South African government policy at the time was to promote medical male circumcision in HIV-uninfected men. While HIV testing was not compulsory for receipt of services at Asiphile, HIV positive men were referred to the nearby St. Mary’s Hospital for further assessment, prior to circumcision. Circumcisions on HIV positive men were reported to be rare, and they were performed in the hospital theatres, rather than at Asiphile. As such, no one was denied circumcision based on status of HIV-infection. HIV-infected men were encouraged to discuss with their doctor the risks and benefits of male circumcision. We do not think that HIV status contributed to the decline in clients.

5. The authors present monitoring data that is not questioned. Additional data would improve the strength of the paper. Much of the paper describes the staff training that was conducted but the number of clinicians, and their cadre was not provided. Thus, the conclusion that the program was successful could not be evaluated by this metric. Nor were we able to consider the long term effect of the training. Please include the number of VMMCs per clinician performed. Did they just get trained or did they also provide VMMC clinical services? We recognize the limitation of monitoring data but as this was not a research study, no confirmatory data are available. There were 10 clinicians trained who were physicians and surgeons employed by the hospital. Yes, the clinicians were trained and performed circumcisions during the reporting period. Trained clinicians rotated on weekly or biweekly basis through the circumcision clinic.

6. On Line 51, the authors state, “The uptake numbers increased throughout 2010 and 2011 and began to level off as the demand of early adopters was met”. There isn’t any data presented to support this statement. If assessments were done regarding the fall off in demand it should be presented to support this claim. We agree that the statement about the leveling off of early adopters is not supported by evidence, and we have altered the statement to read: “The uptake numbers increased throughout 2010 and 2011 and began to level off as the demand of early adopters may have been met”.

7. The increases in demand that are said to coincide with the trainings are interesting. Perhaps this was a factor in the demand decline. But this reviewer also wonders if there was a difference in the type of demand outreach that was done for the training periods as compared to non-training period? Perhaps it was a more effective method? We agree that comparing outreach efforts with the uptake numbers may provide insight into the demand trends and the outreach effectiveness. Unfortunately, the authors also do not have access to any records related to the timing and type of outreach that was conducted.

8. The abstract conclusions should be more fully supported by evidence presented in the paper. There is no information about the role of the international collaborative. Why is that more effective than other implementing partner’ models? The abstract and discussion
mention the use of vans to transport clients. This would be better placed in the Program Description section. Further, the timing for when the vans started being used would be of interest. Was this done at the end of the project when there was no further funding, or was this not successful in improving uptake of services?
The international collaborative is the simply cooperation between St. Mary’s Hospital and the Operation Abraham Collaborative to implement the Asiphile clinic. We have updated the manuscript to make this clearer. We did not intend to state that an international collaborative is more effective than other implementing partner models and have made some changes to the discussion in order to temper any unintended conclusions. Additionally, we have added information about the transportation vans to the program description.

9. Please specify if incentives were provided to VMMC clients and what types.
There were no incentives provided to clients. We have included this information in the manuscript.

Minor Essential Revisions:

10. Minor essential Revision: Add the training dates to Figure 1.
This is a great suggestion. We have done this.

11. Line 65: “high level” is awkward. Suggest finding another way to word this.
We have updated the wording.

12. Line 72: suggest adding a few words about how VMMC fits into combination prevention.
We have added the following sentence to the manuscript: “Circumcision interventions should be implemented as part of a comprehensive HIV prevention strategy that includes testing and counseling, treatment for sexually transmitted infections, and the promotion of correct and consistent use of condoms and safe sexual practices.”

13. Line 80: “…in that South African province” is awkward. Suggest editing this.
Thank you for pointing this out, we have edited this.

14. Line 92: “…to educational and health care services” is awkward. We don’t often think about access to schools as “educational services”. Please reword.
We have reworded.

15. Paragraph starting at line 96, “In order to increase infrastructure....”. It isn’t clear to this reviewer what role the international partnership had, in particular, in setting up the VMMC services. Was there something special about the composition of the partnership that helped make this successful? If so, please provide more details in the text.
The Operation Abraham Collaborative’s role in Asiphile was primarily staff training and the identification of facilities and equipment.

16. Line 132: “converted from small industrial facility”. This is missing an “a”. Also, what type of industrial facility? Was this a factory?
We fixed the typo. The facility was a standard, basic, multi-use industrial unit designed for storage or light engineering. It is also important to note that it had all the licenses necessary for a medical facility at the community level.

17. Line 154: “for systemic monitoring” should read “systematic”.
Thank you. We have made this change.

18. Line 232: “scientific estimates” should be changed to something like “modeling studies” or something similar.
Thank you. We have made this change.

Response to Reviewer 2 (Marc Goldstein)

1. The surgical techniques employed need to be described. Mention of new circumcision devices and rates of complication should be included in the discussion.
More detail on the techniques are provided below.

Major compulsory revisions:
1. Line 153: the IRB approval for this project was from Tulane University, however none of the authors is listed from this institution. Please explain. Technically, they cannot use this IRB without any authors or professional involvement from Tulane University. This is a serious issue.
We agree that although Tulane and the University of Witwatersrand approved the routine collection and monitoring of Asiphile data, none of the authors are currently affiliated with these institutions. The use of de-identified, aggregated, programmatic data has been provided with an exemption by the University of California, Los Angeles Institutional Review Board. Edits have been to the manuscript to reflect this change.

Essential Revisions:
1. Lines 123 - 138: more details are needed for their MC training
Updates to the manuscript have been made to reflect the answers below.
What kind of local anesthesia? Injectable bupivicaine
Describe surgical MC technique or techniques: Forceps-guided method (See WHO manual)
How was customer satisfaction assessed? Voluntary customer satisfaction surveys were not collected as a matter of course. Asiphile fell in line with Hospital complaints policies and suggestion boxes.
How was productivity measured? Number of circumcisions performed per week was the primary outcome measured.

2. Lines 179 - 180: please state the adverse effects seen as well as their treatment course.
Why did they have no long-term follow-up (> 7 days)? Please explain why. The South African Policy for medical male circumcision does not include follow-up beyond 7 days.
How did they conclude only 2% AE at Asiphile clinic? The number of reported adverse events divided by the number of circumcisions
How did they evaluate AE in this study? Explain with more details. Routine collection of adverse events at follow-up visit were recorded in the follow-up record.
Line 185: How did this MC training model work for their course? The OAC Model was endorsed by the University of KZN Medical Faculty for continuing medical education for medical doctors. It is based on medical education theory and practice adapted for training in mass VMMC. It includes medical simulation, using models adapted from urology training; presentations and videos; and hands on training at Asiphile. Additionally, there is a focused effort on teamwork efficiency and know-how transfer from Israeli experience to local needs. The international team was composed of surgeons who have conducted thousands of adult circumcisions and who provided on the spot training and mentoring. The gained experience in Asiphile supported model improvement for training cycles in other facilities and in other countries.

Minor Revisions:
1. Sentence starting at line 77 is long and a little confusion - consider revising and breaking into two sentences.
   Thank you. We have revised this sentence.

2. Sentence starting at line 96 is also long and a little confusing – consider revising and breaking into two sentences.
   Thank you. We have revised this sentence.