OBSTETRICS & GYNECOLOGY

NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Nov 15, 2018
To: "Olivia Chang" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1916

RE: Manuscript Number ONG-18-1916

Implementation of the Alliance for Innovation on Maternal Health Program in a Low-resource Setting

Dear Dr. Chang:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Dec 06, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors are to be congratulated for the monumental effort to not only train but evaluate the results of implementing a program to reduce PPH in Sub Saharan Africa.

The following comments are made:

1) With the exception of one author all authors are Americans. Was all the training and evaluation done by the American team?

2) It is not clear when was hysterectomy performed as a life saving maneuver. There were hysterectomies performed during the three evaluation periods. Was the reason for the high maternal mortality secondary to pph in the hospital, the absence of personnel to perform hysterectomies, and for this reason uterine tamponade made the difference?

3) If there was training for the use of the anti shock garments, why were there so few patients that had this intervention in the post training period? (lack of garments?)

4) In what way is the implementation of the AIM program different than the efforts by FLASOG and FIGO training in pph using uterine tamponade, compression sutures, anti shock garments and estimation of blood loss? Is the difference the evaluation of the program in a low resource setting?

5) The authors should discuss the possibility of sustainability of the initiative by local practitioners.

Reviewer #2: The authors present a manuscript in which they describe their experiences with implementation of the alliance for innovation on maternal health program in a low resource setting. The following items should be addressed:

1. It is not clear from the title of this manuscript that it represents a cohort study. Please re-word.

2. The title and precis also don't mention obstetric hemorrhage or safety culture, which were the primary focus of the remainder of the manuscript.

3. The authors are to be congratulated on the great success their program had in Malawi.

4. There was a striking increase in the rate of uterine rupture before and after your intervention (3.0% vs 18.6% vs 10.1%). Please discuss.

Reviewer #3: The authors should be commended for the introduction of an AIM quality improvement initiative focused on team training, communication, and a bundle around PPH. This is quite novel in this setting and I commend their efforts. The discussion around the respectful just culture scoring lowest in the different domains even after the AIM initiative was interesting and informative. The manuscript is well written and to the point.

I only have a few comments for consideration by the authors:

1) a. Can the authors confirm that the methodology for ascertaining maternal deaths, and causes of death, (as well as hemorrhage interventions) did not differ between the pre-intervention, education, and post-intervention time periods.

b. Were the individuals performing chart review blinded to the epoch (pre, education, post)? Or did this happen more closely to real time?

2) Corollary to question 1, How comprehensive is the ascertainment of maternal deaths in this area? While this might hard to miss, given the absence of computerized records, it is possible that when a maternal death occurs, the paper chart is placed elsewhere for review or audit. From experience, I have found this to be the case is similar settings making maternal mortality a challenge to track.

3) Can the authors present the overall maternal mortality rate during these three time periods as well as the rate specific for obstetrical hemorrhage? Given the focus (unblinded) on reducing mortality from hemorrhage, it is possible that classification (unintentionally) drifted to other causes.

4) Is team training fairly novel in Malawi or similar low resource settings? Are the authors aware of any similar initiatives in other low resource settings?

Reviewer #4: The authors conducted a prospective cohort study comparing obstetric outcomes and measures of the culture of safety before and after implementation of the AIM-Malawi program. The intervention included classroom didactics on obstetric hemorrhage, teamwork protocols, skills lab activities and simulation training. Key findings include that there was a significant increase in the use of B-lynch sutures in the management of uterine atony (P=0.014) and a decrease in maternal mortality from obstetric hemorrhage from 1.2% to 0.2% (P =0.02). Hospital culture of safety scores also improved in four out of five domains. Improving obstetric hemorrhage management in low-resource settings is of significant public health importance and the authors have conducted important work in designing a training intervention with the goal of improving outcomes from obstetric hemorrhage in a low-resource setting.

1. ABSTRACT: Well written.

2. INTRO
a. Third para: I would consider adding a sentence following the first sentence to give a little more information. How was the bundle modified?
b. Third para: I would also add a little more background on the patient safety curriculum.
c. Fourth para: One low resource hospital or two as mentioned in abstract (central hospital and district health center)?

3. METHODS
a. The intervention is described as a two-day course with three components: didactics, skills lab, and simulation training. I think it would be helpful to have more details on how it was modified from the AIM program in the US, what specifically was changed?
b. I am interested in the training background of the Malawian clinicians, how is their education and training structured? Typically, some of the above skills are gained in the US over 4 years of residency training. What was their baseline training in Malawi—4 years of residency? I think this could have important implications for tailored adaption in other low-resource settings. Also, are the attending OBGYNs in house? Or do residents do the deliveries? What year residents? What about the medical and clinical officers and nurse midwives? I am just curious who these skills were implemented by and if those are individuals who are permanently employed by the hospital or will be staying in the field of OBGYN? There is reference later on to "staff turnover rate."
c. Do you have any sense of the accuracy of reporting of the EBL at delivery, it appears this was included in didactics (day 1)—ie could estimations have shifted over time?
d. Can you clarify further "hysterectomies performed for infection"?
e. Did you perform a power calculation to determine if you had a high enough "n" in order to detect a pre-post difference?

4. RESULTS
a. Was the increase in "use of procedures" from 2 to 16 in the pre- and post- intervention periods significant? Or just B-lynch?
b. Did steering committee members complete the 16-month survey? Did departmental staff members complete the baseline survey?

5. DISCUSSION
a. No changes in obstetric hemorrhage/time, but could there have been changes in reporting of this after intervention? Similarly, what about changes in maternal mortality causation as a result of this ongoing study? Or reported indication for hysterectomy?
b. What is important about your study compared to those in Tanzania and Kenya (you do touch on the patient safety piece, but what specifically about the procedural piece)?
c. I don't know that these findings are generalizable to low resource settings in the US, I would remove that sentence.
d. I think you need to mention the low "n" and whether you think this study was powered to detect the differences examined.

6. FIGURES/TABLES
a. Table 3: Why are P values not calculated for the first row, composite "any procedural intervention"?
b. Table 4: Should have footnote stating that all P values are as compared to baseline.
c. S1: I would like to see a table where you have two columns comparing the MI AIM Hemorrhage Bundle elements as standard in the US and then the Malawi-MI AIM Hemorrhage Bundle components that were implemented. That would really clarify for me how the two programs were different and also help with reproducibility for other investigators who may be interested in pursuing partnerships like this one.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: Should include stats analysis of differences in patient characteristics during the 3 time periods. Should include in the column heading, the value of each "N" for each time period.

Table 2: Should include the value of "N" in the column headings.

Tables 2, 3: Should make clear in each Table that the post-intervention column is being compared to the pre-intervention group.

Although the overall file retrieval rates were good, there was an improvement from pre to post intervention of 76.6% to 91.2%. Should comment on this potential limitation to precise estimation of rates and risks from these data.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- Could you provide a bit of background about Baylor's long standing work in Malawi. I think that context is important so others who may want to consider implementing this would understand its not a one and done event that a group of High Income Country docs/nurses fly in, do the course and fly out.

- how long does transport from Area 25 to central hospital? Is the central hospital the Kamuzu hospital?

- are these garments readily available in Malawi? At regional and district birth centers as well?

- in which teams....

- How were the data obtained for this and procedural use?

- I would move this paragraph (lines 205-213) up toward line 186 as it relates directly to your primary outcome.

- You didn't provide any information about comparison between the two sites. Did some staff work at both institutions? Were there differences in outcomes in the 2 cites? Many of the interventions taught would likely not be possible at Area 25 hospital.

- were there staff that were not trained?

- please comment in the discussion section whether this apparent increase rate of chart availability was associated with the AIM program or something else. So key to have chart availability to assess for change--for others, they may wish to know how this happened.

- Could you cite the data for some of the most important positive changes, as well as for the non punitive response to error

- One of your reviewers, in confidential comments to the editor, noted that many organizations and people have done trainings in low and middle income countries to address maternal morbidity and mortality. While this is the first time, perhaps, that these efforts around PPH have been addressed with the AIM structure [and it may be that is way more effective than less structured efforts] its not the first time that similar work has been done.

- It may be a software issue, but this table and the next are not formatted properly.

2. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your signature on the journal's author agreement form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

6. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

7. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

8. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

9. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

10. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly. If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at http://www.acog.org/Resources-And-Publications.

11. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Dec 06, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

_____