Author's response to reviews

Title: Management of abortion complications at a rural hospital in Uganda: A quality assessment by criterion-based audit

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Author's response to reviews: see over
Dear Dr Vincent Boama
March 14, 2015
Associate Editor, BMC Women’s Health

We want to thank you and the reviewers for your careful review and comments. Each comment has been answered and the text has been corrected appropriately. The submitted document follows the prescription indicated in the link we received in the email from you. We now hope that our manuscript will be acceptable for publication.

Best regards
Natja Norup, Bjarke L. Sørensen, Gideon K. Kuriigamba and Martin Rudnicki.

Referee 1

Abstract

Quote: ‘Complications to abortion’ this is an odd phrase. Normally, you would use “complications of unsafe abortion”. The sort of complications reported in this paper does not occur with safe abortion procedures, or occur very very rarely.
Answer: We agree with the reviewer and have changed the phrase to ‘complications of unsafe abortion’.

Quote: It is odd that the most common complications, haemorrhage, infection/sepsis, uterine perforation, are not mentioned at all or only septic abortion 3.4%, which I would have expected to be more often.
Answer: In rural areas documentation is often insufficient. This was also the fact regarding documentation of bleeding amount and consequently, this parameter was impossible to include. But we agree with the reviewer that this is important and therefore we included the parameter ‘dehydration’ – hereby to raise the possibility that undocumented haemorrhage patients are included and audited by the dehydration management.
No cases had documented uterine perforation. One case had a traumatized cervix, which has been included. We also expected more septic abortions. But based on the poor documentation, we cannot conclude this.

Quote: These categories are not exactly complications: threatened abortion 27.7%, inevitable abortion 12.2%, missed abortion 4.2%, but can lead to complications.
Answer: It depends on how you see it, we did not only include unsafe abortions, but all women admitted with needs for abortion related management. And if it was a wanted pregnancy, we would call them complications.
We have changed the phrase to: ‘Abortion complications were distributed as follows: 53% incomplete abortions, 28% threatened abortions, 12% inevitable abortions, 4% missed abortions and 3% septic abortions.’

Quote: Treatment used would normally be mentioned for sepsis, bleeding, etc.
Answer: We agree that this is important information and have included: ‘The audit criteria cover initial clinical assessment of vital signs and management of common severe complications such as sepsis and haemorrhage. Sepsis shall be managed by immediate evacuation of the uterus and
antibiotics in relation to and after surgical management. Shock by aggressive rehydration followed by evacuation.’

**Quote:** There is also no mention of the type of unsafe abortion methods used by the women, which affects the treatment required a great deal. This is an issue again in the methods section.

**Answer:** we agree and have included: ‘In total 3% of the abortions were categorized as unsafe.’ The types of unsafe abortion methods are mentioned in “Results”.

**Quote:** The fact that half the cases were women in the second trimester of pregnancy is very high proportion, and this should be discussed.

**Answer:** We agree with the reviewer and the text has been extended accordingly: ‘Fifty six per cent of the women were in second trimester’

**Background**

**Quote:** line 59, there was a recent article by WHO staff in the WHO Bulletin arguing that the definition of unsafe abortion is changing, especially with the use by women of medical abortion pills outside clinical settings.

**Answer:** We agree that the WHO the definition may change, and the reference has been included.

**Quote:** line 67: “50% of Ugandan women will receive treatment for an induced abortion” - does this mean will have an abortion, or have treatment for an unsafe abortion?

**Answer:** We have changed the text to: ‘Up to 50% of Ugandan women will hereby receive treatment for complications of an induced abortion during their life.

**Methods**

**Quote:** the plural of midwives.

**Answer:** Corrected

**Quote:** Lines 119-23 need to be restated to be much clearer. What was not done in the five steps is not clear enough, nor why not.

**Answer:** We agree with the reviewer that this needs clarification and has changed the text accordingly: ‘Steps one to three of the classic five-step CBA cycle were performed. These steps consist of establishment of criteria for good quality care, data collection and analysis of the findings. We could not complete the audit cycle by implementation of changes (step four) and re-evaluation (step five) because of time constraints. Preliminary results were instead presented to the staff and recommendations on how to improve practice in the future were discussed in plenary.’

**Quote:** The hospital’s local standards for management turned out to be inaccurate, missing, incomplete and remarkably different from international standards (Table 1).” Even if this is outlined in the table, some details should be mentioned in the text here.

**Answer:** As suggested by the reviewer we have extended the text: ‘Thus, manual vacuum aspiration was only part of the hospital’s guideline regarding “unsafe abortion”, and the guideline did not mention the importance of immediate evacuation at signs of sepsis or excessive bleeding, but only that it should be considered after stabilization of the patient with IV fluids and antibiotics. Furthermore, oxytocin and ergometrine should not be used for medical abortion and finally fluid
resuscitation at a blood pressure < 100 mmHg should be managed with two litres of fast running fluids.’

**Quote:** abdominal pain is not just a marker of abortion, so it is odd that it was a main criteria. I wonder how many women were excluded for this when questions were asked. Signs of infection would seem to me to be a marker that should have been used, on the other hand, such as fever, discharge.

**Answer:** We agree with the reviewer that abdominal pain is not a marker of abortion. Consequently, we did not use this as a main criteria. Abdominal pain was a provisional diagnosis given in the OPD that was written in the admission book (which we used to find our possible cases). Some patients did not receive a vaginal examination at the OPD and were therefore admitted with the provisional diagnosis ‘abdominal pain’. After admission, the doctor did further examination and the diagnosis therefore sometimes changed from ‘abdominal pain’ to e.g. ‘incomplete abortion’ – but this is only visible in the journal file. Not to miss these cases, all files for women admitted at the maternity ward with abdominal pain were further investigated. If it turned out the abdominal pain was caused by something else, the file was excluded, but if it turned out to be an abortion, the case was included.

The text has been changed accordingly: ‘Potential eligible cases were identified by provisional diagnosis from the maternity ward’s admission-register, e.g. abortion, vaginal bleeding or abdominal pain. Based on the admission date from the register, we could identify the medical records anonymously from the archive and include or exclude due to the final diagnosis.’

**Quote:** This sentence is unclear: “Missing cases were sought using other variables documented in the admission registers such as name, age and region.

**Answer:** This has been clarified as suggested: ‘In case of missing medical files, these data were sought otherwise either by searching near-by dates in the archive or using other variables documented in the admission registers such as socio-demographic data to control the recordings’.

**Findings**

**Quote:** The reason for the missing cases being missing is unclear. The fact that far more women had sepsis than 3.4% is expected, and yet it seems they are not covered in the paper. It is my impression from this that there was a lot of difficulty with failure to record information. Whether or not this affects the findings remains to be seen. Moving on to vital signs not being recorded in all cases reinforces this concern.

**Answer:** We agree that it is important to clarify the reason for missing cases. However, missing cases is not surprising regarding the local circumstances and the reasons may be multiple. Although we searched for missing files it was not possible to state why the cases were missing. We have extended the paragraph in the ‘discussion’ accordingly: ‘However, this large number of women undergoing unsafe abortion was not supported by our study, and we observed a surprisingly low number of septic abortions. One explanation may be the more widespread use of misoprostol which has been described in several studies [2,5]. Although this may limit the number of unsafe abortions and consequently sepsis, it is impossible to assess whether an informal use of misoprostol exists in this geographic area. Thus this phenomenon needs to be explored more intensively. Another explanation to the low number of septic abortions could be the poor documentation and some septic patients may have been overlooked due to missing recording of vital data.’

**Quote:** the reasons for these delayed evacuations would be useful to know.
We agree with the reviewer, but since the design was retrospective in nature we can only assume the causes. We tried to make a prospective part of the study, but during the data-collecting period, only ten cases of abortion were admitted – none with sepsis. This sample size is too small to make any safe conclusions, and consequently we excluded this part of the study.

Findings, discussion and conclusions - repeat pretty much the same thing. Editing to avoid repetition would be valuable.
Answer: We agree with the reviewer that this section may be a repeat of previous observations. Accordingly we have strengthened the discussion in order to minimize this problem.

References
Quote: a lot of papers about other countries are referenced but the common threads could probably be better presented.
Answer: The two studies from Gabon have been included in the text as recommended.

Tables and figures
Quote: The most relevant details and information from the tables should be summarised in the text. Some tables are messy and hard to read. They need further work in order to be readable without difficulty. Table 4 is particularly difficult to make sense of. The figure breaking down the cases doesn’t add much; it is confusing and a breakdown of cases into better categories, if possible in relation to complications that are usually described, would be better.
The last figure would take up a large page as presented. It doesn’t add much; I would omit it.
Answer: The tables are redone. We changed table 4 to only include fulfilment of the criteria. The key findings from the previous table have been included in the text. We agree to omit figure 2.

Referee 2

Introduction
Quote: The introduction does not cover the scope of the study, it uses old references and fails to provide the reader with essential information to internalise the findings.
Answer: The text has thoroughly revised. Regarding the references presented these are still the most recent estimates. However, we agree with the reviewer that new references may be added in order to clarify the scope of the study and consequently, these have been.

Quote: There is very little written about misoprostol in the introduction. Ignoring misoprostol as an essential part of PAC is very problematic.
Answer: We agree with the referee and have extended the text concerning PAC and misoprostol. The focus of the CBA was on identifying and managing acute life-threatening complications to unsafe abortions, namely septic abortion and haemorrhage. In these emergencies misoprostol does not have a place in the management and so misoprostol has not had a central in this paper.

Quote: The aim is poorly stated and followed by a confusing explanation of the methods used. It is more a justification of the choice of method than an aim of a study.
Answer: We agree with the referee and have rewritten the aim: ‘The objective of this study was by a retrospective criterion-based audit to evaluate the clinical assessment for life-threatening complications and the following management in women admitted with complications from abortion at a rural hospital in Uganda.’

Quote: The methodology should be introduced in the introduction, not in the aim and not in the methods.
Answer: The manuscript has been revised accordingly.

Methods
Quote: Needs subheadings, it is incredibly poor structured and difficult to follow. Look at similar papers and try to structure accordingly to help the reader.
Answer: Subheadings have been added to the methods, and the section is strengthened in order to minimize this problem.

Quote: Was there any kind of power calculation of how much sample would be needed to present sound data?
Answer: Being a descriptive study, a power calculation was not performed, as we were not aiming to assess an effect of an intervention or compare groups. However we had expected to find a higher proportion of life-threatening complications.

Quote: Why were there time constraints? Was the study not planned?
Answer: The time for data collection was limited being part of a master thesis, so there was not time to do a follow up let’s say a year later.

Quote: The authors claim to have made CBA while in fact they have only completed half the method, this is mentioned but conclusions are drawn as if the whole CBA was conducted and hence the study is presented as if data was more sound than it actually is.
Answer: We think this already is clarified in the section ‘discussion’: ‘We did not complete the audit cycle and consequently the impact on improving care cannot be observed.’

Results
Quote: Needs structuring, do not present irrelevant data such as percentages for one or two women.
Answer: Adjustments were made accordingly.

Quote: Data is poor.
Answer: In rural areas it is well-known that data quality is most often of poor quality. It calls definitely for more careful recordings in the medical file, but this matter is difficult to change. However, this CBA will hopefully add more information to be used for quality improvement in the future.

Quote: If this data could be combined with qualitative interview of quality PAC it would be of greater interest. Currently, I am unsure of its contribution. It could potentially serve as a pilot study or a brief commentary on methodology of CBA in a low-resource setting.
Answer: The PI is not trained in doing qualitative interviews, and the approach was considered but abandoned.
Discussion

Quote: Mainly a long list of limitations which makes me wonder why you carried out the study in the first place.
Answer: Changes were made in the script accordingly.

Quote: The following discussion of results is not interesting nor scientifically relevant and poorly written.
Answer: The section is strengthened in order to minimize this.

Quote: Conclusion needs to be tightened.
Answer: We agree, and the conclusion has been rewritten accordingly: ‘Our study revealed that guidelines were not followed resulting in suboptimal care in all but one case audited. This was especially due to missing documentation of vital signs necessary to diagnose life-threatening complications, poor fluid resuscitation at signs of shock, and delayed evacuation of the uterus at septic abortion. It is important to clarify the reasons for this suboptimal care, delays and lack of registration and therefore we suggest that future CBAs have to be carried out prospectively with local ownership and with completion of the full audit cycle.’

Quote: The Abstract needs tightening, consider removing the decimals in the %’s. The conclusion contains results.
Answer: The abstract has been rewritten and the decimals removed. The conclusion has been changed to accordingly.

Quote: The first sentence in the introduction is strange: complications to abortion is the second most important cause - what is an important cause?
Answer: we agree with the referee, and the sentence is changed to: ‘Complications of abortion is the second highest cause of maternal death worldwide and may cause 13% of all pregnancy-related deaths.’

Quote: Also, there are more recent estimates available.
Answer: We think that the recent fact sheets from the Guttmacher Institute are based one the estimates from 2003 in Uganda and 2008 for the rest of the world. It is the same estimates as we use. However the references are included as well.
http://www.guttmacher.org/pubs/fb_IAW.html

Quote: The definition of unsafe abortions have been updated with a comment (WHO 2014), it may be interesting to consider.
Answer: We agree, and have made a comment about this in the introduction and included the reference.

Quote: Is reference 11 correct on line 71?
Answer: Yes, the reference was correct, but we have removed this section.

Quote: The inclusion criteria are referred to before they are explained in the results section (line 100)
Answer: We agree that this might be confusing, and we no longer refer to the inclusion criteria before they are explained.

Quote: Who carried out the vaginal examination (line 111).
Answer: The clinical officers and medical officers. The text is changed to: ‘In cases where ultrasound was not applied the gestation age was established by last normal menstrual period or uterine size estimated by clinical or medical officers.’