

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Severity and management of post-abortion complications among women in Zimbabwe, 2016: a cross-sectional study
<b>AUTHORS</b>	Madziyire, Mugove; Polis, Chelsea; Riley, Taylor; Sully, Elizabeth; Owolabi, Onikepe; Chipato, Tsungai

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Brooke A Levandowski University of Rochester Medical School SUNY Upstate Medical University USA
<b>REVIEW RETURNED</b>	15-Oct-2017

<b>GENERAL COMMENTS</b>	<p>This is a clearly a well-researched and well written use of the Prospective Morbidity Methodology used to describe the severity of complications due to unsafe abortion in Zimbabwe. This study will be clearly important to country level policy efforts, as well as contributing to the African regional and global literature on postabortion care. Improvements to the PMM are timely and helpful towards improving measurement of abortion outcomes. The maximum time delays in care seeking are striking, including the mean of 2 days, and it's helpful to see this type of data included, as it addresses access to care, especially for rural women.</p> <p><b>METHODS</b> The first data collection paragraph indicates that data was collected for 28 days but protocol indicates that this was only for primary care facilities. Suggest including this detail in main paper. Also, it's not clear in the manuscript or protocol why the proportions of each facility type were randomly chosen. 77% of private facilities? Why not 75% or 80%? There may not be room for this in main manuscript but it caught my eye as unexpected. Suggest adding a sentence to the methods and Table 1 to indicate that severity classification was mutually exclusive and women were classified into the most severe category. In the Analyses section, not clear the difference between facility level in first paragraph and facility type in second paragraph. What was the finite population correction that was applied?</p> <p><b>RESULTS</b> Were bivariate analyses conducted to determine if there was statistical significance of the urban/rural distribution of covariates? Depending on Zimbabwean geography, this could easily provide more information, and potentially more convincing evidence, to policy makers. Also, could be done for reasons for delay length by facility type (pg</p>
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	<p>8, line 42)          Are these means? Pg 8, lines 44, 46 (17 &amp; 1 hour) and line 51 income losses of \$41 and \$280?          Pg 10, line 20- is there an adjusted OR to add for the sentence about having children increasing odds of severe morbidity?          Table 4- suggest adding a footnote to indicate how modern contraceptive methods was defined  <b>DISCUSSION</b>          Last sentence of 1st paragraph is uncited. There's a lot of literature on how education levels have been linked to HIV prevention in South Africa, Malawi, and Tanzania, which may be helpful support to this conclusion.          Line 22: am interested to know if free PAC in public facilities is a regional or national law or policy.          Line 42-43, suggesting misoprostol and MVA provision in primary care facilities is confusing since 100% of primary care facilities had misoprostol. Did you just mean MVA? Or are you targeting a larger concept with including misoprostol here?</p>
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<b>REVIEWER</b>	Nasratullah Asnari Jhpiego-Afghanistan
<b>REVIEW RETURNED</b>	23-Oct-2017

<b>GENERAL COMMENTS</b>	<p>General comments: The manuscript is well written and fluent with clear description of the importance of the study, well defined study objectives and outcomes and good justification of the result. Overall, the manuscript describes the severity and factors associated with abortion complications and provision of services by health care providers in Zimbabwean health facilities and provided important recommendations for improving the PAC current situation at the health facilities in the country. This is a good quality manuscript. Well done to the authors!</p> <p>Below are the specific comments and questions:          Abstract: line 8: To make it more clear, it would be better to remove "induced and spontaneous" because the study team could not distinguish between induce and spontaneous which was considered a limitation of the study.</p> <p>Line 11: better to remove 28 days.          Methods: Page 6, line 53: It is mentioned that "We avoided use of standalone clinical signs (e.g., fever and Tachycardia) which may lead to overestimation of severity". It would be much better to explain what you replaced the standalone clinical signs. Did you replace them with the diverse clinical signs?</p> <p>Table 1: The sepsis and its criteria are not aligned with the WHO recent definition. Attached is the WHO statement on Material sepsis, 2017 for your reference. The sepsis criteria needs to be adjusted accordingly.</p> <p>Results: Table 2 and 4: It will be interesting to see if the difference between health facility types were significant or not.          Discussion: Page 14 line 55: In the discussion, the role of midwives in managing PAC needs to be highlighted in all levels particularly in primary health care, not only nurses.</p> <p>Page 15, line 4: Besides in-service training as a class-based approach, coaching and mentorship are necessary for performance improvement of health providers. This needs to be highlighted in the</p>
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	<p>discussion section. Please see a reference that might be useful to cite:          Bluestone J, Johnson P, Fullerton J, Carr C, Alderman J, BonTempo J: Effective in-service training design and delivery: evidence from an integrative literature review. Hum Resour Health. 2013, 11: 51-10.1186/1478-4491-11-51.</p>
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**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1

Reviewer Name: Brooke A Levandowski

Institution and Country: University of Rochester Medical School, SUNY Upstate Medical University, USA

Please state any competing interests: None declared

Please leave your comments for the authors below

This is a clearly a well-researched and well written use of the Prospective Morbidity Methodology used to describe the severity of complications due to unsafe abortion in Zimbabwe. This study will be clearly important to country level policy efforts, as well as contributing to the African regional and global literature on postabortion care. Improvements to the PMM are timely and helpful towards improving measurement of abortion outcomes. The maximum time delays in care seeking are striking, including the mean of 2 days, and it's helpful to see this type of data included, as it addresses access to care, especially for rural women.

Response: We are excited that Dr. Levandowski feels that this manuscript will make a meaningful contribution to the scientific literature and to policy efforts. We appreciate the time she invested in reviewing our paper. We have attempted to address each of her points below, which have helped us to improve the manuscript.

**METHODS**

The first data collection paragraph indicates that data was collected for 28 days but protocol indicates that this was only for primary care facilities. Suggest including this detail in main paper.

Response: We had initially expected a much higher caseload in central and provincial hospitals hence the original allocation of 2 weeks. During the course of fieldwork, we decided to extend this to 4 weeks due to the unexpectedly low case loads. Thank you for noting this discrepancy; we have amended our protocol to acknowledge this. (See protocol page 3: "(Note: The study period was originally planned to be two weeks in central and provincial hospitals due to their expected large caseloads, and four weeks in all other facilities. However, there were lower than expected caseloads in these facilities once fieldwork began, so the study period was extended to 28 days for all facilities.)")

Comment: Also, it's not clear in the manuscript or protocol why the proportions of each facility type were randomly chosen. 77% of private facilities? Why not 75% or 80%? There may not be room for this in main manuscript but it caught my eye as unexpected.

Response: Our sample was stratified by province and facility type so the total sampling proportion does not add up to a round proportion nationally. We sampled 100% of the central hospitals, provincial hospitals and not-for-profit NGO facilities, and 50% of district hospitals.

For primary health centers we sampled 50% in Matabeleland South and Matabeleland North. In Manicaland there were more primary health centers with post-abortion care capacity (N=43), so only 20% of primary health centers were sampled in this province. There were two levels of private facilities (lower and higher levels), so we sampled 100% of high-level private facilities (operating with a similar capacity to provincial hospitals) and 50% of lower-level private facilities and for-profit NGO facilities (operating at a level similar to district hospitals). Due to the different sampling strategies for the two levels of private facilities within each province, the aggregate national proportion results in 77%. The categories we presented the facility level in are not the same as the facility levels we sampled because we had to collapse some facilities together to ensure that no individual facility could be identified.

We have included a note at the bottom of the supplemental Table 1 to provide sufficient detail on our sampling strategy, and included in the main text on page 5 that sampling was stratified by province and facility type.

Comment: Suggest adding a sentence to the methods and Table 1 to indicate that severity classification was mutually exclusive and women were classified into the most severe category.

Response: We have clarified this in the text as suggested, on pages 5 and 6.

Comment: In the Analyses section, not clear the difference between facility level in first paragraph and facility type in second paragraph.

Response: Thank you for raising the attention to lack of consistency. We have changed all the relevant text to facility level to stay consistent.

Comment: What was the finite population correction that was applied?

Response: We applied a Finite Population Correction (FPC) which is an option in the svyset command for Stata 14.2. An FPC was used to account for the reduction in variance that occurs when sampling without replacement from a finite population. This option is applicable in complex sample designs where primary sampling units are sampled in either a high proportion, or with certainty. In our sample, we had some provinces where we sampled a large proportion of facility types (for example, 100% of Central and Provincial hospitals). We also had some provinces with only one facility of a certain type, leading to that facility being sampled with certainty. By using the FPC adjustment in Stata, we were able to ensure our variance accounted for this particular aspect of our sample design. We constructed a variable to indicate the total number of primary sampling units within each strata (by province and facility type), and then included the FPC option specifying this variable when we svyset the data in Stata version 14.2.

We did not include any changes to our description of how we accounted for the complex sample design in the paper. We interpreted the reviewer's comment as asking for a further explanation, rather than requesting a change in the paper itself.

## RESULTS

Were bivariate analyses conducted to determine if there was statistical significance of the urban/rural distribution of covariates? Depending on Zimbabwean geography, this could easily provide more information, and potentially more convincing evidence, to policy makers. Also, could be done for reasons for delay length by facility type (pg 8, line 42)

Response: We have added p-values for delay length by facility type to Table 2, and to Supplemental Table 2 for the urban/rural comparisons.

Are these means? Pg 8, lines 44, 46 (17 & 1 hour) and line 51 income losses of \$41 and \$280? The hours are median; we have clarified this in the text. The \$41 and \$280 are averages; we have also clarified this in the text.

Pg 10, line 20- is there an adjusted OR to add for the sentence about having children increasing odds of severe morbidity?

Response: Thank you for noting this; we have added the following text on page 11 "Having children increased the odds of experiencing increasingly severe morbidity by 68% (1-2 children adjOR: 1.68, 95% CI: 1.33-2.13; 3+ children adjOR: 1.68, 95% CI: 1.13-2.49)."

Table 4- suggest adding a footnote to indicate how modern contraceptive methods was defined The provider was asked "Was the client given modern contraception?". Response options included

Response: Yes, No, or don't know. "Modern contraception" was not explicitly defined within that question. Thus, the reviewer has helped us to identify a potential limitation of this question, and we have added a footnote to Table 4 to address this. We have also added a phrase to the abstract and text to clarify that providers reported that 43% of women received modern contraception, to make it more explicit that this is based on their perceptions.

## DISCUSSION

Last sentence of 1st paragraph is uncited. There's a lot of literature on how education levels have been linked to HIV prevention in South Africa, Malawi, and Tanzania, which may be helpful support to this conclusion.

Response: Thank you for this comment. We have cited a study done in Kenya by Esther Duflo which showed that education subsidies reduced adolescent girls' school dropout, pregnancy, and marriage rates (page 14 citation 35).

Line 22: am interested to know if free PAC in public facilities is a regional or national law or policy. Free PAC is a Ministry of Health national policy for public facilities though it is not enforced rigorously.

Response: We have added some language on page 14 to indicate that this was a Ministry of Health and Child Care national policy.

Line 42-43, suggesting misoprostol and MVA provision in primary care facilities is confusing since 100% of primary care facilities had misoprostol. Did you just mean MVA? Or are you targeting a larger concept with including misoprostol here?

Response: Table 4 indicates that 100% of PAC patients treated in primary health centers in the PMS received misoprostol, but this does not indicate that 100% of primary health centers in Zimbabwe offer misoprostol. There were 63 primary care facilities (supplementary table 1) who had been previously trained as pilot sites for using misoprostol and we sampled 18 of them for the PMS.

Out of those 63 misoprostol-trained facilities that were in the Health Facility Survey sample, not all reported offering misoprostol in the HFS and none of the facilities offered MVA. There are 800+ primary health centers in Zimbabwe that were not part of the misoprostol pilot training, and therefore don't have the capacity to provide PAC. We therefore believe that if misoprostol is rolled out to all of the other primary health centers, it could result in more women getting treated with misoprostol at lower level facilities and not have to be referred to higher level facilities that already have higher caseloads and overcrowding. This includes the primary health centers not included in our study due to

the lack of PAC capacity, as well as the primary health centers in our study that were trained in using misoprostol, but were not offering it due to stock-outs.

Reviewer: 2

Reviewer Name: Nasratullah Asnari

Institution and Country: Jhpiego-Afghanistan

Please state any competing interests: None declared.

Please leave your comments for the authors below

General comments: The manuscript is well written and fluent with clear description of the importance of the study, well defined study objectives and outcomes and good justification of the result. Overall, the manuscript describes the severity and factors associated with abortion complications and provision of services by health care providers in Zimbabwean health facilities and provided important recommendations for improving the PAC current situation at the health facilities in the country. This is a good quality manuscript. Well done to the authors!

Response: We are grateful for these supportive comments from Dr. Asnari, and for the time spent in reviewing our paper. We are happy to hear that the manuscript reads clearly and we appreciate the suggestions below, which we found useful and have tried to address in full.

Below are the specific comments and questions:

Abstract: line 8: To make it more clear, it would be better to remove “induced and spontaneous” because the study team could not distinguish between induce and spontaneous which was considered a limitation of the study.

Response: We feel that it is important that readers be aware that our results pertain to both induced and spontaneous abortions, so we do hope to maintain this information in the abstract. That said, we understand the reviewers concern and have modified the text to read; ‘factors associated with abortion complications (induced or spontaneous)...’ which we feel is clearer.

Line 11: better to remove 28 days.

Response: We would prefer to retain this information, as our feeling is that noting the number of days of data collection provides a sense of the representativeness of the study.

Methods: Page 6, line 53: It is mentioned that “We avoided use of standalone clinical signs (e.g., fever and Tachycardia) which may lead to overestimation of severity”. It would be much better to explain what you replaced the standalone clinical signs. Did you replace them with the diverse clinical signs?

Response: We replaced standalone clinical signs (which may be caused by other conditions) in the severe category with more objective diagnostic categories relevant to severe complications of abortions.

For example, fever alone was not used to classify a woman in the severe category (Table 1) as has been done in other PMS studies because we realized that there are other causes of fever in tropical countries e.g. malaria, typhoid, influenza etc which might distort the results. We instead used diagnoses or a constellation of signs indicative of severe infection. Similarly, tachycardia (which on its own can be caused by anxiety, malaria and other febrile illnesses, or white coat hypertension) was incorporated under shock where it has to be accompanied by a systolic blood pressure  $\leq 90$  (Table 1).

Table 1: The sepsis and its criteria are not aligned with the WHO recent definition. Attached is the WHO statement on Maternal sepsis, 2017 for your reference. The sepsis criteria needs to be adjusted accordingly.

Response: The new WHO definition of: ‘Maternal sepsis is a life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion, or postpartum period’ aligns with sepsis as defined in our near miss category which we collapsed with the severe category during regression analysis. Our criterion includes both septic shock (which we define as persistent systolic blood pressure  $\leq 80$  mmHg alone OR a persistent systolic blood pressure  $\leq 90$  mmHg with a pulse rate at least 120 bpm, and restlessness, reduced consciousness, cold clammy peripheries, requiring administration of IV fluids due to the presence of an infection) and organ/system failure in Table 1. We believe both of these capture infection and organ dysfunction component of maternal sepsis as described in the new WHO definition. We however note that this WHO 2017 definition was released when we had finished data collection, and it also only provides a conceptual definition but no specific practical parameters to operationalize measurement. The on going WHO global maternal sepsis study (GLOSS) seeks to develop and validate a set of criteria for identification of maternal sepsis amongst some of its main objectives. We look forward to its operationalization and will update our morbidity criteria as needed for future studies when it is released.

Results: Table 2 and 4: It will be interesting to see if the difference between health facility types were significant or not.

Response: We have added p- values to Tables 2 and 4 (and in response to a comment from Reviewer #1, also to Supplemental Table 2).

Discussion: Page 14 line 55: In the discussion, the role of midwives in managing PAC needs to be highlighted in all levels particularly in primary health care, not only nurses.

Response: Thank you for highlighting this important omission. We have now added ‘midwives or nurses’ to the text (page 14).

Page 15, line 4: Besides in-service training as a class-based approach, coaching and mentorship are necessary for performance improvement of health providers. This needs to be highlighted in the discussion section. Please see a reference that might be useful to cite:

Bluestone J, Johnson P, Fullerton J, Carr C, Alderman J, BonTempo J: Effective in-service training design and delivery: evidence from an integrative literature review. Hum Resour Health. 2013, 11: 51-10.1186/1478-4491-11-51.

Response: Thank you very for this useful addition to our recommendations; we have added this citation to accompany a sentence on this issue in the Discussion section (page 15).

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Brooke A Levandowski University of Rochester Medical School, SUNY Upstate Medical University, USA
<b>REVIEW RETURNED</b>	19-Dec-2017
<b>GENERAL COMMENTS</b>	The manuscript will greatly contribute to the literature. Thank you for your changes.
<b>REVIEWER</b>	Nasratullah Ansari

	Jhpiego-Afghanistan
<b>REVIEW RETURNED</b>	15-Dec-2017

<b>GENERAL COMMENTS</b>	The authors have addressed my comments and suggestions on the manuscript. Their responses are acceptable for me.
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