

Potentially harmful medication use and the associated factors among pregnant women visiting antenatal care clinics in Mbarara regional referral hospital, southwestern Uganda

John Isiiko*, Joshua Kiptoo, Tadele Mekuriya Yadesa, Daniel Chans, Rachel Alinaiswe,
Joseph Ngongi, Paul E. Alele

*Corresponding author

John Isiiko

Department of Pharmacy, Mbarara University of Science and Technology, Mbarara, Uganda
Department of Pharmacy, Uganda Cancer Institute, Mbarara, Uganda.

Handling editor:

Michal Heger

Department of Pharmaceutics, Utrecht University, the Netherlands

Department of Chemistry, Utrecht University, Utrecht, the Netherlands

Department of Pathology, Erasmus Medical Center, the Netherlands

Department of Pharmaceutics, Jiaxing University Medical College, Zhejiang, China

Review timeline:

Received: 23 June, 2022

Editorial decision: 4 November, 2022

Revision received: 26 November, 2022

Editorial decision: 28 November, 2022

Revision received: 28 November, 2022

Editorial decision: 28 November, 2022

Revision received: 29 November, 2022

Editorial decision: 29 November, 2022

Published online: 28 December, 2022

1st Editorial decision

04-Nov-2022

Ref.: Ms. No. JCTRes-D-22-00081

Potentially Harmful Medication Use and The Associated factors Among Pregnant Women
Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern
Uganda

Journal of Clinical and Translational Research

Dear Dr Isiiko,

Reviewers have now commented on your paper. You will see that they are advising that you
revise your manuscript. If you are prepared to undertake the work required, I would be
pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below and attached to this email.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript. Also, please ensure that the track changes function is switched on when implementing the revisions. This enables the reviewers to rapidly verify all changes made.

Your revision is due by Dec 04, 2022.

To submit a revision, go to <https://www.editorialmanager.com/jctres/> and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #2: 1. There are some grammatical and typographical errors through out the document; thus, the document needs revision.

Abstract

1. The methodology section of the abstract should contain the sample size, sampling technique used, the study period, and statistical analysis method employed.

Introduction

1. Should show the reader prevalence of potentially harmful medication use during pregnancy from previous studies.
2. Most of the references used are very outdated; replace them with recent articles
3. Cross referencing is also there (pregnancy risk category of drugs)- use the original article

Method

1. A final sample size of 209 can be obtained when 'p' and 'q' are taken as 0.162 and 0.838 NOT 0.17 and 0.83; thus, make corrections accordingly.
2. There are unfinished statements (line 4 and 30 of the methodology section)
3. You should briefly explain the study setting
4. What type of questionnaire was used? structured, semi-structured or unstructured questionnaire? and how did you develop it? how did you assure its validity and reliability? Did you carry out pretest?
5. Statistical method used for identifying associated factors is not clearly stated, neither the Cut-off points?
6. What did you use to sketch the graphs?
7. The term prospective should not be used with cross-sectional study design. prospective or retrospective study are used in cohort studies. thus, I recommend to omit this term.

Result

1. What was your source for classification of drugs under the different pregnancy risk category?
2. "potentially harmful medication" must be operationalized (when did you categorize a drug

as a potentially harmful drug?

3. There is a heading named "factors affecting herbal medicine use". Did you mean factors associated with use of potentially harmful medication?

4. Some results are not clear and lacks consistency (e.g.1-The number of pregnant mothers who used warfarin were 2 (table 2), but in the discussion section it is mentioned as 3 . e.g.2-age is mentioned as one factor that affects use of potentially harmful medication during pregnancy (line 6 of page 12), but table 5 indicates it is herbal medicine use not age that has significant associated with the outcome variable.

5. Figures are not written in their sequence (figure 2 is mentioned after figure 4 (renumber them)

6. Under patterns of prescribed drug use, line number 7 needs to be cited.

7. In some places the frequency of drug use is considered as number of medications used by pregnant mothers.(e.g-23 different types of known herbs were used by pregnant mothers not 200).

8. According to your result, the number of pregnant women taking more than 7 medications were 113 (54%) which is less probable; besides, the number of pregnant mothers with chronic disease were only 29 (13.8%). How do you explain these discrepancy?

Discussion

1. It is well written but there are some new results discussed in the discussion section not mentioned in the result section. (e.g. line 55 of the discussion section)

Conclusion

1. The conclusion written is just a summary of the main findings. a conclusion should answer "What can be said based on your major findings?" and provide possible solutions for it.

Limitation of the study should be added.

reference number for the ethical issue obtained should be mentioned.

Reviewer #3: General comments

The manuscript is well written and sectioned well making it easy to read. However, it can be improved through editing and properly numbering the pages.

I would also suggest that the figures are reduced to 2 or 3; they seem many, in addition to the many tables.

Introduction

Page 1: it is unclear to me why the authors undertook this study; was it student research, an objective of a project running? Etc?

Related to the above, may you explain the period for which the study was conducted: why was it that short?

Line 4: complete the sentence; the study was conducted...

Methods

Line 31: complete sentence; multivariate logistic regression was used to determine...

Results

Participant characteristics

Page 4; why did you use 24 years as cut off, was it the median age?

-What is the definition of married in this study?

-Monthly income: how did you arrive at using 250,000/=; the average Ugandan doesn't earn this much so why use this cut off?

Page 6: Patterns of prescribed drugs; I would simply call it "drugs used" because I don't see any patterns described.

Page 10:

-Figure 2 missing?

-the text is enough without figure 3 which is rather confusing (I suggest that figure 3 is left out)

Page 12: Factors associated with herbal medicine used; is this what you intended to name this section?

Figure 2? Is missing.

Conclusion

The authors simply paraphrased the results; may they write out a more meaningful conclusion to the study.

There is additional documentation related to this decision letter. To access the file(s), please click the link below. You may also login to the system and click the 'View Attachments' link in the Action column.

Authors' response

The Chief Editor

Journal of Clinical and Translational Research

RE: Response to Reviewers' comments

Title: *Potentially Harmful Medication Use and The Associated factors Among Pregnant Women Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern Uganda.*

Reviewer 3

General comments

The manuscript is well written and sectioned well making it easy to read. However, it can be improved through editing and properly numbering the pages.

The manuscript has been edited and the page numbers have been updated accordingly.

I would also suggest that the figures are reduced to 2 or 3; they seem many, addition to the many tables.

The total number of figures have been reduced to 3 (Fig 2 and 3 have been removed).

Introduction

Page 1: it is unclear to me why the authors undertook this study; was it student research, an objective of a project running? Etc?

This was a study comprising of both senior and junior researchers of different disciplines to address the gap of data on the use of potentially harmful medicines among pregnant women at MRRH.

Related to the above, may you explain the period for which the study was conducted: why was it that short?

During the five weeks study period, we encountered a total of 1,250 pregnant women at the ANC clinic. We used a simple rotary method (papers numbered and rolled), to select 1 out of every 6 encounters until we achieved the target sample size.

Line 4: complete the sentence; the study was conducted...

This has been corrected by removing the hanging statement

Methods

Line 31: complete sentence; multivariate logistic regression was used to determine...

The statement has been completed accordingly

Results

Participant characteristics

Page 4; why did you use 24 years as cut off, was it the median age?

We used 24 years as cut off based on the WHO age bracket of 18 – 24 years for youth.

-What is the definition of married in this study?

The operational definition of “married” in our study was a mother living with her spouse during the study period.

-Monthly income: how did you arrive at using 250,000/=; the average Ugandan doesn't earn this much so why use this cut off?

We based on the World Bank's report of Uganda's Per capita income for the year 2021.

Page 6: Patterns of prescribed drugs; I would simply call it “drugs used” because I don't see any patterns described.

This correction has been made in the manuscript as guided.

Page 10:

-Figure 2 missing?

Figure 2 has been removed

-the text is enough without figure 3 which is rather confusing (I suggest that figure 3 is left out)

Figure 3 has been removed as suggested

Page 12: Factors associated with herbal medicine used; is this what you intended to name this section?

This has been corrected accordingly.

Conclusion

The authors simply paraphrased the results; may they write out a more meaningful conclusion to the study.

The conclusion has been revised accordingly.

Reviewer #2:

1. There are some grammatical and typographical errors throughout the document; thus, the document needs revision.

Grammatical and typographical errors have been corrected throughout the document.

Abstract

1. The methodology section of the abstract should contain the sample size, sampling technique used, the study period, and statistical analysis method employed.

The abstract has been updated as guided.

Introduction

1. Should show the reader prevalence of potentially harmful medication use during pregnancy from previous studies.

We have added prevalence of potentially harmful (category C, D, X) medications from previous studies in the region but none was recovered from Uganda.

2. Most of the references used are very outdated; replace them with recent articles

We have replaces the outdated references with the most recent ones.

3. Cross referencing is also there (pregnancy risk category of drugs)-
use the original article.

This has been updated accordingly

Method

1. A final sample size of 209 can be obtained when 'p' and 'q' are taken as 0.162 and 0.838 NOT 0.17 and 0.83; thus, make corrections accordingly.

Correction has been added. Previously we made inaccurate rounding off to two decimals.

2. There are unfinished statements (line 4 and 30 of the methodology section)

We removed the incomplete statement in line 4 and completed the statement in line 30.

3. You should briefly explain the study setting

The study setting has been explained in details.

4. What type of questionnaire was used? structured, semi-structured or unstructured questionnaire? and how did you develop it? how did you assure its validity and reliability? Did you carry out pretest?

We used structured questionnaire as now added in the 'Data collection and study variables' section. We developed the questionnaire based on the FDA pregnancy risk classification tool and we pretested the questionnaire among ten pregnant women in Mbarara Regional Referral Hospital, ANC clinic.

5. Statistical method used for identifying associated factors is not clearly stated, neither the Cut-off points?

We have now added details on the analysis to determine the associated factors.

6. What did you use to sketch the graphs?

We used MS WORD document (insert charts) to sketch the graphs.

7. The term prospective should not be used with cross-sectional study design. prospective or retrospective study are used in cohort studies. thus, I recommend to omit this term.

Correction has been made as suggested.

Result

1. What was your source for classification of drugs under the different pregnancy risk category?

We used the United States FDA pregnancy Risk classification to determine the risk categories of all drugs. We have now cited the US FDA webpage that we used in our 'Introduction' section.

2. "Potentially harmful medication" must be operationalized (when did you categorize a drug as a potentially harmful drug?)

We have now operationalized 'Potentially harmful medication' in pregnancy as those falling in categories C, D or X. This has been added to the manuscript under 'Data management and analysis' section.

3. There is a heading named "factors affecting herbal medicine use". Did you mean factors associated with use of potentially harmful medication?

Yes, it was meant to say factors associated with use of potentially harmful medication. Corrections have been made.

4. Some results are not clear and lacks consistency (e.g.1-The number of pregnant mothers who used warfarin were 2 (table 2), but in the discussion section it is mentioned as 3. e.g.2-age is mentioned as one factor that affects use of potentially harmful medication during pregnancy (line 6 of page 12), but table 5 indicates it is herbal medicine use not age that has significant associated with the outcome variable.

Age was mentioned as one of the factors at the Univariate analysis level.

However, it was not significant in the multivariate regression model.

5. Figures are not written in their sequence (figure 2 is mentioned after figure 4 (renumber them).

The sequence of figures has been updated accordingly

6. Under patterns of prescribed drug use, line number 7 needs to be cited.

The citation has been added accordingly.

7. In some places the frequency of drug use is considered as number of medications used by pregnant mothers.(e.g-23 different types of known herbs were used by pregnant mothers not 200).

This correction has been done accordingly

8. According to your result, the number of pregnant women taking more than 7 medications were 113 (54%) which is less probable; besides, the number of pregnant mothers with chronic disease were only 29 (13.8%). How do you explain these discrepancy?

Majority of the participants who had over 7 drugs received antimicrobials and anti-anemic medications (most frequently prescribed) as shown in the table 3 with indication of prophylaxis of infection and nutritional supplementation (table 2). This is the underlying explanation despite the small number of participants with chronic diseases.

Discussion

1. It is well written but there are some new results discussed in the discussion section not mentioned in the result section. (e.g. line 55 of the discussion section).

This correction has been done in the manuscript.

Conclusion

1. The conclusion written is just a summary of the main findings. a conclusion should answer "What can be said based on your major findings?" and provide possible solutions for it.

The conclusion has been revised accordingly.

2. Limitation of the study should be added.

The study design was cross-sectional which did not allow for follow-up of participants.

3. Reference number for the ethical issue obtained should be mentioned.

The Ethical Approval reference number (MUST-2022-375) has been added to the manuscript.

Thank you

Sincerely,

Authors.

2nd Editorial decision
28-Nov-2022

Ref.: Ms. No. JCTRes-D-22-00081R1

Potentially Harmful Medication Use and The Associated factors Among Pregnant Women Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern Uganda
Journal of Clinical and Translational Research

Dear author(s),

Reviewers have submitted their critical appraisal of your paper. The reviewers' comments are appended below. Based on their comments and evaluation by the editorial board, your work was FOUND SUITABLE FOR PUBLICATION AFTER MINOR REVISION.

If you decide to revise the work, please itemize the reviewers' comments and provide a point-by-point response to every comment. An exemplary rebuttal letter can be found on at <http://www.jctres.com/en/author-guidelines/> under "Manuscript preparation." Also, please use the track changes function in the original document so that the reviewers can easily verify your responses.

Your revision is due by Dec 28, 2022.

To submit a revision, go to <https://www.editorialmanager.com/jctres/> and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Dear authors, thank you for submitting a revised version of your manuscript.

I have gone through it and have deemed the level of changes sufficient to warrant publication. However, before we finalize the manuscript I would like to request that you proofread the manuscript, as it contains too many fragmented sentences and grammar/spelling errors and inconsistencies. It is a hard criterion for publication, as stipulated in our author guidelines.

Thank you and good luck,

Michal Heger
Editor

Authors' response

The Chief Editor

Journal of Clinical and Translational Research

RE: Response to Reviewers' comments

Title: *Potentially Harmful Medication Use and The Associated factors Among Pregnant Women Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern Uganda.*

Reviewer's comments

I have gone through it and have deemed the level of changes sufficient to warrant publication. However, before we finalize the manuscript I would like to request that you proofread the manuscript, as it contains too many fragmented sentences and grammar/spelling errors and inconsistencies. It is a hard criterion for publication, as stipulated in our author guidelines.

We have proofread the manuscript and corrected all the fragmented sentences as well as the grammar and spelling errors throughout the document.

Thank you

Sincerely,

Authors.

3rd Editorial decision

28-Nov-2022

Ref.: Ms. No. JCTRes-D-22-00081R2

Potentially Harmful Medication Use and The Associated factors Among Pregnant Women Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern Uganda

Journal of Clinical and Translational Research

Dear author(s),

Reviewers have submitted their critical appraisal of your paper. The reviewers' comments are appended below. Based on their comments and evaluation by the editorial board, your work was FOUND SUITABLE FOR PUBLICATION AFTER MINOR REVISION.

If you decide to revise the work, please itemize the reviewers' comments and provide a point-by-point response to every comment. An exemplary rebuttal letter can be found on at <http://www.jctres.com/en/author-guidelines/> under "Manuscript preparation." Also, please use the track changes function in the original document so that the reviewers can easily verify your responses.

Your revision is due by Dec 28, 2022.

To submit a revision, go to <https://www.editorialmanager.com/jctres/> and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger

Editor-in-Chief

Journal of Clinical and Translational Research

Reviewers' comments:

Dear Dr. Isiiko,

"A cross-sectional study was conducted from April 1st to June 6th, 2021. Involving 26 pregnant women on follow-up at a referral hospital in southwestern Uganda."

The latter is not a correct English sentence.

This gives me no confidence your team has done a sufficient job following my specific request to polish the language.

Please take my request seriously or else we'll be circling back and forth on this matter.

Thanks,

Michal Heger
Editor

Authors' response

The Chief Editor

Journal of Clinical and Translational Research

RE: Response to Reviewers' comments

Title: *Potentially Harmful Medication Use and The Associated factors Among Pregnant Women Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern Uganda.*

Reviewer's comments

I have gone through it and have deemed the level of changes sufficient to warrant publication. However, before we finalize the manuscript I would like to request that you proofread the manuscript, as it contains too many fragmented sentences and grammar/spelling errors and inconsistencies. It is a hard criterion for publication, as stipulated in our author guidelines.

We have proofread the manuscript and corrected all the fragmented sentences as well as the grammar and spelling errors throughout the document accordingly.

Thank you

Sincerely,

Authors.

4th Editorial decision
29-Nov-2022

Ref.: Ms. No. JCTRes-D-22-00081R3
Potentially Harmful Medication Use and The Associated factors Among Pregnant Women Visiting Antenatal Care Clinics in Mbarara Regional and Referral Hospital, Southwestern Uganda
Journal of Clinical and Translational Research

Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Please notify our assistant editor/production editor when you receive the proofs if your article should belong to a special issue specifying the issue's title.

Thank you for submitting your work to JCTR.

Kindest regards,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: