Author’s response to reviews

Title: Effect of a Postpartum Family Planning Intervention on Postpartum Intrauterine Device Counseling and Choice: Evidence from a Cluster-Randomized Trial in Tanzania

Authors:
Erin Pearson (pearsone@ipas.org)
Leigh Senderowicz (lsendero@mail.harvard.edu)
Elina Pradhan (epradhan@worldbank.org)
Joel Francis (joelmfrancis@gmail.com)
Projestine Muganyizi (promuga@yahoo.com)
Iqbal Shah (ishah@hsph.harvard.edu)
David Canning (dcanning@hsph.harvard.edu)
Mahesh Karra (mvkarra@bu.edu)
Nzovu Ulenga (nulenga@mdh-tz.org)
Till Bärnighausen (till.baernighausen@uni-heidelberg.de)

Version: 1 Date: 25 Feb 2020

Author’s response to reviews:

Author Responses to Reviewer Comments: BMWH-D-19-00770

Authors: We thank the reviewers for their helpful comments and have provided a point-by-point response below.

Reviewer 1

This is a well-written manuscript describing an important intervention and evaluation. My main question for the authors relates to the description of the primary analysis as a difference in difference analysis when it appears that it is simply a comparison of pre vs post intervention or control vs. intervention. The paper could also be strengthened with a bit more context about the intervention in the introduction.

Authors: Thank you for these comments. We have included a detailed response to these questions below.

Abstract
1. The second sentence is very long and somewhat hard to follow.
Authors: Agreed. We have edited to break this into two sentences. The revised text reads, “This study is an evaluation of an intervention that sought to improve women’s access to PPFP in Tanzania. The intervention included counseling on PPFP during antenatal and delivery care and introducing postpartum intrauterine device (PPIUD) insertion as an integrated part of delivery services for women electing PPIUD in the immediate postpartum period.”

2. The results presented appear to be a difference between pre and post intervention rather than difference in difference between two groups receiving an intervention.

Authors: Thank you for this question. You are correct that we are looking at the difference between pre- and post-intervention periods. The difference-in-difference analysis does not require that both groups receive an intervention – instead, it assesses the relative difference of the outcome between the pre/post period in an intervention group compared to the difference in the outcome in a control group over the same time. The key identifying assumption of this analytic approach, referred to as the “parallel trends” assumption, is that the change in the outcome in the intervention group between the pre- and post-periods would have been the same as the observed change in the control group over the same period had the intervention group not received the intervention. Any deviation from the relative parallel trend of the outcome into the post-intervention period between the two groups can therefore be attributed to the effect of intervention on the outcome. One description of this approach can be found here: https://www.mailman.columbia.edu/research/population-health-methods/difference-difference-estimation

Introduction
3. Page 3 Line 28: Are you referring to LMICs only or globally?

Authors: We were referring to LMICs and have clarified this in the text. The revised text now reads, “However, PPIUD insertion requires specialized skills and is often unavailable in health facilities that offer delivery services in low- and middle-income countries.”

4. It would help to provide more context for the intervention. Why was this implemented in Tanzania? What was the origin?

Authors: The intervention was implemented by FIGO in six countries, and our team conducted an evaluation of the intervention in three of these countries (Tanzania, Nepal and Sri Lanka). We are not privy to FIGO’s process of selecting the countries, but we have added the information that this was part of a larger project. On p. 3-4, the revised manuscript now reads, “The intervention was implemented by the International Federation of Obstetricians and Gynecologists (FIGO) in partnership with its Tanzanian affiliate, the Association of Gynecologists and Obstetricians of Tanzania (AGOTA), as a part of a larger project that implemented and evaluated the FIGO PPFP intervention in three countries: Tanzania, Nepal and Sri Lanka. The results of the evaluations in Nepal and Sri Lanka are published elsewhere.”

Methods
5. Page 4 Line 21: More description is needed of the Groups: why the early intervention implementation and late intervention implementation? Why were the two Groups defined as they were, i.e., 3 months and 9 months of baseline data collection? What was the rationale? What was the original goal in comparing these two Groups?
Authors: The original goal in comparing the two groups was to evaluate the effectiveness of the intervention, and this goal has not changed. The cluster-randomized stepped-wedge design was selected to maximize benefit to women delivering in study hospitals by ensuring that all had an opportunity to receive the intervention. The stepped-wedge design is characterized by the staggered intervention implementation (early implementation in Group 1 vs. late implementation in Group 2, which is outlined in the graphic below). This allows you to implement the intervention in all study facilities compared to a regular cluster-randomized trial where only half of the sites would have an opportunity to be exposed to the intervention. The length of the baseline data collection periods in Group 1 and Group 2 were determined based on our sample size calculations, but to simplify the language and use more consistent terminology, we have removed the detail about the length of the baseline periods. We have provided more information about the stepped-wedge design on p. 4, which now reads, “For this cluster-randomized stepped-wedge trial, six large, tertiary care facilities were selected by AGOTA, the implementing agency for the intervention, to provide coverage of PPIUD services for different regions of Tanzania. The stepped-wedge design was selected to measure intervention effectiveness because it is characterized by staggered intervention implementation in all study facilities, which ensured that all women delivering in study facilities could potentially benefit from the intervention.”

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Group 1 (Hospitals 1-3)</th>
<th>Group 2 (Hospitals 4-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>4-9</td>
<td>X</td>
<td>O</td>
</tr>
<tr>
<td>9-12</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

where X=PPIUD intervention and O=control (standard of care provided)

6. Since the intervention data for Group 2 are not presented, why include them in this analysis? Why not just compare pre and post intervention in Group 1?

Authors: It is an option to drop Group 2 altogether and conduct only a pre/post analysis of Group 1 as you suggest. We retained Group 2 in our analysis because this allows us to use the difference-in-difference analysis approach described above and take advantage of the randomization that was conducted for the stepped-wedge design. We feel that this is a stronger analytic approach because it allows us to estimate the causal effect (average treatment effect) of the intervention on our outcomes. A pre-post approach would likely be more limited in assessing the effect of the intervention because it does not consider the counterfactual condition that indicates what would have likely happened to the Group 1 hospitals had the Group 1 hospitals not received the intervention. We have clarified the advantages of this approach over a pre-post intervention on pages 4-5 as follows: “As a result, we have dropped the intervention period for the Group 2 hospitals and will consider the Group 2 hospitals as control facilities that are only observed in a state where they do not receive the intervention even as the Group 1 hospitals receive the intervention. This set-up of the data allows us to conduct the analysis as a treatment/control study of a cluster-randomized trial using a difference-in-difference approach. The difference-in-differences approach compares the change in an outcome that is observed in the Group 1 (treatment) hospitals between the pre- and post-intervention periods relative to the change in the outcome that is observed in the Group 2 (control) hospitals over the same period of time. The key identifying assumption of this analytic approach, referred to as the “parallel trends” assumption, is that the change in the outcome in the treatment hospitals between the pre- and post- periods would have been the same as the observed change in the control hospitals over the same period had the treatment hospitals not received the intervention. More specifically, the average outcome in the two groups would have evolved in parallel over time in the absence of the intervention, even if the average outcome between the Group 1 hospitals and Group 2 hospitals in the period had differed in the pre-period, before the Group 1 hospitals received the intervention. In this manner, any deviation from the relative parallel trend of the outcome into the post-intervention period between the Group 1 and Group 2
hospitals can be attributed to the effect of intervention on the outcome.”

7. Should add mention of IRB approval(s)

Authors: Thank you for this suggestion. We have added the information about the ethics approvals in the first paragraph in the Methods section. The text now reads, “The study also received ethical approval from the National Institute of Medical Research (NIMR) in Tanzania (protocol number: NIMR/HQ/R.8a/Vol.IX/2006). The study received a human subjects exemption from the institutional review board at Harvard University (protocol number IRB15-1605) as only de-identified data were received by the Harvard evaluation team.”

8. Page 4 Line 45: How is the analysis difference in difference? Seems like it is just difference between pre and post intervention; treatment vs. control. How this is a difference in difference analysis needs to explained more clearly.

Authors: Part of the confusion was likely that we were trying to transition from describing the stepped-wedge design to the difference-in-difference analysis approach, and the terminology is somewhat different between the two. We have now streamlined the language to improve clarity. We have removed references to the “baseline period”, which was the terminology from the stepped-wedge design and instead use the terminology of “pre- and post-intervention”, which is more commonly used with difference-in-difference analysis. On p. 4-5 we have also explained more clearly how this is a difference-in-difference analysis as mentioned above.

9. Page 5 Line 23: Who were the RAs? Were they trained?

Authors: The RAs were trained by the study team and had previous experience in conducting surveys. This information has been added in the first sentence of the Data Collection section on p.5, which now reads, “Trained Research Assistants with previous experience in conducting surveys were posted in post-natal wards of study hospitals where they conducted an interviewer-administered survey with women who consented to participate.”

10. Page 5 Line 50: Main reasons for ineligibility?

Authors: Eligibility criteria included: 1) age 18 or older, 2) delivered in one of the five study hospitals, and 3) resident of Tanzania. The vast majority (5.4% of the 6%) were ineligible because they were under age 18. We have added this information in the first sentence of the Analytic Sample section on p.6, which now reads, “A total of 16,930 women who delivered during the study period (15th January 2016 – 15th September 2016) in five hospitals were screened for study eligibility (age 18 or older, delivered in one of the five study hospitals, and resident of Tanzania), 15,912 (94%) were eligible (ineligibility primarily due to age under 18 years), and 15,264 (96%) of them consented to participate (Figure 1).”

11. Page 5 Line 54: Main reasons for missing outcomes/covariates?

Authors: Reasons for missing data included refusal to give a response to a given question or ending the survey early. This information has been added in the last sentence of the Analytic Sample section on p.6, which now reads, “The CommCare data collection application required a response to each question, and missing data are due to participant refusal to give a response or ending the survey early.”
12. Page 6 Line 7: As above, how is it difference in difference if you are just comparing intervention exposed to not exposed?

Authors: Please see response above.

13. Page 6 Line 35: What are the "measured aspects of quality in counseling"?

Authors: We have added this information in the text on p. 7 in the third paragraph of the Analysis section, which now reads, “This analysis focuses on measured aspects of quality in counseling, including timing of counseling, whether IEC materials were used (leaflet given and video seen), whether they were given an opportunity ask questions during counseling and the types of information they recall from the PPIUD counseling they received, and women’s socio-demographic characteristics that are associated with choice of PPIUD.”

Results

14. Why not just show percentages in Tables 1 & 2?

Authors: We have changed these from means to percentages in the revised version of the manuscript.

15. Table 3: Are these percentages or do they need to be multiplied by 100? I would suggest showing percentages in all tables.

Authors: You are correct that we were again presenting means rather than percentages. We have presented them as corrected percentages in the revised version of the manuscript.

16. What is the difference between Other Christian and Protestant?

Authors: The Protestant group was composed of Lutherans and Anglicans, and the Other Christian group was primarily Pentecostal (not considered Protestant in the Tanzanian context). We have revised the manuscript to provide this more detailed information, replacing “Protestant” with “Lutheran and Anglican” and replacing “Other Christian” with “Pentecostal and Other Christian”.

17. Page 7 Line 53: Again, how is this difference in difference? Seems it is just the effect of the intervention compared to no intervention. Please clarify.

Authors: These results are for the difference between the pre- and post-intervention periods in Group 1 (treatment) compared to Group 2 (control), which is what makes it difference-in-difference. If we were only using the post-intervention data, this would be the effect of the intervention compared to no intervention. We have clarified this in the text on p. 8-9 in the Difference-in-Difference Analysis section, which now reads, “The effect of the intervention was a 19.8 percentage point increase in PPIUD counseling (95% CI: 9.1 – 22.6 percentage points) between the pre- and post-intervention periods in Group 1 (treatment) compared to Group 2 (control).” and “The effect of the intervention was a 6.3 percentage point increase in choice of PPIUD (95% CI: 2.3 – 8.0 percentage points) between the pre- and post-intervention periods in Group 1 (treatment) compared to Group 2 (control).”

Discussion

18. Page 9 Line 41: Why argue against post-admission counseling when your results show that this increased uptake significantly. The literature is murky on how effective antenatal FP counseling is on PPFP uptake. This may be of interest: https://nam02.safelinks.protection.outlook.com/?url=https%3A
Authors: Thank you for this point. We initially focused on post-admission counseling as a negative because this was not initially the way the intervention was intended to be implemented (the thought being that counseling during ANC would maximize time for informed decision-making). We agree with you that the evidence is mixed on ANC counseling and clearer on post-admission/pre-discharge counseling, and we have reframed this paragraph accordingly. The second paragraph under Interpretation on p. 10 now reads, “Among women who were counseled on PPIUD, 57.0% reported counseling during ANC or both during ANC and after admission for delivery, and the remaining 43.0% only received counseling after admission for delivery. The intervention initially sought to counsel only during ANC to maximize the amount of time women had for informed decision-making, but counseling was also offered at the time of delivery to ensure that any women who wanted to use the PPIUD had the opportunity. The adjusted model found that women who were counseled after admission were more likely to choose PPIUD, corroborating findings from a recent review article, which found that interventions providing counseling in postnatal wards are effective in increasing postpartum contraceptive uptake.16”


Authors: We have added the aspects of quality that are included in the Methods section on p. 7, which now reads, “This analysis focuses on measured aspects of quality in counseling, including timing of counseling, whether IEC materials were used (leaflet given and video seen), whether they were given an opportunity ask questions during counseling and the types of information they recall from the PPIUD counseling they received, and women’s socio-demographic characteristics that are associated with choice of PPIUD.”

20. Page 9 Line 52: Why is provision of a leaflet "emblematic of a provider who has a strong commitment to high quality counseling"?

Authors: This was a hypothesis for the reason receipt of the leaflet was associated with uptake. We have not been able to find support for this hypothesis in the literature and have deleted this sentence in the revised version of the manuscript.

Reviewer 2

This is a well-designed and relevant study but has one major limitation as the authors correctly pointed out. There is a potential for better findings with wider generalisability, had it been implemented in lower facilities.

1. Under background, line 53, authors mentions that "the analysis focuses on the effect of the intervention on this newly added service, including effects on PPIUD counseling and women's choice of PPIUD (i.e having a PPIUD inserted) before being discharged from hospital after delivery. Under outcomes of interest authors mentioned that (line 39) "Choice of PPIUD was measured as a dichotomous variable based on both woman's report and the provider's report…..(line42) If either the woman or the provider reported PPIUD insertion, the woman was considered to have chosen the PPIUD" . It appears that the phrase "PPIUD choice" and "PPIUD insertion" are being used
interchangeably and bring confusion. A woman can choose PPIUD but not go for insertion. In addition, regarding line 42, was there a procedure to verify a woman's report of PPIUD insertion in the provider's report/documents? If such procedure was not in place it would rather be better to strictly use "PPIUD choice" and do away with "PPIUD insertion" as it was used under your conclusions.

Authors: Thank you for these points. You are correct that “PPIUD choice” refers to women who chose PPIUD and had a PPIUD inserted. We have updated the language throughout to remove reference to “PPIUD insertion” and use only “PPIUD choice”, which is now more clearly defined in the Methods section. There was a procedure to verify a woman’s report of PPIUD insertion in the provider data, but there were some instances where the insertion was only reported in either the woman’s survey or the provider’s survey. Our definition of “PPIUD choice” includes insertion reported either on the woman’s survey or the provider’s survey. We have included additional information about this in the Methods section on p. 6, which now reads, “Choice of PPIUD was measured as a dichotomous variable based on both the woman’s report and the provider’s report of PPIUD insertion. Occasionally, a woman would choose to have a PPIUD inserted after she completed her survey, and the insertion would be reported only on the provider survey. If either the woman or the provider reported PPIUD insertion, the woman was considered to have chosen the PPIUD.”

2. The implementers of the intervention have been mentioned as FIGO/AGOTA and their roles widely described. It would enlighten the reader to highlight whether data collection was also coordinated by FIGO/AGOTA or if there were any work related links with FIGO/AGOTA.

Authors: Yes, there were work-related links between the study team and FIGO/AGOTA. The research assistants were hired by AGOTA to collect data over their three-year intervention implementation period. However, during the evaluation data collection period the research assistants were managed by the local research partner to ensure quality and consistency of data collected. This information has been added in the Data Collection section on p. 5-6, which now reads, “Research Assistants were employed by AGOTA to collect data over the full project implementation period, but they were managed by the local research organization, Management and Development for Health (MDH), during the evaluation data collection period.”

3. Figure 1 Study Flow chart. The flow of numbers in group 2 is not correct and might need your attention, (particularly for those who did not consent, n=648).

Authors: Thank you for catching this error. You are correct that the Group 2 number who did not consent was incorrect. This should have been 314 rather than 648. We have updated Figure 1 accordingly and double-checked that the other numbers in the figure are correct.

4. Under results, in page 7, line 29: authors refer to the trends in PPIUD choice…approximately 18% in Mbeya and 6% in Muhimbili, but when you turn to the figure it is less than 15% for Mbeya and less than 5% for Muhimbili. Again, as mentioned earlier, authors have used PPIUD choice in the text and PPIUD insertion as the title of the figure which is confusing.

Authors: Thank you for noting this inconsistency. We have updated the title of Figure 3 to use the language of “Choice of PPIUD” rather than referring to PPIUD insertion rates. The results in the text are referring to the maximum percentage of women choosing PPIUD in a given month over the four-month post-intervention period. Mbeya shows up at less than 15% in September 2016, but the text is referring to the maximum of 18%, which was observed in July 2016. We have revised the text on p. 8 to make this reporting of results clearer, “Women’s choice of PPIUD varied between Group 1 hospitals
with a maximum of approximately 20% selecting PPIUD in Dodoma, 18% in Mbeya, and 6% in Muhimbili National Hospital in a given month over the four-month post-intervention period."