Evaluation of a multi-level intervention to improve post-partum intrauterine device services in Rwanda [version 1; peer review: 3 approved with reservations]

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Abstract
Background. The copper intrauterine device is one of the most safe, effective, and cost-effective methods for preventing unintended pregnancy. It can be used post-partum irrespective of breastfeeding to improve birth spacing and reduce unintended pregnancy and maternal-child mortality. However, this method remains highly underutilized.

Methods. We developed a multi-level intervention targeting supply, demand, and sustainability to increase uptake of the post-partum intrauterine device (PPIUD, defined as insertion up to six weeks post-delivery) in Kigali, Rwanda. High-volume hospitals and health centers were selected for implementation of promotions and service delivery. Formative work informed development of a PPIUD promotional flipchart delivered in-clinic (during antenatal care, labor and delivery, or infant vaccination visits) or in the community. Two-day PPIUD didactic counseling, insertion/removal, and follow-up trainings were provided to labor and delivery and family planning nurses followed by a mentored practicum certification process. Stakeholders were involved from intervention development through dissemination of results.

Results. Two hospitals (and their two associated health centers) and two health centers were selected. In the 6-months prior to our
intervention, only one nurse and one midwife from each hospital were providing PPIUD services, and just 46 PPIUDs had been placed at the selected health facilities. From August 2017-July 2018, we trained 83 promotional agents and 39 providers to provide PPIUD services. N=9,073 women received PPIUD promotions who later delivered at a selected health facility, and of those n=2,633 had PPIUDs inserted (29% uptake). Most PPIUDs (60%) were inserted within 10 minutes of delivery of the placenta, with an additional 13% intra-cesarean, 17% between 10 minutes and 48 hours after delivery, and 8% between 4 and 6 weeks after delivery.

**Conclusions.** This successful, comprehensive intervention has the potential to make a significant impact on PPIUD uptake in Rwanda. The intervention is scalable and adaptable to other sub-Saharan African countries.

**Keywords**
Post-partum, contraception, birth spacing, family planning, intrauterine device, Rwanda

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Introduction

The World Health Organization (WHO) recommends post-partum family planning as safe, effective, and cost-effective for prevention of unintended pregnancy, prevention of abortion, birth spacing, and improvement of maternal and newborn health. Like many sub-Saharan African countries, Rwanda is committed to reducing unmet family planning need, particularly in postpartum women.

The 2015 Rwandan Demographic and Health Survey (DHS) estimated that 19% of women have an unmet need for family planning and the 2010 Rwandan DHS estimated that 51% of women had an unmet need for postpartum family planning (within two years of delivery) family planning. In particular, the copper intrauterine device (IUD) is highly-effective, cost-effective, and can be used immediately post-partum or after 4 weeks post-partum regardless of breastfeeding. However, the post-partum IUD (PPIUD) remains extremely underutilized across sub-Saharan Africa, including in Rwanda.

In much of the developing world, women with limited access to medical care are often able to attend antenatal care (ANC), labor and delivery (L&D), and infant vaccination services making these visits unique opportunities to address post-partum family planning needs. The Rwandan Ministry of Health (MOH) previously supported efforts to implement PPIUD services in four district hospitals and eight health centers and found that clinic staff successfully incorporated new skills into ANC and maternity services, inserting 478 PPIUDs over 15 months. As a result, the Rwandan MOH developed training curricula and reporting mechanisms, and PPIUD is part of the Government’s Family Planning 2020 Commitment.

However, despite capacity building and interest, uptake of PPIUD services in Rwanda remains extremely low, and overall, the IUD only comprises 2.5% of the method mix among contraceptive women between the ages of 15–49 in the 2015 Rwandan DHS (see Family Planning 2020 site).

This low IUD uptake is hypothesized to be due to lack of clinic ‘champion’ stakeholders promoting the service, low provider motivation and comfort with the IUD, lack of optimized operational procedures, the often overlooked role of male involvement, and lack of demand-creation strategies informed by clients’ needs and preferences. Research particularly highlights the need to create demand through providing comprehensive information on contraceptive methods to increase knowledge about benefits and side effects, address misconceptions, and discuss family planning desires with women and couples. Educational and demand creation efforts are particularly important for the IUD which is less well-known versus other modern methods in sub-Saharan Africa.

Our objective was to develop and pilot test an evidence-based, multi-level intervention targeting both supply, demand, and sustainability to increase uptake of the PPIUD (defined here as uptake up to six weeks after delivery) in Kigali, the capital of Rwanda. Our primary aims were to increase the number of: workers trained to promote the PPIUD to couples/clients in health facilities and the community, providers trained and certified to insert and remove PPIUDs, couples/clients receiving PPIUD educational promotions, and women receiving a PPIUD up to six weeks after delivery. This study was conducted by researchers at Projet San Francisco (PSF).

Methods

Ethical considerations and consent

The Emory University Institutional Review Board (IRB) and the Rwanda National Ethic Committee (RNEC) approved the research component (focus group discussions and surveys) of the project (IRB 00001497). Written informed consent was obtained from all participants prior to enrollment. The Emory University IRB determined the programmatic service delivery component of the project (PPIUD promotions and insertions provided by government clinic staff) was exempt from review.

Intervention framework

To develop an evidence-based, multi-level intervention to improve PPIUD supply and demand coordination, our innovative strategy combined behavioral science and operations research methods, specifically using a multi-level implementation science framework based on Greenhalgh et al. and the Theory of Planned Behavior. Drawing on input from stakeholders, providers, community health workers, and couple/clients, we designed the intervention to address barriers at multiple-levels. This framework is outlined in Figure 1 and indicates intervention activities designed to change an agent’s attitudes, norms, and perceived control, which in turn affect their intention to either support, provide, promote, or take up a PPIUD. These activities are described in detail below.

Early stakeholder involvement

Throughout the intervention we received logistical and technical support from a collaborative group of stakeholders at community, facility, non-governmental, and governmental levels. This included the Rwanda MOH, the District Mayors, the Rwandan Family Planning Technical Working Group, and clinic directors and nurse-administrators at the selected hospitals and health centers.

Health facility selection and needs assessments

In May-June 2017, a PSF nurse counselor (RS) and a study physician (RI) reviewed government monthly reports from Kigali health facilities to select the highest L&D-volume hospitals and health centers. Two hospitals (and their two associated health centers) and two additional health centers were selected. A PSF nurse counselor (RS) and a study physician (RI) then assessed infrastructure, staff trained in long-acting reversible contraception (IUD or implant) insertions, staff in L&D and family planning, and staff interested as potential trainees for PPIUD services in the selected health facility. They reviewed IUD stocks and any procedures supporting PPIUD supply or demand.
**Figure 1. Framework of the PPIUD intervention at multiple levels of the healthcare system.** Grey boxes indicate intervention activities designed to change attitudes, norms, and perceived control. PPIUD: post-partum intrauterine device; PPFP: post-partum family planning; FPTWG: Family Planning Technical Working Group; ANC: antenatal care; L&D: labor and delivery; FP: family planning; CHW: community health worker; PBF: performance-based financing; MOH: Ministry of Health.
PPIUD demand creation development

Through formative work in May-July 2017, PSF staff evaluated knowledge, attitudes, and practices regarding PPIUD services among community health workers (CHW) and providers at two high volume health centers which were not selected for our intervention (unpublished manuscript under review; Da Costa V, Ingabire R, Sinabamene R, Karita E, Umutooni V, Hoagland A, Allen S, Mork E, Parker R, Mukamuyango J, Haddad L, Nyombayire J, Wall KM). An exploratory analysis of factors associated with interest in postpartum intrauterine device (IUD) uptake among pregnant women and couples in Kigali, Rwanda. Submitted 2018; unpublished manuscript under review; Da Costa V, Ingabire R, Sinabamene R, Karita E, Umutooni V, Hoagland A, Allen S, Mork E, Parker R, Mukamuyango J, Haddad L, Nyombayire J, Wall KM. Perceptions of the postpartum intrauterine device (PPIUD) and implant among pregnant women and couples in Kigali, Rwanda. Submitted 2018). As Rwanda uses a performance-based financing (PBF) system, we also explored provider knowledge of the current PBF structure and other insurance programs for family planning method provision, and asked whether these influenced the methods they provide. We also evaluated knowledge, attitudes, and practices among pregnant women and couples during early ANC visits (men often attend these visits with their partners). Survey and focus group topics included: demographics; previous pregnancy, birth spacing, and family planning history; postpartum long-acting reversible contraception knowledge, attitudes, and practices; and personal and community perceptions of long-acting reversible contraception. Each survey and focus group discussion took approximately 45 minutes to complete, and each individual study participant was compensated $3.60 United States Dollars (USD). Information gathered from this formative work led to the development of the PPIUD educational and promotional flipchart (Supplementary File 1).

Post-partum IUD service delivery training

In August 2017, health care providers (nurses and midwives working in L&D and family planning) from our selected government health facilities were trained by two national PPIUD trainers located at the selected district hospitals. The training included a 2-day didactic session conducted at PSF (adapted from didactic and practical training materials developed by JHPIEGO and USAID in collaboration with the MOH). We trained a maximum of 12 trainees per didactic session. The didactic training included information about IUD and PPIUD insertion and removal procedures and follow-up, the use of the PPIUD flipchart in counseling, mock counseling sessions, as well as PPIUD insertion and removal trainings using ‘Mama-U’ (Laerdal Medical) postpartum uterus models. Pre- and post-training tests (adapted from the USAID and Maternal and Child Health Integrated Program Postpartum IUD Training Guide24; Supplementary File 2) consisted of 10 true or false questions and were administered before and after the training.

After passing the didactic training session, two trainees at a time would conduct PPIUD insertions at a selected district hospital under the supervision of a national trainer. The trainees were required to insert correctly and comfortably five PPIUDs under supervision to be PPIUD certified. These five insertions had to include at least one of the following PPIUD insertion timings: immediate post-placental, 10 minutes to 48 hours post-delivery, and 4-6-weeks post-delivery. Checklists for PPIUD insertion practices guided the certification process. Intra-cesarean and post-abortion IUD insertions were provided by previously trained doctors and those certified in PPIUD.

Demand creation

In addition to training PPIUD providers to use the PPIUD promotional flipchart, we trained government clinic staff in family planning, ANC, L&D, and infant vaccination to promote the service at the selected facilities. Trainings were comprised of a 3-hour long didactic session led by PSF staff followed by one supervised promotion session. Additionally, we trained CHWs affiliated with the selected health facilities to use the flipchart to promote post-partum family planning in the community beginning in March 2018. CHWs received a 1-day training on the use of the PPIUD flipchart and couples’ family planning counseling strategies. Women were referred to the facility by their CHW if interested to receive an IUD. Thus, women and couples were provided with PPIUD information at many different time points at the selected health facilities (during ANC, L&D, and infant vaccination up to 6 weeks post-delivery) as well as in the community.

Follow-up procedures

PPIUD follow-up appointments were scheduled 10 days after IUD insertion. Those who had insertions within 48 hours of delivery and who missed their 10-day follow-up visit were assessed at their infant’s first vaccination visit 6 weeks post-partum. Women coming for follow-up appointments were asked if they had complaints, and a pelvic exam for infection and IUD placement was performed. IUD strings were trimmed as needed and a pelvic ultrasound was recommended if the strings were not visible during physical exam. Women whose IUDs expelled or who requested a removal were offered the family planning method of their choice. To increase follow-up, in March 2018 we began providing CHWs with lists of clients in their catchment areas who were pending follow-up to remind those women about their appointments.

Reimbursements and other compensation

PPIUD trainees were provided with per diem and transport reimbursement for the time spent training ($5.79 USD per day for approximately two weeks of training). All other reimbursements began in March 2018. Reimbursements to the selected facilities for administrative costs associated with implementing the PPIUD program were provided at $57 USD per month. Using the PBF system as a guide27, CHWs were incentivized $0.57 USD per client presenting their referral when requesting a PPIUD and providers were reimbursed $1.20 USD/PPIUD insertion. These payments were made to their facility and included with their regular PBF pay. We began providing transportation reimbursement for women to attend PPIUD follow-up visits ($2.29 USD/client) as follow-up visits were not part of the routine schedule for new mothers.
Data collection
PPIUD service delivery and promotions began in August 2017. A unique code unlinked to patient identifiers allowed tracking of clients from the community and ANC through L&D and infant vaccination. Since promotions occurred in several settings, promotions given by CHW were tracked using referral slips. Promotions in ANC included a group talk followed by one-on-one counseling for those expressing interest in post-partum family planning. Those receiving one-on-one counseling had their method of interest and estimated date of delivery recorded. During insertion, provider perception of ease of insertion, client anxiety during insertion, and client pain during insertion were captured on scales of 1–10. During follow-up, data collected included method expulsion, genital infection, or method failure (i.e., incident pregnancies occurring after insertion), and client satisfaction with the method was captured on a scale of 1–10. Data was recorded in government log books, extracted and cleaned for data entry into tablets weekly by the PSF field team through the mobile data collection platform Survey CT O v2.41 (Dobility, Cambridge, USA), and finally uploaded into a Microsoft Access database.

Analyses
Analyses were performed using SAS version 9.4 (Cary, NC). We tabulated, by facility: number of providers trained and certified; number of promoters trained; number of clients who received a one-on-one promotion from a CHW or in a health facility; total number of PPIUDs inserted (overall and by timing of insertion); and number of follow-up visits. From these data, we calculated the proportion of PPIUD uptake among women who delivered at one of our selected facilities and the proportion of insertions by insertion timing (Table 1). We also plotted PPIUD uptake over time by facility (Figure 2) and by timing of insertion (Figure 3), both after implementation of the intervention and in the six months prior. We then used descriptive statistics to describe insertion and follow-up data (Table 2).

Results
Health facility selection and needs assessments
The health facilities selected included Muhima and Kacyiru hospitals (and their associated health centers) and Remera and Kinyinya health centers. The two hospitals, Muhima and Kacyiru, provide routine L&D services for their adjoining health centers and also receive referrals of high-risk and complex obstetric cases from several other health centers. Muhima and Kacyiru health centers provide ANC, family planning, and infant vaccination. The other two health centers, Kinyinya and Remera, were distant from the selected hospitals and from each other, and included routine L&D as well as ANC, family planning, and infant vaccination services. Complex and high-risk obstetric cases from these latter two health centers were referred to nearby hospitals not included in this study. All facilities had infrastructure for IUD insertions and procurement but did not have PPIUD insertion kits or Kelley forceps which were procured.

Table 1. PPIUD demand creation and service delivery outcomes (August 2017–July 2018).

| Facility                          | Muhima Hospital and Health Center | Kacyiru Hospital and Health Center | Remera Health Center | Kinyinya Health Center | Total |
|----------------------------------|-----------------------------------|-----------------------------------|----------------------|------------------------|-------|
| Pregnant women promoted to       | 3790                              | 2656                              | 2025                 | 2089                   | 10560 |
| Women promoted to who delivered  | 3277                              | 2564                              | 1540                 | 1692                   | 9073  |
| Women promoted to who delivered  |                                   |                                   |                      |                        |       |
| in a study L&D ward*             | 3277                              | 2564                              | 1540                 | 1692                   | 9073  |
| Promotions delivered during:     |                                   |                                   |                      |                        |       |
| Antenatal care                   | 401                               | 20                                | 585                  | 780                    | 1786  |
| L&D                              | 2769                              | 2544                              | 332                  | 216                    | 5861  |
| Post-partum                      | 1                                 | 0                                 | 0                    | 296                    | 551   |
| Infant vaccination visit         | 106                               | 0                                 | 369                  | 400                    | 875   |
| Total number of PPIUD inserted   | 1061                              | 994                               | 310                  | 268                    | 2633  |
| Post-placental                   | 513                               | 744                               | 197                  | 136                    | 1590  |
| Intra-cesarean                   | 189                               | 148                               | 0                   | 0                      | 337   |
| 10 minutes to 48 hours           | 268                               | 55                                | 79                   | 47                     | 449   |
| 4 to 6 weeks                     | 58                                | 22                                | 34                   | 85                     | 199   |
| Post-abortion                    | 33                                | 25                                | 0                   | 0                      | 58    |

PPIUD: post-partum intrauterine device; L&D: labor and delivery
*Denominator for total PPIUD uptake proportions
PPIUD demand creation

Four client focus groups comprised of 32 participants and 14 provider interviews informed the development of surveys which were conducted among 14 health providers, 24 CHWs, and 150 women or couples attending ANC visits. Information gathered from this formative work led to the development of the PPIUD promotional flipchart.

The PPIUD flipchart contained information on the importance of birth spacing, a description of the IUD including efficacy and side effects, and also explained PPIUD insertion timing and expulsion rates. The flipchart included answers to the most frequent client misconceptions about the PPIUD including breastfeeding, heavy bleeding, and its effect on sexual intercourse. Though the focus of the promotional flipchart was on the PPIUD, the promotions included discussion of the other post-partum contraceptive options which are more well-known and widely available. The flipchart was designed to be delivered by clinic providers during ANC, L&D, infant vaccination, or by CHWs in the community to both pregnant women and couples.

Post-partum IUD demand creation and service delivery outcomes

We trained a total of 83 staff to promote PPIUD to couples/clients in-clinic and in the community. 39 providers were trained to deliver the service and 90% of those were certified. Trainees were midwives and nurses working in L&D (85%) or from family planning clinics (15%). All trainees were women.
From August 2017-July 2018, n=9,073 pregnant women were promoted to who later delivered at one of the selected facilities (48% of these expressed interest in PPIUD at the time of promotion). Most promotions took place during L&D (65%) or ANC (20%). Most (95%) of the women only received one promotion, with 4% receiving two promotions (and 1% receiving three to four promotions). Overall, n=2,633 PPUIDs were inserted (29% PPIUD uptake) (Table 1). Timing of promotion was associated with uptake (p<0.05), with highest uptake for promotions delivered during L&D (35%) versus the lowest uptake for promotions delivered during ANC (9%, Dataset 128). Increasing number of promotions received was not statistically significantly associated with PPIUD uptake, but a trend was observed (p=0.07, Dataset 128).

PPIUD insertions over time by facility
In the 6-months prior to the intervention (February 2017-July 2017), 46 PPIUDs were inserted in the selected health facilities. The percent increase comparing monthly PPIUD insertions between February 2017-July 2017 to August 2017-July 2018 was 2,749% (Figure 2). We saw an immediate increase in PPIUD uptake as training/promotions began which decreased slightly after initial trainings/supervised certifications ended. Once PBF-incentives began along with training of CHWs to promote PPIUDs in the community, we again observed an increase in insertions. Insertions decreased in June 2018 as seven PPIUD certified nurses began their annual or maternity leave, followed by a subsequent increase as certified providers rearranged their workloads accordingly to compensate.

PPIUD insertions over time by insertion timing
In the initial three months of the program, insertions placed between 10 minutes to 48 hours post-delivery were the most common, but from November 2017 onward post-placental insertions were the most common. Overall, 60% of insertions were immediately post-placental, 17% occurred 10 minutes to

Table 2. Insertion outcomes among women receiving a PPIUD (August 2017–July 2018).

|                                | Muhima Hospital and Health Center | Kacyiru Hospital and Health Center | Remera Health Center | Kinyinya Health Center | Total |
|--------------------------------|----------------------------------|-----------------------------------|----------------------|------------------------|-------|
|                                | Mean/N SD/%                      | Mean/N SD/%                       | Mean/N SD/%          | Mean/N SD/%            | Mean/N SD/% |
| Among women receiving a PPIUD insertion (N = 2,633) |                                  |                                   |                      |                        |       |
| Age (mean, SD)                 | 28.3 6.4                          | 28.8 5.6                          | 28.1 5.5             | 27.8 6.2               | 28.4 6.0 |
| Parity (mean, SD)              | 2.4 1.4                           | 2.4 1.5                           | 2.6 1.4              | 2.5 1.4                | 2.4 1.4 |
| Provider perception: ease of insertion (mean, SD)* | 9.4 0.7                           | 8.5 1.1                           | 9.7 1.0              | 9.7 0.6                | 9.2 1.0 |
| Patient perception: anxiety during insertion (mean, SD)* | 1.1 0.4                           | 2.2 0.7                           | 3.9 2.1              | 1.1 0.6                | 1.8 1.3 |
| Patient perception: pain during insertion (mean, SD)* | 1.1 0.4                           | 2.5 0.9                           | 3.6 2.0              | 1.0 0.2                | 1.9 1.3 |
| Among attending PPIUD follow-up (N = 1,418) |                                  |                                   |                      |                        |       |
| Expulsion (N, %)               |                                  |                                   |                      |                        |       |
| Yes                            | 37 7%                             | 29 5%                             | 6 3%                 | 8 5%                   | 80 6%  |
| IUD reinserted                 | 27 73%                            | 10 34%                            | 3 50%                | 7 88%                  | 47 59% |
| Implant inserted               | 2 5%                              | 5 17%                             | 1 17%                | 1 13%                  | 9 11%  |
| No LARC inserted               | 8 22%                             | 14 48%                            | 2 33%                | 0 0%                   | 24 30% |
| No                             | 465 93%                           | 514 95%                           | 191 97%              | 168 95%                | 1338 94% |
| Infection (N, %)               |                                  |                                   |                      |                        |       |
| Yes                            | 5 1%                              | 1 0%                              | 0 0%                 | 0 0%                   | 6 0.4% |
| No                             | 497 99%                           | 540 100%                          | 197 100%             | 176 100%               | 1410 100% |
| Failure (N, %)                 |                                  |                                   |                      |                        |       |
| Yes                            | 0 0%                              | 0 0%                              | 0 0%                 | 0 0%                   | 0 0%   |
| No                             | 502 100%                          | 543 100%                          | 197 100%             | 176 100%               | 1418 100% |
| Removal (N, %)                 |                                  |                                   |                      |                        |       |
| Yes                            | 7 1%                              | 6 1%                              | 4 2%                 | 3 2%                   | 20 1%  |
| No                             | 494 99%                           | 536 99%                           | 193 98%              | 173 98%                | 1396 99% |
| Patient report of satisfaction with PPIUD (mean, SD)* | 9.9 0.6                           | 9.9 0.5                           | 10.0 0.2             | 9.9 0.4                | 9.9 0.5 |

*From a score of 1–10
SD: standard deviation; PPIUD: post-partum intrauterine device; LARC: long-acting reversible contraception
48 hours post-delivery, 8% occurred 4 to 6 weeks post-delivery, 13% occurred intra-cesarean section, and 2% occurred post-abortion (Figure 3).

Insertion outcomes among women receiving a PPIUD
Of the 2,633 women receiving PPIUDs, the average age was 28.4 and average parity was 2.4. Provider perception of ease of insertion was high across facilities (average score of 9.2/10), and patient perception of anxiety and pain were low (average scores of 1.8/10 and 1.9/10, respectively) (Table 2). Remera health center had slightly higher than average patient anxiety and pain scores relative to the other facilities.

N=1,418 (60%) women who were due for PPIUD follow-up visits attended them. Overall proportions of expulsions were low at 6% (N=80), and over half (59%) of women who experienced an expulsion had an IUD reinserted. Expulsion proportions were similar for post-placental, 10 minutes to 48 hours post-delivery, intra-caesarian, and 4 to 6 weeks post-delivery insertions, but the small number of post-abortion insertions had a higher expulsion proportion (3/18, 17%, Dataset 19). Infections were extremely uncommon across all facilities at 0.4%, and no cases of IUD failure were identified. One percent of women requested removals, with the most commonly cited reason for removal being that the husband (30%) or the woman (25%) did not like the method (Dataset 19). Overall satisfaction with the PPIUD was very high across all facilities (average score of 9.9/10).

Discussion
In this PPIUD implementation in government health facilities, we focused on supply, demand, and stakeholder engagement to significantly increase the provision and uptake of the PPIUD. The proportion of women who were made aware of this service and selected this method after delivery was very high (29%) as was the proportion of insertions that were post-placental (60%). Client satisfaction with the service was high and removal, expulsion, and infection proportions were low.

Supply
This study demonstrated that it is feasible to train government providers to deliver consistent, quality PPIUD services that are adaptable with their current workload. Staff turnover and leave was a challenge, and new and refresher trainings will be needed over longer timeframes. However, staff began to train each other near the end of the implementation and took over intra-caesarean section insertions from previously trained doctors, indicating the sustainability of our model. PBF-type incentives appeared to support providers and facilities in providing the service (offsetting administrative costs incurred by facilities and time costs to providers). Though we encountered no issues with stockouts, other studies have observed such challenges, and the potential for device stockouts must be monitored.

PPIUD demand creation and uptake
Provider training and infrastructure alone is not sufficient to ensure the success of PPIUD services and increase demand, especially for the less well-known IUD10,11, and several demand creation strategies may be needed. We observed a significant increase in PPIUD uptake pre- versus post- intervention after PPIUD supply and demand coordination began. Demand was generated by both in-clinic promotions as well as by CHWs affiliated with facilities. In future studies, we will expand CHW promotions and conduct comparative effectiveness studies of these two promotional strategies. A study in Nigeria showed that repeated post-partum family planning promotions over multiple ANC sessions increased post-partum family planning use11, as we similarly observed a trend for the effect of multiple promotions.

PPIUD insertion timing
Most PPIUD insertions were post-placental (60%) and the second most frequent timing of insertion was 10 minutes to 48 hours after delivery indicating that our promotions often lead to insertion before women leave the facility after delivery. In a study that integrated PPIUD services into maternal care facilities in six low- and middle-income countries, researchers found that in Rwanda, 27% of PPIUD insertions were post-placental, 43% were intra-cesarean, and 30% were within 10 minutes to 48 hours of delivery; in this study, insertion timings varied widely by country with Rwanda having the lowest proportion of insertions being post-placental10. In a study in providing post-partum family planning services in West and Central Africa, most PPIUD insertions were intra-cesarean (33%) with relatively fewer being post-placental (20%). The authors suggest this may be due to weak post-partum family planning counseling in ANC clinics10.

PPIUD follow-ups
PPIUD follow-up proportions may be affected by women attending other nearby health centers not included in this study for follow-up, or simply not attending follow-up visits. Similarly, in a study in providing post-partum family planning services in West and Central Africa, 42% of women who had a PPIUD inserted also attended follow-up (13.8% in person at the clinic between 2–6 weeks, and 28.6% by phone at 6 weeks)10.

Of those with PPIUD follow-up appointments, reported satisfaction with the method was high, and we observed very few adverse outcomes during the study. PPIUD expulsions were relatively rare (6%) and were highest for post-abortion insertions. Infections and removals were also rare (<1% of insertions) and no failures were observed. Similarly, in a study that integrated PPIUD services into maternal care facilities in low- and middle-income countries, expulsion rates were low (ranging from 2–4%), infection rates were low (0–1%), and removals ranged from 1%–11%10. In a study in providing post-partum family planning services in West and Central Africa, 0.8% of PPIUD users self-reported expulsions and only 0.5% (n=12) requested removal (10 desired pregnancy and two had husbands who disapproved of the PPIUD)12. These and our data are reassuring regarding PPIUD insertions and adverse events.

Given that the majority of the removals in our study were due to male partner’s not liking the method, male involvement during promotions may be important. A review of 26 post-partum family planning studies in low- and middle-income
countries found that male partner involvement may increase knowledge and use of postpartum contraception, and other studies found male partner involvement is important for post-partum contraception uptake and continued use. We are currently conducting focus groups and surveys to further explore the role of male involvement in post-partum family planning choices.

PBF-type incentives
PBF-type incentives appeared to increase the uptake of PPIUDs in our study. Under the current Rwandan PBF structure, providers receive a flat rate for all family planning methods provided to a new user. Thus, the IUD which takes considerably more time and skill to provide is reimbursed at the same rate as methods that are easier to administer such as OCPs and injectables. This could create a disincentive to providing IUDs. We are currently exploring stakeholder and policymaker perceptions related to restructuring the PBF reimbursements for family planning methods based on the skill and time it takes to provide them.

Limitations
Several limitations warrant discussion. Group promotions were often conducted in ANC, L&D, and infant vaccination and time constraints limited the number of women who could receive a subsequent one-on-one counseling session to those who were interested in post-partum family planning. As a result, more women heard about the PPIUD than were recorded. The two hospitals had large volume L&D services that included referrals of high-risk and complex cases from non-participating clinics. If those PPIUD clients did not return to one of our selected health facilities for follow-up assessment, they would not be captured. Because we were collecting service delivery data, we do not have extensive demographic information to explore demographic factors associated with uptake. Similarly, we did not collect data on why women selected or did not select the PPIUD. We are currently conducting surveys with women who received our post-partum family planning promotions to explore these reasons. Finally, given the pre-post study design, it is not possible to rule out the effect of secular changes on PPIUD uptake, though no national interventions or other similar projects were taking place in the capital during our implementation.

Conclusion
With renewed interest in post-partum IUD services, this comprehensive multi-level intervention is extremely well-timed and has the potential to make a significant impact on PPIUD uptake in Rwanda. Lessons learned from this and other PPIUD interventions show the critical and interconnected role of advocacy, training, mentored supervision, demand creation, and monitoring and evaluation. We are working with stakeholders to share best practices, and a cost-effectiveness analysis of the intervention is underway. We are planning to expand the service to other hospitals and health centers in Kigali which could become training centers for other facilities. We believe that our PPIUD implementation model, which achieved high PPIUD acceptance with high satisfaction and low adverse effects, is replicable and expandable.

Consent
The Emory University Institutional Review Board (IRB) and the Rwanda National Ethic Committee (RNEC) approved the research component (focus group discussions and surveys) of the project (IRB 00001497). Written informed consent was obtained from all participants prior to enrollment. The Emory University IRB determined the programmatic service delivery component of the project (PPIUD promotions and insertions) was exempt from review.

Data availability
Underlying data is available from Harvard Dataverse. Dataset 1: Replication Data for: an interim evaluation of a multi-level intervention to improve post-partum intrauterine device (PPIUD) services in Rwanda https://doi.org/10.7910/DVN/WLZ7PC

Data is available under a Creative Commons Zero (“CC0”) Public Domain Dedication Waiver

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Supplementary material
Supplementary File 1: Post-partum intrauterine device educational and promotional flipchart.
Click here to access the data.

Supplementary File 2: Pre- and post-training test.
Click here to access the data.
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I agree with the other reviewer's comments and will therefore try to add in a few others rather than repeat.

The paper adds to other important work in this area showing that an intense, comprehensive, and inclusive intervention strategy can bring about change. Clearer explanation of the steps for the intervention would be helpful.

One reviewer asks were these facilities and trainees involved in previous PPIUD programs in Rwanda? Several organizations (FHI, Jhpiego, and others) have worked on PPFP and PPIUD programs. It would be good to know this both in terms of sustainability of this project but also how previous work may have fallen short.

Demand generation utilizing community health workers and performance-based financing may be part of the difference or increased uptake but the author's reflection on this would be very helpful.

Definition of PPIUD: Consider changing the definition of PPIUD to resemble categories 1 &2 in WHO MEC. IUDs are category 2 for postpartum women during the initial 48 hours after expulsion of the placenta. A woman may have an IUD, four weeks after childbirth. This type of insertion technique is completely different than a PPIUD. In light of the fact that the study only had 8% of uptake of PPIUDs during this time (4-6 weeks), we suggest that you drop the results. It is interesting to note that the uptake is low at this time and worth mentioning as an opportune time for FP but clarification is needed.

- Similarly, including the PAC clients, is again a different insertion technique than the PPIUD. Since the numbers were so small, the technique is different, and this is a hot political topic, we believe that adding this data does not serve the post-obstetrical services or clients and
suggest that it is dropped. Patients for PAC are often in a different state of mind emotionally as well, so FP counseling is very different.

**Follow-up:** It is not clear why the study had a 10-day follow-up. The study reported that it used the Jhpiego training that has been developed based on evidence. These training materials advise 6-week follow-up if the client does not have any problems. Frequently the IUD strings have not yet descended since involution of the postpartum uterus is not complete. It would be helpful to explain why the researchers deviated from the 6-week follow-up visit.

- An explanation of what occurred at the follow up is needed. Was it a pelvic exam (bi-manual? speculum??). What is the protocol for a no-string visualized/palpated at time of exam? Is this cost effective to use USG? How will this play out in areas outside of the capital? Again we note that if using the Jhpiego training there is an algorithm for no strings. This may be more generalizable in settings where no ultrasound is available. Was this a needed deviation from protocol or new protocol?

**PPIUD Promotion:** We had concerns over the use of the word promotional materials, CHW promoting PPIUDs, and "promoted to". A better explanation of why the unifocal promotion of PPIUD is needed. Did women have a choice on the full range of methods available to them as postpartum women? It would be interesting to know what other methods women chose in the facilities where the study occurred. One may question how ethical it is to “promote” one method. PFPP counseling should be comprehensive to include all available methods. including permanent methods.

- We also had questions about incentivizing the provider with money for the provision of one particular method. This needs to be better explained in the study, how was this overcome, or why the study did not look at this or explain more details.

- Similarly, the CHW piece of the project needs to be better explained—was there an incentive? what are/were the CHW’s other tasks? how were they selected to participate in this project? Did they get FP training added onto their other tasks? what was rationale for adding them into the project and how were they financed, i.e., will this be sustained?

**Counseling:** the study developed a flip chart that “promoted” PPIUDs” How was the training rolled out for this? Was this counseling based on any evidence-based counseling techniques such as Balanced Counseling Strategy? The study mentioned that counseling most often occurred during labor. Was this active labor? A clarification about this time and explanation for using this time.

The intervention does not seem to be clearly stated. A clarification of the counseling, the cadre of staff inclusive of CHWs, the clinical component; as mentioned earlier PPIUD technique is different from Interval (after 4 weeks) and post-abortion. What was done with the technical working group, were these the stakeholders? If so, who were they or what were their roles, how did the project engage them?

We are also confused by the clinical training...was it 2 days with follow up mentoring for 2 weeks? Please clarify.

**Edits:** In American English, postpartum is one word. Please identify what the initials stand for throughout the study. Consider deleting one of the unpublished studies mentioned in the PPIUD demand creation section. In the organization Jhpiego, only the “J” is capitalized. Remove criticizing other studies in the discussion section. Focus on the result of the study at hand.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: I am an employee of Jhpiego, whose training materials were referenced. We have been involved in PPIUD trainings for several years in Rwanda, with other funding streams (USAID) and this may be one of the facilities where we've worked or provided technical support. Personally, I've not been involved in the PPIUD trainings, but our in country Jhpiego colleagues have been.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.
MCH services, the authors might consider referencing past work in the PPFP community that identifies these “no missed opportunities” and raises challenges with each of those platforms (ANC, L&D, PoNC, vaccination, etc.) - consider looking at PPFP Toolkit on K4Health. In addition, the Programming Strategies for Postpartum Family Planning document from WHO and USAID is an important reference.

In the 5th paragraph in Intro, the authors nicely articulate the literature regarding barriers to uptake of IUD but could benefit from some time spent also summarizing key challenges providing postpartum women with services, including limited understanding of return to fertility. These are within references cited in the document but suggest pulling them out in a few sentences or a paragraph.

The intervention framework is clear. As noted by the other reviewer, it would be better to talk about “counseling” rather than “promoted to” in most cases, though it may be related to limited promotion that certain providers offered. However, a clarifying statement could be made and then counseling referred to afterward and throughout. In addition, the authors frequently refer to “supply, demand, and sustainability” but those terms are not featured within the framework. Consider incorporating if possible or referring to them in the explanation of the framework.

A dedicated emphasis on stakeholder engagement is good to see. However, within the paragraph on early stakeholder engagement, it would be nice to articulate that the FPTWG includes other NGOs and FP implementing organizations. The authors indicated that stakeholders provided “logistical and technical support” through the intervention; it would be helpful to offer some specific examples of how local stakeholders guided the intervention. For example, did government stakeholders participate in selecting participating health facilities (per the following section)? Furthermore, stakeholder engagement during the implementation of the intervention is not clearly described. This is important for replication and points toward sustainability (see comment further down). The authors also mention “champions” a few times but with no description or explanation. This is likely an important element of the design and corresponds to past experiences (including the FHI-supported intervention) and should be included here. These details are helpful for future replication.

Under health facility selection, the “procedures” referred to in the last sentence are not very clear - are we referring to family planning operational guidelines?

In general, the intervention is described well and was thoughtfully designed, but could benefit from addressing a few gaps and organizational considerations. Overall, it is important to link the design of this intervention to past work that has been done globally and, especially, in the country. Past efforts in Rwanda (including those supported by us at FHI 360) were cited but more should be said about how this intervention built upon and/or differed from previous efforts. For example, were the selected facilities for this study also involved in past studies? As noted earlier, while the authors refer several times to “supply, demand and sustainability,” it is not clear what components are linked to sustainability. It would be helpful to more clearly articulate this. In addition, it would be interesting to provide a justification for why the authors chose to include the 4-6-week period for PPIUD insertions rather than focus on the first 48 hours only.

Regarding the supply side: Several studies have shown that the supply-side component of PPIUD services is feasible in LMICs, so what, if anything, differed here? It would seem that the training
period was shorter, so that may be something to highlight. Was the number of supervised insertions required for certification fewer than in the past? The FHI-supported intervention made use of a stamp on ANC cards to indicate method choice if a woman selected a method during ANC counseling. The authors refer on p.6 (under data collection, which appears to be misplaced) to having a method recorded, but don’t indicate how. Also related to supply (though perhaps it should also be tagged as related to sustainability), the discussion of PBF includes specific dollar figures. It would be more helpful to include how the $57 per month was calculated, and how the amounts cited compare to standard PBF-payments for FP.

Past experiences have also shown that it is often the demand-side that requires significant attention. The authors likely have more to contribute here, given the formative research that was conducted, however the results of this are not shared, nor linked to how they impact the intervention design. So again, what is new/different here and what builds on past efforts? Did the study team refer to past promotional materials (such as those available from the FHI-supported study)? There are several mentions of male involvement, and the fact that men often attend ANC sessions. In the FHI-supported intervention, we specifically learned to encourage providers to incorporate the PPFP counseling into the first ANC visit, when more men attend. Did you have any similar learnings or lessons to share regarding how men are involved in PPFP decision-making and how the intervention was designed to address that? Given that you also refer to male engagement in the discussion, more details would be helpful. The role of CHWs seems to be a notable difference from past interventions, and one the authors felt important, so more information regarding the decision to include this would be helpful.

**Is the study design appropriate and is the work technically sound?**

The paper discusses the intervention framework and model, and a compilation of service statistics is used to describe outputs and proximal outcomes. The work presented in this paper does not involve primary data collection.

Two hospitals and four health centers with high labor and delivery volume in Kigali were selected for the intervention. The authors should provide a rationale for the number of sites selected and the decision to focus only on Kigali, which is likely to offer a different context compared to other regions of Rwanda. It would also be helpful to note (if known) whether the participating sites had previously participated in PPIUD interventions.

The paper references formative work including focus group discussions and surveys. However, these were conducted to inform some of the intervention components and are not part of the results presented in this paper. Therefore, the statement on ethical considerations and consent does not seem relevant. The discussion on p. 7 of PPIUD demand creation should shift to earlier, as part of the description of the intervention itself and more detail on results added (per an earlier comment). The authors should provide information pertaining to the methods and results presented in this paper. As a note, later in the paper under methods, information on the duration of FGDs and surveys and on compensation similarly does not seem relevant.

As mentioned by the authors, this is a pre-post design with no control group, which carries limitations, although the authors offer a justification by saying that there were no other interventions or changes over the study period and the striking change is convincing. However, findings related to uptake over time still need to be interpreted cautiously due to other possible underlying trends and to changes in the intervention model (e.g. addition of promotion by CHWs
and introduction of PBF).

One barrier identified in the introduction is male involvement, and the intervention mentions promotion to couples. Are there any data on promotion to couples that can be included? This seems to be a potential gap in the paper which otherwise seems to address many of the barriers identified in the background.

The focus of the intervention is on PPIUD. However, some components – notably around demand-generation – address PPFP more broadly, which makes sense in the context of choice. Were any data captured in government logbooks that could provide insight into the possibly larger contribution of this intervention to PPFP beyond the PPIUD? The paper would also be strengthened by providing additional data that may put some of the service statistics in perspective. For example, are there any data on the total number of women attending the different services that could be cited to allow the reader to gauge the proportion that was reached through promotional activities? Or are there any data on the total number of institutional deliveries that could be provided for context?

Are sufficient details of methods and analysis provided to allow replication by others?
The methods in the abstract should cover data collection and not only the intervention model. Some of the results (about the six months prior to the intervention) are not clearly mentioned in the paper itself.

Regarding the methods section, the authors should cross-reference the results section with the methods (in particular data collection) section to make sure that all relevant information is included. For example, the paper would benefit from additional information regarding: selection criteria for providers trained in PPIUD service delivery (was being a woman a selection criterion? Why were 85% of providers from L&D and only 15% from FP? Did providers have prior experience with PPIUD insertion given the national curricula?); how information on client age and parity was obtained; who collected information on provider ease, client anxiety, and client pain (and could this be a source of bias?) and on what tool; how information on follow-up outcomes was documented. The data collection section mentions that data was recorded in government logbooks; however, there seems to be more information that is typically routinely collected in many countries or can easily fit in one logbook. Collecting and extracting service statistics can be challenging and time-consuming, and others may be interested in how so much information was collected for replication. Were registers adapted? Were other tools used? Was the study team able to link all data with unique identifiers (as mentioned) or were there missing data?

Please note that the reference to the two unpublished manuscripts under PPIUD demand creation development may not be placed in the right sentence (the sentence mentions CHWs and providers, but the papers seem to be based on data collected with women and couples).

The paper offers a description of most of the analyses, but a few details are missing. The authors should for example describe the tests used to assess the association between timing of promotion and uptake and consider whether a statistical test is justified. Results on promotion do not seem to include promotion by CHWs. One challenge is that this component was only included later. However, some information on its contribution would be interesting. The authors should also clarify how promotions were counted when the same person was reached more than once. Were they excluded from Table 1 or counted based on the first contact, for example?
If applicable, is the statistical analysis and its interpretation appropriate? The analyses are descriptive and cover the different aspects of the intervention. In some cases, the authors may want to add some information to provide the reader with more insight. Some examples are: breakdown of the 83 providers trained to promote PPIUD by CHWs vs. facility (and by FP, ANC, L&D, IZ); more information on why 10% of providers trained in PPIUD service delivery were not certified (and possibly data on pre- and post-test scores); and women promoted to by CHWs. Additionally, more text that expands on the data presented in the tables, particularly when variation across sites exists, would be helpful. It would also be helpful to spend time in the discussion offering hypotheses for why the type of insertion changed over time and differs from other studies. In particular, the low level of intra-cesarean is notable, especially since the two large hospitals likely do a fair number of cesareans. The authors offer references to show the comparison with other countries but don't offer ideas for why. Much of the gray literature spends time discussing the challenges with training providers to offer the different types of insertion, their comfort level, etc. - this would be an interesting discussion to include here as well.

Figure 2 shows PPIU insertions over time, and the insertion of arrows showing the timing of different events is useful. There is a very clear increase at the beginning of the intervention; however, conclusions regarding the possible effect of adding PBF-incentives or promotion by CHWs (beyond an initial spike) are complicated by the few data points available and staffing changes. In addition, since both PBF-incentives and CHW promotion were added at the same time, it is difficult to separate their possible contributions. More broadly, a few months after each intervention component, the number of insertions seems to decline. This raises questions regarding sustainability (although levels still seem to be above the baseline). It would be interesting to offer potential hypotheses explaining this.

Are all the source data underlying the results available to ensure full reproducibility? The authors submitted a dataset and codebook that seems to include variables related to insertion and follow-up outcomes. The codebook mentions a variable which is a count of promotion contacts but does not seem to include information on type of contacts. Variables related to test scores of providers during training are not provided but are currently not discussed in the paper.

Are the conclusions drawn adequately supported by the results? A lot was accomplished through this project, from intervention development through implementation, reaching many women and inserting thousands of PPIUDs, which is note-worthy given historical challenges with IUD uptake in general, and the service delivery challengers with PPIUD. The conclusions are largely supported by the results and the discussion also draws on other studies for additional context. However, given the design, the authors may want to avoid the word “significantly” in the conclusion. Another area that may benefit from some clarification or rewording is the section on supply. Earlier work in Rwanda already demonstrated that PPIUD is feasible, and the authors should clarify in what way this project adds to earlier evidence. In addition, the authors note there was some (spontaneous?) training and mentoring and highlight this as a sign of sustainability. Additional information on the quality of services provided by the newly trained staff (given the earlier focus on pre- and post-testing and certification) may be useful to support this statement. Likewise, the authors should elaborate as to why PBF-incentives appeared to support providers and facilities, and how this affects sustainability. Overall, given earlier work on PPIUD in Rwanda leading to the development of a national curriculum and
reporting mechanisms but subsequently low levels of uptake (including at one of the facility which was both included in the earlier work and in this study), sustainability is an important question. As noted previously, we would encourage the authors to spend a bit more time describing what components of the intervention were hypothesized to contribute to the sustainability approach, and what evidence supports whether those components were effective. These likely include the stakeholder engagement, champions, cost (it is nice that cost information is included), as well as the extent to which this built on local capacity and past experiences. It would be important to link this study to others in the past, drawing conclusions about what supports sustainable PPIUD services in Rwanda, what else needs to be in place, and what might we expect to see in the future.

**Is the work clearly and accurately presented and does it cite the current literature?**
Partly

**Is the study design appropriate and is the work technically sound?**
Partly

**Are sufficient details of methods and analysis provided to allow replication by others?**
Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**
Partly

**Are all the source data underlying the results available to ensure full reproducibility?**
Yes

**Are the conclusions drawn adequately supported by the results?**
Partly

**Competing Interests:** No competing interests were disclosed.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Reviewer Report 03 September 2018

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One lesson from this paper is that, when change is large and abrupt in the presence of an intervention, a simple before-and-after study is as convincing as a randomized control trial with regards to causal attribution. In the 6 months prior to the intervention only 46 PPIUDs had been inserted. In the 12 months following, the total rose to 2633 at the four study facilities. Clearly, the intervention had a large impact. Moreover, follow-up data indicate a low level of adverse events, such as expulsions, removals and infection. This an important addition to the sparse literature on PPIUDs in low income countries though some aspects of the presentation need improvement.

The single most remarkable result is that 29% of the 9063 women counseled on IUDs and who delivered at one of the facilities had an insertion, the majority of which were post-placental and over 90% before discharge. Previous similar multi-country PPIUD interventions recorded acceptance rates of 2-7% among counseled women (Pfitzer et al. and Pleah et al., both cited in the paper). In view of this huge difference, suspicions are raised about the validity of the estimates of numbers of women counseled. And indeed there are surprising elements in the data on counselling. If I have understood table 1 and the text correctly, 95% of women were counseled only once: 65% in the labour/delivery ward, 20% at ANC, 10% at immunization clinics and 6% postpartum. Given the involvement of community health workers in IUD promotion, this distribution of the timing of counselling is strange and rather disturbing. Can women in the trauma of delivery give fully informed consent? In a busy labour ward, how can accurate records be kept of who does and does not receive counselling? Why were so few women counseled more than once? Surely many of the 1786 women counseled at ANC were also counseled in the L&D ward or was some mechanism in place to avoid duplicated counselling, which could explain the low level (9%) of uptake among those counseled at ANC. The paper would be strengthened if these issues were fully discussed. It would also be helpful to know the total number of deliveries at the 4 facilities during August 2017-July 2018 to place the results in a broader context.

I wonder what role performance-based financing (PBF) played in the success of the intervention. The authors write that a flat sum is routinely paid for FP provision to a new user, regardless of the method. How much is that routine sum? Was the new payment of $1.20 to providers for each insertion instead of the routine sum or in addition to it? How does $1.20 compare to the salaries paid to nurses and midwives?

Two small points: Why use the awkward phrase “promoted to” instead of counseling? The bottom row of table 2 should be labelled “dissatisfied” not satisfied.

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Partly

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Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

**Are the conclusions drawn adequately supported by the results?**
Partly

**Competing Interests:** No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.