RESEARCH NOTE

REVISED Cost per insertion and couple year of protection for postpartum intrauterine devices and implants provided during service scale-up in Kigali, Rwanda [version 4; peer review: 1 approved, 2 approved with reservations]

Previously titled: Cost per insertion and couple year of protection for post-partum intrauterine devices and implants provided during service scale-up in Kigali, Rwanda

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Abstract

Introduction: In two high-volume government hospitals, their two affiliated health facilities, and two additional health facilities, we developed and implemented postpartum intrauterine device (PPIUD) and postpartum (PP) implant promotional counseling and service delivery procedures between May-July 2017 in Kigali, Rwanda. Between August 2017 and July 2018, 9,073 pregnant women received PPIUD/PP implant promotions who later delivered in one of our selected facilities. Of those, 2,633 had PPIUDs inserted, and 955 had PP implants inserted. The goal of the present analysis is to detail implementation expenditures and estimate incremental costs per insertion and couple years of protection (CYP) for PPIUD and PP implant users.

Methods: We detail the incremental costs during the implementation from the health system perspective (including both the implementation costs and the cost of contraceptive methods) and use of standard methods to estimate the cost per insertion and CYP for PPIUD and PP implant users. In addition to the incremental costs of labor and supplies, the costs of promotional activities are included. Research costs for formative work were excluded.

Results: A total of $74,147 USD was spent on the implementation between August 2017 and July 2018. The largest expense (34% of total expenses) went toward personnel, including doctoral-level, administrative, data management and nurse counseling staff. Training for PPIUD and implant

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providers and promoters comprised 8% of total expenses. Recruitment and reimbursements comprised 6% of expenses. Costs of implants to the government comprised 12% of the expenses, much higher than the cost of IUDs (1%). Costs per insertion were $25/PPIUDs and $77/PP implant. Costs per CYP were $6/PPIUDs and $21/PP implant.
Conclusion: Understanding the cost per PPIUD/PP implant inserted and CYP can help to inform the cost of scaling up PPIUD/PP implant service implementation activities and resource allocation decision-making by the Rwandan Ministry of Health.

Keywords
Couple year of protection, post-partum, intrauterine device, contraceptive implant, Rwanda

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Any reports and responses or comments on the article can be found at the end of the article.

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REVISED **Amendments from Version 3**

We appreciate these thoughtful comments which have further improved the manuscript. In the introduction, we clarify that the estimate of 51% unmet need is based on a prospective assessment as a less biased means to predict women's family planning need in the postpartum period. We now highlight in the introduction the sizable opportunity to provide PPFP counseling/services at time points when women are already engaged in the healthcare system. The CYP for the contraceptive methods are now calculated adjusting to remove any 'double coverage' caused by overlap with post-partum non-susceptibility to pregnancy, and we discuss changes in postpartum pregnancy risk as well as frequency of breastfeeding, LAM, and periodic abstinence in this population. Reimbursements for providers were higher for the IUD versus the implant because IUD insertion required additional training and certification time and each IUD takes longer to insert versus an implant. For further context, we now describe (as reported previously and in an upcoming publication), of women to whom we promoted PPFP to who delivered at a study facility, 11% selected the implant and 29% the selected the IUD. The average age and parity of women selecting the IUD or implant, as well as frequency of removals, side-effects, pain/anxiety during insertion, and satisfaction are now reported. An improved understanding of differences in women who uptake the IUD versus implant (versus another method entirely) would be informative for future scale-up, as now mentioned. We clarify that the driver of the difference in implant versus IUD costs are commodity costs. The wide range of cost per CYP estimates from other studies are related to variation across countries in costs of trainings; consumable supplies; instruments; and labor for counseling, insertion, removal, and resupply.

Any further responses from the reviewers can be found at the end of the article

Introduction

Voluntary family planning (FP) is one of the most cost-effective public health interventions, reducing both maternal and child mortality and improving national economies[1]. Postpartum FP in particular is critical to improve maternal-child health via birth limiting and spacing[2]. However, there is high unmet need for family planning in the developing world, especially in postpartum periods. In postpartum periods, 61% of women across 21 low- and middle-income countries experienced unmet need[3], while 95% of women across 5 countries desired to avoid pregnancy for at least 1 year after delivery[4]. In Rwanda, although only 2% of postpartum women report a desire for another child within 2 years of delivery, the unmet need in the postpartum period is 51%[5]. The authors of this analysis defined unmet need for family planning prospectively as a less biased means to predict women's family planning need in the postpartum period. This measure comprised assessment of women's fertility preferences, timing of any desired subsequent pregnancy, and current contraceptive method use[5].

To meet women's postpartum fertility goals and improve maternal-child health via birth spacing or limiting[6], the Rwandan government has made postpartum family planning a key objective of the Rwandan Family Planning 2020 Commitment (Objective 2: 'Scale up the postpartum family planning (PPFP) in all health facilities in Rwanda to increase method choice including access to long term methods…') with the goal of preventing 250,000 unintended pregnancies annually[7]. There is a sizable opportunity to provide PPFP counseling or services among women at timepoints during which they are already engaged in the healthcare system such as during antenatal care (ANC), labor and delivery, and infant vaccination.

Long-acting reversible contraceptive (LARC) methods (the hormonal and copper intrauterine device (IUD) and hormonal implant) are not only the most effective reversible methods (lasting 5–10 and 3–5 years, respectively, with typical use failure rates <1%/year), but are very cost-effective[8–12]. A copper postpartum IUD (PPIUD) can be inserted immediately after delivery of the placenta, during a cesarean delivery, up to 48 hours after childbirth, or beginning at 4 weeks after delivery[13,14] (https://www.mcsprogram.org/resource/pathway-of-opportunities-for-postpartum-women-to-adopt-family-planning/). A postpartum (PP) implant can be inserted any time after delivery (https://www.mcsprogram.org/resource/pathway-of-opportunities-for-postpartum-women-to-adopt-family-planning/). and the WHO Medical Eligibility Criteria were recently revised for postpartum implants[15]. IUDs make up a relatively small share of method use in Rwanda (2.5% of the method mix), while implants make up 16.9% of the method mix (http://www.familyplanning2020.org/entities/81).

This relatively low uptake is thought to be related to lack of method promotions to both women and their male partners as well as limited provider comfort counseling on and delivering these methods[16–20]. Because baseline knowledge about the LARC methods among potential users is lower than for other methods[21–25], demand creation strategies must include comprehensive information addressing method benefits, side-effects, and misconceptions[21,26,27]. To address these issues, funding from a Bill and Melinda Gates Grand Challenge Award was received to improve PPIUD supply and demand in Kigali, Rwanda, with supplementary funding from Emory University to provide PP implant services. Briefly, in two large health centers (providing ANC, family planning, and infant vaccination services), their two adjoining referral hospitals (providing routine and complex labor and delivery), and two additional large health centers (providing ANC, family planning, routine labor and delivery, and infant vaccination services), Emory-based non-governmental organization Projet San Francisco (PSF) developed and implemented PPIUD and PP implant promotional counseling and service delivery procedures in August 2017. The PPIUD and PP implant were promoted during ANC and labor and delivery to target women prior to delivery. Promotions also occurred during infant vaccination visits which have been shown to be an acceptable and high-impact venue to reach postpartum women in Rwanda[28] and are considered a potentially high-impact target for integration since immunization services have broad reach[29]. By July 2018, 9,073 pregnant women received PPIUD/PP implant promotions who later delivered in one of our selected facilities. Of those, 2,633 had PPIUDs inserted, and 955 had PP implants inserted. These published findings represented a significant increase in PPIUD and PP implant uptake versus the 6 months prior to our implementation ($p<0.001$)[30].

The goal of the present analysis is to detail expenditures during the implementation and estimate the incremental cost per PPIUD insertion, PP implant insertion, and couple years of protection (CYP) for PPIUD and PP implant users to inform decision-making by the Ministry of Health and to estimate the cost of scaling up activities. Importantly, in addition to the costs of labor and supplies, the costs of promotional activities are included when calculating the costs and cost-effectiveness estimates of this intervention because postpartum LARCs are still relatively unknown (this is especially true for the IUD for which baseline knowledge is low[21–25]) and require a significant investment in demand creation.

Methods

PPIUD/PP Implant program development and operations

The PPIUD/PP implant intervention (described in detail previously[30]) was developed with input from stakeholders, providers, community health workers (CHW), and couples/clients. Stakeholders included the Rwanda Ministry of Health, the District Mayors, the Rwandan Family Planning Technical Working Group, and clinic directors. Through formative work between May and July 2017, we evaluated knowledge, attitudes, and practices regarding PPIUD/PP implant services among community health workers and providers and clients/couples. This formative work led to the development of intervention operational procedures and a promotional counseling flipchart to be delivered to women or couples. Promotional counseling was conducted primarily by counselors during ANC, labor and delivery, and infant vaccination services or within the community by CHW. In addition, dedicated promoters were hired to administer promotions. In August of 2017, nurses and midwives working in labor and delivery and family planning departments began training in PPIUD insertions (implant insertion training had been previously provided). Clinic staff and CHWs were trained to promote the PPIUD/PP implant services. Follow-up appointments were scheduled for PPIUD clients within 6 weeks after PPIUD insertion (typically coinciding with the 6-week infant vaccination visit).

Pre-intervention postpartum LARC services were conducted by two national PPIUD trainers located at two of our selected district hospitals. One of these national PPIUD trainers was collecting PPIUD insertion and follow-up data in a logbook specifically for PPIUD services. In the 6-months prior to our intervention (from February-July 2017), n=46 PPIUDs were inserted (average of 7.7 insertions/month) and n=182 PP implants were inserted (average of 30.0 insertions/month) in the selected health facilities. The percent increase comparing monthly PPIUD insertions between February-July 2017 to our intervention period of August 2017-July 2018 was 2,687% for PPIUD and 169% for PP implant.

Incremental PPIUD/PP implant program costs

We used a standard, comprehensive micro-costing approach as recommended to calculate the incremental cost of the PPIUD/PP implant intervention from the health system perspective[31]. Using standardized data collection tools, resource use data was collected from expenditure records, study case report forms, and interviews with program implementers. Costs of labor, promotions, and supplies are included as detailed below, and no research costs are included. Thus, the costs included are the incremental costs required to implement the promotional counseling and service delivery intervention above the minimal existing pre-intervention postpartum LARC services described above. Study coordinators and the nurse counselor were responsible for arranging training activities, organizing PPIUD certifications, scheduling providers across the hospitals and health centers, and other implementation logistics. The data manager was responsible for extracting and recording the government logbook data to enable monitoring of PPIUD uptake and occurrence of PPIUD side-effects (e.g., infections) and expulsions. We envision that these would be regular activities required to implement and monitor a large-scale implementation. Part-time salaries and fringe were provided for three Emory staff and the PSF Director. PSF-based personnel included a dedicated physician with part-time support from two project physicians, two study coordinators, a senior nurse counselor, a data manager, and two promotions managers.

Per diems were provided for trainees during training activities. Training costs included the costs of training providers to insert PPIUDs during a 2-day didactic training and mentored practical certification process, and the costs of training PPIUD/PP implant promotional agents. Field travel included travel for Emory-based staff and transportation for local staff. Field travel was required to transport staff to trainings (which would be recurring during future implementation stages) and the implementation clinics. Other field expenses included wire transfer fees, transcription and translation services, and meals during trainings. Transcription and translation services were required to produce implementation tools in two of the main languages spoken in Rwanda (Kinyarwanda and French).

Recruitment/reimbursement expenses began in February/March 2018 and included: PPIUD client transport reimbursement for follow-up visits ($2.29 United States Dollars [USD]/client), reimbursements for CHW promoters ($0.57 USD/client presenting their referral when requesting a PPIUD or PP implant), reimbursements for providers ($1.20 USD/PPIUD and $0.57 USD/PP implant insertion), and reimbursements to the selected facilities for administrative costs associated with implementing the PPIUD/PP implant program ($57 USD/facility/month). Reimbursements for providers were higher for the IUD versus the implant because IUD insertion required additional training and certification time and each IUD takes longer to insert versus an implant. CHW and clinic provider reimbursements used the Rwandan performance-based-financing (PBF) system as a guide[32]. Reimbursements for providers included the cost of providers' time/labor to provide insertions. This was provided to them in addition to their regular salary (the average monthly salary for family planning or labor and delivery nurses is $124-364 USD, depending on their education). Communications expenses included internet and phone airtime for staff. Field consumables/office supplies included specula, forceps, batteries, logbooks, chargers for tablets, PPIUD kits and various office supplies. Tablets were used to collect data from logbooks for quality assurance/control.

We also included the cost of methods (estimated from the prices incurred by the United Nations Population Fund (UNFPA) in 2015 of $0.37 USD per copper T380 IUD and $8.93 USD per Jadelle levonorgestrel rod implant (http://mshpriceguide.org/en/home/), and converted to 2018 USD ($0.39 and $9.49 USD, respectively). Expenditures are reported by activity in 2018 USD.

Only implementation costs related to service provision were included (i.e., we did not include research costs for formative work conducted between May and July 2017). Thus, the expenses presented represent the frontline incremental costs required to implement the program between August 2017 and July 2018 from the health system perspective. No discounting of costs was performed given the short time horizon. We follow the Consolidated Health Economic Evaluation Reporting Standards[31].

PPIUD/PP implant program outcomes

Outcomes of interest include the number of PPIUDs and PP implants inserted and the cumulative couple years of protection (CYP) for PPIUD and PP implant users. CYP is a commonly used estimate of the length of contraceptive protection against pregnancy provided per unit of that method and is estimated at 4.6 for the Copper T380 IUD and 3.8 CYP for Jadelle (5 year) implant[33] (https://www.measureevaluation.org/prh/rh_indicators/family-planning/fp/cyp)

CYP for the contraceptive methods are calculated by adjusting to remove any 'double coverage' caused by overlap with post-partum LAM during our 1 year time horizon. Using Rwandan DHS data, an analysis of sexually active women found pregnancy risk increases from 12% during the first six months postpartum to 53% from 6–12 months (and then decreases to 48% from 12–24 months)[5]. According to this data, during the first 2 years postpartum only 5% of women practice at least periodic abstinence and over 85% of women breastfeed[5]. Per DHS and USAID data, we assumed that all women were conferred protection by LAM during the first 6 months postpartum and that no women were protected by LAM after 6 months; we also assumed that there was no 'double coverage' due to abstinence, which is only practiced periodically[5] (https://www.fhi360.org/sites/default/files/media/documents/postpartum-family-planning-immunization-integration-rwanda-2013.pdf). The estimated CYP for LAM is 0.25 CYP per user (https://www.measureevaluation.org/prh/rh_indicators/family-planning/fp/cyp). Thus, the adjusted CYP for implant in our study is 3.7 and the adjusted CYP for the IUD is 4.5.

Using the incremental cost measures and outcomes of interest, we calculated the cost per PPIUD inserted, cost per PP implant inserted, cost per CYP for PPIUD users, and cost per CYP for PP implant users. No discounting of outcomes was performed given the short time horizon of the 12-month implementation.

Ethical considerations and consent

The Emory University Institutional Review Board (IRB) and the Rwanda National Ethics Committee (RNEC) approved the research component 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 performed in government clinics) was exempt from review.

Results

Raw data for this study are available in Dataset 1[34].

Incremental PPIUD/PP implant program costs

Program costs are summarized in Table 1. A total of $74,147 USD was spent on the implementation between August 2017 and July 2018. The largest expense (34% of total expenses) went toward personnel, including doctoral-level (MD and PhD) staff, and administrative, data management and nurse counseling staff. Trainings for PPIUD and implant promotional counselors and PPIUD providers comprised 8% of total expenses. Recruitment and reimbursements comprised 6% of expenses. Costs of implants to the government comprised 12% of the expenses, much higher than the cost of IUDs (1%).

PPIUD/PP implant program outcomes

Program outcomes are summarized in Table 2. Costs per insertion were $25/PPIUDs and $77/PP implant. Costs per CYP were $6/PPIUDs and $21/PP implant.

Discussion

Our implementation provided services at a cost per insertion of $25 and $77 for the PPIUD and PP implant, respectively, and CYP of $6 and $21 for the PPIUD and PP implant, respectively. Understanding the cost per PPIUD/PP implant inserted can help to inform decision-making by the Ministry of Health and to estimate the cost of scaling up PPIUD/PP implant service

Table 1. Allocation of costs for the PPIUD/PP implant implementation by activity (August 2017–July 2018). Only direct costs included; all costs in 2018 USD.

Costs incurred by implementation team	USD	Percentage of total
Salaries and fringe: PSF and clinic staff	$25,051	34%
Salaries and fringe: Emory employees	$14,225	19%
Trainings	$6,099	8%
Field travel	$5,363	7%
Other field expenses	$5,820	8%
Recruitment/reimbursement	$4,510	6%
Communication	$1,427	2%
Field consumables/office supplies	$1,129	2%
Field facilities	$433	1%
Cost of methods		
Cost of implants*	$9,063	12%
Cost of IUDs*	$1,027	1%
Total Expenses	**$74,147**	

*$0.39/IUD and $9.49/implant (2018 USD). PPIUD, postpartum intrauterine device; PP, postpartum, IUD, intrauterine device; USD, United States Dollars.

Table 2. Outcomes of interest for the PPIUD/PP implant implementation (August 2017–July 2018). All costs in 2018 USD.

IUD outcomes	Value
PPIUDs inserted (N)	2,633
Cumulative CYP for PPIUD users*	11,783
Cost per PPIUD inserted	$25
Cost per CYP for PPIUD users	$6
Implant outcomes	
PP Implants inserted (N)	955
Cumulative CYP for PP implant users*	3,510
Cost per PP implant inserted	$77
Cost per CYP for PP implant users	$21

*Assumes CYP for IUD is 4.5 and for the Jadelle implant is 3.7. PPIUD, postpartum intrauterine device; PP, postpartum; CYP, couple years of protection; USD, United States Dollars.

Table 3. Comparison of CYP for different contraceptive methods (not specifically postpartum) from select studies.

Method	Cost per CYP	Reference
Copper IUD	$1.37-$23.35	35–37
Implant	$4.06-$15.15	36, 37
OCP	$6.88-$31.45	35, 36
DMPA injectables	$7.07	36
Implants and injectables (combined in four of the studies included)	$19.84-$58.54	35

CYP, couple years of protection; IUD, intrauterine device; OCP, oral contraceptive pill; DMPA, depot medroxyprogesterone acetate

implementation activities. Since cost per CYP is a standard and commonly used measure, our estimates of cost of CYP also help the government to determine contraception funding priorities.

For comparison, in a previous study conducted in Rwanda, 478 PPIUDs were inserted over 15 months in 12 sites at an incremental cost of $95,004 USD. After amortization of training costs over three years, investigators estimated outcomes of $110/PPIUD inserted and $24/CYP for the PPIUD[16].

For context, as reported previously[30] and in an upcoming publication, of women to whom we promoted PPFP to who delivered at a study facility, 11% selected the implant and 29% the selected the IUD. The average age of women receiving the IUD was 28.3 (standard deviation=6.0) and the implant was 27.0 (standard deviation =5.6) and average parity of IUD and implant users was 2.4 (standard deviation =1.4) and 2.3 (standard deviation =1.3), respectively. Among those who selected the IUD, 6% were expulsed (of those, 60% had an IUD reinserted and 12% had an implant inserted), 1% were removed, and 0.4% experienced infection[30]. No postpartum implant side-effects were noted. Patients perceptions of anxiety and pain were low for both methods (2/10 on a Likert scale for the implant and 1.8/10 for the IUD), and reported satisfaction was high (>9.5/10)[30]. An improved understanding of differences in women who uptake the IUD versus implant (versus another method entirely) would be informative for future scale up.

Though few additional postpartum contraception studies exist for comparability, other studies (summarized in Table 3) have made estimates of method cost per CYP, though not specifically in postpartum periods. The World Bank estimated that the cost per CYP for reversible modern methods in Ethiopia, Uganda, Burkina Faso, and Cameroon was lowest for the IUD ($4.14-$23.35), while the costs per CYP for oral contraceptive pills (OCPs) ($17.00-$31.45) and implants and injectables ($19.84-$58.54) were much higher[35]. Using data from 13 USAID tier one priority reproductive health countries and service delivery costs, researchers estimated that the cost per CYP was $1.37 for the copper IUD, $4.67 for Sino-Implant, $7.07 for DMPA, $6.88 for combined OCPs, and $4.06 for Jadelle[36]. Finally, a study in Zambia estimated costs per CYP were $8.69 for the IUD and $15.15 for the implant[37]. The wide range of cost per CYP estimates are related to variation across countries in costs of trainings; consumable supplies; instruments; and labor for counseling, insertion, removal, and resupply.

The cost per CYP for the PPIUD and PP implant in our study were within the range of these other non-postpartum focused studies. Although it is difficult to compare estimates of cost per CYP across studies because of different approaches to measuring and including costs and because of the different implementation models used (for example, Neukom *et al.*[37] used a dedicated provider model whereas in our study PPIUD and PP implant services were provided by existing providers in addition to their regular duties with promotions being conducted by those providers and dedicated promoters), these studies indicate that the IUD has the lowest cost per CYP versus other reversible methods, and that estimated costs per CYP are generally higher for the implant versus the IUD, largely because of difference in commodity costs which is the main driver in the difference of the costs of these two methods (http://mshpriceguide.org/en/home/).

Importantly, these studies did not include the cost of demand creation activities. The cost of promotional counseling activities is important for implementers to consider when evaluating postpartum and LARC-focused interventions because postpartum LARCs are still relatively unknown and require a significant investment in demand creation. Studies support that such promotional activities should also educate men[38–41], as done in this study, which incurs additional costs above focusing promotional activities on women alone. Once social diffusion is achieved and the target population is knowledgeable about postpartum LARC methods, demand creation activities can decrease.

While the IUD was promoted in the context of the full range of method options, we dedicated more time to discussing the PPIUD because it is the least well-known method in sub-Saharan Africa, including in Rwanda[22,42–45], which explains the relatively high uptake of the IUD relative to the implant. Other LARC implementation studies have observed that the implant is more popular than the IUD[46,47] but that this trend shifts after focused IUD educational and counseling efforts, community-based and media efforts, and provider refresher IUD trainings[25,48]. Thus, though the IUD is less well-known versus the implant in much of sub-Saharan Africa[22,42,43,45,49] and providers may have lower baseline comfort promoting and inserting IUDs[18–20], concerted promotional counseling and training efforts can be successfully employed as was achieved in these examples and our study to increase IUD demand.

There is very limited literature on the cost of the PP implant, making our findings timely especially in light of the WHO Medical Eligibility Criteria (MEC) updates related to the postpartum implant[15]. Women who are <6 weeks postpartum and breastfeeding can use the implant with a MEC of 2 (meaning the method is generally recommended) while all other women can use the implant regardless of breastfeeding with a MEC of 1 (meaning no restrictions on use). Given the preference for the implant observed in some studies[46,47], if the commodity costs for implants were reduced this method could become even more affordable for health systems to scale-up.

Limitations

Similar to the other studies cited here, we included costs from the health system perspective only; however, we recognize that more detailed costing analyses including the societal perspective including women's time and the value of their time would be informative and may strengthen evidence to increase LARC services (since women are saved time traveling to clinic for OCP refills or 3-monthly injectables). It would have also been informative to estimate the cost per promotional method employed (e.g., promotions occurring during ANC, labor and delivery, infant vaccination, or delivered in the community by CHW), but as many women received multiple promotions from several places and our promotional strategies evolved over time, this was not possible in the present study. Given our short time horizon, we did not amortize our training costs as in another PPIUD/PP implant in Rwanda[16], though the education provided during trainings may translate into service provision over several years in the future; amortization would have decreased our estimated costs per insertion and CYP. We did not collect the data needed to divide the costs of consumables such as specula by their number of uses to arrive at per insertion costs. Additional supplies such as alcohol pads and gauze were among government supplies used and were not measured or included in our calculations. It is not certain whether the cost outcomes estimated here would apply directly larger scale-up activities. We hypothesize that economies of scale may be gained, for example when training a larger number of nurses simultaneously, but it remains to be seen whether quality services can be provided for the same (or reduced) CYP at scale. Finally, our results are most generalizable to sub-Saharan African countries.

Conclusions

There is consensus in the international community that greater investment in postpartum family planning, and the IUD in particular, is needed. We have developed a successful, multi-level intervention that increases PPIUD and PP implant uptake that has relatively low costs per insertion and CYP. Future analyses will explore whether the intervention is cost-effective (or potentially cost-saving).

Data availability

Underlying data are available from Harvard Dataverse. Dataset 1: Replication Data for an interim evaluation of a multi-level intervention to improve postpartum intrauterine device (PPIUD) services in Rwanda (https://doi.org/10.7910/DVN/WLZ7PC)[34].

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Open Peer Review

Current Peer Review Status: ? ✓ ?

Version 4

Reviewer Report 14 April 2020

https://doi.org/10.21956/gatesopenres.14293.r28636

✓ **Kate H. Rademacher**
FHI 360, Durham, NC, USA

Thank you for addressing these comments and for your thoughtful responses.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Family planning, reproductive health, costing, LARCs, LNG IUS, PPFP, FP-Immunization-integration

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.

Version 3

Reviewer Report 09 September 2019

https://doi.org/10.21956/gatesopenres.14061.r27631

? **Aisha N.Z. Dasgupta**
United Nations Population Division, New York, NY, USA

Thank you for the opportunity to review this paper, which provides useful insights into cost per method, and cost per CYP, for postpartum IUD/implants. It is a helpful contribution to the literature because of the

evidence around value for money of such projects. I recommend Approval with reservations.

Introduction:

- In the first paragraph, I was at times a little confused when you write about unmet need during the postpartum period. Is this about need at that particular point in time based on prospective fertility intentions, or were women determined to have unmet need based on their retrospective fertility intentions regarding their current pregnancy/most recent birth? For example, “In Rwanda, although only 2% of postpartum women report a desire for another child within 2 years of delivery, the unmet need in the postpartum period is 51%”. Is this 51% based on prospective fertility intentions which suggests a current unmet need? Or is some of this 51% based on the retrospective fertility intentions regarding the most recent birth? This is important to know as it influences how to interpret such a figure. If a notable portion of the 51% is based on retrospective fertility intentions, then it does not necessarily follow that postpartum family planning services is the answer to addressing high levels of unmet need, as these postpartum women might not be currently at risk of unintended pregnancy. Instead it could point to a general failure of services that lead to women having an unintended pregnancy (not necessarily during the postpartum period) who then appear in the unmet need estimate simply based on their retrospective reports of fertility intentions. I think it is important to know, because it helps us to understand exposure to unintended pregnancy during the postpartum period (I come back to this again later), and justifies the interest in the postpartum period and any related postpartum FP interventions.

- Related to this, perhaps the authors could point to other reasons why there is interest in interventions during the postpartum period. E.g. an opportunity to engage with and target women as they are typically already in contact with the health care system for themselves and their infants (ANC, labor/delivery, vaccinations etc.).

- A general comment for the paper: My main reservation is there is no mention of the risk of pregnancy in this population during the postpartum period, and the implications for the analysis. For example, I would like to know a little more information about any practice of postpartum abstinence, and how long is postpartum amenorrhea? What are the breastfeeding practices in this population? It would be possible to provide this type of information on duration of postpartum insusceptibility from the Demographic and Health Survey and perhaps other sources. I took a quick look at the 2014-2015 DHS and it looks like women are either still amenorrheic or still abstaining for around one year.

- As the authors explain, a strength of LARCs is they can provide protection for 5-10 (IUD) and 3-5 (implant) years, and the CYP is 4.6 for IUD and 3.8 for implant. But, is it fair to claim full CYPs in this analysis, when it is known that the population being provided with IUDs and implants are on average at lower risk of pregnancy, at least for around the first year postpartum? This is a limitation of the analysis and should be acknowledged in the discussion.

Methods:

- Could you comment on the reimbursements to promoters and providers and why it was different for the two methods? What kinds of incentives did this create and could it have influenced which method was being recommended to potential clients?

Results:

- There is an impressive number of study participants. Could you give any information on number of refusals to participate in the study? Is there any information on IUD/implant

removals/discontinuation, side-effects, dissatisfaction?

- The results section seems a little thin. I was curious to know anything about the clients that were reached – is there any demographic information – age, marital status, education, wealth – anything? Were there any differences between implant/IUD users, in terms of background characteristics? This might help the reader to understand the value for money in terms of the two methods, particularly if one method was more popular with a hard-to-reach group.

- Could you provide a little more understanding of why implants were more expensive? Is this only because the commodity is more expensive, or were there other factors as well? Would the cost per PP implant have been lower, if a larger number of clients had been reached?

Discussion:

- I note in Table 3 such a wide range of estimates of cost per CYP for IUD, which is quite hard to interpret. In Table 3, should the title of the table and/or the column title be “cost per CYP”, rather than “CYP”? Perhaps you could also provide a column providing the CYP itself for each of these methods.

- “**The CYP** for the PPIUD and PP implant in our study were within the range of these other non-postpartum focused studies.” Do you mean the “cost per CYP”?

- I appreciate your second-to-last paragraph in the discussion, on the possibility of IUDs in sub-Saharan Africa.

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

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

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

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

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.

Reviewer Expertise: Demography, family planning

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.

Author Response 26 Feb 2020

Kristin Wall, Emory University, Atlanta, USA

We appreciate these thoughtful comments which have further improved the manuscript.

In the introduction, we clarify that the estimate of 51% unmet need is based on a prospective assessment as a less biased means to predict women's family planning need in the postpartum period. We now highlight in the introduction the sizeable opportunity to provide PPFP counseling/services at timepoints when women are already engaged in the healthcare system. The CYP for the contraceptive methods are now calculated adjusting to remove any 'double coverage' caused by overlap with post-partum insusceptibility, and we discuss changes in postpartum pregnancy risk as well as frequency of breastfeeding, LAM, and periodic abstinence in this population. Reimbursements for providers were higher for the IUD versus the implant because IUD insertion required additional training and certification time and each IUD takes longer to insert versus an implant. For further context, we now describe (as reported previously and in an upcoming publication), of women to whom we promoted PPFP to who delivered at a study facility, 11% selected the implant and 29% the selected the IUD. The average age and parity of women selecting the IUD or implant, as well as frequency of removals, side-effects, pain/anxiety during insertion, and satisfaction are now reported. An improved understanding of differences in women who uptake the IUD versus implant (versus another method entirely) would be informative for future scale-up, as now mentioned. We clarify that the driver of the difference in implant versus IUD costs are commodity costs. The wide range of cost per CYP estimates from other studies are related to variation across countries in costs of trainings; consumable supplies; instruments; and labor for counseling, insertion, removal, and resupply.

Competing Interests: No competing interests were disclosed.

Version 2

Reviewer Report 19 March 2019

https://doi.org/10.21956/gatesopenres.14020.r26919

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Kate H. Rademacher
FHI 360, Durham, NC, USA

The authors made substantial improvements in this version of the paper. Thank you for revising.

As part of this, thank you for clarifying that the cost analysis described in the paper did not include the costs of implementing the research. However, I am still confused why salaries for "study coordinators" and "data managers" were included – these sound like they were costs associated with research. Please

clarify, and revise analysis if needed.

In addition, here are some other more minor comments:

- Introduction – consider a transition sentence between the first two sentences – e.g. discuss the benefits of PPFP. Also, in the third sentence, please clarify that citation #3 refers to a study that took place in 5 countries (not the 21 that you referenced earlier in the sentence – citation #2).

- Introduction – most hormonal IUD products are registered for 5 years duration. Please clarify in text.

- Introduction – you state that IUDs and implants make up "a relatively small share of method use in Rwanda." However, I'm not sure it's fair to lump these two methods together as 17% for implants seems like a relatively high proportion. Rwanda was not included in the analysis in this recent paper by Jacobstein (2018[1]), but still it would be good to more fully acknowledge the growing popularity and use of implants in SSA.

- Note some minor typos – e.g. name of Project San Francisco – "project" is misspelled.

- Discussion section – I would include mention of this study among PP women in Rwanda: Dulli *et al.* (2016[2]). Related to this suggestion, it sounds like promotion of PPIUD and PP implants in your intervention occurred in part in clinics which offer child immunization services. You may want to highlight this because FP-Immunization integration is considered a "promising" High Impact Practice by USAID, UFNPA and others. See here: https://www.fphighimpactpractices.org/briefs/family-planning-and-immunization-integration/.
- Discussion – you noted that in your intervention you "focused your promotions on the IUD" – please clarify the meaning here, as it is important to clarify if the IUD was promoted in the context of full method choice.

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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?
Partly

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Family planning, health economics, long-acting reversible methods, postpartum family planning and immunization integration

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.

Version 1

Reviewer Report 17 December 2018

https://doi.org/10.21956/gatesopenres.13941.r26758

Kate H. Rademacher
FHI 360, Durham, NC, USA

Postpartum family planning is a very timely and important topic, and I appreciate the authors efforts to conduct a costing analysis of the PPIUD and PP-implant intervention described. However, I have substantial concerns about the methods described, and therefore am not recommending indexing of the article in its current format. I encourage the authors to consider re-doing the costing analysis to incorporate the feedback below.

A summary of my concerns about the methods are as follows:

1. The authors say that they use “a standard, comprehensive micro-costing approach as recommended to calculate the net cost of the PPIUD/PP implant intervention from the payer perspective.” They reference the CHEERS economic standards described in the paper by Husereau et al. However, in the paper by Husereau et al, there is no recommendation for calculating “net costs” which is what the authors say they did. Instead, in the CHEERS checklist in the Husereau et al. paper, they indicate that *incremental* costs should be calculated/reported. The reporting of "net costs" begs the question net of what? I encourage the authors to re-do the analysis and report incremental costs of the intervention (see comment #2 below for more on this).

2. The biggest concern I have about the methods is that it appears that research costs were included in the cost calculation. This is not typical in a micro-costing analysis like this. Typically, only the incremental costs of the intervention itself are included in a costing analysis (unless the authors

expect the research component to continue as part of the standard way that the service is provided moving forward). As such, I would not include costs in your analysis such as salaries for researchers, salaries for study coordinators, travel for research staff, tablets (if used for data collection), transcription of research interviews, etc.

3. In addition to the issues noted above, the authors indicate that they are reporting from the "payer" perspective but they do not indicate who the "payer" is. The client? The health system? This is important because some costs that were included in the analysis should potentially be removed depending on who the payer is. For example, if you're reporting costs from the health system perspective, then the "client transport reimbursement for follow-up visits" should not be included if that is a cost only incurred by the woman.

4. A smaller comment: please also indicate if costs of consumables/ supplies (such as specula, forceps) were divided by an estimated number of uses to get a per insertion cost.

5. Related to #2 above, the authors conclude that the results can "inform decision-making…to estimate the cost of scaling up activities." But is unclear if/how the intervention costs would differ from scale-up costs. It would be helpful to know which components of the intervention, if any, were only included in the pilot phase vs. would be included in potential later scale-up phase(s).

6. The authors make the statement that "The PPIUD/PP implant service implementation provided services at a low cost per insertion and CYP.". However, it not clear what comparison is used to draw this conclusion. Low compared to what? In the Discussion section, the authors compare the costs to another PPIUD study in Rwanda and indeed, the cost per insertion and cost per CYP of the PPIUD was lower in the intervention described in this paper than in the previous anlaysis. But what about the cost of the PP-implant described in this paper? That cost is relatively quite high compared to the PPIUD and the authors do not comment on that. Other data from the World Bank and another paper by Tumlinson et al also cited, but it is not clear which of these data are being used for the comparison to the results described in this paper. One potential take-away is that the cost of the PP-IUD is much lower the cost of PP-implants. There is not much in the literature about the cost of provision of PP-implants given that the WHO Medical Eligibility Criteria (MEC) was recently updated regarding PP provision of implant, so a discussion about this would be a valuable addition to the literature.

Additional smaller comments:

- In the first paragraph of the introduction, the following statement is made: "In post-partum periods, 50–90% of women experience unmet need, while 95% of women desire to avoid pregnancy for at least 1 year after delivery." However, the research that is cited (Pasha et al.) only includes data from five countries whereas the statement the authors make is very broad. Consider revising to clarify. Also, see paper with analysis of data from 21 countries by Moore Z *et al*. (2015)[1].

- Introduction – authors should acknowledge that WHO MEC was recently updated regarding PP insertion of implants[2].

- In the third paragraph of the Introduction– the category of LARCs also includes the hormonal IUD (the LNG-IUS). Suggest revision to acknowledge this; it could just be a footnote.

- Introduction – citation 7 – This is a white paper form 2005. there are many more recent papers that document the effectiveness and cost-effectiveness of FP methods. Suggest replacing with a more

recent citation.

- Note that the analysis in the paper in citation #18 by Tumlinson et al was updated in a more recent paper. I encourage you replacing the data/citation here this this more recent work. See: Rademacher *et al.* (2016)[3].

- In the Ethics section, it was confusing how the focus group discussions and surveys related to the costing component, if at all. Consider revising to clarify.

- I realize that you describe the intervention in-depth in another paper, but I suggest that you clarify in this article what the baseline service delivery model was for PPFP at the sites before the intervention was introduced. That will allow you describe and calculate the incremental costs of the new PPIUD and PP-implant intervention being evaluated.

- The Neukom et al paper that is cited (Citation #18) used a dedicated provider model. Related to point above, it would be good to clarify if dedicated providers were employed as part of the intervention, or it PPIUD and PP-implant were added to the scope of work for existing providers at the facilities. If it was the latter, this would not be a fair comparison to the costs described in the Neukom et al paper as the models are different. And again, the key is to calculate the incremental costs of the intervention you described – so only the incremental costs of having providers add PPIUD/PP-implants to their service package.

Thank you for the chance to review. Again, this is an important topic, and I hope the authors will consider revising and re-submitting.

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2. Medical eligibility criteria for contraceptive use: Fifth Edition. *World Health Organisation*. 2015.
3. Rademacher K, Solomon M, Brett T, Bratt J, et al.: Expanding Access to a New, More Affordable Levonorgestrel Intrauterine System in Kenya: Service Delivery Costs Compared With Other Contraceptive Methods and Perspectives of Key Opinion Leaders. *Global Health: Science and Practice*. 2016; **4** (Supplement 2): S83-S93 Publisher Full Text

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?
No

Are sufficient details of methods and analysis provided to allow replication by others?
No

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

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

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Family planning, health economics, long-acting reversible methods, postpartum family planning and immunization integration

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Reviewer Report 03 September 2018

https://doi.org/10.21956/gatesopenres.13941.r26628

?

Katherine Tumlinson
Department of Maternal and Child Health, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Overall: This is a well-written paper that makes a valuable contribution to the current body of literature by describing the cost per couple year of protection of LARC methods in Rwanda, after factoring in the cost of activities/materials designed to increase demand for these methods.

I would encourage the authors to be more explicit about why such promotional activities are necessary for LARCs and why it is important to factor in the cost of promotional/demand-creation activities when calculating CYP for LARCs.

I would also encourage the authors to include the cost of labor and supplies required for LARC insertion in their calculation of LARC CYPs (or to make this more explicit if they have already done so).

Additionally, in the discussion section, I would encourage the authors to present the data comparing the CYP of other methods in a visual format so that readers can more easily interpret the results presented in this paper relative to the CYPs of shorter-acting methods or other LARC + promotion CYP calculations.

These recommendations are described in more detail below, along with more minor suggestions. Once these concerns are addressed, I strongly recommend indexing. Thank you for the opportunity to review this paper.

Abstract:

1. The introduction presents the results of the parent study/intervention which was designed to increase demand for LARCs within a small number of facilities in Kigali. I encourage the authors to re-write this paragraph to better lay the foundation for the specific goal of this current paper. The

authors may want to consider a short statement of the high unmet need during the postpartum period and the low prevalence of LARCs and the value of better understanding CYP for LARCs after factoring in the cost of promotional/demand-creation activities.

2. Similarly, the methods section of the abstract falls a little bit short; it would be helpful to indicate that the authors utilized a standardized method for calculating net cost of the intervention.

Introduction:

1. Overall the introduction is very well written and pleasantly concise. However, I would recommend insertion of a short paragraph that helps the readers to understand a key challenge of LARCs: promotional or demand creation activities are often necessary to increase uptake. Few prior studies (to my knowledge) have been able to calculate a CYP for a LARC that includes the cost of these demand creation activities. This is an important strength of this paper and should be highlighted.

2. An additional recommendation for the introduction involves the description of the parent study/intervention. In the second sentence of paragraph four, the authors briefly describe the results of the parent study in terms of the enormous increase in uptake. This is important information; however, it feels as if the authors have cut and paste from the abstract of the prior paper and – on first glance – it was confusing as I didn't realize the authors were describing the intervention study and I mistakenly thought the results of the current paper were being summarized in the introduction. I recommend revisions so that this paragraph does a better job of explaining that there was a parent study/intervention that was found to be enormously successful in increasing the uptake of LARCs in select Kigali facilities and now the authors are writing this paper with the goal of understanding the CYP of LARCs, factoring in the cost of these very effective promotional activities.

Methods:

1. I would consider moving the first paragraph (ethics) to the end of the methods section, if possible. I was confused to read about focus group discussions in the first sentence, since I didn't yet understand that formative research was done prior to designing effective promotional activities, neither of which are the real focus of this paper.

2. Are there available data on the cost of the supplies needed for insertion and the cost of provider's time for insertion? For example, in a paper I wrote (which the authors cite, reference #17) that included CYP of various methods, we included the cost of supplies ($1.24) and labor (2.91) when calculating CYP for Sino-Implant ($12.10 total direct cost). I see the authors include "reimbursements for providers" but it's not clear if this is the cost of labor (and, if so, it seems low). I also see consumables and supplies which appear to include specula and forceps, but I imagine there may be other supplies needed, for example alcohol pads, gauze/bandage, etc. It should not be difficult to obtain this data if not currently in hand.

Results: Excellent and concise presentation of exciting results!

Discussion: Again, well written and compelling. I have just a few suggestions for improvement:

1. The authors discuss data from a prior study in Rwanda and also recent World Bank data collected across multiple countries. Is it possible to present any of these data in a visual format alongside the results of this paper? It appears that the promotional approach used in the intervention study represents an improvement over prior efforts to increase LARC uptake in Rwanda – 3500 LARCs were inserted within one year in just 6 facilities and the total cost was under $75k. Can the authors

create a graph that compares CYP from this study to the CYP from the FHI study so that readers can quickly see/digest that the CYP in this study was about one-fifth of the prior FHI study?

2. Can the authors present their calculated CYP for LARCs in a graph alongside the current CYP for shorter-term methods in Rwanda? This could help to highlight important differences in CYP across methods and make the case for larger investment in LARCs (or, at least, IUDs) as well as scaling up of the promotional flip-chart and training activities incorporated in the parent intervention.

3. When discussing the World Bank and USAID data, the authors should also indicate whether these prior studies included the cost of any demand generation activities (probably not).

4. In the last paragraph, prior to discussing limitations, the authors discuss the overall finding that IUDs represent significant cost savings over implants, largely due to the difference in the cost of the commodities. Some may argue, however, that IUDs represent a more difficult “sell” because they are more invasive (and painful?) to insert. Yet numerous women in the current study opted for the IUD over the Implant. Could the authors include data that might explain the comparative popularity of the IUD over the Implant among women in this study and discuss any implications?

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

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

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

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?
Yes

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.