



RESEARCH ARTICLE

REVISED Introduction of subcutaneous depot medroxyprogesterone acetate through use of community-based distributors in Zambia [version 2; peer review: 1 approved, 1 approved with reservations, 1 not approved]

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v2 First published: 28 May 2019, 3:1474
<https://doi.org/10.12688/gatesopenres.13020.1>
 Latest published: 04 Jun 2020, 3:1474
<https://doi.org/10.12688/gatesopenres.13020.2>

Abstract

Background: The majority of women in Sub-Saharan countries including Zambia use intramuscular Depot Medroxyprogesterone Acetate (DMPA IM) as their preferred method of contraception. However, nearly one-third of the women who start on DMPA IM discontinue within 12 months due to access barriers. Sayana® Press, low-dose, prefilled subcutaneous depot medroxyprogesterone acetate (DMPA-SC), suitable for even lower-level healthcare providers and potential for self-injection administration, has been developed. This pilot aimed to understand the feasibility of DMPA-SC in Zambia through use of community-based distributors (CBDs).

Methods: The pilot was implemented from May 2017 to July 2017 in 29 public health facilities in three districts. A total of 161 CBDs received a comprehensive training in DMPA-SC, which included counselling about the method, potential side effects, correct administration and waste management. Post-training mentorship and supervision was conducted. Routine client level data was collected through Ministry of Health management information system.

Results: During the pilot, 12,818 clients were provided with modern voluntary FP methods, with 16.4% (2,100) opting for DMPA-SC. The age range of clients opting for DMPA-SC was between 15 and 50 years, with an average of 31 years. Slightly less than half (43%) of DMPA-SC clients were adolescents and young women, with 11% aged

Open Peer Review

Approval Status

	1	2	3
version 2			
(revision)			
04 Jun 2020	view	view	
version 1			
28 May 2019	view	view	view

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

15–19 and 32% aged 20–24. No adverse events were reported during or immediately subsequent to the introduction of DMPA-SC administration by CBDs.

Conclusion: The pilot demonstrated that CBDs can safely provide DMPA-SC at the community level with appropriate public sector coordination and oversight.

Keywords

Feasibility, Introduction, Distribution, DMPA-SC, Community level, Zambia

This article is included in the [International](#)



[Conference on Family Planning](#) gateway.

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Competing interests: No competing interests were disclosed.

Grant information: This study was funded by the United States Agency for International Development (USAID) under the terms of Award No. AID-611-A-15-00001 (Sexual and Reproductive Health for All Initiative - SARAI). The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of USAID. Publication of this study was sponsored by The Bill and Melinda Gates Foundation (Investment ID: OPP1181398).

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

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How to cite this article: Phiri J, Smith GM, Tembo F *et al.* **Introduction of subcutaneous depot medroxyprogesterone acetate through use of community-based distributors in Zambia [version 2; peer review: 1 approved, 1 approved with reservations, 1 not approved]** Gates Open Research 2020, 3:1474 <https://doi.org/10.12688/gatesopenres.13020.2>

First published: 28 May 2019, 3:1474 <https://doi.org/10.12688/gatesopenres.13020.1>

REVISED Amendments from Version 1

Following key edits were made to the manuscript prompted by peer review comments:

1. Clarity in the Pilot description
2. Details of CBD profiles before the beginning of the pilot
3. Clarity on definition of a 'model facility' and 'adverse event'
4. Deletion and replacement of Figure 2 to show the age groups of clients who switched from other methods to DMPA-SC
5. Clarity on the results and conclusion for the determination that CBDs were safely able to administer DMPA-SC
6. Reviewed the manuscript for typos, as well as rewording of some sentences/paragraphs.

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

Introduction

Over the last decade, the modern contraceptive prevalence rate (mCPR) in Zambia has increased from 25% to 45%. Despite this increase, unmet need for family planning (FP) stands at 21%¹. Like other Sub-Saharan countries, injectable contraceptives are the most widely used modern method among currently married women in Zambia¹⁻³. However, nearly one-third of the women who start on contraceptive injectables discontinue within the first year of use, partly due to access barriers such as long distances between a woman's home and a health facility⁴. In response to the aforementioned, the Zambian Ministry of Health (MoH) introduced community-based distribution of short-term FP methods, including administering of injectable contraceptives by community-based distributors (CBDs)².

Subcutaneous depot medroxyprogesterone acetate (DMPA-SC), brand name Sayana® Press, is a contraceptive injectable that uses a combination of low-dose DMPA in a pre-filled Uniject® system that eliminates preparation of needle and syringe⁵. With its unique Uniject® feature coupled with minimum level of training and supervision, DMPA-SC can be easily transported and safely administered by lower-level healthcare providers, including community health workers, and even self-administered by women themselves; thus, it may increase access to injectable contraceptives and improve method continuation, and ultimately address unmet need for FP⁴. Evidence from other similar pilots has shown that DMPA-SC is safe, acceptable and feasible in low- and middle-income country (LMIC) settings⁶⁻¹⁰.

In 2017, Society for Family Health – Zambia (SFH) a non-governmental organization in partnership with the Zambian MoH, Population Services International (PSI), ChildFund International and Development Aid from People to People (DAPP), conducted a pilot introduction of DMPA-SC in Zambia. This pilot was part of a five-year (2015–2020) United States Agency for International Development (USAID)-funded project titled *Sexual and Reproductive Health for All Initiative* (SARAI). The pilot aimed at understanding the feasibility of introduction community-based distribution of DMPA-SC in the community through use of CBDs.

Methods

Ethics statement

Ethics approval (REF No. 006-12-13) to conduct the pilot was obtained from The University of Zambia Biomedical Research Ethics Committee (UNZAREC) to analyse routine client-level data on reproductive health. On consideration that SARAI was already being implemented in the pilot health facilities and that FP clients would be served as per routine by CBDs during project implantation, the ethics committee waived the need for participant consent. 'Participant' in this context refers to CBDs who were already volunteering for the project as well as clients who would receive DMPA-SC as an additional choice to the FP method mix that existed at the time.

Pilot description

The pilot was conducted from May 2017 to July 2017 in 29 SARAI-supported public health facilities across three districts (Kalulushi, Mafinga and Kawambwa). Voluntary FP services were routinely offered with established community-based distribution programs in which CBDs provided Intramuscular depot medroxyprogesterone acetate (DMPA-IM), oral pills and condoms.

At the time of the pilot, CBDs in Zambia were only authorized to distribute contraceptives other than condoms to returning clients only. This was a deliberate regulation by the Ministry of Health to ensure that only eligible clients, assessed by professional health workers were provided with appropriate FP services as new users. CBDs were part of community volunteers, who could read and write in English without necessarily having any medical or clinical background. They were provided with basic training and were observed for competence in provision of a particular health service within the catchment of their communities. In cases where CBDs encountered clients who had never used any modern contraception before, they provided general sexual and reproductive health counselling and refer such clients to a nearest health facility for eligibility assessment and possible commencement of FP services.

Sample selection

The pilot was implemented only in public health facilities that met the criteria of a "model facility" under SARAI. The project defined a model facility as one that encompasses the key components and systems needed at the community level to respond effectively to the family planning needs of the population. These systems included, skilled service providers; expanded method mix; client-centered care offering age appropriate information, outreach to vulnerable populations; supervision; mentoring for health care providers; youth and adolescent reproductive health services; community involvement through organized and trained community members who mostly are volunteers and data collection and analysis to track progress. Model facilities were selected because the project had already established necessary structures at facility and district levels to monitor and supervise community-based distribution of FP commodities. The CBD model under SARAI in Zambia is implemented in a way that CBDs operate in the

peripherals of the catchment area of a health facility to distribute FP commodities and messaging. Each CBD is accountable to a nearby supervising facility and they submit monthly distribution and stock reports to the supervisors. All CBDs (163) in all model health facilities (29) supported by SARAI were selected to participate in the pilot.

Training

A cascaded training approach was implemented which allowed introduction of DMPA-SC at all levels of the health system. In November 2016, prior to the pilot a 3-day training session for 25 national-level MoH master trainers drawn from all 10 provinces of Zambia was conducted. DMPA-SC master trainers with SRH expertise and experience drawn from key departments of the ministry of health were engaged to train 35 CBD supervisors drawn from three pilot implementing districts namely Kalulushi (13 supervisors), Kawambwa (12 supervisors) and Mafinga (10 supervisors). These supervisors included MoH health facility-based CBD supervisors and district-level supervisors with the following roles:

- i. Post-training supervision to ensure CBDs attain proficiency
- ii. Ensure CBDs adhere to injection safety standards
- iii. Facilitate accurate data management and record keeping
- iv. Commodity stock management
- v. Monitoring and management of adverse events

There was 3 days of DMPA-SC training for 163 CBDs from implementing facilities, representing an average of five CBDs per facility, conducted. This training was in addition to the DMPA-IM training which was conducted prior to the pilot.

Post-training mentorship and supervision

Each CBD was attached to a health facility, where he/she was to provide at least five DMPA-SC injections under supervision before being allowed to practice in the community. The standard MoH DMPA-SC injection step by step procedure was used to assess CBD competency in injection safety. Supervisors also conducted regular field-level supervision, which focused on data management and safe disposal of clinical waste, once a week for facility-based and twice a month for district health office-based supervisors. This supervision focused on safety of clients and CBDs during the administration of injections, data management and safe disposal of clinical waste. In order to comprehensively assess the pilot and draw lessons from the pilot, the National Family Planning Technical Working Group (NFPTWG) under the ministry of health conducted onsite monitoring visits to all implanting districts. The NFPTWG observed CBDs administering injections to clients, inspected storage sites for commodities stored by CBDs and assessed the clinical waste disposal process from the point of generation to the point of final disposal. The assessment measured safety of clients and CBDs based absence of injury during administration of injections, absence of AEs as well as safe disposal of clinical waste.

The NFPTWG also conducted in-person interviews with CBD supervisors as well as clients to obtain their views on the pilot.

Stock management

Stock consumption data obtained from the health information management system of the ministry of health for the three months (February-April 2017) that preceded the pilot showed that on average, each CBD administered 10 doses of DMPA-IM per month. Therefore, based on that precedence, each CBD was issued with 10 doses of DMPA-SC as initial post training stock. In order to avoid possible commodity stock out, each facility was given 30 doses as buffer stock. All CBDs were advised to re-order once 50% of stock on hand was used up. In addition, all CBDs were supplied with stock-tracking forms and were given lockable wooden boxes for storing commodities. Throughout the three months of the pilot, a total of 6,530 DMPA-SC doses were issued to implementing districts.

Waste management

All trained CBDs were provided with supplies for waste management, including sharps boxes, buckets and bin liners. In line with MOH policy, CBDs ferried all waste generated during service provision to the nearest health facility for final disposal once the bin liners were three quarters full.

Adverse event (AE) management

The pilot developed a framework for identifying, monitoring and real time reporting of AE's. CBDs received training to identify, analyze and classify AEs in terms of nature and cause. An adverse event in this context refers to severe side effects from using the method. A referral system was established between the CBDs and the nearest health facility to link clients with suspected AEs.

Data collection and analysis

CBDs captured client level data on clients receiving DMPA-SC doses using standard MoH registers, which had been adapted to include DMPA-SC as a new FP method. Demographic (i.e., age) and service information (i.e., client type and switching behaviours) for clients that voluntarily opted for reproductive health services, particularly DMPA-SC, were extracted from the registers and entered into Microsoft Excel software. For analysis, the study used data without personal identifying information for clients and were part of routine data collection during project implementation. IRB approval to use this level of data was obtained. Data analysis which included generation of descriptive statistics through tables, graphs cross-tabulations and frequencies was conducted using Statistical Package for Social Sciences (SPSS) version 21. CBDs characteristics data were collected by the project upon completion of the initial FP service provision training which was conducted prior to the pilot and were updated at the time of DMPA-SC training.

Pilot Limitations

The pilot only focused on SARAI supported facilities that met the prescribed criteria for a 'mode facility', therefore, findings may not be generalized.

Results

Of the 163 CBDs, 161 successfully completed the training; two CBDs discontinued due to personal reasons.

CBD characteristics

All the CBDs trained had previous training in FP counseling, distribution of oral pills and condoms and administration of DMPA-IM and were providing these services in the catchment of their communities prior to the pilot period. Below are the characteristics of the CBDs. Characteristics of CBDs that completed training are shown in [Table 1](#).

FP Provision during pilot period

A total of 12,818 clients were provided with various FP methods/products during the pilot period as shown in [Figure 1](#).

The majority of the clients (37%) were provided with male condoms while combined oral contraceptives at 5% accounted for the least method provided. DMPA-SC clients accounted for 16%

of all the clients seen during the pilot period. Overall, clients that received injectable contraceptives (i.e., DMPA IM & SC) accounted for nearly half (i.e. 48%) of all the clients provided with FP methods/products during the pilot period.

Pilot results showed a 17% increase in the number of injectable DMPA (IM and SC) doses provided during the pilot period compared to the total for the three months preceding the pilot. [Table 2](#) below compares FP provision before and during the DMPA-SC pilot.

Before the DMPA-SC pilot was introduced, each CBD distributed an average of 10 doses of injectable DMPA-IM per month. After the DMPA-SC pilot was introduced, each CBD provided an average of 13 doses of injectable DMPA per month (i.e., DMPA-SC=5, DMPA IM=8).

Number of clients who switched from other methods to DMPA-SC

Out the 2,100 clients who were provided with DMPA-SC, 2,037 substituted their previous methods with DMPA-SC while the rest were new acceptors with no previous method. [Figure 2](#) below shows the number of clients who switched from other FP methods to DMPA-SC disaggregated by age group.

Table 1. Community-based distributor (CBD) characteristics.

Variable	CBDs, N*
Total trained in DMPA-SC	161
Gender	
Male	66
Female	95
Education	
Primary	21
Secondary	140
Average age, years	35
Previous trained in DMPA-IM	161

*Unless indicated. DMPA-IM, intramuscular depot medroxyprogesterone acetate.

Table 2. Family planning provision before and after subcutaneous depot medroxyprogesterone acetate (DMPA-SC) introduction.

Variable	Prior to pilot (3 months)	Pilot period (3 months)
DMPA-SC doses	N/A	2,100
DMPA-IM doses	5,284	4,090
Total DMPA	5,284	6,190
# of CBDs	163	161
Avg. DMPA doses/3 months	32	38
Avg. DMPA doses/month	11	13

DMPA-IM, intramuscular DMPA; CBD, community-based distributor.

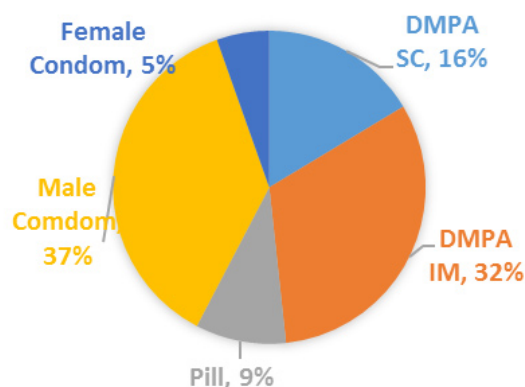


Figure 1. Percentage distribution of clients provided with family planning methods (N=12,818).

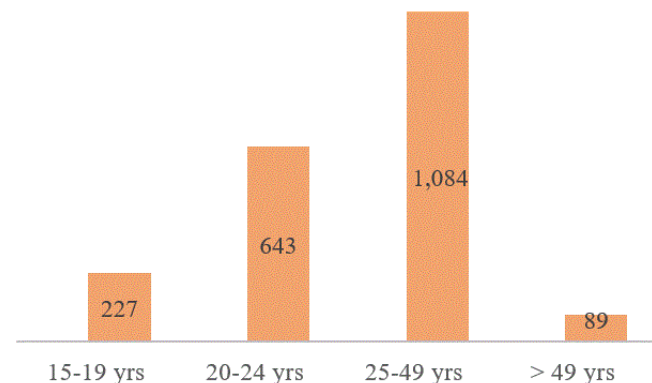


Figure 2. No. of Clients who switched from other FP methods to DMPA-SC (N = 2,037). IM, intramuscular.

DMPA-SC clients by age distribution

Nearly half (43%) of the DMPA-SC clients were adolescents and young women below the age of 25. Figure 3 shows DMPA clients by age distribution.

DMPA-SC provided by client type

The Majority of DMPA-SC clients (about 97%) were revisits on FP, while only 3% of DMPA-SC users were new acceptors, as indicated in Figure 4.

Proportion of clients switching to DMPA-SC

Figure 5 shows the proportion of FP clients (re-visiting) that switched to DMPA-SC.

About 80% of FP clients switched from DMPA-IM to DMPA-SC, while 20% of the clients switched from other FP methods to DMPA-SC.

AE management

A robust AE reporting system was established in all 29 implementing facilities. Routine monitoring data revealed that no

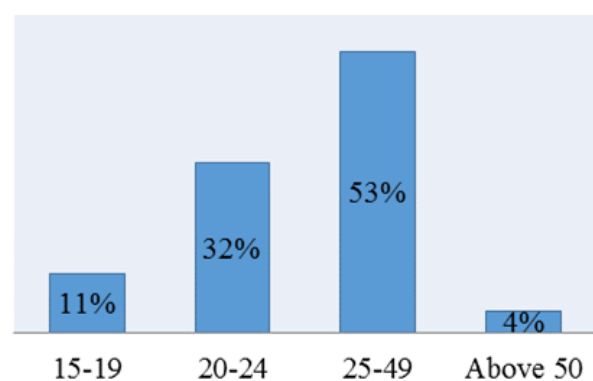


Figure 3. Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) clients by age distribution (N=2,100).

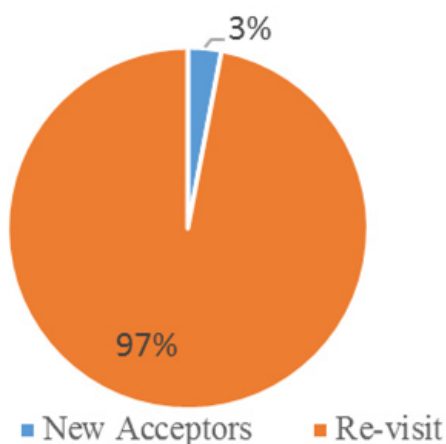


Figure 4. Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) provided by client type (N=2,100).

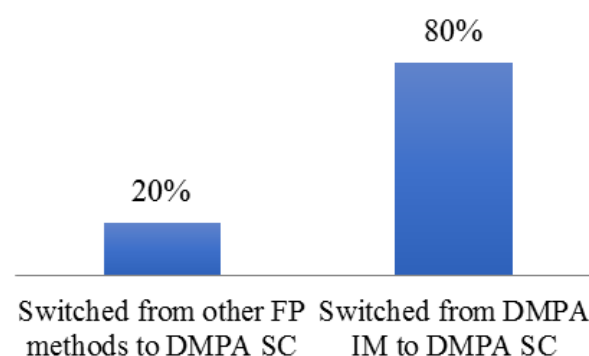


Figure 5. Proportion of family planning (FP) clients that switch to Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) (N=2,043). IM, intramuscular.

AEs were reported following DMPA-SC administration at all service delivery sites.

Discussion

These findings provided useful insights to inform development of the national road map for the national scale-up of DMPA-SC in Zambia. This was the first study in Zambia to explore introduction of DMPA-SC in the community through use of CBDs. According to assessments carried out by CBD supervisors and the NFPTWG, trained CBDs were able to safely administer and appropriately store DMPA-SC, they were also able to dispose of resultant waste according to laid down procedures.

Similar to other DMPA-SC pilots conducted in Niger, Senegal and Uganda, this pilot revealed that nearly half DMPA-SC doses were administered to women younger than 25 years of age¹¹. This was however a continuation of the similar trend for DMPA-IM even before the pilot. Each CBD distributed five doses of DMPA-SC doses per month on average compared to similar pilot in other countries (Senegal, Niger and Uganda), where each provider administered three doses per month¹¹. Therefore, it is evident that DMPA-SC has the potential to provide an additional contraception choice for women especially the adolescents thereby reducing unintended pregnancies. Despite DMPA-SC being only available in the community, some facility-based CBD supervisors/FP providers in a few facilities included the method during FP counselling. Hence, new FP users who opted for DMPA-SC were assessed for eligibility and referred to CBDs for service provision. Due to policy differences between Zambia and other countries on FP service provision by CBDs and definition of 'new acceptors of FP', this finding contradicted with pilot results from other countries that showed a substantial number of women categorised as ("new users") choosing DMPA-SC¹¹.

Conclusion

The DMPA-SC Pilot demonstrated that CBDs can safely provide DMPA-SC within the existing family planning method mix. Secondly, the pilot demonstrated that DMPA-SC has potential to be a method of choice for adolescent and young women.

Data availability

Open Science Framework: DMPA SC dataset. <https://doi.org/10.17605/OSF.IO/X23FE>¹².

Underlying data are available in file Dataset.zip, which contains the following data:

- DMPA SC aggregated dataset.xlsx (aggregated data from all locations).
- KALULUSHI data.xlsx (underlying data from Kalulushi).

- KAWAMBWA data.xlsx (underlying data from Kawambwa).
- MAFINGA data (underlying data from Mafinga).

Extended data

Figshare: CBD Profiles Dataset. <https://doi.org/10.6084/m9.figshare.11829534.v1>¹³

Data are available under the terms of the [Creative Commons Zero “No rights reserved” data waiver](#) (CC0 1.0 Public domain dedication).

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Open Peer Review

Current Peer Review Status:   

Version 2

Reviewer Report 06 July 2020

<https://doi.org/10.21956/gatesopenres.14282.r28900>

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General appreciation: The manuscript is greatly improved from its original version, with additional information clarifying much of the initial questions from this reviewer. However, some revisions are still needed for this paper to be publishable.

We appreciate the figures and tables, however, there seem to be too many of them sometimes only describing basic frequencies that could fit in a single sentence (e.g. figure 4, figure 5) or could best be summarized in a table.

Some English editing issues persists, e.g.:

- Decide between “*Injectable contraceptives*” (preferred) and “*contraceptive injectables*” or simply “*injectables*”
- *Within the catchment **area** of their community*
- *mode**l** facilities*
- *As indicated in**n** Figure 4*

The background and pilot description is confusing because CBDs are already offering DMPA-IM (technically more complicated than DMPA-SC) but only to returning clients. If it had already been established that CBD could perform intramuscular injections, what was the reasoning behind asking whether they could also provide sub-cutaneous (much easier to perform) injections? This is very different from other contexts where CBDs were not authorized to perform any kind of injections before DMPA-SC was introduced. In the context of Zambia, the benefits of introducing DMPA-SC at the community level (no need for additional supplies, simpler medical procedure) should be better detailed.

Figure 2 The use of absolute numbers is confusing. Right now it looks like the authors are looking at percentage of each [age group] among all switchers (which basically reflects the age

distribution for FP users), but it might also make sense to look at the percentage of switchers per age group, to assess which category of users DMPA-SC might “appeal” the most.

Table 2 is confusing. What are you trying to show here? The possible substitution of IM for SC should be discussed at length in this manuscript. This was a concern in many countries where DMPA-SC was introduced, that would not expand the contraceptive prevalence but simply capture women who were already using DMPA-IM. The manuscript should acknowledge that the pilot design does not really permit this kind of analysis since there is no data on “new users” On that note, how were 3% of women “new users” if CBDs were not permitted to offer methods to women who hadn’t already been seen by a medical professional? To be discussed.

The “Pilot limitations” section should fit under Discussion as part of an expanded “Limitations” paragraph(s).

This pilot is interesting in its approach of DMPA-SC introduction at the community level but differs significantly from others (including those referred in the Discussion section) and thus, the limitations in terms of results comparison should appear more clearly.

Finally, the conclusion simply repeats the key findings without engaging with policy, programmatic or additional research implications.

Additional comments from first review that still need to be addressed include:

Methods

- How reliable are routine statistics (stock management and service data) in Zambia? Was special attention paid to data collection and reporting under the pilot? In that case, any comparison with pre-pilot routine statistics may be flawed due to over/ under-reporting.
- The point above is of particular importance in discussing Table 2 data
- How was 'safely' measured (absence of AE?). This is never discussed in the manuscript.

Results

- A recurring issues with the findings of this article: Table 2 suggests that they may have been at least some substitutions between DMPA-IM and DMPA-SC but the authors never discuss this point.
- The analysis of age distribution would have been more interesting in terms of changes recorded in method distribution among different age groups after the introduction of DMPA-SC.
- How reliable is the "New Acceptors" indicators? Routine statistics analysis conducted in other countries (see for example Track20 initiative) suggest that it is poorly recorded ("new" meaning "new to DMPA-SC", "new to injectable", "new to this facility", "new to modern contraceptives" more or less interchangeably)
- Again, define AE, what level of severity would have justified recording as "AE".

Discussion

- Since CBD in Zambia apparently already provided DMPA-IM, the authors need to explain what the added value of could be of introducing DMPA-SC in the range of methods they

provide.

- What was the distribution of methods by age group prior to the introduction of DMPA-SC? Are there other factors (in the pilot or in the study design) that may explain the high proportion of youth clients?
- The comparison with result from studies conducted in other countries needs to be nuanced. None of the study mentioned measured "feasibility" exclusively in terms of volume of DMPA-SC provided at the community level (and a "better" performance of 5 vs 3 doses per month in the highly controlled environment of a pilot project seems hardly significant).
- The methodology used in Senegal, Niger and Uganda (and several other countries not mentioned in the paper) and the findings were more complex than suggested here and deserve to be fully engaged when comparing to results presented in this manuscript.

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.

Reviewer Report 02 July 2020

<https://doi.org/10.21956/gatesopenres.14282.r28899>

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Anthony K. Mbonye

College of Health Sciences, Makerere University, Kampala, Uganda

I have read the revised manuscript and I am satisfied with responses the authors have given.

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.

Version 1

Reviewer Report 27 September 2019

<https://doi.org/10.21956/gatesopenres.14128.r27770>

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✖ **Jenny Liu** 

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² Institute for Health and Aging, Department of Social and Behavioural Sciences, University of California, San Francisco, CA, USA

I am pleased to see more information about the CBD pilot that was done in Zambia. It is highly important that these findings be shared more publicly and widely, contributing to the growing knowledge base surrounding DMPA-SC introduction. That being said, this article would benefit from more clearly articulating and detailing the Zambian experience in several ways. Furthermore, the main conclusions stated in the discussion session are not directly supported by the results. Specific suggestions are listed below:

Background:

- More information is needed about how CBDs conduct their community-based activities and identify clients in need. Where/how did they find the 12,808 clients served?

Methods:

- Is the participant consent (that was waived) referring to the participating CBDs? Please clarify.
- Was there a particular reason why the 3 districts were chosen for the pilot?
- What are the qualifications/training to become a CBD? Is this cadre of health worker considered volunteers or formal employees of the public health system? What are their regular duties?
- Who were the master trainers? What were their qualifications?
- What does the standard MOH injection supervision checklist look for? Did this need to be adapted for DMPA-SC?
- How regular were the supervisory field visits?
- Did CBDs also provide DMPA-IM in communities prior to the pilot? It seems to suggest so, but it would be helpful to state explicitly.
- Each CBD was given 10 doses of DMPA-SC per month? Or just initially after training?
- How was the data on the characteristics of the CBDs collected? This is not described anywhere despite the data being shown in the results.

Results:

- Do the clients served include both men and women? Please clarify. If so, method distribution by gender would be useful to understand method choice of DMPA-SC among the other options.
- How were "revisits" identified? Is this determined by the provider or the client? Does this only pertain to methods available at facilities (as opposed to traditional methods, for example)? Similarly, what is the definition of a "new acceptor" and how are they identified? Were these definitions consistently applied?
- Related to the above, why are there 3% of newly accepting clients? Weren't CBDs only allowed to service returning FP clients? What explains this discrepancy?

- The subheading and text describing Figure 5 is confusing. What is the denominator? It seems to be anyone switching from another method to DMPA-SC and not necessarily FP clients who are revisits, but this isn't what is conveyed in the text.

Discussion:

- Based on the data shown, I don't think you can conclude that "CBDs were able to safely administer, appropriately store, and dispose of DMPA-SC." You did not show any information on measures of safety; lack of AE reports does not necessarily reflect the safety of administration, but rather the safety of the drug itself. How did you know that the products were appropriately stored? What data do you have to show that storage was proper? That disposal was also proper? What monitoring was done to check that CBDs were following instructions? Is this from the supervisory visits? If so, then the data from those visits should be reported.
- Be careful about use of overly general language, such as "performed better." It is not clear that administering higher numbers of doses per month reflects "better" performance. Does this truly reflect better service delivery? Reach? Coverage? Or more efficient service provision? Or simply poorer quality services to more people?
- How did you conclude that DMPA-SC has "the potential to reduce unmet need?" Since CBDs can only attend to returning clients, then this doesn't seem to be a case where the contraceptive user base is being expanded. You also did not disaggregate client type by age, so it's not clear how you can conclude that unmet need among adolescents is "especially" addressed.

Other:

- The dataset for the CBD characteristics is not provided.

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?

No

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

Partly

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

No

Are the conclusions drawn adequately supported by the results?

No

Competing Interests: No competing interests were disclosed.**Reviewer Expertise:** Contraceptives, DMPA-SC, adolescent health, sexual and reproductive health, health services delivery, behavioral economics

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.

Author Response 06 Feb 2020

Gina Smith

I am pleased to see more information about the CBD pilot that was done in Zambia. It is highly important that these findings be shared more publicly and widely, contributing to the growing knowledge base surrounding DMPA-SC introduction. That being said, this article would benefit from more clearly articulating and detailing the Zambian experience in several ways. Furthermore, the main conclusions stated in the discussion session are not directly supported by the results. Specific suggestions are listed below:

Background:

- More information is needed about how CBDs conduct their community-based activities and identify clients in need. Where/how did they find the 12,808 clients served?

Response: By design, the CBD model under SARAI in Zambia is implemented in a way that CBDs operate in the peripherals of the catchment area of a health facility to distribute FP commodities and messaging. Each CBD is accountable to a nearby supervising facility and they submit monthly distribution and stock reports to the supervisors. In the three months of the pilot each of the 161 CBDs served an average of 27 clients with various FP commodities. CBDs conduct health education sessions which mostly focus on family planning as well as HIV prevention. Health facilities also encourage revisit clients to seek services from a CBD nearest to them when returning for a refill. This text has been included in the manuscript edit

Methods:

- Is the participant consent (that was waived) referring to the participating CBDs? Please clarify.

Response: The waiver applied to DMPA-SC users

- Was there a particular reason why the 3 districts were chosen for the pilot?

Response: Yes, the three districts were chosen because they had all facilities meeting the 'model facility' criteria as defined by the project in consultation with the ministry of health

- What are the qualifications/training to become a CBD? Is this cadre of health worker considered volunteers or formal employees of the public health system? What are their regular duties?

Response: CBDs are volunteers selected from within the community by community members. Basic qualifications are ability to read and write, reside within the catchment of the community. Once CBDs are recruited, they become part of the Neighborhood health committee which is a recognized structure by the ministry of health for community-based health service delivery and they are responsible to the public health facility that encompasses their catchment areas.

- Who were the master trainers? What were their qualifications?

Response: These were SRH experts from key departments of MoH

- What does the standard MOH injection supervision checklist look for? Did this need to

be adapted for DMPA-SC?

Response: The checklist is a step by step procedure for administration of DMPA-SC

- How regular were the supervisory field visits?

Response: Once a week for facility-based and twice a month for district health office-based supervisors.

- Did CBDs also provide DMPA-IM in communities prior to the pilot? It seems to suggest so, but it would be helpful to state explicitly.

Response: Yes, CBDs were providing DMPA-IM prior to the pilot, text will be added to clarify that.

- Each CBD was given 10 doses of DMPA-SC per month? Or just initially after training?

Responses: The 10 doses of DMPA-SC were issued to CBDs as post training initial stock because previous data indicated that each CBD distributed an average of 10 doses of DMPA per month. More doses were issued to CBDs who needed more, depending on demand in their communities.

- How was the data on the characteristics of the CBDs collected? This is not described anywhere despite the data being shown in the results.

Response: Data about CBDs was part of the training database for CBDs which was kept by the project. This data was collected during the initial selection process for DMPA-IM training and was updated during the DMPA-SC training.

Results:

- Do the clients served include both men and women? Please clarify. If so, method distribution by gender would be useful to understand method choice of DMPA-SC among the other options.

Response: Yes, clients served during the 3 months of the pilot includes men, male clients were only provided with male condoms hence, under the method switching analysis, only female clients were included as they're the only ones capable of switching to any other method.

- How were "revisits" identified? Is this determined by the provider or the client? Does this only pertain to methods available at facilities (as opposed to traditional methods, for example)? Similarly, what is the definition of a "new acceptor" and how are they identified? Were these definitions consistently applied?

Response: The context taken for each type of visit was based on modern contraceptive methods. Therefore, a revisit client is a client who have used one or more of the modern contraceptive methods before their current visit to a CBD or a health facility to seek other Family Planning services. A New acceptor is a client receiving a modern contraceptive method for the first time ever. These definitions were consistently used by all CBDs and data verifiers, it formed part of the both training for CBDs.

- Related to the above, why are there 3% of newly accepting clients? Weren't CBDs only allowed to service returning FP clients? What explains this discrepancy?

Response: The 3% of new clients were those who were provided with counselling and assessed for eligibility at the health facility but still opted to be provided with DMPA-SC, which was only administered by CBDs at the time hence referrals were made by health facilities staff to CBDs.

- The subheading and text describing Figure 5 is confusing. What is the denominator? It seems to be anyone switching from another method to DMPA-SC and not necessarily FP clients who are revisits, but this isn't what is conveyed in the text.

Response: The denominator is 2,043, which is the total number of clients who switched from other methods to DMPA-SC. For a client to qualify to be a switcher of FP methods, they must be revisits because a new acceptor would not be on any method prior to their visit.

Discussion:

- Based on the data shown, I don't think you can conclude that "CBDs were able to safely administer, appropriately store, and dispose of DMPA-SC." You did not show any information on measures of safety; lack of AE reports does not necessarily reflect the safety of administration, but rather the safety of the drug itself. How did you know that the products were appropriately stored? What data do you have to show that storage was proper? That disposal was also proper? What monitoring was done to check that CBDs were following instructions? Is this from the supervisory visits? If so, then the data from those visits should be reported.

Response: The author has included a write up a reference to the assessment conducted by the National Family Planning Technical Working Group

- Be careful about use of overly general language, such as "performed better." It is not clear that administering higher numbers of doses per month reflects "better" performance. Does this truly reflect better service delivery? Reach? Coverage? Or more efficient service provision? Or simply poorer quality services to more people?

Response: The comparative reference here only refers to quantities, text to be edited to omit usage of better.

- How did you conclude that DMPA-SC has "the potential to reduce unmet need?" Since CBDs can only attend to returning clients, then this doesn't seem to be a case where the contraceptive user base is being expanded. You also did not disaggregate client type by age, so it's not clear how you can conclude that unmet need among adolescents is "especially" addressed.

Response: The context which the author is considering for this conclusion is that when information DMPA-SC was attractive to new users, though not part of the design of the pilot. The conclusion has been edited to only make reference to the addition of more options for clients resulting from the inclusion of DMPA-SC to the method mix that existed. Other:

- The dataset for the CBD characteristics is not provided.

Response: The database will be added to the link for datasets used.

Competing Interests: No competing interests were disclosed.

Reviewer Report 16 September 2019

<https://doi.org/10.21956/gatesopenres.14128.r27769>

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Julie Hernandez 

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² Department of Health Management and Policy, School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA, USA

General appreciation:

While this paper contributes to the growing body of evidence regarding the feasibility and acceptability of introducing the provision of DMPA-SC at the community-level in Sub-Saharan Africa, by adding a new country (Zambia) to the list of environment where this strategy has been piloted to improve access to and use of family planning services, major revisions are required before it is suitable for indexing.

Overall, the manuscript does not satisfactorily address its stated goal of evaluating the “feasibility” of introducing DMPA-SC at the community level. This stems partly from the fact that the research design is different from previous pilots exploring the same research questions, which included primary data collection (including systematic interviews of both DMPA-SC clients and CBDs, plus focus group discussions or / and in-depth interviews with key stakeholders). The research presented here only engages with routine service statistics and this creates limitations in the scope and validity of the findings which should be directly addressed in the manuscript. This is not to say that only pilots using primary data collection should be presented, however the authors need to be realistic in presenting what the available datasets can and cannot contribute to the existing body of evidence on the introduction of DMPA-SC for provision by community-based distributors.

Introduction:

- Figures and percentages cited would benefit from scientifically recognized sources such as DHS and/or other population-based surveys.
- Reference (4) in the first paragraph seems incorrect (not addressing barriers to access in Zambia).
- Additionally, regarding ref (4), there is at this point enough literature on the introduction of DMPA-SC at the community level in Sub-Saharan Africa for the authors to engage directly with this corpus, rather than experiences conducted in Europe.
- In general, the Introduction needs to engage with methods and findings from the aforementioned corpus and position the presented research accordingly. Feasibility of introducing DMPA-SC at the community level is now fairly well established in multiple low-income environments, so it is important for the authors to clarify what their research add to the existing body of research/for future developments of the model.
- How exactly is “feasibility” going to be measured? According to which criteria?

Methods:

- First paragraph under “Pilot description” is very unclear (“with established and having established”?)

- Authors need to detail the CBD profiles before the beginning of the pilot: are they volunteers? Do they have any clinical background or training prior to the start of the pilot?
- Description of “model facilities” is confusing, explain how this was a “community-based distribution” model: where did the CBD operate? Did they work alone or in groups? Door-to-door or during community events? Multiple models of CBD exist in SSA (including some where CBD operate in the courtyard of health facilities) so this section needs to give more details as to what CBD operating in Zambia are specifically capable of doing/allowed to do.
- In addition, the fact that these CBD came from “model facilities” creates a bias in the generalizability of the findings that should be addressed in the Discussion section.
- How reliable are routine statistics (stock management and service data) in Zambia? Was special attention paid to data collection and reporting under the pilot? In that case, any comparison with pre-pilot routine statistics may be flawed due to over/under-reporting.
- Adverse event: the authors need to explain what counts as “adverse events” (side-effects from using the method? Allergic reaction? Pregnancy?) While severe adverse events have rarely been recorded during DMPA-SC introduction pilot in DRC, side-effects are a key reason for methods discontinuation and should be discussed in this manuscript as CBD are often poorly trained in side-effect explanation and management.

Results:

- The first statement is incorrect (and 17% does not match the 16% indicated on Figure 1). The methodology used cannot measure an “increase in the share of DMPA injectable users” since available data does not include method substitution.
- This is a recurring issue with the findings of this article. Table 2, for example, suggests that they may have been at least some substitution between DMPA-IM and DMPA-SC but the authors never discuss this point.
- Delete repetition of “Figure 2 below...”
- The analysis of age distribution would have been more interesting in terms of changes recorded in method distribution among different age groups after the introduction of DMPA-SC.
- We suggest deleting Figure 2 since the graph does not add relevant information that is not already included in the text.
- The analysis of “New” vs “Re-visit” acceptors needs to be presented in the Methods section.
- How reliable is the “New Acceptors” indicators? Routine statistics analysis conducted in other countries (*See for example Track20 initiative*) suggest that it is poorly recorded (“new” meaning “new to DMPA-SC”, “new to injectable”, “new to this facility”, “new to modern contraceptives” more or less interchangeably).
- Again, define AE, what level of severity would have justified recording as “AE”?

Discussion:

- Since CBD in Zambia apparently already provided DMPA-IM, the authors need to explain what could be the added-value of introducing DMPA-SC in the range of methods they provide.
- What was the distribution of methods by age group prior to the introduction of DMPA-SC? Are there other factors (in the pilot or in the study design) that may explain the high proportion of youth clients?
- Since “new acceptors” only represent 3% of all recorded clients (of that number is reliable) and method distribution strongly suggest some method switching/substitution, the authors need to better explain how the introduction of DMPA-SC at the community level might reduce unmet need? The data presented here is insufficient to support that claim.
- The comparison with results from studies conducted in other countries needs to be nuanced. None of the study mentioned measured “feasibility” exclusively in terms of volume of DMPA-SC provided at the community level (and a “better” performance of 5 vs 3 doses per month in the highly controlled environment of a pilot project seems hardly significant).
- The methodology used in Senegal, Niger and Uganda (and several other countries not mentioned in the paper) and the findings were more complex than suggested here and deserve to be fully engaged when comparing to results presented in this manuscript.

Conclusion:

- How was “safely” measured (absence of AE?). This is never discussed in the manuscript.
- The second sentence (on potential to reach underserved population) is not adequately supported by findings from the manuscript.

Writing and figures:

- We suggest using an English editor to review the manuscript for typos, as well as reword some sentences/paragraphs.
- Review the manuscript to avoid use of passive voice as much as possible.
- We believe the wording should be “injectable contraceptives” and not “contraceptive injectables”.
- Reword: “*de-identified data for analysis that is part of the routine data collection for which IRB approval was obtained.*”

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?

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.

Reviewer Expertise: Sexual and Reproductive Health in Sub-Saharan Africa

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 06 Feb 2020

Gina Smith

CONDITIONALLY Approved

General appreciation:

While this paper contributes to the growing body of evidence regarding the feasibility and acceptability of introducing the provision of DMPA-SC at the community-level in Sub-Saharan Africa, by adding a new country (Zambia) to the list of environment where this strategy has been piloted to improve access to and use of family planning services, major revisions are required before it is suitable for indexing.

Overall, the manuscript does not satisfactorily address its stated goal of evaluating the “feasibility” of introducing DMPA-SC at the community level. This stems partly from the fact that the research design is different from previous pilots exploring the same research questions, which included primary data collection (including systematic interviews of both DMPA-SC clients and CBDs, plus focus group discussions or / and in-depth interviews with key stakeholders). The research presented here only engages with routine service statistics and this creates limitations in the scope and validity of the findings which should be directly addressed in the manuscript. This is not to say that only pilots using primary data collection should be presented, however the authors need to be realistic in presenting what the available datasets can and cannot contribute to the existing body of evidence on the introduction of DMPA-SC for provision by community-based distributors.

Introduction:

- Figures and percentages cited would benefit from scientifically recognized sources such as DHS and/or other population-based surveys.

Response: the author cited credible and recognized sources with up to date data pertaining

to Zambia e.g. Zambia Demographic Health Survey 2013-14 and Integrated Family Planning Scale-up Plan 2013 - 2020.

- Reference (4) in the first paragraph seems incorrect (not addressing barriers to access in Zambia).

Response: True! Correct reference in number 5 (Integrated Family Planning Scale-up Plan 2013 - 2020), to be edited.

- Additionally, regarding ref (4), there is at this point enough literature on the introduction of DMPA-SC at the community level in Sub-Saharan Africa for the authors to engage directly with this corpus, rather than experiences conducted in Europe.

Response: Noted! However, the author used ref 4 as a source of information for the product (DMPA-SC) and not in relation to provision at any setting.

- In general, the Introduction needs to engage with methods and findings from the aforementioned corpus and position the presented research accordingly. Feasibility of introducing DMPA-SC at the community level is now fairly well established in multiple low-income environments, so it is important for the authors to clarify what their research add to the existing body of research/for future developments of the model.

Response: Well noted, text has been added

- How exactly is “feasibility” going to be measured? According to which criteria?

Response: Client and environmental safety assessments carried out by the Family Planning Technical Working Group of the ministry of health and stakeholders.

Methods:

- First paragraph under “Pilot description” is very unclear (“with established and having established”?)

Response: To be edited to read ‘Voluntary FP services are routinely offered with established community-based distribution programs in which CBDs provided Intramuscular depot medroxyprogesterone acetate (DMPA-IM), oral pills and condoms.’

- Authors need to detail the CBD profiles before the beginning of the pilot: are they volunteers? Do they have any clinical background or training prior to the start of the pilot?

Response: comment well noted, the same CBDs profiled during and post DMPA-SC pilot were trained to provide DMPA-IM prior to the pilot period, additional training was provided as alluded to during the introduction of DMPA-SC. Text will be added to provide clarity on CBD profiles prior to the pilot.

- Description of “model facilities” is confusing, explain how this was a “community-based distribution” model: where did the CBD operate? Did they work alone or in groups? Door-to-door or during community events? Multiple models of CBD exist in SSA (including some where CBD operate in the courtyard of health facilities) so this

section needs to give more details as to what CBD operating in Zambia are specifically capable of doing/allowed to do.

Response: Observation well noted! The text will be edited as follows: 'The pilot was implemented only in public health facilities that met the criteria of a "model facility" under SARAI. The project defined a model facility as one that encompasses the key components and systems needed at the community level to respond effectively to the family planning needs of the population. These systems must include, skilled service providers; expanded method mix; client-centered care offering age appropriate information, outreach to vulnerable populations; supervision; mentoring for health care providers; youth and adolescent reproductive health services; community involvement through organized and trained community members who mostly are volunteers and data collection and analysis to track progress. Model facilities were selected because the project had already established necessary structures at facility and district levels to monitor and supervise community-based distribution of FP commodities. By design, the CBD model under SARAI in Zambia was implemented in a way that CBDs operate in the peripherals of the catchment area of a health facility while submitting monthly reports to the supervisors based at the facility. All CBDs (163) in all model public health facilities (29) supported by SARAI were selected to participate in the pilot.

- In addition, the fact that these CBD came from "model facilities" creates a bias in the generalizability of the findings that should be addressed in the Discussion section.

Response: True! The reason for selecting CBDs from model facilities was because the project had trained the CBDs in provision of other FP methods including DMPA-IM. These facilities also had trained facility staff in CBD supervision and data compilation. Part of the recommendation for the roll out of the model was that a facility must meet the criteria of a model facility. A section has been added to declare this as a limitation of the pilot.

- How reliable are routine statistics (stock management and service data) in Zambia? Was special attention paid to data collection and reporting under the pilot? In that case, any comparison with pre-pilot routine statistics may be flawed due to over/under-reporting.

Response: Data on stock management is part of the Health Management Information System which is compiled by all public health facilities on a monthly basis. CBDs are supervised by qualified health facility staff, trained in stock management and facility reports includes data generated by CBDs as part of commodity accountability. The project in collaboration this MoH staff conducted data quality audits prior and during the pilot in all health facilities.

- Adverse event: the authors need to explain what counts as "adverse events" (side-effects from using the method? Allergic reaction? Pregnancy?) While severe adverse events have rarely been recorded during DMPA-SC introduction pilot in DRC, side-effects are a key reason for methods discontinuation and should be discussed in this manuscript as CBD are often poorly trained in side-effect explanation and management.

Response: Well noted, notes will be added to qualify the definition in context. An adverse event in this context refers to severe side effects from using the method. CBDs were trained to report all adverse events (including other mild side effects associated with DMPA) to the facility as soon as they occur. Facility staff were also trained to record and report to project

staff immediately.

Results:

- The first statement is incorrect (and 17% does not match the 16% indicated on Figure 1). The methodology used cannot measure an “increase in the share of DMPA injectable users” since available data does not include method substitution.

Response: The first statement refers to clients who accessed various methods (including condoms and oral contraceptives) distributed by CBDs during the pilot which is 12, 818 and DMPA-SC distribution accounted for 16% of that number. The 17% increase is in reference to table 2 and only includes DMPA-IM and SC distribution. The increase indicated is pertaining to quantities distributed for the two periods, before and during the pilot and not a proportional share.

- This is a recurring issue with the findings of this article. Table 2, for example, suggests that they may have been at least some substitution between DMPA-IM and DMPA-SC but the authors never discuss this point.

Response: Well noted, the author discusses this point under figure 5 which demonstrates the proportion of clients who switched from DMPA-IM to DMPA-SC. However, text has been added as part table 2 analysis to allude to this finding.

- Delete repetition of “Figure 2 below...”

Response: Well noted

- The analysis of age distribution would have been more interesting in terms of changes recorded in method distribution among different age groups after the introduction of DMPA-SC.

Response: comment noted, the age disaggregates have been added as figure 2.

- We suggest deleting Figure 2 since the graph does not add relevant information that is not already included in the text.

Response: The figure has been deleted

- The analysis of “New” vs “Re-visit” acceptors needs to be presented in the Methods section.

Response: This aspect was not part of the design, it occurred during the pilot that some new clients were provided with the service by CBDs as referrals from health facilities. The author saw it fit to add this part of analysis in order to present a true picture of the findings.

- How reliable is the “New Acceptors” indicators? Routine statistics analysis conducted in other countries (*See for example Track20 initiative*) suggest that it is poorly recorded (“new” meaning “new to DMPA-SC”, “new to injectable”, “new to this facility”, “new to modern contraceptives” more or less interchangeably).

Response: The determination of New Acceptors was done by professional health workers according to the definition in the national HMIS procedures manual i.e ‘a new acceptor is a client receiving a modern contraceptive method for the first time ever’. New acceptors were assessed by professional health care workers at facilities but were referred to CBDs for service provision as DMPA-SC was only provided at community level during the pilot period.

- Again, define AE, what level of severity would have justified recording as “AE”?

Response: Well noted, notes will be added to qualify the definition in context. An adverse event in this context refers to severe side effects from using the method. CBDs were trained to report all adverse events (including other mild side effects associated with DMPA) to the facility as soon as they occur. Facility staff were also trained to record and report to project staff immediately.

Discussion:

- Since CBD in Zambia apparently already provided DMPA-IM, the authors need to explain what could be the added-value of introducing DMPA-SC in the range of methods they provide.

Response: The value added by the introduction of DMPA-SC to the mainstream of FP products in Zambia is to allow clients have a wide range of choices. The other factor is that the packaging of DMPA-SC is comprehensive thereby making it easy to store especially at community level.

- What was the distribution of methods by age group prior to the introduction of DMPA-SC? Are there other factors (in the pilot or in the study design) that may explain the high proportion of youth clients?

Response: While there were no deliberate messaging strategies aimed at the youth only, it was noted from the pilot results that the response was higher from the youth than any other age group. This trend is however did not only present itself in DMPA-SC distribution but also before the pilot was conducted.

- Since “new acceptors” only represent 3% of all recorded clients (of that number is reliable) and method distribution strongly suggest some method switching/substitution, the authors need to better explain how the introduction of DMPA-SC at the community level might reduce unmet need? The data presented here is insufficient to support that claim.

Response: The assumption taken by the author is that DMPA which has been the most preferred method by clients, if provided in another package such as DMPA-SC which according to the survey, clients indicated that it was less painful, could lead to more clients opting for FP.

- The comparison with results from studies conducted in other countries needs to be nuanced. None of the study mentioned measured “feasibility” exclusively in terms of volume of DMPA-SC provided at the community level (and a “better” performance of 5 vs 3 doses per month in the highly controlled environment of a pilot project seems hardly significant).

Response: Comment well noted, the use of the word better has been dropped.

- The methodology used in Senegal, Niger and Uganda (and several other countries not mentioned in the paper) and the findings were more complex than suggested here and deserve to be fully engaged when comparing to results presented in this manuscript.

Response: comment well noted and attended to

Conclusion:

- How was “safely” measured (absence of AE?). This is never discussed in the manuscript.

Response: Yes, the author is relying on the absence of AE to determine that all clients seen during the period were safely provided with the method. The national Family Planning Technical Working Group, which was independent of the pilot carried out onsite assessments by observing CBDs providing the actual service and how they disposed resultant waste.

- The second sentence (on potential to reach underserved population) is not adequately supported by findings from the manuscript.

Response: Well noted, the conclusion the author is driving at is that of DMPA-SC administered at community level having potential to reach the people who are located in areas far from health facilities.

Writing and figures:

- We suggest using an English editor to review the manuscript for typos, as well as reword some sentences/paragraphs.
- Review the manuscript to avoid use of passive voice as much as possible.
- We believe the wording should be “injectable contraceptives” and not “contraceptive injectables”.
- Reword: “*de-identified data for analysis that is part of the routine data collection for which IRB approval was obtained.*”

Response: The script has been scrutinized for grammatical and phrasing related errors.

Competing Interests: No competing interests were disclosed.

Reviewer Report 29 July 2019

<https://doi.org/10.21956/gatesopenres.14128.r27379>

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The study aimed to assess the feasibility of introduction of subcutaneous depot

medroxyprogesterone acetate through use of community-based distributors in Zambia.

The design should have included key informant interviews and Focus Group Discussions to assess acceptability and sustainability of this intervention.

How were the views of clients assessed? This was important for the sustainability of the intervention

How were the views of providers assessed? This was also important for the sustainability of the intervention

Did clients wish to continue with the method? If yes why? If no why?

These data would have provided insights in the sustainability of the intervention.

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?

Partly

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?

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.

Author Response 06 Feb 2020

Gina Smith

The study aimed to assess the feasibility of introduction of subcutaneous depot medroxyprogesterone acetate through use of community-based distributors in Zambia.

Q. The design should have included key informant interviews and Focus Group Discussions to assess acceptability and sustainability of this intervention. How were the views of providers assessed? How were the views of clients assessed? This was also important for the

sustainability of the intervention.

Response: During the pilot period, the Family Planning Technical Working Group (FP TWG) constituted by the Ministry of Health conducted client and environmental safety assessments which included in In-Person Discussions with CBDs, clients as well as providers. The results of these assessments indicated a positive outcome of the intervention and recommended for a nation wide roll out.

Notes: Include comments/ quotes from clients and providers

Response: The assessments were standardized and followed a predetermined format, no direct quotes were recorded

Q. Did clients wish to continue with the method? If yes why? If no why?

These data would have provided insights in the sustainability of the intervention.

Response: The dose for DMPA-SC lasts for 3 months, there was no follow-up interviews with clients or providers as the pilot was for three months as well.

Competing Interests: No competing interests were disclosed.