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 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 1; peer review: 1 approved with reservations] Gates Open Research 2019, 3:1474 (https://doi.org/10.12688/gatesopenres.13020.1)

First published: 28 May 2019, 3:1474 (https://doi.org/10.12688/gatesopenres.13020.1)
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%. Like other Sub-Saharan countries, contraceptive injectables are the most widely used modern method among currently married women in Zambia. 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 facility. In response to the aforementioned, Zambia Ministry of Health (MoH) introduced community-based distribution of short-term FP methods, including administering of contraceptive injectables by community-based distributors (CBDs).

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 syringe. With its unique Uniject® feature, 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 contraceptive injectables and improve method continuation, and ultimately address unmet need for FP. Evidence has shown that DMPA-SC is safe, acceptable and feasible in low- and middle-income country (LMIC) settings.

In 2017, Society for Family Health – Zambia (SFH) a non-governmental organization in partnership with Zambia 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 of DMPA-SC in the community through use of CBDs.

Methods

Ethics statement
Ethics approval (REF No. 006-12-13) was received from University of Zambia Biomedical Research Ethics Committee (UNZAREC) to analyze routine client-level data on reproductive health. The ethics committee waived the need for participant consent.

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 are routinely offered with established and having established community-based distribution programs in which CBDs provided intramuscular DMPA (DMPA-IM), oral pills and condoms.

In Zambia, CBDs are not authorized to provide FP services to new users. CBDs refer new FP users to nearest health facility for medical assessment and subsequent commencement of services. CBDs are only authorized to attend to returning clients.

Sample selection
The pilot was implemented only in “model facilities” 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 FP 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 and data collection and analysis to track progress. All CBDs (n=163) in all model public health facilities (n=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 master trainers drawn from all 10 provinces of Zambia was conducted. DMPA-SC master trainers 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 training for 163 CBDs from implementing facilities, representing an average of five CBDs per facility, conducted.

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 injection supervision checklist 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.

Stock management
Stock consumption data from 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, each CBD was given 10 doses of DMPA-SC following training. In order to avoid 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. A total of 6,530 DMPA-SC doses were given 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 75% full.

Adverse event (AE) management
The pilot developed a framework for identifying, monitoring and reporting of AE’s. CBDs received training to identify, analyze and classify AEs in terms of nature and cause. 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, was extracted from the registers and entered into Microsoft Excel software. The study used de-identified data for analysis that is part of routine data collection for which IRB approval was obtained. Data analysis involving generating of descriptive statistics through tables, graphs cross-tabulations and frequencies was conducted using Statistical Package for Social Sciences (SPSS) version 21.

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. 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 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.

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>CBDs, N*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total trained in DMPA-SC</td>
<td>161</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>66</td>
</tr>
<tr>
<td>Female</td>
<td>95</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>21</td>
</tr>
<tr>
<td>Secondary</td>
<td>140</td>
</tr>
<tr>
<td>Average age, years</td>
<td>35</td>
</tr>
<tr>
<td>Previous trained in DMPA-IM</td>
<td>161</td>
</tr>
</tbody>
</table>

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

Pilot results showed a 17% increase in the number of injectable DMPA doses given after the introduction of DMPA-SC pilot. Table 2 below compares FP provision before and after DMPA-SC introduction.

Before the DMPA-SC pilot was introduced, each CBD gave an average of 11 doses of injectable DMPA-IM per month. After the DMPA-SC pilot was introduced, each CBD gave an average of 13 doses of injectable DMPA per month (i.e., DMPA-SC=5, DMPA IM=8).

DMPA-SC doses as a proportion to DMPA IM doses
A total of 6,190 injectable contraceptives were provided during the pilot period. DMPA-SC accounted for 34% (i.e., 2,100 DMPA-SC doses) of the total injectable contraceptives administered. Figure 2 below shows DMPA-SC doses provided as a proportion of total injectable contraceptives.

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

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

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

Figure 2. Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) as a proportion of total injectable contraceptives (N = 6,190). IM, intramuscular.

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

Figure 4. Proportion of family planning (FP) clients that switch to Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) (N=2,043). IM, intramuscular.

AE management
A robust AE reporting system was established in all 29 implementing facilities. Routine monitoring data revealed that no 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 is the first study in Zambia to explore introduction of DMPA-SC in the community through use of CBDs. Trained CBDs were able to safely administer, appropriately store and dispose of DMPA-SC.

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 age. Each CBD gave five doses of DMPA-SC doses per month on average. The pilot performed relatively better than similar pilot in other countries (Senegal, Niger and Uganda), where each provider administered three doses per month. Therefore, it is evident that DMPA-SC has the potential to reduce unmet need among 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 referred to CBDs after clinical assessment. Due to differences in policies on FP service provision by CBDs, this finding contradicted with pilot results from other countries that showed a substantial number of women using modern family planning for the first time (“new users”) choosing DMPA-SC.
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 reach underserved populations such as adolescent and young women.

Data availability

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).

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

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

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4. Pfizer’s Sayana® Press becomes first injectable contraceptive in the United Kingdom available for administration by self-injection. 2015; [accessed 04.29.19]. Reference Source
Open Peer Review

Current Peer Review Status: ?

Version 1

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.