Community-based Distribution of DMPA in Montepuez and Chiure Districts in Cabo Delgado, Mozambique

Final Report

April 2015
ACKNOWLEDGEMENTS

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# TABLE OF CONTENTS

Acknowledgements ........................................................................................................... i
List of Figures and Tables ................................................................................................. iii
Acronyms ........................................................................................................................ iv
Introduction ......................................................................................................................... 1
  1. Background .................................................................................................................. 1
     1.1. Unmet need for family planning in Mozambique .................................................. 1
     1.2. Injectable contraception as method of choice ....................................................... 1
     1.3. Community health workers and community distribution of family planning .......... 1
     1.4. Current debate on the use of DMPA and HIV risk ............................................... 1
     1.5. Rationale for the study ......................................................................................... 2
  2. Goals and Objectives ................................................................................................. 2
  3. Study Sites .................................................................................................................. 3
Methods .............................................................................................................................. 3
  1. Project Personnel ........................................................................................................ 3
  2. Training and Supervision ............................................................................................ 4
  3. Project Design ............................................................................................................ 5
     3.1 Enrollment ............................................................................................................. 5
     3.2 Data collection and management ........................................................................... 5
     3.3 Data analysis ......................................................................................................... 6
Results ............................................................................................................................... 7
  1. Enrollment .................................................................................................................. 7
  2. Follow-up .................................................................................................................... 8
  3. Demographic Profile ................................................................................................. 10
  4. Prior Contraceptive Usage ......................................................................................... 11
  5. Client Reasons for Using DMPA ............................................................................... 11
  6. Counseling from Providers ....................................................................................... 12
  7. Side Effects ................................................................................................................ 13
     7.1. Morbidities at injection site .................................................................................. 13
     7.2. Side effects of DMPA in three months since last injection .................................... 13
  8. Client Satisfaction ..................................................................................................... 14
     8.1. Satisfaction with provider ................................................................................... 14
     8.2. Satisfaction with DMPA ..................................................................................... 15
  9. Preference for Point of Service .................................................................................. 15
  10. Willingness to Pay ................................................................................................. 16
Limitations ......................................................................................................................... 17
Conclusions ....................................................................................................................... 17
Recommendations and Implications for Programs ........................................................... 18
References ....................................................................................................................... 19
Appendix 1. Client screening checklist ............................................................................. 20
LIST OF FIGURES AND TABLES

Figure 1: Project sites ..................................................................................................................3
Figure 2: Data collection and injection timeline...........................................................................5
Figure 3: Cumulative enrollment, by provider ..................................................................................8
Figure 4: Summary of client enrollment and follow-up .................................................................8
Figure 5: Previous use of contraception among participants, by provider ..................................11
Figure 6: Counseled on side effects and STIs/HIV, by provider ................................................12
Figure 7: Offered condoms in addition to DMPA, by provider ......................................................13
Figure 8: Morbidities at injection site following first and second injections, by provider ..........13
Figure 9: Side effects experienced after second and third injections, by provider ......................14
Figure 10: Satisfaction with provider at the time of injection, by provider .................................14
Figure 11: Satisfaction with DMPA as family planning method, by provider ..............................15
Figure 12: Willingness to pay for DMPA, by provider ..................................................................16
Figure 13: Mean amount willing to pay for DMPA injection, by provider ....................................16

Table 1: Enrollment, by district ....................................................................................................7
Table 2: Discontinuation and loss to follow-up, by provider ........................................................9
Table 3: Reasons for discontinuation, by provider .......................................................................10
Table 4: Characteristics of women, by provider ..........................................................................10
Table 5: Reasons for DMPA use at study enrollment, by provider ............................................12
Table 6: Preferred location for injection, by provider .................................................................15
<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>Definition</th>
</tr>
</thead>
</table>
| APE     | *Agente Polivalente Elementar*  
(Polyvalent elementary health worker) |
| AMOG    | *Associação Moçambicana de Obstetras e Ginecologistas*  
(Mozambican Association of Obstetricians and Gynecologists) |
| CBD     | Community-based distribution |
| CHW     | Community health worker |
| DHS     | Demographic and Health Survey |
| DMPA    | Depot-medroxyprogesterone acetate |
| MISAU   | Mozambique Ministry of Health |
| TBA     | Traditional birth attendant |
| TFR     | Total fertility rate |
| WHO     | World Health Organization |
INTRODUCTION

1. BACKGROUND

1.1. UNMET NEED FOR FAMILY PLANNING IN MOZAMBIQUE
Mozambique maintains a high total fertility rate that increased from 5.5 in 2003 to 5.9 in 2011, with the highest levels of fertility found in rural areas (total fertility rate (TFR) 6.6) and among the poorest (TFR 7.2) and least educated women (TFR 6.8). Since the implementation of family planning interventions in 1980, Mozambique has made notable progress in increasing awareness and knowledge of family planning, yet the most recent Demographic and Health Survey (DHS) shows that only 11.3% of married women 15-49 years old use modern methods of contraception. This is a similar level compared to the 2003 DHS (11.7%), demonstrating no progress in modern contraceptive prevalence between 2003 and 2011. The fertility control choices for women are often limited by an inability to access health facilities and lack of preferred contraceptive methods at those facilities. Therefore it is not surprising that there is a high unmet need (29.9%) for contraceptives in Mozambique.

1.2. INJECTABLE CONTRACEPTION AS METHOD OF CHOICE
In order for women to achieve their fertility goals in terms of number and timing of pregnancies, women must have access to contraceptives that fit their lifestyle needs and preferences. Injectable contraceptives are the leading method of family planning in sub-Saharan Africa and have played a major role in recent increases in contraceptive prevalence in the region. At a 2009 meeting hosted by the World Health Organization (WHO), international experts reviewed existing research studies on the safety, effectiveness and acceptability of community-based provision of injectable contraceptives and concluded that injectables can be provided safely at the community level by appropriately trained community health workers. Such task-shifting approaches are critical in sub-Saharan Africa, where many people—especially those who live in rural, remote areas, those in the lowest socio-economic groups, and other marginalized groups—have little or no access to health facilities.

In Mozambique, the current supply of contraceptives is not meeting the current demand as 40.1% of women express desire for any method of contraception, with only 29% of demand met. At the time of the 2003 DHS, when this indicator was last measured, the preferred method for future contraception use was depot-medroxyprogesterone acetate (DMPA) for over 42% of women of reproductive age. A single dose of the injectable contraceptive DMPA offers protection for three months, is female controlled and is non-coital dependent, thus explaining its popularity.

1.3. COMMUNITY HEALTH WORKERS AND COMMUNITY DISTRIBUTION OF FAMILY PLANNING
Community-based distribution (CBD) models of DMPA have been successful in a number of developing country contexts. Studies conducted in Uganda, Madagascar, Malawi and Ethiopia have demonstrated that with sufficient training in screening women, injection technique, and counseling, community health workers (CHW) were able to provide DMPA injections to women with comparable safety, acceptability and continuation rates as women who received DMPA from clinic-based providers.

1.4. CURRENT DEBATE ON THE USE OF DMPA AND HIV RISK
A recent systematic review found a moderate increased risk for HIV among women taking DMPA in the general population. The review, which included a meta-analysis of 12 studies based in sub-Saharan Africa, found a pooled hazard ratio of 1.40 (95% CI 1.16–1.69); with around half the available studies suggesting an increased risk, while the other half showed no increased risk. It is important to note that the potential for some hormonal contraceptives to raise a woman’s risk of HIV infection has been the
subject of inquiry and scientific debate since the beginning of the HIV epidemic. Assessing associations between hormonal contraceptive use and HIV infection with data from observational studies is challenging and analytically complex. Studies have used inconsistent approaches and generated a body of evidence that is complicated and difficult to interpret. Thus, more research is underway using randomized controlled trials to determine whether DMPA use increases the risk of HIV infection. Meanwhile, existing results need to be taken into account when deciding contraceptive options for women who desire DMPA. One study modeling the trade-offs between the risks of removing DMPA from the contraceptive method mix and the risk of HIV transmission found that the effect estimate is critical in estimating maternal and HIV-related deaths.\(^{10}\)\textbf{WHO reviewed research on the issue and concluded that data currently available does not support restrictions on the use of injectable contraceptives and agreed to a revised guidance in relation to DMPA.} As new evidence becomes available WHO guidance will likely need reconsideration. In the meantime, caution is recommended but restriction of DMPA use is unwarranted.

\textbf{1.5. RATIONALE FOR THE STUDY}

Despite significant strides to improve family planning in Mozambique, access is still limited. In July 2010, with the Family Planning Strategy 2010-2014, the Mozambique Ministry of Health (MISAU) approved the revitalization of the \textit{Agente Polivalente Elementar} (APE) Program, as well as the use of traditional birth attendants (TBAs) to mobilize the community for increased utilization of family planning methods. Historically, APEs have focused on improving the health status of the community through promotional and preventive activities. They served as liaison between the community and health facilities and provided community case management for malaria, diarrhea and respiratory infections for children, but did not play a role in family planning uptake. The project described in this report is the first to test a model for CBD of DMPA in Mozambique and to our knowledge the first in the world to test CBD of DMPA with TBAs. From 2014-2015, under leadership of the Mozambican Society of Obstetricians and Gynecologists (AMOG) and with technical support from the Bixby Center for Population, Health, and Sustainability at the University of California, Berkeley, Pathfinder International implemented a pilot study on the distribution of DMPA by both APEs and TBAs.

\textbf{2. GOALS AND OBJECTIVES}

The overarching goal of this study is to provide evidence of a strategy that could help increase contraceptive prevalence and reduce the current high unmet need for family planning in rural areas of Mozambique. The purpose of the study was to conduct a safety and feasibility assessment of a CBD program of DMPA in two districts of northern Mozambique. The study aims to explore the effectiveness of training two groups of community-based agents, APEs and TBAs, to administer DMPA and provide evidence to policymakers to expand CBD of DMPA in areas in Mozambique where APEs and TBAs are present.

Building on the study goal, the specific aims of this project were to:

- Provide evidence that APEs and TBAs can safely and effectively distribute and facilitate supply of DMPA to rural women.
- Demonstrate that APEs and TBAs can administer DMPA with safety, effectiveness and acceptability among clients.
- Increase access to DMPA through the utilization of APEs and TBAs.

The main outcomes of the study included:

- DMPA continuation rates (acceptance up to the third injection);
• Client satisfaction rates with the provider and with the product;
• Client knowledge on key information regarding DMPA (proxy for counseling received);
• Incidence of side effects; and
• Safety of injection administration.

3. STUDY SITES

From February 2014 to April 2015, the study was conducted in two districts in northern Mozambique. Chiure and Montepuez Districts are located in the Cabo Delgado Province of Mozambique with estimated populations of 241,754 and 221,915, respectively.11

Ethical approval for this project was granted by the Committee for Protection of Human Subjects at the University of California, Berkeley (CPHS # 2012-06-4460) and from the Mozambique Ministry of Health Comite de bioetica para a safude (IRB00002657, Ref: 197/CNBS/13).

METHODS

Three survey instruments were used over the course of the project: 1) an enrollment questionnaire; 2) a 13-week follow-up questionnaire; and 3) a 6-month follow-up questionnaire. These tools were developed in English and translated into Portuguese.

Pathfinder International conducted monitoring of the study with support from the Bixby Center at the University of California, Berkeley and AMOG. The APE or TBA providing DMPA injections collected the enrollment data, and nurses from catchment area health facilities served as project supervisors and conducted the 13-week (post-second injection) and 26-week (post-third injection) questionnaires.

1. PROJECT PERSONNEL

The lead investigators of this project were Drs. Cassimo Bique and Momade Usta of AMOG; Ana Jacinto from Pathfinder International Mozambique; and Dr. Ndola Prata, Associate Professor of Maternal and Child Health and Director of the Bixby Center at the University of California, Berkeley. Staff at the Pathfinder International Cabo Delgado provincial office oversaw coordination and organization of the DMPA training, distribution, data entry and data management. In addition, Pathfinder field staff provided monthly supervision visits to each district.
2. TRAINING AND SUPERVISION

Twenty-five APEs and 34 TBAs from the target areas were included in the study. Selected APEs were those operating in the district and selected TBAs were those registered and currently working collaboratively with health facilities in the district. Training received by both arms of providers was standardized. After recruitment of the providers, four physicians conducted a five-day training in February 2014 that included topics in family planning methods, study protocol, screening requirements for exclusion of participants, injection administration, infection prevention and reporting procedures. APEs and TBAs who successfully completed the classroom training progressed to a two-stage clinic-based practical training emphasizing safe injection technique. Training was given until participants were confident in administering injectable contraception. All participants gave injections to volunteers before they were considered qualified to distribute DMPA for the pilot study.

After completion of classroom training, all trainees participated in a one-week internship in a health facility of their catchment area. APE and TBA roles and responsibilities during the internship included: obtaining informed consent; completing the medical screening form to assess eligibility for DMPA; enrolling participants and assigning a client number; completing an enrollment questionnaire; providing counseling and administering DMPA; and planning for reinjection.

A total of 18 nurses (one per health facility in the catchment area) were trained as supervisors. Nurse supervisors’ roles and responsibilities included: interviewing women in their homes after the second and third injections, corresponding to 13-week and 26-week questionnaires, respectively; insuring completion of the enrollment questionnaire; ensuring supply of DMPA; and conducting monthly supervision and bi-weekly meetings with APEs and TBAs.

Project supervision was enforced at three levels: 1) monthly supervision by nurse supervisors; 2) monthly supervision by Cabo Delgado Province project coordination team; and 3) quarterly supervision by study investigators.

All APEs and TBAs received cotton rolls, swabs and a cardboard box with one entry for disposal of needles and syringes. When full, the boxes were taken to the nearest health facility for incineration. A 3-month intramuscular DMPA (150mg vial = 1ml; single use 2 ml syringe with a needle 0.8 x 40mm) was supplied by MISAU through the national health system supply chain with logistical support from the project.
3. PROJECT DESIGN

The study was a prospective non-randomized community intervention trial designed to test the provision of DMPA by APEs and TBAs. Safety, acceptability and continuation outcomes were assessed and compared among clients in both provider groups (TBAs and APEs). Women in the community were made aware of the project and the opportunity to request DMPA from a community provider assigned to their district.

3.1 ENROLLMENT

If a woman visited an APE or TBA, was eligible for DMPA and consented to participate, she was enrolled in the study. If a woman requesting DMPA from an APE or TBA did not consent to participate in the study, she was referred to a health facility to obtain DMPA.

All women of reproductive age who approached an APE or TBA for a contraceptive method and wished to use DMPA were invited to participate in the study. Participation was voluntary. After obtaining consent to participate in the study, the APE or TBA screened the client for DMPA eligibility (see Appendix 1). During the course of their training, both APEs and TBAs became familiar with client screening and exclusion criteria. Women who desired to initiate DMPA use were asked a number of screening questions based on current WHO recommendations for medical eligibility for contraceptive use, including history of heart problems and any possibility of current pregnancy (see Appendix 1). Screenings occurred at the site where the APE or TBA administered the DMPA injection. No personal identifying information was collected as part of the screening process.

If a client was eligible for DMPA, the APE or TBA administered an enrollment questionnaire, provided the injection, and informed the client about the schedule for re-injection and follow-up interviews. During this first encounter, APEs and TBAs would agree on the location of the following injection. However, the provider was instructed to seek the client for re-injection if the next appointment was missed. If a client was ineligible for the method, the APE or TBA referred the woman to the nearest health facility for further follow-up, consistent with their usual practice. The study did not compensate participants and DMPA was given free of charge during the course of the study, which is aligned with Mozambique government policy that mandates free prevention services.

3.2 DATA COLLECTION AND MANAGEMENT

Data collection occurred at three different points of service (Figure 2). Study enrollment was conducted between February and November 2014, after which point new participants were no longer enrolled, as they would not have sufficient time to complete the 26-week follow-up period.

Figure 2: Data collection and injection timeline
**Enrollment:**
At enrollment, the provider administered a private enrollment questionnaire that lasted no more than 10 minutes.

The enrollment questionnaire contained demographic history, questions on past contraceptive use, and assessed a client’s willingness to be contacted in 13 weeks for follow-up. If a participant did not want to be interviewed at her home for follow-up, she could choose to meet at the nearest clinic or another agreed upon location.

The APE or TBA then administered the DMPA injection according to study protocol. Clients were counseled about side effects and told that their second shot would be due in 12 weeks. Nurses were onsite as supervisors for the study and ensured that study protocol was followed. Nurse supervisors also acted as health research assistants who then administered the follow-up questionnaires (at 13 and 26 weeks after enrollment).

**13 Weeks After Enrollment:**
After 13 weeks, clients were re-visited by nurse supervisors who administered the follow-up questionnaire. Thirteen weeks corresponds to one week beyond the full 12-week cycle for DMPA. Thirteen weeks was chosen because it gave clients a one-week “grace period” to be late for their re-injection appointment, yet still allowed good recall of the 12-week re-injection. It was assumed that most clients planning to have a second injection would receive it by 13 weeks.

As part of the follow-up questionnaire, women were asked about their satisfaction with DMPA as a method, provider satisfaction, acceptability of the method, and any side effects at the injection site (to determine safety of injection by the provider). Women were also asked about side effects they had experienced that they considered a result of DMPA use. If the women had chosen to discontinue DMPA use, they were asked to provide the reason(s). Willingness to pay for DMPA and preferred point of DMPA administration was also assessed during this interview.

After the short follow-up interview, women were asked if they agreed to be contacted again in 13 weeks for another follow-up questionnaire to assess further continuation.

**26 Weeks After Enrollment:**
Women were contacted for a follow-up questionnaire 26 weeks from their initial project enrollment and injection and 13 weeks after the second injection. Women were asked the same questions about acceptability, satisfaction and side effects, as well as any reasons for discontinuation.

According to study protocol, every effort was made for all participants to complete all three questionnaires; even those clients who chose to discontinue the method. Thus, all women initially enrolled in the study were contacted and interviewed.

**3.3 Data Analysis**
Data were entered in Epi Info (version 7.1.4.0). Analysis was conducted with Stata version 13. The following summary report contains information generated through frequency and cross-tabulations. Differences in responses between the two client groups (TBAs and APEs) were assessed with \( \chi^2 \) tests for association among categorical variables and t-tests for independent samples to determine differences between group means. Discontinuation and continuation rates overall and between providers were estimated over time from first injection to second injection and from first injection to third injection.
Data from 13-week and 26-week questionnaires were used to estimate continuation, discontinuation and lost to follow-up data. Continuation at 13 weeks and at 26 weeks represents the women who reported receiving their second and third injections respectively. Discontinuation during this same period was estimated if a woman reported in her 13-week and 26-week questionnaire that she did not receive her second or third injection. Lost to follow-up was estimated with the enrollment questionnaire when women received their first injection serving as a baseline and their complete absence from 13- and 26-week questionnaires.

**Variables:**
Most outcomes in this report were the result of questions asked directly to clients.

First-time users of DMPA were considered to be those reporting no previous use of contraception, as well as those who had used a contraceptive method in the past, not including DMPA.

Follow-up continuation was determined to be those women who reported in their 13-week and 26-week questionnaires that they had received their next shot of DMPA. Women who were reached for a follow-up questionnaire, but reported reasons for terminating use of DMPA were classified as discontinued. In addition, those women who reported not yet receiving their next injection, but either not desiring to continue use or outside of the 13-week time were also considered discontinued. Women who could not be found for a follow-up questionnaire were considered lost to follow-up.

**RESULTS**

1. **ENROLLMENT**

A total of 1,432 eligible women were enrolled in the study and given the first injection of DMPA. Enrollment began in February 2014 and continued through November 2014, however the majority of enrollment occurred between February and May 2014. TBAs worked in Montepuez and recruited 782 women, while APEs worked in Chiure and recruited 649 women into the study (Table 1). Figure 3 presents details on cumulative enrollment during the study period.

<table>
<thead>
<tr>
<th>District</th>
<th>TBA clients</th>
<th>APE clients</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiure</td>
<td>-</td>
<td>649</td>
<td>649</td>
</tr>
<tr>
<td>Montepuez</td>
<td>782</td>
<td>-</td>
<td>782</td>
</tr>
<tr>
<td>Total</td>
<td>782</td>
<td>649</td>
<td>1,432</td>
</tr>
</tbody>
</table>
2. FOLLOW-UP

The summary of enrollment and follow-up is illustrated in Figure 4. Of the total 1,432 women who enrolled in the study and received the first injection, 1,242 were provided a 13-week questionnaire. Of those given the 13-week questionnaire, 48 women refused to answer the questionnaire resulting in a response rate of 96%. At six months, 1,264 women were provided the 26-week questionnaire, including 22 women assumed lost to follow-up at three months. The response rate for those given the 26-week questionnaire was 98.6%. The 22 women who did not give consent for the 13-week questionnaire and gave consent for the 26-week questionnaire were asked about their second injection and if the second injection was received, were added to the continuation rates.

Table 2 describes the discontinuation and loss to follow-up rates by type of provider. The discontinuation rate was estimated from enrollment to the 3-month, second injection time frame, and from enrollment to the 6-month, third injection time frame.
Overall, the project shows a high continuation rate (81.1%) after three injections and a low discontinuation rate of 5.2%. When compared to APE clients, TBA clients had statistically significantly higher continuation rates both at three months and at six months. Conversely, APE clients had significantly higher discontinuation rates than TBA clients. Between enrollment and the second injection, APEs had a discontinuation rate of 13.7%, while the TBAs discontinuation rate was 1.4%.

Loss to follow-up rates were overall 13.8% for the entire project period between enrollment and the 6-month time frame, however APEs had 20.8% loss to follow-up compared to 7.8% among TBA clients.

Table 2: Discontinuation and loss to follow-up, by provider

<table>
<thead>
<tr>
<th></th>
<th>Second injection</th>
<th>Third injection</th>
<th>Total after 3 injections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TBA clients</td>
<td>APE clients</td>
<td>TBA clients</td>
</tr>
<tr>
<td>Received injection</td>
<td>627 (80.2%)</td>
<td>442 (68.1%)*</td>
<td>716 (91.6%)</td>
</tr>
<tr>
<td>Discontinuation</td>
<td>11 (1.4%)</td>
<td>89 (13.7%)*</td>
<td>5 (0.6%)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>144 (18.4%)</td>
<td>118 (18.2%)</td>
<td>61 (7.8%)</td>
</tr>
</tbody>
</table>

*Comparison TBA vs. APE p<0.05; one client was missing provider information

Table 3 outlines women’s reasons for discontinuation. Overall, 174 women discontinued DMPA during the study period. Most reported that they were planning to continue with DMPA, but had not yet received her shot. Many gave other reasons or reported that they forgot.

At 3-month follow-up, there were 100 women who discontinued DMPA: 89 who were clients of APEs and 11 TBA clients. For APE clients, the most common reason given for discontinuation (50.6%) was that the woman was planning to get her shot, but had not yet visited the APE provider. This was also common among TBA clients who discontinued (36.4%), though more TBA clients (45.5%) stated other reasons but did not specify. A substantial proportion of APE clients (28.1%) forgot to return for the second injection. Very few women discontinued due to side effects or because “the injection did not make me feel good” (Table 3). One woman, a client of a TBA, became pregnant or realized she was pregnant between her first and second shot. Six APE clients began using a different method between the first and second injection, which is not considered an issue, and is in fact encouraged so that each woman can find the contraceptive method that works best for her.

Fewer clients discontinued between the second and third injection. Five TBA clients and 69 APE clients reported discontinuation for a total of 74 clients. Most TBA clients reported other reasons than those listed, but one forgot to return for her third shot. The majority (53.6%) of discontinuing APE clients reported that they were planning to get the shot, but had not yet reached the APE to receive it. A few APE clients forgot, 34.8% stated other reasons but did not specify, and one client became pregnant or realized she was pregnant between her second and third injection.
Table 3: Reasons for discontinuation, by provider

<table>
<thead>
<tr>
<th>Reason for discontinuation</th>
<th>Discontinued at 3 month questionnaire</th>
<th>Discontinued at 6 month questionnaire</th>
<th>Total discontinued by 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TBA clients (n=11)</td>
<td>APE clients (n=89)</td>
<td>TBA clients (n=5)</td>
</tr>
<tr>
<td>Forgot</td>
<td>1 (9.1%)</td>
<td>25 (28.1%)</td>
<td>0%</td>
</tr>
<tr>
<td>Planning to go</td>
<td>4 (36.4%)</td>
<td>45 (50.6%)</td>
<td>1 (20.0%)</td>
</tr>
<tr>
<td>Don’t know where to get it</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>The first injection did not</td>
<td>0%</td>
<td>5 (5.6%)</td>
<td>0%</td>
</tr>
<tr>
<td>make me feel good</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trying to get pregnant</td>
<td>0%</td>
<td>1 (1.1%)</td>
<td>0%</td>
</tr>
<tr>
<td>Using another method</td>
<td>0%</td>
<td>6 (6.7%)</td>
<td>0%</td>
</tr>
<tr>
<td>Became pregnant</td>
<td>1 (9.1%)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Other reason given</td>
<td>5 (45.5%)</td>
<td>7 (7.9%)</td>
<td>4 (80.0%)</td>
</tr>
</tbody>
</table>

3. DEMOGRAPHIC PROFILE

Table 4 outlines the demographic profile and other key indicators for the women in the study at enrollment. The average age of all clients across the study was 29.5, the same for APE and TBAs. The average number of living children per woman was also statistically the same, 4.5 across all clients.

The majority of APE clients (83.1%) and TBA clients (83.8%) were married or cohabiting. Most clients reported no education but APEs had significantly more clients with no education than TBAs. Approximately 62% of TBA clients had no education, while 31.5% reported primary education. For APE clients, 72.7% reported no education and 18% were educated up to the primary level. Less than 1% of both client groups had secondary or higher education.

Most women reported support from their husbands for DMPA use. About 81% of APE clients and 79% of TBA clients said that their husbands were supportive. Covert use was low and not significantly different as about equally 9.6% of TBA clients and APE clients reporting that their husbands did not know they were using DMPA or were not supportive.

Table 4: Characteristics of women, by provider (N=1,431**)

<table>
<thead>
<tr>
<th></th>
<th>TBA clients (n=782)</th>
<th>APE clients (n=649)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Means</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at enrollment</td>
<td>29.3±6.9</td>
<td>29.9±7.6</td>
</tr>
<tr>
<td>Number of living children</td>
<td>4.2±2.1</td>
<td>4.8±2.6</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/living together</td>
<td>655 (83.8%)</td>
<td>539 (83.1%)</td>
</tr>
<tr>
<td>Single, never married</td>
<td>52 (6.7%)</td>
<td>52 (8.0%)</td>
</tr>
<tr>
<td>Divorced/separated/widowed</td>
<td>64 (8.2%)</td>
<td>40 (6.2%)</td>
</tr>
<tr>
<td>Education</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>None</td>
<td>488 (62.4%)</td>
<td>472 (72.7%)*</td>
</tr>
<tr>
<td>Only read and write</td>
<td>38 (4.9%)</td>
<td>49 (7.6%)</td>
</tr>
<tr>
<td>Primary</td>
<td>246 (31.5%)</td>
<td>177 (18.0%)*</td>
</tr>
<tr>
<td>Secondary or higher</td>
<td>6 (0.8%)</td>
<td>6 (0.9%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Husband supportive of using DMPA</th>
<th>n (%)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>614 (78.5%)</td>
<td>526 (81.1%)</td>
</tr>
<tr>
<td>No</td>
<td>47 (6.0%)</td>
<td>46 (7.1%)</td>
</tr>
<tr>
<td>Husband not aware</td>
<td>28 (3.6%)</td>
<td>16 (2.5%)</td>
</tr>
<tr>
<td>Not married/Does not know</td>
<td>70 (9.0%)</td>
<td>48 (7.4%)</td>
</tr>
</tbody>
</table>

Percentages include missing, not shown
*One client of the total recruited was missing provider type
**Comparison TBA vs. APE p<0.05

4. PRIOR CONTRACEPTIVE USAGE

For the majority of women, this study was the first time they had used a contraceptive method. Almost 63% of TBA clients and 65.6% of APE clients reported “none” when asked what types of methods they had used previously to prevent pregnancy. Approximately 30% of all clients reported previous use of DMPA, and less than 10% reported using pills or condoms to prevent pregnancy. Figure 5 provides details on previous types of methods used.

Figure 5: Previous use of contraception among participants, by provider (N=1,432)

5. CLIENT REASONS FOR USING DMPA

In this study, the most commonly reported reason among clients for using DMPA was that “it is a method that lasts longer” (Table 5). More than 60% of both APE and TBA clients reported longer duration of effectiveness as the reason why they preferred DMPA. The next most commonly reported reason was husband approval. About 29% of TBA clients and 20% of APE clients reported that they chose to use DMPA because their husbands permit this method. Additionally, nearly 10% of TBA clients reported that they chose DMPA for the convenience, while 24.2% of APE clients like DMPA because there are “fewer side effects.”
Table 5: Reasons for DMPA use at study enrollment, by provider (N=1,431*)

<table>
<thead>
<tr>
<th>Women’s responses**:</th>
<th>TBA clients (n=782)</th>
<th>APE clients (n=649)</th>
</tr>
</thead>
<tbody>
<tr>
<td>More convenient</td>
<td>74 (9.5%)</td>
<td>12 (1.9%)</td>
</tr>
<tr>
<td>Fewer side effects</td>
<td>38 (4.9%)</td>
<td>157 (24.2%)</td>
</tr>
<tr>
<td>Used before</td>
<td>26 (3.3%)</td>
<td>6 (0.9%)</td>
</tr>
<tr>
<td>It is the only method I know</td>
<td>59 (7.5%)</td>
<td>38 (5.9%)</td>
</tr>
<tr>
<td>Husband allows</td>
<td>228 (29.2%)</td>
<td>129 (19.9%)</td>
</tr>
<tr>
<td>Privacy</td>
<td>14 (1.8%)</td>
<td>12 (1.9%)</td>
</tr>
<tr>
<td>It is a method that lasts longer</td>
<td>492 (62.9%)</td>
<td>391 (60.3%)</td>
</tr>
<tr>
<td>Other reason reported</td>
<td>0 (0%)</td>
<td>11 (1.7%)</td>
</tr>
</tbody>
</table>

*One client of the total recruited was missing provider type
**Women were invited to select all that applied

6. COUNSELING FROM PROVIDERS

Clients of APEs reported more counseling on both side effects and STIs/HIV than TBA clients. However, the proportion of clients who reported side effects and STI/HIV counseling improved from the 3-month to the 6-month follow-up in both groups (Figure 6). The proportion of TBA clients who reported receiving counseling on side effects of DMPA increased from 70% at three months to 80% at six months, while the proportions for APEs during these time frames were 89% and 94%, respectively. The proportion of TBA counseling on STIs/HIV was substantially lower than TBA side effect counseling and lower than STI/HIV counseling provided by APEs. About 36% of TBA clients and 70% of APE clients reported receiving STI/HIV counseling at three months. At six months, 45% of TBA clients and 78% of APE clients reported counseling on STIs/HIV.

Figure 6: Counseled on side effects and STIs/HIV, by provider (N=1432*)

*One client of the total recruited was missing provider type

The proportion of APE clients who reported being offered condoms in addition to DMPA by their provider was higher when compared to TBA clients (Figure 7). At three months, 31% of TBA clients and 48% of APE clients reported being offered condoms. At six months, those proportions were 21.3% and 54.8%, respectively.
**7. SIDE EFFECTS**

The side effects of DMPA and morbidities at the injection site were assessed after the first and second injections. Morbidities were self-reported by women.

**7.1. MORBIDITIES AT INJECTION SITE**

The majority of clients reported no problems at the injection site after the first and second injections. Figure 8 demonstrates that less than 0.5% of women reported any other issues, including induration or abscess at the injection site.

**Figure 8: Morbidities at injection site following first and second injections, by provider (N=1432)**

*One client of the total recruited was missing provider type*

**7.2. SIDE EFFECTS OF DMPA IN THREE MONTHS SINCE LAST INJECTION**

Most clients reported no side effects of the DMPA at 3-month and at 6-month follow-up. Figure 9 outlines the most prevalent side effects that were reported. At three months, less than 10% of women reported experiencing amenorrhea, spotting, heavy bleeding or irregular bleeding. At six months, most of these side effects were reported less than at the 3-month time point. In addition to these side effects, the study also asked about headache, weight gain, weight loss, irritability and hair loss. The proportion
of women reporting any of these effects was negligible. At three months, more clients of APEs reported side effects, while at six months more TBA clients reported side effects.

Figure 9: Side effects experienced after second and third injections, by provider (N=1432*)

*One client of the total recruited was missing provider type

8. CLIENT SATISFACTION

Clients were asked to report on their level of satisfaction with DMPA and with their provider at three and six months.

8.1. SATISFACTION WITH PROVIDER

Most women were satisfied with their provider. At three months, 73.7% of TBA clients and 89.1% of APE clients reported satisfaction with their provider, while 21% of TBA clients and 5.9% of APE clients reported being “dissatisfied” (Figure 10). At six months, reported client satisfaction improved to 89.8% among TBA clients and 94.1% among APE clients. Dissatisfaction at six months was 9% among TBA clients and 4% among APE clients.

Figure 10: Satisfaction with provider at the time of injection, by provider (N=1432*)

*One client of the total recruited was missing provider type
8.2. SATISFACTION WITH DMPA
Almost 90% of women in the study were satisfied with DMPA as a method of contraception, and the proportion increased from the 3-month follow-up period to the 6-month follow-up period (Figure 11). Among TBA clients, 74.7% were “satisfied” with DMPA at three months, while 18.2% were “dissatisfied.” For APEs, the proportions were 88.2% and 8.7%, respectively. At six months, 90.1% of TBA clients and 89.2% of APE clients reported satisfaction with the method, while 8.1% of TBA clients and 8.5% of APE clients reported being dissatisfied with DMPA.

Figure 11: Satisfaction with DMPA as family planning method, by provider (N=14332*)

9. PREFERENCE FOR POINT OF SERVICE
Table 6 outlines women’s preferred point of service for receiving their injection. During the study women received the injection in their home or at the home of their provider. Overall, at three months women preferred to receive the injection at the APE or TBA’s home. About 70% of women reported wanting to receive the injection at their health worker’s home versus 15% who preferred to receive the injection in her own home and just 7% who preferred to receive the injection at the health facility. At six months, women preferred to receive the injection both at home (45%) and in the health worker’s home (45%), versus just 5% who reported a preference for the health facility.

Table 6: Preferred location for injection, by provider

<table>
<thead>
<tr>
<th>Preferred location</th>
<th>13 week questionnaire</th>
<th>6 month questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TBA clients (n=680)</td>
<td>APE clients (n=561)</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Health center</td>
<td>57 (8%)</td>
<td>27 (4.8%)</td>
</tr>
<tr>
<td>Client’s home</td>
<td>102 (15%)</td>
<td>79 (14%)</td>
</tr>
<tr>
<td>Health worker’s home</td>
<td>466 (69%)</td>
<td>403 (72%)</td>
</tr>
<tr>
<td>DK/no response</td>
<td>55 (8%)</td>
<td>52 (9.2%)</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td></td>
<td>57 (7.7%)</td>
<td>8 (1.5%)</td>
</tr>
<tr>
<td></td>
<td>538 (73%)</td>
<td>25 (4.7%)*</td>
</tr>
<tr>
<td></td>
<td>104 (14.1%)</td>
<td>460 (87.3%)*</td>
</tr>
<tr>
<td></td>
<td>38(5.2%)</td>
<td>34(6.5%)</td>
</tr>
</tbody>
</table>

*Comparison TBA vs. APE p<0.05; One case is missing type of provider
10. WILLINGNESS TO PAY

Figures 12 and 13 outline clients’ willingness to pay for DMPA. Overall, 64% of women in the study reported that they would be willing to pay for DMPA. The mean amount women were willing to pay across all clients was approximately 34 meticais ($0.93).

There was a substantial difference in willingness to pay and mean amount clients are willing to pay by provider. At three months, 78% of TBA clients were willing to pay for DMPA versus 33% of APE clients. At six months, the proportion of TBA clients willing to pay increased to 87%, while only 32% of APE clients reported willingness to pay.

The mean amount women were willing to pay was about 39 meticais ($1.07) among TBA clients and 5 meticais ($0.13) among APE clients at three months. At six months, those averages rose to 40 meticais ($1.10) and 7 meticais ($0.19), respectively.

Figure 12: Willingness to pay for DMPA, by provider

<table>
<thead>
<tr>
<th>% of women responding yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 month</td>
</tr>
<tr>
<td>6 month</td>
</tr>
</tbody>
</table>

Figure 13: Mean amount willing to pay for DMPA injection, by provider

<table>
<thead>
<tr>
<th>Mean amount willing to pay (metrical)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 month</td>
</tr>
<tr>
<td>6 month</td>
</tr>
</tbody>
</table>
LIMITATIONS

To accurately estimate continuation and discontinuation rates, this study would have to gather information on second and third injections from all women. In this study 197 women (14%) were lost to follow-up. There is no information from these women and thus it cannot be determined that these women discontinued the use of DMPA. Because the verification of injection was completed through an interview of the client, many women who refused to be interviewed were not captured in the continuation and discontinuation rates. One exception was 22 women who refused the 13-week questionnaire but accepted the 26-week questionnaire (see Figure 4). The lost to follow-up number does include women who were interviewed but did not have recorded data about whether or not they received DMPA. This number of women without data was small (nine women for the 13-week and one for the 26-week questionnaire). In addition, even among women followed the study did not achieve 100% response rate in the 13-week or 26-week questionnaires.

Lost to follow-up rates between 15-20% are common in similar studies, especially those in rural areas where health providers act as supervisors and data collectors. Difficulties accessing certain areas, time availability and other constraints make it challenging to follow all eligible women for an interview within the allotted time frame. In addition, the rotation of nurses in health facilities that were tasked as nurse supervisors required new training of incoming nurses contributing to delays in following women for the 13- or 26-week questionnaires. Regardless, results outline in this study provide insights and important lessons learned into the feasibility of organizing a community-based distribution program of DMPA.

CONCLUSIONS

This study produced important information on the feasibility, safety, acceptability and effectiveness of a community-based DMPA program among rural populations in northern Mozambique. The majority of women in the study started using contraception for the first time during the study period and very few experienced side effects or morbidities at the injection site. Satisfaction with community-based providers was high and improved over the entire study period. Overall continuation rates for DMPA were high for 3-month and 6-month injections, with higher continuation rates among TBA clients than APE clients. These rates are similar to what can be found in other pilots of community-based distribution of DMPA such as in Ethiopia. Women’s willingness to pay for DMPA, particularly among the clients of TBAs was notable and highlights the demand for injectables and the opportunity to develop cost recovery approaches to injectable delivery. These findings underscore the demand for contraceptive services in Cabo Delgado, and the need to improve access to injectable contraceptives among rural women.

The community-based delivery of DMPA by APEs and TBAs was feasible, safe and acceptable to women. Strengthening service delivery through improvements in counseling about side effects and HIV/AIDS should be considered during the development of CBD DMPA programs. Training for APEs and TBAs in DMPA provision should consider emphasizing: 1) repeated client follow-up to ensure adherence to DMPA without the risk of pregnancy; 2) the importance of side effects counseling; 3) the importance of STI/HIV counseling and condom provision; and 4) supportive supervision that ensures these strategies are carried out in each interaction between DMPA providers and clients.

The study demonstrated that both APEs and TBAs had the ability to successfully recruit women and provide the first contraceptive visit and subsequent follow-up visits. For first-time users of contraception
this measure should not exclude the importance of the current recommendations in Mozambique of integrated consultation. In fact, APEs and TBAs can be used to create awareness in the community about the need to visit a health facility as well as awareness among all women of reproductive age to screen for other reproductive health issues.

And finally, this study also revealed that the supply and distribution of commodities for a CBD project can be done through the current distribution system. Health facility commodities should forecast for the CBD program in their catchment areas and establish distribution to its community health workers. However, health facility data collection tools need to be able to collect data on community activities and supplies so that each district can have information about the CBD program contribution to its contraceptive prevalence.

RECOMMENDATIONS AND IMPLICATIONS FOR PROGRAMS

In order to meet the contraceptive needs of the most vulnerable populations in Mozambique, policymakers and program planners should note several key insights when developing programs to increase access to contraceptives through community-based distribution:

- Integrate APEs and TBAs in family planning service provision with emphasis on demand generation and provision of DMPA in the community.
- Ensure quality counseling on all family planning methods, including dual protection, with focus on informed choice.
- Reinforce APE and TBA counseling about the importance of visiting health facilities for other reproductive health services (i.e. screening for other diseases and long-acting reversible contraceptives).
- Increase supportive supervision to ensure that community health workers provide quality services in the provision of DMPA at the community level.
- Adapt data collection tools to improve commodity logistics while ensuring its availability.
REFERENCES

**APPENDIX 1. CLIENT SCREENING CHECKLIST**

**Checklist for Screening Clients Who Want to Initiate DMPA**

To determine if the client is medically eligible to use DMPA, ask questions 1–7. As soon as the client answers YES to any question, stop, and follow the instructions below.

| NO | 1. Have you ever had a stroke, blood clot in your legs or lungs, or heart attack? | YES |
| NO | 2. Have you ever been told you have breast cancer? | YES |
| NO | 3. Do you have a serious liver disease or jaundice (yellow skin or eyes)? | YES |
| NO | 4. Have you ever been told you have diabetes (high sugar in your blood)? | YES |
| NO | 5. Have you ever been told you have high blood pressure? | YES |
| NO | 6. Do you have bleeding between menstrual periods, which is unusual for you, or bleeding after intercourse (sex)? | YES |
| NO | 7. Are you currently breastfeeding a baby less than 6 weeks old? | YES |

If the client answered NO to all of questions 1–7, the client can use DMPA. Proceed to questions 8–13.

If the client answered YES to any of questions 1–3, she is not a good candidate for DMPA. Counsel about other available methods or refer.

If the client answered YES to any of questions 4–6, DMPA cannot be initiated without further evaluation. Evaluate or refer as appropriate, and give condoms to use in the meantime. See explanations for more instructions.

If the client answered YES to question 7, instruct her to return for DMPA as soon as possible after the baby is six weeks old.

Ask questions 8–13 to be reasonably sure that the client is not pregnant. As soon as the client answers YES to any question, stop, and follow the instructions below.

| YES | 8. Did your last menstrual period start within the past 7 days? | NO |
| YES | 9. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then? | NO |
| YES | 10. Have you abstained from sexual intercourse since your last menstrual period or delivery? | NO |
| YES | 11. Have you had a baby in the last 4 weeks? | NO |
| YES | 12. Have you had a miscarriage or abortion in the last 7 days? | NO |
| YES | 13. Have you been using a reliable contraceptive method consistently and correctly? | NO |

If the client answered YES to at least one of questions 8–13 and she is free of symptoms of pregnancy, you can be reasonably sure that she is not pregnant. The client can start DMPA now.

If the client began her last menstrual period within the past 7 days, she can start DMPA immediately. No additional contraceptive protection is needed.

If the client began her last menstrual period more than 7 days ago, she can be given DMPA now, but instruct her that she must use condoms or abstain from sex for the next 7 days. Give her condoms to use for the next 7 days.

If the client answered NO to all of questions 8–13, pregnancy cannot be ruled out.

She must use a pregnancy test or wait until her next menstrual period to be given DMPA.

Give her condoms to use in the meantime.