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Introduction of DMPA-SC self-injection in Ghana: A feasibility and acceptability study using Sayana® Press

Dela Nai
Population Council

Patrick Aboagye

Kamil Fuseini

Elizabeth Tobey
Population Council

Aparna Jain
Population Council

See next page for additional authors

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Authors

Dela Nai, Patrick Aboagye, Kamil Fuseini, Elizabeth Tobey, Aparna Jain, Nora Maresh, and Rebecca Fertziger

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Dela Nai, Associate I, Population Council Ghana

Patrick Aboagye, Director of Family Health Division, Ghana Health Service

Kamil Fuseini, Programs Officer, Population Council Ghana

Elizabeth Tobey, Staff Associate, Population Council D.C.

Aparna Jain, Associate II, Population Council D.C.

Nora Maresh, Family Health Team Leader, USAID

Rebecca Fertziger, Deputy Director, Health Office, USAID

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RESEARCH REPORT

The Evidence Project

Population Council
4301 Connecticut Avenue, NW, Suite 280
Washington, DC 20008 USA
tel +1 202 237 9400
evidenceproject.popcouncil.org

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Photo credit on cover page: A woman self-injects the contraceptive DMPA-SC (brand name Sayana® Press). PATH/Gabe Biencyck.

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List of Acronyms

CHPS	Community-Based Health Planning and Services
CPR	Contraceptive prevalence rate
CSPro	Census and Survey Processing System
DDPH	Deputy Director for Public Health
DHS	Demographic and Health Survey
DMPA	Depot Medroxyprogesterone Acetate
DMPA-IM	Depot Medroxyprogesterone Acetate intramuscular
DMPA-SC	Depot Medroxyprogesterone Acetate subcutaneous
FDA	Food and Drugs Authority
FP	Family planning
FP2020	Family Planning 2020
FHD	Family Health Division
GHS	Ghana Health Service
IM	Intramuscular
INGO	International non-governmental organization
JSS/JHS	Junior secondary school/junior high school
mCPR	Modern contraceptive prevalence rate
NGO	Non-governmental organization
PSI	Population Services International
SC	Subcutaneous
SSS/SHS	Senior secondary school/Senior high school
TAG	Technical Advisory Group
TFR	Total fertility rate
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development

Executive Summary

As articulated in its FP2020 Commitment, Ghana aims to increase the modern contraceptive prevalence rate (mCPR) among currently married or in-union women from 22 percent to 29 percent and among unmarried adolescents from 32 percent to 35 percent by 2020, with a focus on improving access in peri-urban and rural areas and at all service delivery levels, building the capacity of health providers, and improving the contraceptive method mix. Injectables are the most commonly used family planning (FP) method among married women in Ghana, with 8 percent of married women using the method, and a commonly used method among sexually active unmarried women, with 7 to 8 percent using the method.

Most injectable users use depot medroxyprogesterone acetate (DMPA) administered intramuscularly (DMPA-IM), though recently, a subcutaneous version of DMPA (DMPA-SC) has become more widely available. DMPA-SC—also known by its brand name Sayana® Press (a registered trademark of Pfizer Inc.)—has a shorter needle and slightly lower dosage than DMPA-IM, but maintains a three-month injection frequency and has similar safety features and potential side effects as DMPA-IM. DMPA-SC is suitable for community-based distribution as well as self-injection by clients, due to it being small, light, and easy to use, and requiring minimal training. The possible benefits of self-injection include increased access, privacy, and autonomy for its users.

The Evidence Project, led by the Population Council with support from the United States Agency for International Development (USAID)/Ghana, collaborated with the Ghana Health Service (GHS) to conduct a feasibility and acceptability study introducing DMPA-SC to health providers and FP clients in Ghana, results of which would inform the scale-up of DMPA-SC, including self-injection, in the public and private sectors of the country. The objectives of the study were to:

1. Assess the feasibility and acceptability of DMPA-SC service provision by FP providers and clients in Ghana.
2. Assess the feasibility and acceptability of client self-injection by FP providers in Ghana.
3. Assess the feasibility and acceptability of self-injection by FP clients in Ghana.

The study was conducted in rural, peri-urban, and urban areas of the Ashanti and Volta regions of Ghana. All FP-related providers at selected health facilities were eligible to participate in the study. Providers received a three-day training on DMPA-SC counseling and subcutaneous administration, training clients to self-inject, and observing and supervising clients' use of DMPA-SC. Immediately before and after the training, providers completed pre- and post-training assessments to gauge improvements in knowledge.

Clients who sought FP services and chose to use DMPA-SC after receiving counseling on the method were eligible to participate in the study. After choosing DMPA-SC, clients were given the option to be trained on self-injection and, if deemed competent by the provider, to self-inject under supervision of the provider and to take two doses of DMPA-SC home for future self-injection. Clients who agreed to participate in the study were interviewed at the facility after their first injection and over the phone or in person following their scheduled second injection (3-month interview) and third injection (6-month interview).

A total of 568 clients who chose DMPA-SC agreed to participate in the study. Sixty percent were 18 to 29 years old, 73 percent were married or in-union, and 71 percent had attained junior secondary level of schooling or higher. Of 150 trained providers who participated in the study, 65 percent were community health nurses and 88 percent had at least one year of experience in their professional capacity. Key findings of the study included:

New family planning users chose DMPA-SC

Approximately four out of ten (41%) DMPA-SC clients in this study had never used any (modern or traditional) method of FP.

- Forty-eight percent of clients had recently used intramuscular injectables (DMPA-IM).
- Seventy-one percent of clients who were new FP users continued to use DMPA-SC at 6 months, compared with 64% of clients who had ever used any method of FP.

Most women chose to self-inject 3 months and 6 months after their first injection

- While just over one-third of DMPA-SC clients chose to self-inject their first time using DMPA-SC (35%), nearly two-thirds (65%) chose to self-inject at 3 months and 6 months.
- At 6 months, self-injection was more common among women 18 to 29 years (76%) compared to women 30 years and above (68%), never-married women (81%) compared to ever married/in-union women (69%), first-time FP users (81%) compared to previous modern FP users (65%), and women living in rural areas (87%) compared to urban residents (64%).

Most women continued to use DMPA-SC for nine months

- At 6 months, two out of three clients (67%) continued using DMPA-SC, a total of 9 months of protection.
- Continuation of DMPA-SC was more common among never-married (74%) compared to currently married (65%) and previously married (59%) women. Women from the Volta region were more likely to continue (75%) compared to women in the Ashanti region (58%).

Home self-injection of DMPA-SC was acceptable and feasible

- 44 percent of DMPA-SC clients chose to self-inject at home.
- At 6 months, clients who took DMPA-SC doses home reported high satisfaction (98%) and comfort (100%) with home self-injection.
- Home self-injectors also reported benefits such as not having to travel to the facility (71%), not having to wait at the facility (47%), privacy (42%), and not having to see a provider (37%).
- Nearly all home self-injectors knew how to correctly store (96%) and dispose of (98%) the used Uniject™ device, found it easy to store (94%) and dispose of (96%), and reinjected on time (85%) (within an 11-to-17-week window after the previous injection).

Providers' knowledge of DMPA-SC characteristics increased after the training

At the end of the training, over 90 percent of providers correctly answered questions on five key characteristics of DMPA-SC:

- 98 percent knew that Uniject™ is the injection device for DMPA-SC, an increase from 34 percent before the training.
- 93 percent knew that DMPA-SC is administered subcutaneously, up from 29 percent before the training.
- 99 percent knew DMPA-SC is administered every 3 months, an increase from 52 percent before the training.
- 100 percent knew that DMPA-SC must be stored at room temperature, compared to 55 percent before the training.

- 100 percent could name at least one location on the body where DMPA-SC can be injected, compared to 61 percent before the training.

Providers felt very well prepared to provide DMPA-SC services after the training

At the end of the training, almost all providers reported that they were very well prepared to offer DMPA-SC services to clients:

- 94 percent of providers felt very well prepared to counsel clients on DMPA-SC.
- 93 percent felt very well prepared to administer DMPA-SC.
- 93 percent felt very well prepared to train clients to self-inject.
- 98 percent felt very well prepared to observe and supervise clients during self-injection.

The findings of this study suggest that providers can be trained to counsel their clients on DMPA-SC, administer DMPA-SC, and train and supervise their willing clients to self-inject. Additionally, both providers and clients found self-injection of DMPA-SC to be feasible and acceptable. The following recommendations aim to guide the Ghana Health Service as it scales DMPA-SC up nationally:

Scale up:

- Develop an implementation strategy for staggered rollout across the nation, in public and private health facilities.
- Utilize a cascade training approach similar to the study, whereby national and regional resources persons are trained to become Master Trainers, who then train providers on-site. This will efficiently allow for the number of providers who are trained to be maximized across the country.
- Engage pharmacies and over-the-counter medical sellers in commodity resupply, enabling them to sell DMPA-SC to women who have received self-injection training at the facility and amplifying the role of the private sector in increasing uptake of DMPA-SC in Ghana.

Policy and Standards:

- Develop national guidelines and standards governing home self-injection of DMPA-SC, to be included in the next edition of the National Reproductive Health Service Policy and Standards.
- Develop national guidelines and standards for disposal and waste management of used devices for facilities and home self-injection clients.

Demand generation:

- Raise awareness by integrating DMPA-SC in relevant health promotion and social marketing activities in the community and at health facilities.

Monitoring and Evaluation:

- Enforce the use of the standard Adverse Reaction Reporting Form in public and private facilities as well as pharmacies and over-the counter medical seller shops as part of pharmacovigilance.
- Add DMPA-SC and its modalities as a method option on FP registries and daily logs, to enable public and private facilities to contribute to national monitoring and reporting of DMPA-SC use.
- Include global DMPA-SC indicators in monitoring and evaluation tools to enable comparisons of trends with other countries.

- Develop an action plan for monitoring disposal and waste management for facilities and home self-injection clients. While 95 percent of clients stored DMPA-SC correctly and 98 percent disposed of it correctly, this study did not follow women for long enough to know if they would also return their disposal container to the facility at the time of resupply.
- Conduct regular assessments of client experiences with DMPA-SC, including reinjection, storage, and disposal practices, as well as reasons for discontinuation of DMPA-SC, and a comparison of these reasons to those for discontinuation of DMPA-IM. As self-injection is a new mode of administration in Ghana, monitoring its use from the clients' perspective will be critical in understanding successes and challenges of home injection for learning across the region.

Background

Ghana's Family Planning 2020 (FP2020) commitments include increasing the modern contraceptive prevalence rate (mCPR) among currently married or in-union women to 29 percent and among unmarried adolescents to 35 percent by 2020, with a focus on improving access to voluntary family planning (FP) in peri-urban and rural areas. Specifically, the Government of Ghana has made a commitment to increase the number of women using modern contraception from 1.46 million as of 2015 to 1.93 million in 2020 via increased access and availability of services at all service delivery levels, building capacity of health providers, improving the contraceptive method mix, and increasing demand for FP services (FP2020 2017).

The most recent nationally representative data, the Ghana Demographic and Health Survey conducted in 2014 and the Ghana Maternal Health Survey conducted in 2017, indicate that the mCPR among married women is between 22 percent (GSS et al. 2015) and 25 percent (GSS et al. 2018), and among sexually active unmarried women is between 31 percent (GSS et al. 2017) and 32 percent (GSS et al. 2018), with a total fertility rate between 3.9 and 4.2 births per woman (GSS et al. 2018; GSS et al. 2015). A sizeable unmet need for FP remains, with approximately 30 percent of married women and 42 percent of unmarried women in Ghana wanting either no more children or to postpone childbearing for at least the next two years, but not using any method of contraception (GSS et al. 2015).

In 1988, 0.3 percent of married women in Ghana reported using injectables; this proportion steadily increased to 8 percent in 2014 (GSS et al. 2015), making injectables the most commonly used method among married women. Among married modern contraceptive users, nearly one-third (32 percent) reported using an injectable, and among unmarried modern contraceptive users, 22 percent use an injectable (GSS et al. 2017). With a failure rate of less than one percent for perfect use and less than 4 percent for typical use (Trussell 2011; Polis et al. 2017), injectable contraceptives are highly effective, reversible, and convenient to use, and can ensure privacy and secrecy (Adetunji 2011).

The most commonly used injectable contraceptive method by women around the world, including women in Ghana, is the progestin-only depot medroxyprogesterone acetate (DMPA). DMPA can be administered either as an intramuscular (IM) injection or as a subcutaneous (SC) injection. There are several similarities between DMPA-SC and DMPA-IM, including three-month injection frequency, safety, and side effects (Figure 1, adapted from PATH). Compared to DMPA-IM, DMPA-SC has a shorter needle and slightly lower dosage, and the subcutaneous injection is administered using the all-in-one Uniject™ device (Figures 1 & 2). DMPA-SC is small, light, and easy-to-use, and requires minimal training (PATH 2017a; PATH 2017b). DMPA-SC is often referred to by its brand name of Sayana® Press¹, a registered trademark of Pfizer, Inc.

The Uniject™ injection system has been described as especially suitable for community-based distribution and for women to administer themselves through self-injection (PATH 2017a; PATH 2017b). As such, DMPA-SC and the possibility of self-injection have become promising pathways for increasing access to a safe and effective contraceptive option in low-resource settings (Keith et al. 2014). In addition, self-injection of DMPA-SC is a method of self-care for women, and thus has the potential to increase the privacy and autonomy of users to decide whether, when, and how many children to have (Murray et al. 2017). As of December 2018, DMPA-SC

¹ In this report, DMPA-SC is used for general references to the injectable contraceptive method, while Sayana® Press is used for specific references to the product used in the study and mentioned in data collection tools. At the time the study was conducted, the product was widely referred to as Sayana® Press in Ghana and elsewhere. Of note is that providers were trained on DMPA-SC, but for consistency with the product packaging, providers counseled and trained clients using the name Sayana® Press.

was available in about 20 FP2020 countries and has been approved by regulatory bodies in more than 40 countries around the world (PATH 2018). In Ghana, it is registered as Sayana® Press by Pfizer, Inc. and is approved for use by the Food and Drug Authority.

Between 2012 and 2015, pilot studies on the feasibility and acceptability of DMPA-SC were undertaken in Senegal and Uganda (Burke et al. 2014). Introductions of DMPA-SC began in Burkina Faso, Niger, Senegal, and Uganda in 2014 through a variety of channels, including clinic and community-based health providers. In a span of two years (2014–2016), providers administered more than 490,300 doses of DMPA-SC to women and reached 135,000 women who were first-time users of modern FP (PATH 2017a).

The pilot studies revealed a demand for self-injection. In Senegal and Uganda, close to 90 percent of clients participating in studies demonstrated competency to self-inject three months after being trained by a provider, and a large proportion of women in these studies expressed a desire to continue with self-injection (Cover et al. 2017a; Cover et al. 2017b). Subsequent studies on continuation conducted in Malawi, Senegal, Uganda, and the United States all showed that over a 12-month period, women who self-injected DMPA-SC at home continued using this injectable contraceptive method longer than their counterparts who received injections from clinic or community-based providers (Burke et al. 2018; Cover et al. 2018; Cover et al. 2019; Kohn et al. 2018).

FIGURE 1. SIMILARITIES AND DIFFERENCES BETWEEN DMPA-IM AND DMPA-SC

Rationale

In 2016, the Ghana Health Service (GHS) reached out to its partners, namely the United States Agency for International Development (USAID), the United Nations Population Fund (UNFPA), Population Services International (PSI), and Population Council, to undertake a feasibility and acceptability study regarding DMPA-SC self-injection, and, by extension, the introduction of the contraceptive method to the country (see Appendix 1 for study partner roles). At the time, acceptability studies had been conducted in Senegal and Uganda which examined clients' willingness to self-inject (Burke et al. 2014). Introduction of DMPA-SC through service-delivery channels had commenced in Burkina Faso, Niger, Senegal, and Uganda.

Although three self-injection studies were ongoing in 2016 in Malawi, Senegal, and Uganda, results were not available at the time the present study was conceived. There was, therefore, a palpable need to broaden the evidence base on the feasibility and acceptability of DMPA-SC self-injection in Ghana and other sub-Saharan countries. Moreover, Ghana aimed to contribute to the growing body of evidence by conducting a study in a context where DMPA-SC and self-injection would be introduced simultaneously.

The current research study was funded by USAID/Ghana and led by the Population Council through the Evidence Project. It was carried out in two regions and across eight public health facilities (four in the Ashanti region and four in the Volta region), over an 8-month period.

This report details the study, including the objectives, intervention components, methodology, and results. It also includes a discussion section that interprets the findings and a final section that highlights the utilization of research findings to inform DMPA-SC scale-up.

FIGURE 2. A VISUAL OF THE UNIJECT™ SYSTEM

Names of the parts of Uniject

Photo credit: PATH, copyright 2018.

Objectives

The aim of the study was to introduce DMPA-SC (using Sayana® Press) to health providers and FP clients in Ghana. The study had three primary objectives:

1. Assess the feasibility and acceptability of DMPA-SC service provision by FP providers and clients in Ghana.
2. Assess the feasibility and acceptability of client self-injection by FP providers in Ghana.
3. Assess the feasibility and acceptability of self-injection by FP clients in Ghana.

Results of the study have informed the scale-up of DMPA-SC, including self-injection, in the public and private sectors of the country.

Methods

Study design

The study was implemented with providers and clients of DMPA-SC in the Ashanti and Volta regions of Ghana. The study included a quantitative self-assessment among providers trained in providing DMPA-SC and in training clients to self-inject DMPA-SC. The assessment was implemented before the training and right after the training concluded. For DMPA-SC clients, a prospective cohort study design was implemented. Clients who selected DMPA-SC were interviewed at the facility after receiving their first injection and then again over the phone after the scheduled second and third injections, which could have occurred at the facility or at home. In some instances, clients' second and third interviews were conducted in person when a phone interview was not feasible either due to connectivity issues and/or client expressing a strong preference for an in-person interview.

Study sites

The study was implemented in selected public health facilities in the Ashanti and Volta regions. The Ashanti region is currently the most populous region of the country with approximately 5 million people. The total fertility rate (TFR) in the Ashanti region is 4.4 births per woman and modern contraceptive prevalence rate (mCPR) is 21 percent. The 2014 Demographic and Health Survey (DHS) showed that approximately 6 percent of married women are using an injectable (GSS et al. 2015). The Volta region is home to approximately 3 million people. The TFR is 3.6 births per woman and the mCPR of 30 percent is the highest in the nation (GSS et al. 2015). Furthermore, 14 percent of married women in the Volta region are using an injectable (GSS et al. 2015). Both Ashanti and Volta regions are predominantly rural.

In each region, four facilities—two rural, one peri-urban, and one urban—were selected across four districts (Table 1). The facilities were eligible for the study based on their rural/urban location, monthly caseload of injectable users, and tracking of service statistics using rsLog.² At the national level, the GHS Family Health Division (FHD) informed the Regional Directors of the Ashanti and Volta Regional Health Directorates about the study. The Regional Director and Deputy Director in Charge of Public Health (DDPH) then contacted District Directors and Facility In-Charges of eligible facilities to inquire about their willingness to participate as a study site.

TABLE 1. STUDY SITES, BY LOCATION

Ashanti Region	Volta Region	Location
Maternal and Child Health Hospital	Council Hall Family Health Unit	Urban
Abuakwa Health Centre	Juapong Health Centre	Peri-Urban
Piase CHPS	Tsito Health Centre	Rural
Fumso Health Centre	Helekpe Health Centre	Rural

² rsLog is a health management information system tool developed by the GHS with technical assistance from Population Council that allows for: monitoring of individual health worker performance by cadre; disaggregation of data by facility, district, regional, and national levels; and generation of monthly electronic reports.

Study population and recruitment

Providers

Providers at selected facilities who had at least six months of experience providing FP services were eligible for participation in the study. Eligible providers included community nurses, enrolled nurses, midwives, and others providing FP services. Facility In-Charges were informed about the study and asked to provide a list of eligible FP-related providers (i.e., reproductive and child health unit, antenatal unit, and outpatient unit) reporting to the facility. These providers were informed about the study during a site visit in October 2017 and all FP-related providers agreed to be recruited into the study in November 2017.

Clients

Clients eligible for the study included women aged 18-49 years who were seeking FP services at the selected health facilities. Women who were planning on becoming pregnant in the next three months and those less than 6 weeks postpartum and breastfeeding were excluded from the study, as were those who were unable to provide a phone number as a contact or unwilling to be reached by phone.

Trained providers counseled clients seeking FP services on a range of contraceptive methods. Providers were trained to counsel clients on DMPA-SC and self-injection mode of administration and to provide an opportunity to train clients on-site to self-inject. After a client who had chosen DMPA-SC received an injection (either through self-administration or provider administration), providers informed them about the research study. Clients who agreed to learn more about the study were introduced to a research team member stationed at the facility. The research team member implemented the informed consent process. Written informed consent was obtained from all clients. Clients who were not able to sign their name attested that the consent form had been read and explained to them by a member of the research staff by marking the space with an “x.”

Clients were enrolled from December 2017 to January 2018 in the Ashanti and Volta regions until the desired sample size was reached. The desired sample size was calculated based on an estimated 25 percent of DMPA-SC users choosing to self-inject after six months (or at the third injection).

The sample size was calculated based on the following formula:

$$n = \frac{Z^2 p(1 - p)}{d^2}$$

Where, n = minimum sample size

Z= 1.96 (standard)

p = 0.25 (estimated proportion of DMPA-SC users who opt for self-injection at t0+6months)

d = 0.05 (5% absolute precision or margin of error)

The minimum sample size derived from this formula is 289. Given the longitudinal nature of the research, the design effects, non-random sampling of women seeking FP services, and loss to follow-up were considered. The calculated sample sizes were multiplied by a standard factor of 1.5 (design effect) and divided by 0.80 (20% loss to follow up). This results in a total minimum sample size of 540 DMPA-SC users across both regions. The

samples were divided equally between both regions with approximately 60 percent from the urban facilities (Table 2).

TABLE 2. EXPECTED CLIENT SAMPLE SIZE, BY REGION

	Ashanti	Volta
Urban/Peri-urban		
<i>Health Facility 1</i>	81	81
<i>Health Facility 2</i>	81	81
Rural		
<i>Health Facility or CHPS Compound 1</i>	54	54
<i>Health Facility or CHPS Compound 2</i>	54	54
Total	270	270

Data collection

Data collector training

Thirty-two data collectors (16 per region) were recruited in October 2017 and trained in November 2017 to conduct client interviews. In rural facilities where the expected client enrollment was 54, three data collectors were recruited to conduct 18 interviews each. Likewise, five data collectors were recruited for each urban and peri-urban facility where the expected client enrollment was 81. To equalize the number of interviews conducted by each data collector, the enrollment was increased to 90 in the urban and peri-urban facilities.

In both regions, data collectors were trained over a 3-day period. The training included an overview of the study and its goals; FP methods available and use trends in Ghana; the principles of research, including ethical conduct, privacy, and confidentiality; the informed consent process and consent forms; the role of the data collector in administering informed consent forms and ensuring confidentiality and privacy; review of the different study instruments, interview questions, and their respective purposes; and data collection timelines and data management.

Both trainings included a combination of PowerPoint presentations, quizzes, role-plays, and practice using the tablets and troubleshooting data collection issues. The study instruments were developed in English and translated orally into Ewe (the predominant language in the Volta region) and Twi (the predominant language in the Ashanti region) during the trainings. In the event of disagreements, data collectors deliberated and came to a consensus on terminology to use. Client interviews were conducted in the participant's preferred language (i.e., English, Ewe, or Twi), while the provider self-administered questionnaires were in English.

Data collected

Providers

Providers completed self-administered paper-based questionnaires before and after the training in November 2017. The purpose of these questionnaires was to evaluate changes in knowledge related to FP counseling and contraceptive methods in general, and particularly DMPA-SC counseling and administration, as a result of the training received. The pre-training questionnaire gathered information on providers' sociodemographic characteristics (age, educational level, gender) as well as professional data (length of service provision, cadre, average number of clients served per month). In addition, the questionnaire asked providers about FP counseling

and provision experience as well as clinical practice. Providers completed the same questionnaire at pre-training and post-training, although the latter included some additional questions about the training experience and self-reported preparedness to administer DMPA-SC and teach self-injection to clients.

Clients

Data collection with clients began in the first week of December 2017 in Ashanti Region and second week of December 2017 in Volta Region. Three rounds of client interviews were conducted. Data collection about clients' first injection experiences ended in the last week of January 2018 in both regions. Data collection about clients' second and third injection experiences spanned March to April 2018 and June to July 2018, respectively.

The first interview was conducted immediately after the client first received DMPA-SC at the health facility, and the second and third interviews were conducted at three-month intervals, at 3 months and 6 months, to correspond with clients' scheduled reinjection dates. The first interview was conducted in-person at the facility, after the first injection. The majority of these interviews were conducted in a private space at the health facility, although some clients preferred to be interviewed in another private space outside of the facility. Interviews at 3 months and 6 months were originally intended to be conducted over the phone after the scheduled reinjection window for each client. However, some clients encountered connectivity issues, while others perceived that they would face social harms for spending long periods of time on the phone, preferring instead that the interviews be conducted face to face at the facility or at home, which the research team accommodated. Home self-injectors identified a private space for the interview, usually in their homes.

The questionnaire about clients' first injection experience included information on sociodemographic characteristics, previous FP use, awareness of Sayana® Press, quality of care during the FP visit, Sayana® Press counseling messages received, experiences with Sayana® Press injection training and administration, intention to continue using Sayana® Press, home self-injection pack received (for those administering at home), and reporting of serious adverse reactions. Additional questions in the 3-month and 6-month interviews focused on the most recent injection experience, experience of side effects, and experiences with home self-injection for those who chose to administer DMPA-SC at home, including ease of home self-injection, storage and disposal of the device, and reinjection dates.

Clients who declined to participate in the study after the first injection, withdrew from the study by 3 months or 6 months, or discontinued using DMPA-SC by 3 months or 6 months were asked to participate in a separate interview with questions about their reasons for declining, withdrawing, or discontinuing the method.

Health service statistics

DMPA-SC service delivery data were collected throughout the study using rsLog, a health management information system (HMIS) tool developed by the GHS with technical assistance from Population Council. Unlike the typical national HMIS used in the majority of West African countries into which aggregated data is entered, rsLog allows for monitoring of individual health worker performance, by cadre; disaggregation of data by facility, district, regional, and national levels; and generation of monthly electronic reports. Using rsLog, the number of doses of DMPA-SC administered daily by cadre of health worker was captured. Data from rsLog was collected for 10 months to help gauge continuation of DMPA-SC after the study period. Data from rsLog was used for monitoring purposes and as part of the assessment of the feasibility of introducing DMPA-SC in health facilities in Ghana. These data were not analyzed for this report.

Data management and analysis

Data management

Provider responses from the pre- and post-training questionnaires were double entered manually into Census and Survey Processing System (CSPro) by two different data analysts to reconcile any inconsistencies.

Interviews with clients were conducted using an electronic tablet pre-loaded with time-appropriate questionnaires. Data collectors entered client responses into CSPro software installed on tablets. The data were sent via a secure server to data supervisors who checked them for completeness and accuracy. Raw provider and client data were accessible only to the research management team, namely the data supervisors, principal investigator, program manager, research specialist, and the technical director. Only de-identified and aggregated data were shared with stakeholders.

Data analysis

For both the provider and client data, descriptive statistics and bivariate analyses were conducted using Stata 15 software. Specifically, chi-square tests and t-tests were used to determine significant differences.

Ethical considerations

Ethical review

The research protocol, including the informed consent forms and data collection tools, was approved by the Population Council Institutional Review Board in November 2016 and the GHS Ethical Review Committee in April 2017.

Informed consent

Structured and written informed consent forms were administered in-person to providers before the trainings began and to willing FP clients after taking their first DMPA-SC injection. All who agreed to participate in the study were asked to sign the forms and were given a copy for their records. Clients who were not able to sign their name attested that the consent form had been read and explained to them by a member of the research staff by marking the space with an “x.” In subsequent rounds, clients provided verbal consent to data collectors to conduct the interviews. The informed consent forms detailed the (a) study purpose, objectives, and duration; (b) methodology; (c) interview procedures; (d) measures to protect their privacy, confidentiality, and anonymity of information provided; (e) risks and benefits; (f) right to withdraw from the study or to refuse answering questions at any point of the study; (g) compensation (clients were compensated with a bar of soap for their time); (h) contact information of ethical review boards; and (i) who to contact for additional information or if there was a problem. Master Trainers read the informed consent form to providers and explained its contents and data collectors did the same with clients before seeking their written consent if they agreed to be part of the study. All who declined to participate in the study were informed that they would be asked a few questions to help understand their reasons, to which they were also given the choice to decline responding.

Confidentiality

Each respondent was assigned a unique identification (ID) number prior to completing the first interview or responding to the “Decline, Withdraw, or Discontinue” (DWD) interview. The unique ID was prefilled for subsequent interviews. For providers, the unique ID was assigned when entering the data. As such, the questionnaires with their names were kept in a locked cabinet at the Population Council office in Accra, Ghana and will remain locked until 2022 as per Population Council research data and confidentiality procedures. Informed consent forms were kept in a separate locked cabinet in the same office.

Description of the Intervention

Stakeholder engagement

Technical Advisory Group

The Population Council convened a Technical Advisory Group (TAG) in August 2016 to discuss and agree on the self-injection study objectives. Comprising stakeholders from the public, private, and non-governmental sectors (see Table 3 for list of participant organizations), the TAG remained active to provide guidance on study regions, study design and methods, study intervention, product registration approach, and expected roles of study partners. The diverse composition of the TAG was deliberate and based on the expected private sector role in the event of a scale-up of DMPA-SC. The TAG held six face-to-face meetings between August 2016 and November 2018 during which data collection updates were presented, findings discussed, and input and feedback received. Outside of face-to-face meetings, the TAG remained engaged throughout the study period via regular email updates.

Regional Health Directorate meetings

Sayana® Press was approved as a contraceptive product by the Food and Drugs Authority (FDA) in November 2016, paving the way for discussions with the Regional Health Directorates of the Ashanti and Volta Regions. In both regions, meetings were held in January 2017 with the Regional Health Director, Deputy Director for Public Health (DDPH), and the Regional Public Health Nurse to discuss the study, intervention, and proposed study sites. Upon agreement, the Regional Health Directors delegated their DDPH to further inform respective District Directors and Facility In-charges.

Inception meetings

Inception meetings were organized in the two regions: one in the Ashanti region in February 2017 and another in the Volta region in March 2017. In both regions, meetings were attended by the GHS leadership at the regional, district, and facility levels. The meetings were also attended by the leadership of the GHS Family Health Division (national) and by representatives of USAID/Ghana's Health, Population, and Nutrition Office. The meetings included a presentation on the study rationale, objectives, intervention, and other proposed activities, followed by discussions on topics such as storage, waste, disposal, stock availability, and pricing of DMPA-SC.

Facility visits

All In-Charges of the facilities communicated their willingness to be selected as a study site to the Regional Health Directorate. In October 2017, the study team visited the eight study facilities to engage directly with the In-Charges as well as the providers to discuss the study, introduction of DMPA-SC in Ghana using Sayana® Press, a recap of the inception meeting, and the provider trainings. This was also an opportunity for providers to ask questions and clarify that their training would be separate from their consent to participate in the research study.

DMPA-SC training

The study involved a three-step training cascade:

1. Training of Master Trainers

The Family Health Division (FHD) of the GHS identified eight of its Regional Resource Trainers (four per region) to be trained by a Master Trainer from PATH Uganda, a country where DMPA-SC and self-injection feasibility and acceptability studies had been conducted. The 4-day training took place in mid-October 2017. The training focused on DMPA-related topics outlined in Box 1 using PowerPoint slides derived from a standardized training guide developed by PATH. At the request of the FHD, a one-page information sheet for clients on adverse and severe adverse reactions as well as actions to take was developed and reviewed in the training. This form was separate from the Adverse Reaction Reporting Form developed by the FDA for pharmacovigilance and used by GHS. The training also included role-plays for providers to practice how to administer DMPA-SC and train clients on self-injection.

Before the training, the Regional Resource Trainers completed a pre-training evaluation. They completed a post-training evaluation on the last day of the training to ascertain gains in DMPA-SC knowledge from the training. The PATH Master Trainer certified the Regional Resource Trainers as Ghana Master Trainers in DMPA-SC and self-injection.

2. Training of health providers

The eight Ghana Master Trainers trained a total of 150 health providers (71 in Ashanti Region and 79 in Volta Region) across the eight selected study facilities. Each week in November 2017, 3-day trainings were conducted simultaneously in each region (except for 2-day trainings in two rural facilities, due to small staff size). In each facility, training was conducted among staff from various FP-related departments (e.g., antenatal, reproductive and child health, nutrition) and of different cadres (i.e., community nurses, enrolled nurses, midwives, and others) (Table 6).

The Ghana Master Trainers used the same PATH resources and training guide to train the health providers. The topics and lessons were delivered via PowerPoint presentations, and hardcopies of the job aids were made available. The tools used in the training included:

1. *Provider injection checklist*: This checklist was used by the Master Trainers to observe providers practicing administering DMPA-SC injections on clients.

2. *Observation checklist for Sayana® Press self-injection practice*: This observation checklist developed by PATH was used by the Master Trainers to observe providers during their role play of training clients to practice DMPA-SC self-injection and by the providers to observe clients during their actual practice of self-injection.

3. *Reinjection calendar (2017-2018)*: This calendar spanning two years aided clients in remembering when to return to the facility for reinjection or when to reinject at home. All home self-injection clients were given the calendar.

Box 1: Overview of topics covered in self-injection training for providers

1. General overview of family planning
2. Overview of DMPA
 - a. What is DMPA-SC?
 - b. What is Uniject™?
 - c. DMPA-IM and DMPA-SC: similarities and differences
 - d. Mode of action and route of administration
3. Screening women for DMPA
4. Counseling women for DMPA
5. HIV risk and hormonal contraceptives including DMPA
6. Safe storage and handling sharps
7. Provider-administered DMPA-SC injection
8. Counseling women on DMPA-SC self-injection
9. Training women to self-inject
10. Training clients to safely store DMPA-SC
11. Training clients to safely dispose of used Uniject™ devices
12. Training clients to calculate reinjection dates
13. Side effects management
14. Client follow up options

4. *Client self-injection instruction sheet*: This one-page sheet (front and back) with pictorial instructions was designed as a visual aid for clients to remember the steps required for safe self-injection. All home self-injection clients were given this sheet.

5. *Adverse Reaction Reporting Form*: This form was developed by the FDA and is used by GHS as part of pharmacovigilance. Providers were (re)trained to use this form to report adverse reactions to the GHS.

6. *Adverse reaction information sheet for clients*: This one-page sheet was developed for the purposes of the study to help clients recognize the signs of severe adverse reactions and where to seek immediate medical attention.

7. *DMPA-SC job aids for providers*: These job aids developed by PATH were given to each provider to take back to their facilities and use when providing DMPA-SC services.

Additionally, providers completed a self-administered questionnaire to determine their knowledge before the training and a similar questionnaire after the training to gauge any changes in knowledge on FP in general and DMPA-SC in particular. These questionnaires were developed for the purposes of the study.

In Volta region, providers were also trained on inputting data into rsLog, the health information system. No trainings were needed in Ashanti region as providers in the study facilities were already using the rsLog system.

3. Training of family planning clients

Trained providers counseled FP clients at the facility on all available contraceptive methods, including DMPA-SC and on its two modes of administration (i.e., provider-administered or client self-administered). Among clients who desired to use DMPA-SC, their eligibility to receive the method was based on the World Health Organization's Medical Eligibility Criteria for Contraceptive Use (WHO 2015).

Providers offered clients an option to be trained by the provider to self-inject or to receive the injection by the provider. If a client chose to self-inject, she was given the opportunity to practice self-injection up to five times on a condom filled with salt, to mimic the fat under skin, under the supervision of the provider. The provider deemed the client competent to self-inject when a client successfully executed the five critical self-injection steps (out of 11 total steps) (see Box 2, critical steps in bold), using the observational checklist (tool #2 listed in training description above) and his or her own clinical judgement. Providers also trained self-injection clients on calculating future injection dates, safe home storage, and safe disposal into a puncture-proof container.

Clients who chose provider-administered injection and did not practice self-injection or despite a self-injection practice, clients who failed to be competent in self-injection were informed about their follow-up visit, and the date for the

Box 2: Checklist for DMPA-SC self-injection practice

Step 1: Washes hands.

Step 2: Selects an appropriate injection site and cleans it if needed.

Step 3: Opens the Sayana® Press pouch by tearing from the notch.

Step 4: Mixes the liquid by shaking the device vigorously for about 30 seconds.

Step 5: Pushes the needle cap and port together to activate the device.

Step 6: Removes the needle cap.

Step 7: Pinches the "skin" at the injection site to form a "tent".

Step 8: Inserts the needle completely so that the port is in full contact with the skin.

Step 9: Presses the reservoir slowly to inject for about 5 to 7 seconds.

Step 10: Removes the device from the injection site while still pinching the skin.

Step 11: Immediately places the used device in a sharps disposal container without replacing the needle cap.

Bold indicates critical steps.

visit was indicated on their FP card. Clients who were trained to self-inject and deemed competent were given up to two DMPA-SC doses for home self-injection, along with the 2017-2018 reinjection calendar with dates for the next injections circled, the self-injection instruction sheet, and the puncture-proof disposable container for disposing of the used devices. Self-injection clients were also asked to return the container with the used devices to the facility at any point during the study for final disposal, but especially after the third injection when they returned to receive additional doses.

Commodities and logistics

The UNFPA procured 6,000 doses of DMPA-SC (Sayana® Press), which were sent to the Central Medical Stores. Given that no requisition forms existed for the DMPA-SC, the commodities were transported to the regional health directorates by the Evidence Project with approval from GHS-FHD and received by the respective Regional Public Health Nurses.

The number of commodities per facility was determined by assuming a scenario in which all clients chose self-injection. Calculations took into consideration the three doses needed for each client, regardless of mode of administration, four doses needed for self-injection practice, and one dose to cover an additional three months after the study. Each client was allocated a total of eight doses. An additional 30 percent of doses were added for clients who selected DMPA-SC but declined participation in the study. A reserve of doses was stocked at the regional medical stores for procurement during and after the study. Each rural facility received 562 doses of DMPA-SC while each peri-urban and urban facility received 936 doses.

TABLE 3. LIST OF ORGANIZATIONS INVOLVED IN TECHNICAL ADVISORY GROUP

Organizations	Sector represented
United States Agency for International Development (USAID)	Donor
Ghana Health Service (GHS)	Public
The Evidence Project, through Population Council	INGO
United Nations Population Fund (UNFPA)	Donor
Population Services International (PSI)	INGO
Strengthening Health Outcomes through the Private Sector (SHOPS)	INGO
Pfizer, Inc.	Private
Planned Parenthood Association of Ghana (PPAG)	NGO
Health Keepers Network (HKN)	NGO
DKT International	NGO – Social Enterprise

Monitoring and supervision

Supportive supervision of trained providers

In both regions, Master Trainers conducted supportive supervision visits to each study facility three months post-training (February 2018). At each facility, using the observation checklist for self-injection practice, Master Trainers observed each provider simulating the steps for training clients to self-inject. Where necessary, the Master Trainers aided providers to improve technique and reinforce knowledge. Additionally, Master Trainers completed a supportive supervision form to assess the readiness of the facility and of providers to successfully continue providing DMPA-SC services.

Supervision of data collectors

Immediately following the data collectors' training, a WhatsApp group was created for each region. The groups included the respective data collectors, the research team, and the data management team. This platform was used to exchange information from the research management team and for data collectors to initiate any discussions related to tips or any challenges encountered during fieldwork. The platform also served as a tool for continued supervision by the data management team.

TAG monitoring visit

Representatives from the TAG, specifically USAID/Ghana, GHS Family Health Division, and Population Council, visited the Volta region in May 2018. Alongside two Master Trainers, the TAG representatives met with the Regional Health Directorate followed by visits to Helekpe Health Centre and Council Hall Family Health Unit. During these visits, they interacted with the providers and In-Charges. TAG members took the opportunity to ask questions about providers' experiences with DMPA-SC, training clients on self-injection, and waste and disposal, as well as any implementation challenges encountered. Providers also took the opportunity to ask questions about GHS' plans for expansion and scale-up after the study ended.

Results

Client sociodemographic characteristics

Across both regions, 568 clients who chose DMPA-SC agreed to participate in the study. Table 4 presents the sociodemographic characteristics of clients enrolled in the study at the time of their first injection. More than half of respondents were between 18 and 29 years old (60%), and the majority were married or in-union (73%). Half had attained junior secondary school/junior high school (JSS/JHS) level (50%) and 22 percent had attained senior secondary school/senior high school (SSS/SHS) level or higher. More clients were enrolled in urban areas (60%), though by region, the distribution was almost equal. Enrollment by facility was a function of the estimated sample size. Almost 60 percent of clients had previous experience using a modern or traditional FP method and over three-quarters (76%) of respondents reported that their partner supported their use of FP. For most clients (72%), the travel time to the facility was less than 30 minutes.

TABLE 4. PERCENT DISTRIBUTION OF STUDY PARTICIPANTS BY SOCIODEMOGRAPHIC CHARACTERISTICS AT FIRST INJECTION (N=568)

	N	Percent
Age group*		
18-24	185	32.6
25-29	156	27.5
30-34	107	18.8
35-39	62	10.9
40-44	33	5.8
45+	24	4.2
Marital status		
Never married	155	27.3
Ever married/in-union	413	72.7
Education		
No education	55	9.7
Primary	107	18.8
JSS/JHS	282	49.7
SSS/SHS or higher	124	21.8
Region		
Ashanti	278	48.9
Volta	290	51.1
Residence		
Rural	226	39.8
Urban	342	60.2
Facility		
Maternal & Child Health Hospital	90	15.9
Abuakwa Health Centre	79	13.9
Piase CHPS	54	9.5
Fumso Health Centre	55	9.7
Council Hall Family Health Unit	84	14.8
Helekpe Health Centre	55	9.7
Tsito Health Centre	62	10.9
Juapong Health Centre	89	15.7
Contraceptive experience		
Previous FP user	334	58.8
New FP user	234	41.2
Partner supports FP use		
No/don't know	137	24.1
Yes	431	75.9
Travel time to reach facility		
Less than 30 minutes	410	72.2
30 minutes to 60 minutes	130	22.9
More than 60 minutes	28	4.9
Total	568	100.0

*Percentages may not add to 100 percent due to missing values

New family planning users chose DMPA-SC

Notably, 41 percent of respondents had never used any method of FP (Figure 3), while 59 percent had previously used either a modern or traditional method (Table 4). Figure 3 shows the FP method most recently used by clients before choosing DMPA-SC. Nearly half of respondents (48 percent) reported having used an injectable most recently, and 6 percent reported having used an implant. The remaining 5 percent reported having used oral contraceptive pills, withdrawal, male condoms, emergency contraception, abstinence, or the Standard Days Method®.

FIGURE 3. MOST RECENTLY USED FAMILY PLANNING METHOD AMONG DMPA-SC CLIENTS (N=568)

Most women chose to self-inject 3 months and 6 months after their first injection

During their FP counseling sessions, clients who selected DMPA-SC were offered an opportunity to be trained in self-injection and, if deemed competent by the provider, could self-inject. Otherwise, the provider could inject the DMPA-SC. Figure 4 shows the administration mode selected by clients at each injection among respondents who were successfully interviewed at each follow-up interview. For the first injection, about one-third of clients (35%) were successfully trained in and completed self-injection at the facility. At 3 months, 65 percent of clients surveyed selected self-injection (21% on site at the facility and 44% at home), while 29 percent selected provider-administered injection and 7 percent discontinued using DMPA-SC. By the end of the study, at 6 months, most clients (65 percent) selected self-injection (23% at the facility and 42% at home), 24 percent selected provider-administration, and 11 percent discontinued DMPA-SC.

FIGURE 4. CLIENTS' SELECTED MODE OF INJECTION ADMINISTRATION, BY INTERVIEW

Figures 5-9 detail the distribution of clients' selected administration mode of DMPA-SC at 6 months, by select sociodemographic characteristics (additional information on mode of injection administration at each interview by background characteristics is available in Appendix 2). Chi-squared tests of significance were conducted to assess differences between provider-administered and self-injection. Those who self-injected at 3 months or 6 months, whether at home or at the facility, were grouped together as self-injectors for these chi-squared tests.

Figure 5 presents clients' mode of injection administration by age. There was a statistically significant difference between age groups in choosing self-injection (p -value <0.05). At 6 months, about three-quarters of 18 to 24-year-olds (78%), 25 to 29-year-olds (74%), and 30 to 34-year-olds (78%) were self-injection clients, compared to 65 percent of 35 to 39-year-olds and 51 percent of those 40 years and older. A greater proportion (49 percent) of those 40 years and older chose provider-administration of DMPA-SC. Self-injectors comprised those who self-injected at home and at the facility. Those 25 to 29 years old were most likely to have self-injected at home at 6 months (56%), followed by 30 to 34 years old (50%) and 18 to 24 years old (45%). Those 35 to 39 years old as well as 40 years and older were less likely to self-inject at home (36% of each age group). On-site self-injection was most likely among those 18-24 (32 percent), followed by 35-39 (29%), and 30-34 (28%) years.

FIGURE 5. CLIENTS' MODE OF INJECTION ADMINISTRATION AT 6 MONTHS, BY AGE (N=378)

At 6 months, there was a significant difference between marital status groups (p -value <0.05) in self-injection of DMPA-SC (Figure 6). Eighty one percent of never married clients and 69 percent of ever married/in-union clients self-administered DMPA-SC, with 55 percent of never married clients and 44 percent of those ever married/in-union being home self-injection clients. Similar proportions of ever-married/in-union women and never married women self-injected on-site, at 25 percent and 26 percent, respectively. A greater percentage of those who were ever married/in-union chose provider-administered injections (31%) compared to those who were never married (20%).

FIGURE 6. CLIENTS' MODE OF INJECTION ADMINISTRATION AT 6 MONTHS, BY MARITAL STATUS (N=378)

There was no statistically significant difference in choosing self-injection among educational groups at 6 months, with 64 percent of those with no education, 79 percent of those with primary, 70 percent of those with JSS/JHS, and 78 percent of those with SSS/SHS self-injecting at 6 months (Figure 7). However, there appears to be an increase in specifically home self-injection by education level, as 35 percent of those with no education, 40 percent of clients with primary, 48 percent with JSS/JHS, and 56 percent of those with SSS/SHS chose to self-inject at home at 6 months. More than one-third of those with primary education chose to self-inject on-site, at 39 percent, followed by 29 percent of those with no education. Similar proportions of those with junior and senior or higher levels of education self-injected on site, at 22 percent each.

FIGURE 7. CLIENTS' MODE OF INJECTION ADMINISTRATION AT 6 MONTHS, BY EDUCATION (N=378)

Respondents who lived in rural locations were significantly more likely to self-inject at 6 months than those in urban locations, with 87 percent of those living in rural locations choosing to self-inject compared to 64 percent of those in urban locations (Figure 8). For home self-injection specifically, 80 percent of respondents living in rural locations chose to self-inject at home, compared to 27 percent of those living in urban areas, whereas 37 percent of women in urban areas chose on-site self-injection compared to 7 percent of rural women.

FIGURE 8. CLIENTS’ MODE OF INJECTION ADMINISTRATION AT 6-MONTHS, BY RESIDENCE (N=378)

Figure 9 demonstrates that those who were first-time FP users were significantly more likely to self-inject, at 81 percent, than those who had used a modern or traditional method of FP prior to using DMPA-SC, at 65 percent. A greater proportion (53%) of first-time FP users also self-injected at home compared to previous FP users (43%), while similar proportions self-injected on-site (28% of first-time FP users compared to 23% of previous FP users).

FIGURE 9. CLIENTS' MODE OF INJECTION ADMINISTRATION AT 6 MONTHS, BY HISTORY OF FAMILY PLANNING USE (N=378)

Most women continued to use DMPA-SC for nine months

Figure 10 presents the proportion of clients who continued to use DMPA-SC through the end of the study, that is, a total of 9 months of protection. At 3 months, 76 percent of clients continued using DMPA-SC, 6 percent had discontinued using DMPA-SC, and 18 percent had withdrawn from the study or were lost to follow-up. By 6 months, 67 percent of clients were still using DMPA-SC, while 8 percent had discontinued³ using DMPA-SC, and 25 percent had withdrawn from the study or were lost to follow-up.

FIGURE 10. CONTINUATION AND DISCONTINUATION OF DMPA-SC AND STUDY WITHDRAWAL/LOSS TO FOLLOW-UP, BY INTERVIEW (N=568)

Table 5 presents differences in continuation of DMPA-SC at 6 months by client characteristics. Continuation of DMPA-SC includes provider-administered, on-site self-injection, and home self-injection clients. Discontinuation includes those who stopped using DMPA-SC, those who were lost to follow-up, and those that withdrew from the study. There were no significant differences in continuation of DMPA-SC by age, education, urban/rural residence, and travel time to reach the facility. However, continuation was statistically different by marital status, with those who were never-married (74%) being more likely to continue using than those who were currently married (65%), and those who were formerly married being the least likely to continue (59%). There were also statistically significant differences in continuation by region, with respondents in Volta region being more likely to continue (75%) than those in Ashanti region (57%). Those who had previous experience using FP were less likely to continue using DMPA-SC (64%) compared with new FP users (71%) although, the relationship was not statistically significant (p-value <0.1).

³ Data were not collected on whether discontinuers of DMPA-SC switched to another FP method.

TABLE 5. CONTINUATION OF DMPA-SC AT 6 MONTHS BY CLIENT BACKGROUND CHARACTERISTICS (N=568)

	Discontinued (%)	Continued (%)	p-value
Age group			
18-24 (n=185)	33.0	67.0	0.481
25-29 (n=156)	37.2	62.8	
30-34 (n=107)	32.7	67.3	
35-39 (n=62)	24.2	75.8	
40+ (n=57)	35.1	64.9	
Marital status†			0.050
Never married (n=155)	26.5	73.5	0.291
Currently married/in-union (n=323)	34.7	65.3	
Formerly married/in-union (n=90)	41.1	58.9	
Education			
No education (n=55)	43.6	56.4	<0.001†
Primary (n=107)	34.6	65.4	
JSS/JHS (n=282)	33.0	67.0	
SSS/SHS or higher (n=124)	29.0	71.0	
Region†			
Ashanti (n=278)	42.4	57.6	0.245
Volta (n=290)	24.8	75.2	
Residence			
Rural (n=226)	36.3	63.7	0.063
Urban (n=342)	31.6	68.6	
Contraceptive experience			
Previous FP user (n=334)	36.5	63.5	0.208
New FP user (n=234)	29.1	70.9	
Travel time to reach facility			
Less than 30 minutes (n=410)	32.2	67.8	0.208
30 minutes to 1 hour (n=130)	39.2	60.8	
More than 1 hour (n=28)	25.0	75.0	
Total (n=568)	33.5	66.5	

†p-value <0.05 indicating significant differences

Clients who discontinued using DMPA-SC but were not lost to follow-up reported a variety of reasons for discontinuing the method (Figure 11). Experiencing side effects was the most common reason, as reported by 44 percent of clients who discontinued using DMPA-SC. Approximately 23 percent reported inconvenience as a reason for discontinuation, while 16 percent discontinued to switch to a different method of FP. Other reasons for discontinuing included that the client was traveling, the possibility of experiencing adverse or serious effects, the fear of getting pregnant, wanting to become pregnant, difficulty storing the devices, and an unsupervised injection environment. Nine percent did not list a reason for discontinuing.

FIGURE 11. CLIENTS' REPORTED REASONS FOR DISCONTINUING DMPA-SC AT 3 MONTHS OR 6 MONTHS (N=80)

Home self-injection of DMPA-SC was acceptable and feasible

Acceptability

Clients who had selected self-injection and were deemed competent to self-inject were given up to two DMPA-SC doses to take home. Those who self-injected at home at 3 months (n=203) and at 6 months (n=178) were asked about different aspects of acceptability of home self-injection (Figure 12). Clients reported high levels of satisfaction (100% at 3 months and 98% at 6 months) and high levels of comfort with their home self-injection experience (100% at 3 months and 6 months). Ninety-five percent at 3 months and 97 percent at 6 months reported that they would recommend DMPA-SC home self-injection to a friend. Almost all intended to continue home self-injection in the future (98% at 3 months and 97% at 6 months).

FIGURE 12. ASPECTS OF ACCEPTABILITY AMONG HOME SELF-INJECTION CLIENTS AT 3 MONTHS AND 6 MONTHS

Benefits

Home self-injection clients reported on the benefits of self-injecting at home (Figure 13). The benefit most often cited was not having to travel to the facility (75% at 3 months and 71% at 6 months). Other benefits commonly reported by home self-injection clients included not having to pay for travel to the facility (48% at both rounds), injecting in the comfort of their own home (45% at 3 months and 53% at 6 months), injecting on their own time (44% at 3 months and 45% at 6 months), and not having to wait at the facility (40% at 3 months and 47% at 6 months).

FIGURE 13. REPORTED BENEFITS OF HOME SELF-INJECTION AMONG CLIENTS WHO SELF-INJECTED AT HOME AT 3 MONTHS OR 6 MONTHS

Storage and disposal

Self-injection clients were trained on how to properly store the DMPA-SC doses and dispose of the used Uniject™ devices, and were asked at 3 months and 6 months how they stored and disposed of the devices (Figure 14). Ninety-one percent of home self-injection clients reported correctly storing the doses in a cool, dry area at room temperature, and this increased to 96 percent at 6 months. Nearly all home self-injection clients reported correctly disposing of the used Uniject™ in a coverable and puncture-proof container (99% at 3 months and 98% at 6 months). At 3 months, 24 percent of home self-injection clients reported returning the puncture-proof container to the health facility and this proportion rose to 37 percent at 6 months. Because respondents would have had only two used devices to dispose of during the study period and a re-supply would only have been necessary at 9 months, returning the container⁴ to the health facility was not necessary by 6 months.

FIGURE 14. CLIENTS' METHODS FOR STORAGE AND DISPOSAL OF THE DMPA-SC UNIJECT™

⁴ The container used in this study could hold up to 5 used Uniject™ devices comfortably (see Appendix 3 for example of the puncture-proof containers).

Figure 15 presents clients’ reported ease of storage and disposal of DMPA-SC. Almost all of home self-injection clients found it easy to store the DMPA-SC doses (95% at 3 months and 94% at 6 months), and at each interview, 96 percent found it easy to dispose of the used device.

FIGURE 15. EASE OF STORAGE AND DISPOSAL OF DMPA-SC

Reinjection

Clients who chose home self-injection were trained on how to calculate future reinjection dates and were given a reinjection calendar to aid their calculation. Figure 16 illustrates clients' reported reinjection time at 6 months, among those who self-injected at home at both 3 months and 6 months. Reinjection time was calculated by counting the days between the reported date of a client's most recent injection at 3 months and the reported date of a client's most recent injection at 6 months. Those who reinjected within the 11-to-17-week reinjection window were considered to have reinjected on-time (PATH 2018), while those who did so before 11 weeks had elapsed were considered early and those who reinjected after more than 17 weeks were considered late. Eighty-five percent of self-injectors reported reinjecting on time, while 13 percent reported reinjecting early and 3 percent reported reinjecting late.

FIGURE 16. CLIENTS' REPORT OF REINJECTION TIME AT 6 MONTHS AMONG THOSE WHO SELF-INJECTED AT HOME AT 3 MONTHS AND 6 MONTHS (N=159)

Provider sociodemographic characteristics

A total of 150 providers were trained across the two study regions. Table 6 presents their background characteristics. The majority of trained providers were under 35 years of age (74%), female (91%) and had completed nursing training college (85%). Although represented by different cadres, almost two-thirds of providers were community health nurses (CHNs). Eighty-eight percent of providers had at least one year of professional experience in their current role, while 81 percent had at least one year of experience providing FP services. A slightly higher proportion of providers were trained in Volta region (53%) compared to Ashanti region (47%). Most facilities had between 21 and 25 FP-related providers trained (a combination of on-site and outreach providers); however, Piase CHPS and Tsito Health Centre, two facilities with smaller client volumes, each had seven providers trained.

TABLE 6. PERCENT DISTRIBUTION OF PROVIDERS BY SOCIODEMOGRAPHIC CHARACTERISTICS (N=150)

	N	Percent
Age group*		
19-24	8	5.3
25-29	41	27.3
30-34	61	40.7
35-39	8	5.3
40-44	3	2.0
45+	10	6.7
Gender		
Male	14	9.3
Female	136	90.7
Education completed		
Senior secondary/High school	5	3.3
Nursing training college	127	84.7
University (undergraduate)	6	4.0
Post graduate degree	4	2.7
Other professional certificate	4	2.7
Professional cadre*		
Enrolled Nurse	9	6.0
Community Health Nurse (CHN)	98	65.3
Community Health Officer (CHO)	9	6.0
Midwife	21	14.0
Other	10	6.7
How long have you been working in this professional capacity?*		
Less than 1 year	13	8.7
1-4 years	59	39.3
5-9 years	41	27.3
10-19 years	23	15.3
20 or more years	9	6.0
How long have you been providing FP*		
Less than 1 year	16	10.7
1-4 years	58	38.7
5-9 years	36	24.0
10 or more years	27	18.0
Region		
Ashanti	71	47.3
Volta	79	52.7
Residence		
Rural	59	39.3
Urban	91	60.7
Facility		
Maternal & Child Health Hospital	21	14.0
Abuakwa Health Centre	21	14.0
Piase CHPS	7	4.7
Fumso Health Centre	22	14.7
Council Hall Family Health Unit	24	16.0
Helekpe Health Centre	23	15.3
Tsito Health Centre	7	4.7
Juapong Health Centre	25	16.7
Total	150	100.0

*Percentages may not add to 100 percent due to missing values

Providers' knowledge of DMPA-SC characteristics increased after the training

Figure 17 shows changes in provider knowledge of DMPA-SC from the pre-training self-administered questionnaire to the post-training self-administered questionnaire. Significant increases were observed across four knowledge questions. Provider knowledge that: the Uniject™ is the type of injection system used for DMPA-SC increased from 34 percent to 98 percent (p-value <0.001), DMPA-SC is administered subcutaneously increased from 29 percent to 93 percent (p-value <0.001), DMPA-SC is administered every three months increased from 52 percent to 99 percent (p-value <0.001), and DMPA-SC is stored at room temperature increased from 55 percent to 100 percent (p-value <0.001).

FIGURE 17. CHANGES IN PROVIDER KNOWLEDGE OF DMPA-SC FROM PRE-TRAINING TO POST-TRAINING (N=150)

† p-value <0.001

Providers were asked where on the body DMPA-SC can be administered. Figure 18 shows that when comparing pre- and post-training responses, more providers correctly identified the location of DMPA-SC administration after receiving the training. While significant increases in knowledge were observed for upper arm (27% to 57%), abdomen (30% to 97%), and upper thigh (45% to 98%) as possible injection sites, only a little more than half of respondents recalled the upper arm as one such site at post-training, likely because the upper arm was not emphasized during the training due to it being a difficult location for clients to self-inject. Overall, all providers knew of at least one location where DMPA-SC could be administered after receiving the training.

FIGURE 18. CHANGES IN PROVIDER KNOWLEDGE OF WHERE DMPA-SC CAN BE ADMINISTERED FROM PRE-TRAINING TO POST-TRAINING (N=150)

†p-value <0.001

Providers felt very well prepared to provide DMPA-SC services after the training

Almost all providers reported that they were very well prepared to offer DMPA-SC services after the training (Figure 19). Ninety-four percent of providers felt very well prepared to counsel clients on DMPA-SC, 93 percent felt very well prepared to administer DMPA-SC and to train clients to self-inject, and 97 percent felt very well prepared to observe and supervise clients during self-injection.

FIGURE 19. PROVIDER-REPORTED PREPAREDNESS TO OFFER DMPA-SC SERVICES AT POST-TRAINING (N=150)*

*Percentages may not add to 100 percent due to missing values

Discussion

This study assessed the feasibility and acceptability of the subcutaneously administered injectable contraceptive known as DMPA-SC, or by its brand name Sayana® Press. The study assessed feasibility and acceptability from the perspective of: (1) service providers in Ghana who received training on DMPA-SC administration and on how to train clients to self-inject and (2) Ghanaian FP clients who voluntarily selected the subcutaneous injectable after counseling. At each injection time over a 6-month period (covering 3 injections), DMPA-SC clients chose between provider-administered injection or self-injection on each of these occasions. Results of the study have been used to inform the scale-up of DMPA-SC, including self-injection, in Ghana's public and private sectors.

New family planning users chose DMPA-SC

Approximately two out of five DMPA-SC clients in this study (41%) had never used any method of FP, while 48 percent of clients had recently used intramuscular injectables (DMPA-IM). Many new users (70%) continued to use the method through the study duration, suggesting that DMPA-SC is a feasible and acceptable option for new users of FP. Adding DMPA-SC to the method mix in Ghana will provide an additional FP option and increase the range of methods offered, which will increase choice for method selection. Reaching both new and previous users of FP with this new method could lead to an increase in modern contraceptive use (Ross and Stover 2013), helping Ghana to meet its FP2020 goals.

Most women chose to self-inject 3 months and 6 months after their first injection

This study originally estimated that by 6 months, 25 percent of DMPA-SC users would choose to self-inject. While just over one-third of DMPA-SC clients chose to self-inject the first time they used DMPA-SC (35%), nearly two-thirds (65%) chose to self-inject at both 3 months and 6 months, suggesting that women may become more comfortable with self-injection after receiving their first injection from the provider. Self-injection was selected more often among 18 to 34-year-olds, never-married women, first-time FP users, and women living in rural areas.

These data confirm that self-injection is acceptable to a variety of women and specifically has the potential to reach vulnerable and marginalized populations with contraceptive needs. For example, women who live in rural areas may live further away from facilities that offer FP and could benefit from an option that allows them to self-inject in the home and return to the facility less often (if at all). Younger and never-married women may value new discrete and private ways of using contraception through self-injection. Expanding the availability of DMPA-SC to the private sector in addition to the public sector may be an opportunity to reach additional women for whom pharmacies and medical sellers are the preferred source of FP due to locations, hours, and privacy, among other conveniences.

Most women continued to use DMPA-SC for 9 months

This study followed women through three cycles of DMPA-SC injection. By 6 months, two out of three (67%) women were still using DMPA-SC, a total of 9 months of protection. Continuation was more common in select subgroups, such as never-married women, women from Volta region, and new FP users. Most women who discontinued (n=80) did so due to method-related reasons, including the experience of side effects (44%), though others found DMPA-SC inconvenient (23%) or switched to a different FP method (16%). The proportion of

discontinuation due to side effects found in the present study is similar to that of DMPA-IM, where, according to the latest Demographic and Health Survey in Ghana, 44 percent of episodes of DMPA-IM use were discontinued due to side effects (GSS 2015).

These findings highlight DMPA-SC's high acceptability and its potential to reduce known barriers to continuation of contraceptive use, especially for clients that may be harder to reach, including never-married women and new FP users. The findings also demonstrate the importance of supporting women who experience side effects to manage their side effects or those who want to discontinue for other reasons to switch to a different FP method as long as their desire to prevent pregnancy remains.

Home self-injection of DMPA-SC was acceptable and feasible

At 3 months, nearly two-thirds (65%) of DMPA-SC clients chose self-injection, including 21 percent that returned to the facility to self-inject in the presence of a provider and 44 percent who self-injected at home. Furthermore, clients who took DMPA-SC doses home reported high satisfaction (98% at 6 months) and comfort (100% at 6 months) with home self-injection, and over 85 percent reported experiencing at least one benefit of home self-injection, such as not having to travel to the facility, not having to wait at the facility, increased visual privacy, and not having to be attended by the provider at the facility. These findings resonate with those of other self-injection studies (e.g., Burke et al. 2014; Cover et al. 2017a) and highlight self-injection of DMPA-SC as a self-care method that can increase women's reproductive autonomy and decision making about timing, spacing, and limiting of childbearing (Murray et al. 2017). In addition to being acceptable to women, responses from interviews confirm that home self-injection is a feasible way to use DMPA-SC. For the majority of women who chose this mode of administration at 6 months, they knew how to correctly store (96%) and dispose of (98%) the used Uniject™ device, found it easy to store (94%) and dispose of (96 percent), and reinjected on time (i.e., 11 to 17 weeks after last injection) (85%). However, 15 percent did not reinject on-time, with 13 percent injecting early and 2 percent injecting late. This suggests that additional training on calculating and remembering reinjection dates would be helpful for home self-injection clients. This may include text message reminders or pocket calendars so that women can identify the reinjection period for the year based on the date of the first injection.

Providers' knowledge of DMPA-SC characteristics increased after the training

Training service providers to administer DMPA-SC as well as to train clients to self-inject was feasible, likely due in part to the fact that: (1) even the lowest cadre of GHS service providers, i.e., community health nurses, are already trained to offer intramuscular contraceptive injectables as well as subcutaneous vaccinations and (2) in-service/on-the-job training was conducted among all providers affiliated with FP at the facility. The training that providers participated in focused on the features of DMPA-SC and client self-injection practice through role plays, which were effective in significantly increasing provider knowledge of key DMPA-SC characteristics. After the training, at least 93 percent of providers could name the type of injection device used, how DMPA-SC is administered, the frequency of DMPA-SC injections, and how to store DMPA-SC, compared to less than 60 percent that could name each before the training. One hundred percent could name at least one location on the body where DMPA-SC could be administered after the training, compared to 61 percent before the training. These findings suggest that by using a standardized training curriculum, FP providers in Ghana can be trained in DMPA-SC and can train clients in DMPA-SC self-injection.

Providers felt very well prepared to provide DMPA-SC services after the training

The training was effective in equipping providers with the tools to offer DMPA-SC services, as almost all providers reported feeling very well prepared to provide DMPA-SC services after the training. Providers reported feeling very well prepared to counsel women on DMPA-SC (94%), administer DMPA-SC to clients (93%), train clients on self-injection (93%), and observe and supervise clients who choose self-injection (97%). The hands-on training and supportive environment—role playing, injection practice, and opportunity to ask questions—may have increased the confidence of providers to provide DMPA-SC services.

Strengths and limitations of the study

Providers did not systematically complete the self-injection practice observation checklist, citing that the steps to observe were easy to memorize. However, this limited study results on one of the indicators of client self-injection competence. The national scale up implementation should consider whether the practice observation checklist would be a viable indicator of client competence during trainings.

Another limitation of this study was the possible introduction of selectivity bias by excluding FP clients who were not unable to provide a phone number as a contact or unwilling to be reached by phone. The necessity of a phone contact was due not only to the longitudinal nature of the study, but also the high chance of clients in our sample opting for home self-injection. National data show that 90 percent or more of Ghanaian households own a mobile telephone (GSS et al. 2015; Laary 2016). Nevertheless, it is possible that the characteristics of FP clients who could not provide a phone number as a contact or were unwilling to be reached by phone would be different from FP who could and were willing.

A third limitation of this study is that it did not include FP clients below 18 years old who sought services at the study sites. While gaining the perspectives of adolescents on the feasibility and acceptability of DMPA-SC and self-injection is important, the TAG decided to exclude this subgroup for two main, related reasons: first, to protect the privacy, anonymity, and confidentiality of the adolescents in the event that their FP use was unknown to their parents or guardians; and second, the short enrollment period could not allow time for data collectors to locate all parents or guardians and seek their consent prior to seeking assent from the adolescent.

This study has several strengths:

- This study responded to a direct need for evidence generation and added to the body of evidence on subcutaneous contraceptive injection in low-resource settings.
- This study followed clients prospectively over 6 months, reducing their recall bias in reporting on experiences using DMPA-SC.
- This study was deliberately designed for clients to decide voluntarily at each injection their preferred administration method, allowing those who chose a provider-administered injection at their first injection to still have the option to self-inject at 3 and/or 6 months and vice versa. As the proportion of clients choosing self-injection nearly doubled from 35 percent at the first injection to 65 percent at 3 months and remained constant at 6 months, this study design showed that more clients may be willing to choose self-injection after experiencing the first injection with a provider.
- By completing this study, Ghana became the first example in sub-Saharan Africa of introducing DMPA-SC and self-injection simultaneously, and successfully doing so.
- A multi-sectoral TAG was created intentionally to include private sector representatives that would provide input from the start and utilize research findings to inform strategy in the event of a national scale-up.

- Results from the research study have been used to inform the national scale up of DMPA-SC and self-injection in public and private facilities, for which implementation planning by GHS began in January 2019. Members of the TAG were called to participate in and contribute to the scale-up working group.

Study Implications and Recommendations

The findings of this study suggest that providers can effectively counsel their clients on DMPA-SC, be trained to provide DMPA-SC, and train clients who voluntarily choose the self-injection mode of administration. The study findings also demonstrate that clients benefitted from the option to self-inject and the personalized training and supervision by the health provider. Training providers to offer DMPA-SC services and train clients to self-inject could expand access to FP for new users and continuation of FP among current or previous FP users. Though home self-injection was feasible for most women, particular attention and support may be needed to ensure that home self-injection clients are able to reinject on time, safely store and dispose of DMPA-SC, and manage side effects, and that those who want to discontinue for method-related reasons are able to switch to a different FP method.

As of 2017, GHS has over 21,000 enrolled nurses and over 15,000 community health nurses (GHS 2018), representing a substantial pool of lower cadre health personnel—more likely to be stationed in rural and peri-urban areas and to conduct outreach/home visits. As shown by this study, these providers can readily be trained on DMPA-SC and client self-injection. The findings of this study support the national scale-up of DMPA-SC, and the following considerations are recommended to assist the GHS:

Scale up:

- Develop an implementation strategy for staggered rollout across the nation in public and private health facilities.
- Utilize a cascade training approach similar to the study, whereby national and regional resource persons are trained to become Master Trainers, who then train providers on-site. This will efficiently maximize the number of providers who are trained across the country.
- Engage pharmacies and over-the-counter medical sellers in commodity resupply, enabling them to sell DMPA-SC to women who have received self-injection training at the facility and amplifying the role of the private sector in increasing uptake of DMPA-SC in Ghana.

Policy and Standards:

- Develop national guidelines and standards governing home self-injection of DMPA-SC, to be included in the next edition of the National Reproductive Health Service Policy and Standards.
- Develop national guidelines and standards for disposal and waste management of used devices for facilities and home self-injection clients.

Demand generation:

- Raise awareness by integrating DMPA-SC in relevant health promotion and social marketing activities in the community and at health facilities.

Monitoring and Evaluation:

- Enforce the use of the standard Adverse Reaction Reporting Form in public and private facilities as well as pharmacies and over-the counter medical seller shops as part of pharmacovigilance.

- Add DMPA-SC and its modalities as a method option on FP registries and daily logs to enable public and private facilities to contribute to national monitoring and reporting of DMPA-SC use.
- Include global DMPA-SC indicators in monitoring and evaluation tools to enable comparisons of trends with other countries.
- Develop an action plan for monitoring disposal and waste management for facilities and home self-injection clients. While 95 percent of clients stored DMPA-SC correctly and 98 percent disposed of it correctly, this study did not follow women for long enough to know if they would also return their disposal container to the facility at the time of resupply.
- Conduct regular assessments of client experiences with DMPA-SC, including reinjection, storage, and disposal practices, as well as reasons for discontinuation of DMPA-SC, and a comparison of these reasons to those for discontinuation of DMPA-IM. As self-injection is a new mode of administration in Ghana, monitoring its use from the clients' perspective will be critical in understanding successes and challenges of home injection for learning across the region.

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Appendices

APPENDIX 1. STUDY PARTNERS AND ROLES

Partner	Roles
GHS	Provide access to family planning users at public health facilities
USAID	Stakeholder and study funder
UNFPA	Supply DMPA-SC commodities (expected 6,000 doses)
Population Council via Evidence Project	Lead research study; coordinate implementation, data analysis, and research utilization

APPENDIX 2. CLIENT'S MODE OF INJECTION ADMINISTRATION AT ALL INTERVIEWS, BY SOCIODEMOGRAPHIC CHARACTERISTICS

	First injection			3 months				6 months			
	Provider-administered	On-site self-injection	Total (n)	Provider-administered	On-site self-injection	Home self-injection	Total (n)	Provider-administered	On-site self-injection	Home self-injection	Total (n)
Age group											
18-24	63.2	36.8	185	28.4	26.2	45.4	141	22.3	32.1	45.5	112
25-29	61.5	38.5	156	29.4	12.8	57.8	109	26.0	17.7	56.3	96
30-34	67.3	32.7	107	30.1	23.7	46.2	93	22.1	27.9	50.0	86
35-39	66.1	33.9	62	34.0	27.7	38.3	47	35.6	28.9	35.6	45
40+	73.7	26.3	57	39.5	25.6	34.9	43	48.7	15.4	35.9	39
Marital status											
Never married	62.6	37.4	155	25.4	23.8	50.8	122	19.5	25.7	54.9	113
Ever married/in-union	65.9	34.1	413	32.8	21.9	45.3	311	30.9	25.3	43.8	265
Education											
No education	74.6	25.5	55	40.0	28.6	31.4	35	35.5	29.0	35.5	31
Primary	70.1	29.9	107	24.1	39.8	36.1	83	21.4	38.6	40.0	70
JSS/JHS	65.6	34.4	282	33.0	17.7	49.3	221	30.7	21.7	47.6	189
SSS/SHS or higher	54.8	45.2	124	27.7	16.0	56.4	94	22.7	21.6	55.7	88
Region											0.00
Ashanti	73.7	26.3	278	50.6	14.1	35.3	170	47.5	15.6	36.9	160
Volta	56.6	43.5	290	17.9	27.8	54.4	263	12.8	32.6	54.6	218
Residence											
Rural	47.8	52.2	226	15.1	4.5	80.5	179	13.2	6.9	79.9	144
Urban	76.3	23.7	342	41.7	35.0	23.2	254	36.3	36.8	26.9	234
Use of family planning											
First-time FP users	60.7	39.3	234	24.1	24.6	51.3	191	18.7	28.3	53.0	166
All previous FP users	68.0	32.0	334	36.0	20.7	43.4	242	34.4	23.1	42.5	212
Total	369	199	568	133	97	203	433	104	96	178	378
Percent	65.0	35.0	100.0	30.7	22.4	46.9	100.0	27.5	25.4	47.1	100.0

APPENDIX 3. VISUALS OF DISPOSABLE PUNCTURE-PROOF CONTAINER, AND USED AND UNUSED UNIJECT™ DEVICES

Photo credit: PATH

The Evidence Project

Population Council
4301 Connecticut Avenue, NW, Suite 280
Washington, DC 20008 USA
tel +1 202 237 9400

evidenceproject.popcouncil.org