
PATH/Will Boase

The introduction of subcutaneous DMPA (DMPA-SC, brand name Sayana® Press) promises to expand women's access to family planning options by increasing opportunities for lower-level health workers and even clients themselves to administer injectable contraceptives. Insights from the first introductions can help inform new country experiences and transitions, whether small pilots or scaled delivery. This section provides a **background of the product and the introduction pilots** in four countries.

## EXPANDING CONTRACEPTIVE ACCESS AND OPTIONS

Injectable contraceptives are an important option for preventing unintended pregnancy, chosen by many women worldwide for their safe and effective protection, convenience, and privacy. Innovative, next-generation products like subcutaneous DMPA, a lower-dose, easy-to-use injectable contraceptive, can dramatically expand family planning access by increasing opportunities for lay health workers—and even clients themselves—to administer injections. The information in this guide is specific to Sayana Press: a branded subcutaneous DMPA product that combines the drug and needle in the prefilled BD Uniject™ injection system.

For decades, PATH has championed the development and delivery of a product like Sayana Press to expand women's family planning access and options—first by developing the Uniject injection system, now licensed to Becton Dickinson (BD), and later by serving as a "matchmaker" between BD and Pfizer Inc., the manufacturer of the injectable contraceptive Depo-Provera (generic: intramuscular DMPA, DMPA-IM). The opportunity to introduce any contraceptive innovation, in the context of informed choice and a broad method mix, can result in increased investment and attention for a country's family planning program.

After years of planning, under a country-led initiative coordinated by PATH, the DMPA-SC

*Sayana Press is a registered trademark of Pfizer Inc. Uniject is a trademark of BD.*

product Sayana Press was made available from family planning providers in Burkina Faso, Niger, Senegal, and Uganda in 2014. These introductions offered injectable contraception in many communities for the first time, closer to where women live. Self-injection research conducted by PATH and government partners in Senegal and Uganda builds on the introductions and indicates that self-injection is likely to be feasible and acceptable.

When DMPA-SC was first presented as an option to the pilot countries prior to 2013, its price per dose was higher than the cost of intramuscular DMPA (DMPA-IM). While interested in the product's potential, international donor agencies and country governments were hesitant to invest in a more expensive presentation of DMPA. Global interest in Sayana Press increased in 2014 when the DMPA-SC product became available to qualified purchasers in the world's 69 poorest countries for one US dollar (US$1) per dose. In 2017, the Bill & Melinda Gates Foundation, Pfizer, and the Children's Investment Fund Foundation announced a new reduction of Sayana Press to $0.85 per dose, nearly equating the cost of intramuscular DMPA and subcutaneous DMPA (Collaboration helps broaden access to Pfizer's contraceptive, Sayana Press (medroxyprogesterone acetate),

**Product pricing for family planning clients in pilot introduction countries**

| | PUBLIC SECTOR | PRIVATE/NGO SECTOR | | |
|---|---|---|---|---|
| | **Product + consultation** | **Product** | **Consultation** | **NGO/delivery channel** |
| **Burkina Faso** | 250 XOF (0.40 USD) | 600 XOF (0.96 USD) | 200 XOF (0.32 USD)* | MSI clinics |
| | | 250 XOF (0.40 USD) | Free | MSI mobile outreach |
| | | 250 XOF (0.40 USD) | 500 XOF (0.81 USD)* | ABBEF clinics |
| | | 250 XOF (0.40 USD) | 300 XOF (0.48 USD)* | ABBEF youth centers |
| | | 250 XOF (0.40 USD) | Free | ABBEF mobile outreach |
| **Niger** | Free | 200 XOF (0.32 USD) | Free | ANIMAS-SUTURA, CBD of SUTURA Press and partner pharmacies |
| **Senegal** | Product 200 XOF (0.32 USD)<br>Consultation 300–1,000 XOF (0.48–1.62 USD) | 200 XOF (0.32 USD) | 2,000-2,500 XOF (3.23–4.00 USD) | MSI clinics or franchise |
| | | 200 XOF (0.32 USD) | 1,000 XOF (1.62 USD) for reinjection | MSI clinics or franchise |
| | | 200 XOF (0.32 USD) | Free | Marie Stopes Ladies and mobile outreach |
| | | Free | Free | MSI youth centers |
| | | 1,000 XOF (1.62 USD) | 1,000 XOF (1.62 USD) | ASBEF |
| | | 1,200 XOF (1.94 USD) | Not offered in pharmacies | Securil Press, sold in pharmacies |
| **Uganda** | Free | 1,000 UGX (0.28 USD) | | MSI and RHU |

*Note: ABBEF, Association Burkinabè pour le Bien-Etre Familial; ANIMAS-SUTURA, Association Nigérienne de Marketing Social; ASBEF, Association Sénégalaise pour le Bien Etre Familial; CBD, community-based distribution; MSI, Marie Stopes International; NGO, nongovernmental organization; RHU, Reproductive Health Uganda; UGX, currency code for Ugandan Shilling; USD, US dollar; XOF, currency code for Communauté Financière Africaine.*

** At reinjection, clients pays for product only (no consultation fee).*

## Lexicon of injectable DMPA products.

**MPA**: Medroxyprogesterone acetate, the active contraceptive agent.

**DMPA**: Depot MPA. When injected intramuscularly or subcutaneously, MPA forms a reservoir or depot that releases the drug over time.

**Intramuscular DMPA (DMPA-IM):** Preferred term to describe DMPA products that are injected into the muscle.

**Subcutaneous DMPA (DMPA-SC):** preferred term to describe DMPA products that are injected under the skin into the fat. This term describes both branded and future generic products.

**Depo-Provera®**: Pfizer Inc. brand of DMPA-IM, available in vials or prefilled syringes.

**Depo-subQ provera 104®**: Pfizer brand of DMPA-SC in prefilled syringes.

**Sayana®**: Pfizer Limited (United Kingdom) brand of DMPA-SC in prefilled syringes, licensed in the United Kingdom and some other countries.

**Sayana® Press**: Pfizer Inc. brand of DMPA-SC that comes prefilled in the UnijectTM injection system; the product available to FP2020 countries.

for women in some of the world's poorest countries [press release]. Available at http://www.businesswire.com/news/home/20170508005585/en/Collaboration-Helps-Broaden-Access-Pfizer%E2%80%99s-Contraceptive-Sayana%C2%AE). Introduction of the product, which includes self-injection research studies, is happening in 14 countries and growing; this is being led by many different groups and funded by a variety of donors. The price of Sayana Press for the end user varies across country settings, depending on the delivery channel and price parameters set by country governments for contraceptive supplies (see table).

PATH, ministries of health (MOHs), and partners have gained experience,


SAYANA PRESS PROJECT

PATH

Sayana Press: Product and Project Summary

Injectable contraceptives are among the world's most widely used methods for preventing pregnancy, offering women safe and effective protection, convenience, and privacy. Until now, access to injectables has often been limited to clinic settings.

Sayana® Press can improve contraceptive access; it is small, light, easy to use, and requires minimal training—making it especially suitable for community-based distribution and for women to administer themselves through self-injection.

IMPROVING ACCESS TO CONTRACEPTION

PATH/Patrick McKern

REPRODUCTIVE HEALTH

PATH

Self-Injection Best Practices Project: Uganda

CONTRACEPTIVE SELF-INJECTION

Access to a range of contraceptive choices allows each woman to find her best option for preventing unintended pregnancies. Injectable contraceptives have been widely used for decades, providing three months of protection from pregnancy between each injection.

Self-injection of contraception is a new option that gives women even more control over whether and when to have children, and it can also decrease time and cost associated with quarterly trips to a clinic. Subcutaneous DMPA (DMPA-SC) is a new, easy-to-use injectable contraceptive that facilitates delivery in a wider variety of places—and its unique design makes it particularly well-suited for self-injection. Sayana® Press is currently the most widely available DMPA-SC product.

UGANDA SELF-INJECTION BEST PRACTICES PROJECT

Evidence from research and introduction in Uganda (see page 2) suggests that women are able to self-inject DMPA-SC following training from health providers. As the Uganda Ministry of Health plans for national rollout of self-injection, there is a need to learn how self-injection can be designed and implemented at scale, under routine conditions. PATH's Self-Injection Best Practices project was developed to address this need. This project:

- Identifies self-injection program components and models (see box) for public-sector facilities, community-based distribution, private-sector outlets, and safe spaces for young women and adolescent girls.
- Implements these program models across delivery channels.
- Evaluates self-injection program models to determine what works.
- Disseminates optimal self-injection program components and delivery models to inform policy and practice in Uganda and beyond.

DEFINITIONS

**Program component:** A specific program design element that can be varied.

**Optional program components:** Those elements achieving the best results in terms of client proficiency, cost-efficiency, accessibility, and satisfaction among clients and providers.

**Program model:** Full set of program components necessary to deliver self-injection.

Sayana Press is a registered trademark of Pfizer Inc.

PROGRESS TO DATE

*Identifying program models to implement/evaluate*

In early 2017, PATH applied principles of user-centered design to identify program models that focus on users' needs, behaviors, constraints, and operating contexts. The process began with reflection on learning and results from self-injection studies and pilots in Uganda, as well as current best practices in family planning delivery in general. Program components spanned multiple topics, as illustrated below.

Specific activities for refining draft program models included:

- **Journey maps:** Program model designs were translated into "journey maps"—tools that help program designers walk through hypothetical client and provider experiences in a self-injection program.
- **Feedback meetings:** Workshops were organized to collect feedback on the journey maps from clients, facility-based family planning providers, community health workers, the Ministry of Health, and implementing partners. To better understand the entire program experience for clients and providers, workshop participants role-played each step of the program using the journey map as a guide. Feedback from the actors and observers was solicited using semi-structured feedback guides.
- **Rapid pilot:** Draft program models were revised following the feedback meetings, and a rapid pilot was launched in May 2017 in four facilities to gather insights from actual delivery experience. The rapid pilot's objective was to assess what program components work best with local staff and clients, making adjustments to the program over a three-month period of intensive monitoring and engagement. (See next page for insights to date.)

NEXT STEPS

*Implementation and evaluation*

Once the designs are finalized, various program models will be implemented and evaluated across the following delivery channels in 2017–2018:

- Public-sector facilities and community health workers in multiple districts.

contraindicated.[3]

HOW IT WORKS

When Sayana Press is administered to a woman every three months, it inhibits the secretion of gonadotropins, preventing follicular maturation and ovulation and causing endometrial thinning. Because MPA is absorbed more slowly when administered subcutaneously, the 30 percent lower dose in Sayana Press allows for a lower peak MPA concentration and above-minimum serum MPA levels, compared with DMPA IM, for suppressed ovulation over a three-month period.[4]

maintained for at least 91 days regardless of ethnicity or injection site. The pharmacokinetic parameters for MPA in these Asian women were similar to those previously reported in Caucasian women.[4]

- The combined results of the Singapore and Los Angeles trials show no difference in suppression of ovulation with subcutaneous DMPA regardless of ethnicity or injection site.[1]

ADMINISTRATION AND DOSAGE

Sayana Press is administered once every three months (12 to 14 weeks). It is labeled for subcutaneous injection into the anterior thigh or abdomen, and recent research demonstrates that it is also effective when injected in the back of the upper

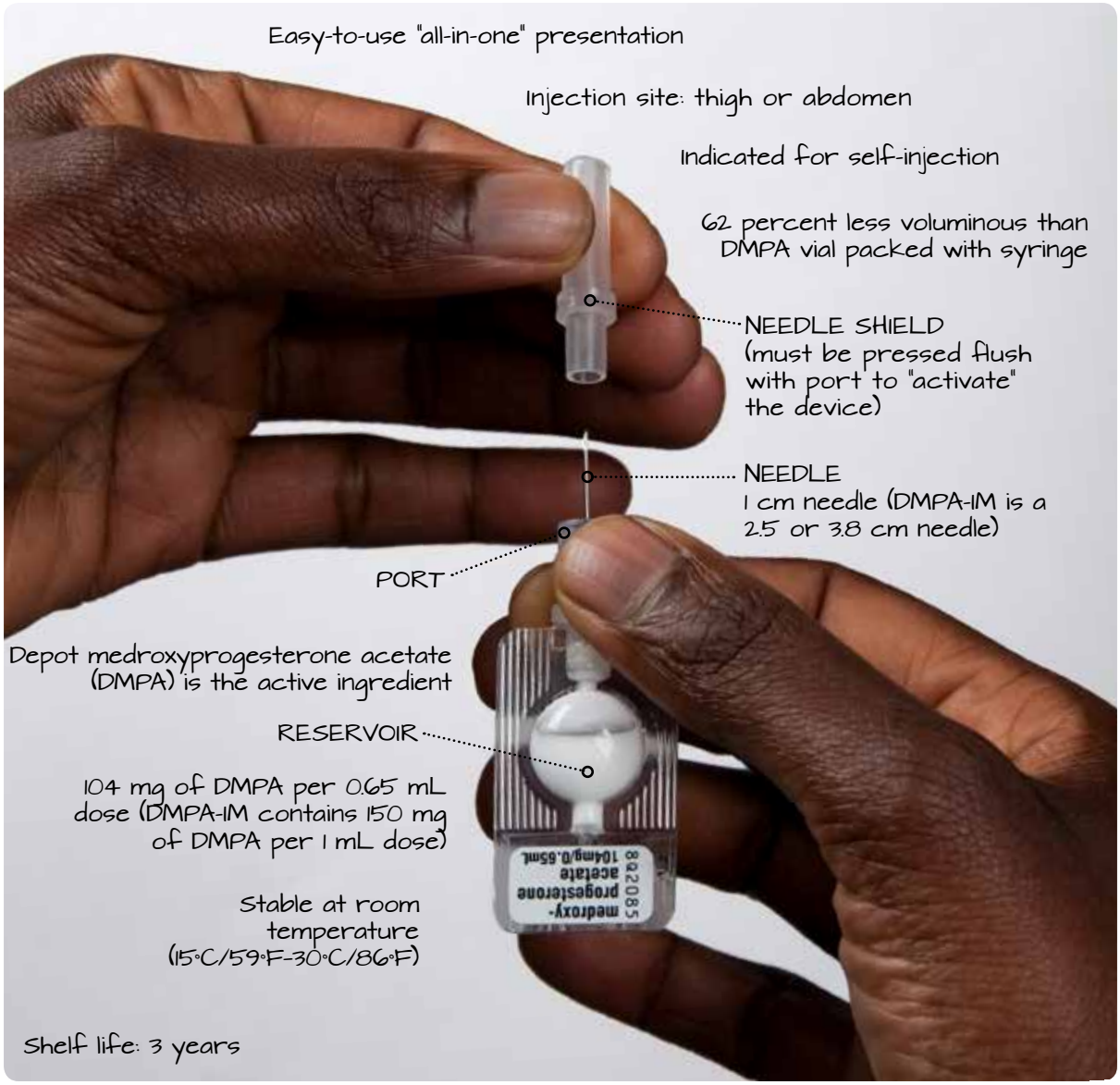
*Depo-Provera (DMPA IM) contains 150 mg/mL depot medroxyprogesterone acetate. The dose is 1 mL.*

*Sayana, Sayana Press, and Depo-Provera are registered trademarks of Pfizer Inc. Uniject is a trademark of BD.*

knowledge, and resources on DMPA-SC use through self-injection—and, eventually, introduction or scale-up of similar products. These can benefit donors, governments, and implementers who are working on DMPA-SC introduction or scale-up. To share this information, results of the pilots, and related resources, PATH has produced this practical guide based on lessons learned through the DMPA-SC pilot introduction project.

## ABOUT THE PRODUCT

DMPA-SC is a new, lower-dose, progestin-only injectable contraceptive that is administered every three months under the skin into the fat, rather than into the muscle. Sayana Press®, the DMPA-SC product available to FP2020 countries, is manufactured by Pfizer Inc. and combines the drug and needle in the prefilled BD UnijectTM injection system. It is small and easy to use, and it requires minimal training, making




it especially suitable for community-based distribution—and for women to administer themselves through self-injection. DMPA-SC can improve access to a safe and effective contraceptive option, and increase women's autonomy, in the context of a full method mix.

The information in this guide is specific to Sayana Press, which has several characteristics that make it well suited for low-income country settings, particularly in remote and rural areas:

- **Ease of use.** Allows use by trained lower-level health workers and offers the potential for self-injection.
- **Prefilled single unit.** Ensures that the correct dose is given, simplifies procurement and logistics, eliminates the need to bundle vials and syringes, and prevents their potential mismatch at service delivery points.
- **Not reusable.** Minimizes transmission of blood-borne pathogens through needle reuse.
- **Compact size.** Eases transport, storage, and disposal. Sayana Press is 62 percent less voluminous than the equivalent DMPA-IM presentation of vial and syringe.

PATH has created several fact sheets as resources for donors, partners, and countries interested in learning more about DMPA-SC introduction and research; these are available at sites.path.org/rh/?p=292#factsheets:

- Sayana Press Clinical Brief
- Self-injection Best Practices Project: Uganda
- Frequently Asked Questions About Sayana Press
- Monitoring Sayana Press Pilot Introduction

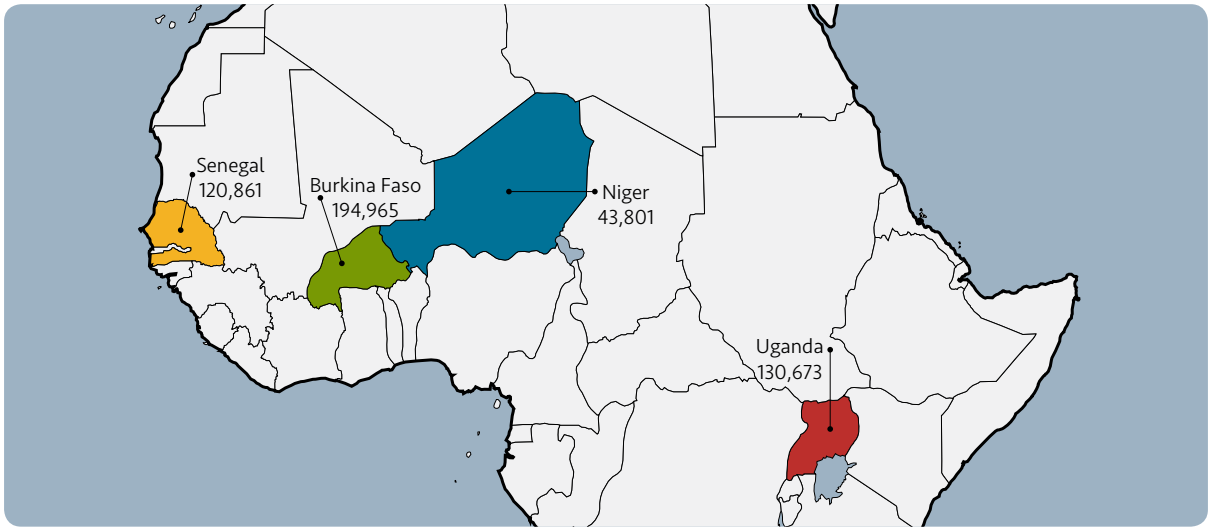
Sayana Press is approved by drug regulatory authorities in the European Union and approximately two dozen countries worldwide. The subcutaneous formulation of DMPA used in Sayana Press is also approved in the United States. An updated product package insert indicating Sayana Press for self-injection was officially approved in 2015 by the United Kingdom's lead stringent regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA). This provides a basis for updated product registrations indicating self-injection in other countries, which are currently being pursued by Pfizer (see Section 5: Registration) (Pfizer's Sayana® Press becomes first injectable contraceptive in the United Kingdom available for administration by self-injection [press release]. Available at www.pfizer.com/news/press-release/press-release-detail/pfizer_s_sayana_press_becomes_first_injectable_contraceptive_in_the_united_kingdom_available_for_administration_by_self_injection). Niger approved the updated insert in 2016, establishing the regulatory foundation for future shifts in policy and practice.

## RESULTS FROM PILOT INTRODUCTIONS

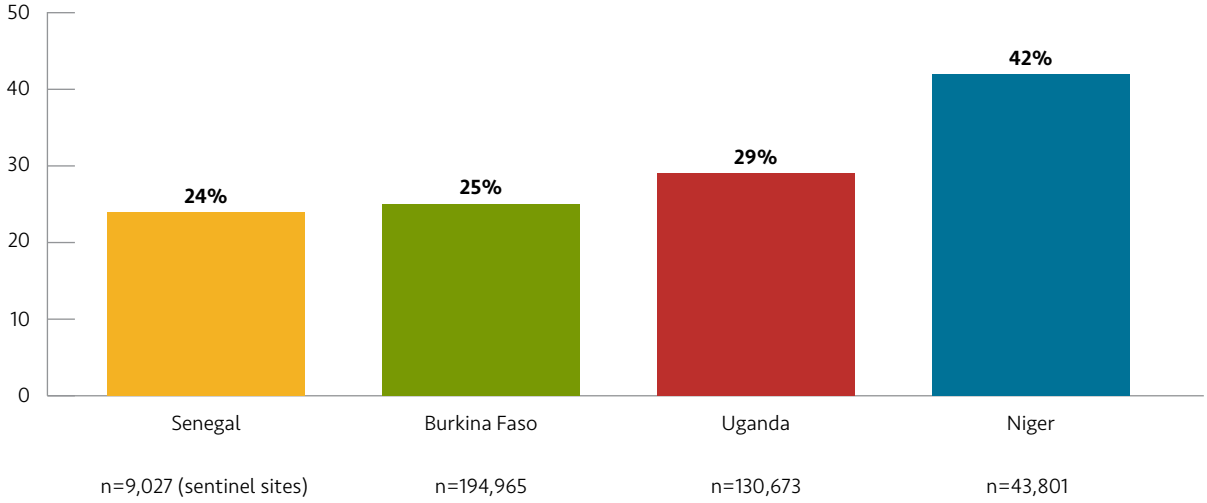
The pilot period for DMPA-SC (specifically Sayana Press) introductions ranged from mid-2014 to mid-2016 in each country. By early 2016, stakeholders in all four countries decided to scale up DMPA-SC. Monitoring data collected and reviewed throughout the pilot introductions—as well as positive feedback on the product from implementers, providers, and clients—informed these decisions. The results of the pilots are crosscutting and robust, offering significant insights regarding the added value of this contraceptive option. For example, across the four countries:

- **Thousands of providers trained.** More than 7,500 facility- and community-based family planning providers were trained to administer DMPA-SC (specifically Sayana Press), including nearly 600 providers who serve as trainers, master trainers, or supervisors.
- **Half a million doses administered.** Nearly half a million doses of DMPA-SC were administered by providers (see map). The total number of doses of DMPA-SC that were administered increased steadily during the pilot.
- **Thousands of new users reached.** More than 135,000 women using modern family planning for the first time ("new users") chose to use DMPA-SC, indicating the product

**Total number of DMPA-SC doses administered, by country (2014–2016)**



**Proportion of DMPA-SC doses administered to new users, by country (2014–2016)**




may help reduce unmet need and increase contraceptive prevalence (see bar graph).

- **DMPA-SC reached young women.** Approximately 45 percent of doses administered across Niger, Senegal, and Uganda were to women younger than age 25 years (age data not available for Burkina Faso). Monitoring data provided real-time insights. Analysis of the monitoring data informed many of the lessons and program implications presented through this guide. Final project monitoring results are summarized in a brief (Monitoring Sayana® Press Pilot Introduction. Available at www.path.org/publications/detail.php?i=2551).

Highlights include:

- **Results are linked to the introduction strategy.** To reach maximum new users, a country may prioritize community-level delivery or offer injectables in areas where they were previously unavailable. To reach maximum volumes, a country might introduce DMPA-SC at all levels of the health system and train providers rapidly using a cascade approach.
- **Increased opportunities for task-sharing.** DMPA-SC offers opportunities to shift injectable administration to the community level, as community health workers administered higher proportions relative to DMPA-IM when both were available.

PATH/Will Boase

Annet, a village health worker, decided to be the first woman in Uganda to receive DMPA-SC while participating in a training session on family planning. She wished she had learned about contraception earlier in her own life. She says, "I decided to see it for myself. Now I talk to my clients from experience and counsel them about their options."

"Sayana Press is easy, and it can be used in private. It's simple to handle, does not take time, and there is no need to go to the hospital. I like that I can use it myself more privately."

*– Family planning client in Uganda, age 19*

- **Switching was not widespread.** Cumulative proportions of doses administered to women switching from DMPA-IM to DMPA-SC (Sayana Press) were not higher than 16 percent in any one country, allaying early concerns about wholesale replacement of DMPA-IM.

## USING PRODUCT INTRODUCTION TO STRENGTHEN HEALTH SYSTEMS

Because of its ease of injection and delivery, DMPA-SC can catalyze service-delivery innovation by expanding access to family planning in nonclinic settings. In other words, countries can make injectable contraceptives available where they have never been available before. The product's ease of use may prompt decision-makers to support and establish policies for task-sharing contraceptive service delivery. Task-sharing involves a team-based approach to delivering contraceptives by community-based workers and volunteers, in addition to health care professionals based at fixed facilities.

Introducing a new method like DMPA-SC can also prompt programs to review and improve their family planning provider training and supervision, commodity distribution, and health information systems. For example, training health workers on a new method can provide an opportunity to refresh or upgrade their overall family planning skills. Logisticians and supply chain managers benefit from refresher skills training that introduction of a new method brings. Finally, working with regional or district teams to review and improve data monitoring systems and quality of data collection contributes to reinforcing their capacity and strengthening the health system overall.

## SELF-INJECTION AS AN EMERGING PRACTICE

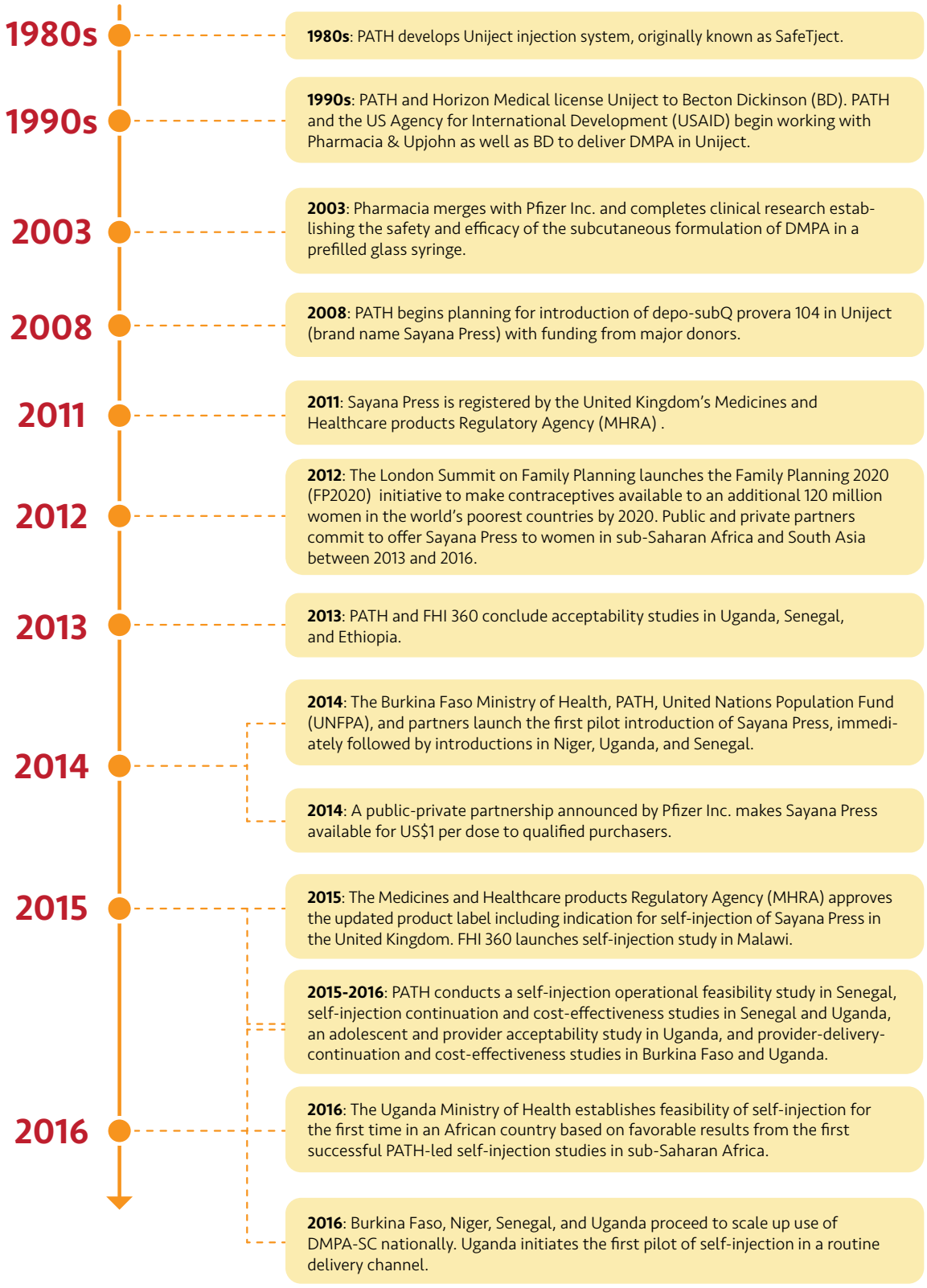
Self-injection of DMPA-SC is expected to roll out in the future as the practice receives regulatory approval in more countries and as evidence of feasibility, acceptability, and impact accumulates. Self-injection could help overcome access barriers and increase women's ability to manage their reproductive health. For example, women who self-inject would have timely access to injectables in places where community-based services are sporadic or unreliable. Studies to date suggest that self-injection of Sayana Press or similar products (e.g., DMPA-SC in a prefilled syringe) is both feasible and acceptable for many women.

"The current research on self-injection builds a case for offering women this option in the future. For example, women in the current study live several kilometers from the nearest health hut or health post, but many have asked the nurses about the possibility of continuing Sayana Press self-injection beyond the study, to save time and prevent having to travel to the clinic, which is not easy for them. . . This shows the tangible impact that the implementation of a self-injection policy could have."

*– Marguerite Ndour, PATH DMPA-SC Coordinator in Senegal*

Together with partners, MOHs in Burkina Faso, Democratic Republic of the Congo, Ghana, Kenya, Malawi, Nigeria, Senegal, and Uganda are conducting or planning research on self-injection to learn how to support women in these settings to self-inject safely and effectively. Results to date from PATH's self-injection operational feasibility studies in Uganda and Senegal indicate that most women can independently self-inject at three months after a single one-on-one training session (A prospective cohort study of the feasibility and acceptability of depot medroxyprogesterone acetate administered subcutaneously through self-injection. Available at www.contraceptionjournal.org/article/S0010-7824(16)30459-0/pdf). In 2015, the World Health Organization (WHO) issued a new technical document that recommends self-injection in specific circumstances in contexts where women have information, training, and support (Health Worker Roles in Providing Safe Abortion Care and Post-Abortion Contraception. Available at http://apps.who.int/iris/bitstream/10665/181041/1/9789241549264_eng.pdf?ua=1&ua=1).

# Milestones: A Short History of Subcutaneous DMPA



## RESOURCES

**Idea to Impact: A Guide to Introduction and Scale.** Available at https://usaid.gov/cii/guide-introduction-and-scale. Idea to Impact is a practical reference for global health practitioners working to introduce or scale up medical devices, diagnostics, or other consumer products. The guide proposes a four-stage model and uses case studies to highlight lessons and factors for consideration. It includes a Practitioner's Workbook and Toolkit.

**Subcutaneous DMPA introduction and research: Expanding access and options web page.** Available at sites.path.org/rh/?p=292. **Subcutaneous DMPA background resources and references web page.** Available at sites.path.org/rh/recent-reproductive-health-projects/sayanapress/sayanapress-resources/. These two web pages are replete with dozens of practical resources about Subcutaneous DMPA, including fact sheets, newsletters, blog posts, and research publications.

**Self-Injection Best Practices Project: Uganda.** Available at https://www.path.org/publications/detail.php?i=2790. This brief provides an overview of PATH's Self-Injection Best Practices project, which aims to evaluate and identify optimal program models for self-injection of DMPA-SC.

**PATH's Framework for Product Introduction.** Available at www.path.org/publications/files/TS_product_intro_framework.pdf. This four-page publication presents a simple but powerful phased approach to advancing public health products from concept to widespread use and summarizes key lessons for maximizing impact in product development, introduction, and integration.