



HOW TO INTRODUCE AND SCALE UP SAYANA PRESS (DMPA-SC IN UNIJECT)

Practical guidance from PATH
based on lessons learned
during pilot introduction

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ABBREVIATIONS

ABBEF	Association Burkinabè pour le Bien-Etre Familial
ADEMAS	L'Agence pour le Développement du Marketing Social (Senegal)
AIS	agents itinerant de santé (outreach workers)
AMC	average monthly consumption
ANBEF	Association Nigérienne pour le Bien-Etre Familial
ANIMAS-SUTURA	Association Nigérienne de Marketing Social
ASBEF	Association Sénégalaise pour le Bien-Etre Familial
BD	Becton Dickinson
CBD	community-based distribution
CDFU	Communication for Development Foundation Uganda
CHW	community health worker
DHS	Demographic and Health Surveys
DMPA	depot medroxyprogesterone acetate
DMPA-IM	generic name for the intramuscular form of depot medroxyprogesterone acetate
DMPA-SC	generic name for the subcutaneous form of depot medroxyprogesterone acetate
FP2020	Family Planning 2020
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
HIS	health information system
HIV	human immunodeficiency virus
IM	intramuscular
IPM	Informed Push Model
IPPF	International Planned Parenthood Federation
MHRA	Medicines and Healthcare products Regulatory Agency
MOH	ministry of health
MSBF	Marie Stopes Burkina Faso
MSI	Marie Stopes International
MSS	Marie Stopes Senegal
NGO	nongovernmental organization
RHU	Reproductive Health Uganda
UHMG	Uganda Health Marketing Group
UK	United Kingdom
UNFPA	United Nations Population Fund
USAID	US Agency for International Development
USD	US dollar
VHT	Village Health Team
WHO	World Health Organization

HOW TO USE THIS DOCUMENT

This document was created to support ministry of health and nongovernmental implementing partners as they develop strategies and activities to introduce and scale up Sayana® Press (generic: DMPA-SC in Uniject) in the hopes of expanding the contraceptive method mix and increasing access. Offering women a new, easy-to-access option for injectable contraception promises to transform family planning, especially for women in remote locations.

The content provides practical guidance based on results, evidence, and learning from the pilot introductions of Sayana Press in four countries in Africa. It focuses mainly on PATH's successful experience coordinating introduction of Sayana Press administered by providers. Self-injection was not yet approved or practiced outside a research context in any of the four countries during the pilot phase.

The document is modular and can be accessed one section at a time or in its entirety. Each section describes PATH's experience during the pilot introductions and includes results, introduction tips and lessons learned, case studies, recommendations, and practical resources. The guide is an introduction planning resource most applicable to countries that have already decided to introduce Sayana Press; the guide does not cover the decision-making process itself. It is organized in 11 sections:

1. Overview
2. Background
3. Stakeholder engagement and coordination
4. Planning the country introduction strategy
5. Registration
6. Quantification and procurement
7. Training and supervising providers
8. Generating demand
9. Product distribution
10. Monitoring and evaluation
11. Moving from introduction to scale

Most steps in the product introduction process are applicable to many products, and numerous resources exist to guide implementers in steps such as planning and conducting a landscape assessment or leading training and supervision. This guide touches only briefly on the generic introduction process and delves more deeply into aspects that were unique to the process of piloting the Sayana Press contraceptive technology.

Insights from the first introductions can help inform new country experiences and transitions, whether small pilots or scaled delivery. The entire PATH Sayana Press team and our valued partners hope you will find this guide to be an inspirational, relevant, and practical resource. You can play a key role in the next round of work to extend the benefits of this transformative contraceptive product to more women and families around the world.

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SETTING THE STAGE FOR EXPANDED CHOICE

In a groundbreaking initiative coordinated by PATH, Sayana® Press (DMPA-SC in Uniject™) was made available from family planning providers in Burkina Faso, Niger, Senegal, and Uganda beginning in 2014. The pilot introductions sought to better understand the potential market for a prefilled injectable and to evaluate the impact of introduction in a variety of country settings and distribution scenarios. Introductions were largely in the public sector in close collaboration with country governments, but also included several private, nonprofit service-provision agencies.

During the two-year life of the pilots, PATH gathered a rich repository of results that point to the product's significant potential to broaden the contraceptive method mix, facilitate the provision of injectables by community health workers as well as health care professionals based at facilities, appeal to new family planning users, and empower women to exercise more control over family planning decisions. This publication distills the most

pertinent results and interesting learnings from the pilot introductions and proposes practical guidance to inform the next generation of Sayana Press introduction and scale-up efforts.

Injectable contraceptives are an important option for preventing pregnancy, chosen by many women worldwide for their safe and effective protection, convenience, and privacy. Innovative products such as Sayana Press, a lower-dose formulation and “all-in-one” subcutaneous presentation of Depo-Provera®, can expand family planning access by increasing opportunities for lower-level health workers and even clients themselves to administer injections. The pilot introductions offered injectable contraception to many communities for the first time, closer to where women live. The results presented in this guide have supported decisions to scale up Sayana Press in the four pilot countries. They can also help stakeholders in other settings make informed decisions about whether and how to include this option in their family planning programs in the future.

Self-injection research conducted by PATH and government partners in Senegal and Uganda

built on the introductions and indicated that self-injection is likely to be feasible and acceptable. Results available to date indicate that self-injection has compelling potential to expand access and empower women to manage their reproductive health effectively and privately.

PATH, ministries of health, and partners have gained experience, knowledge, and resources that can benefit donors, governments, and other groups working to introduce and scale up use of Sayana Press or similar products. Based on lessons learned by PATH and our partners during the pilot introductions, we offer a number of key recommendations, as outlined below.

STAKEHOLDER ENGAGEMENT AND COORDINATION

- **Build relationships with ministry of health counterparts.** Building and nurturing strong, two-way relationships with ministry of health (MOH) counterparts will help ensure a smooth transition toward scale-up.
- **Designate an individual or agency responsible for coordinating stakeholders and their activities.** A well-defined lead person or agency can keep activities moving forward, assist in sharing of information and resources, and serve as a clear point for communications among all partners, including the MOH and donors.
- **Define partners' roles and mechanisms for coordinating introduction in a written plan.** Given the complexity of new product introduction, there is a great risk that planning and implementation will be stalled without a clear plan for engagement and coordination among the MOH and civil society organizations.
- **Widely share experience and results from product introduction.** Many stakeholders across settings will benefit from learnings on product introduction and may identify exciting new opportunities for the product to increase women's contraceptive access.

PLANNING THE COUNTRY INTRODUCTION STRATEGY

- **To reach large volumes, introduce Sayana Press at all levels of the health system in large geographies.** Do not discount the potential for more remote and community-level channels to achieve large volumes as well, particularly when supported by communication and outreach efforts.
- **To reach the largest number of new users, prioritize community-level delivery and offer injectables where previously unavailable.** Increasing the number of new family planning users can contribute to reducing unmet need and increasing contraceptive prevalence.
- **Expect high volumes of Sayana Press compared to DMPA-IM in community-level delivery channels.** Data from the pilot introductions reinforce early research data on acceptability of, and preference for, Sayana Press among community-level providers and their clients.
- **Consider opportunities for Sayana Press to increase access for young women.** Explore a variety of public and private delivery channels and consider what additional training, supervision, and communications activities are needed to support and sustain access for young women and adolescent girls.
- **Invest in total market introduction from the origins of introduction planning and beyond.** Limited data available on Sayana Press introduction in private-sector channels indicate that these outlets hold great potential to increase access.

PRODUCT REGISTRATION

- **Get up to speed on the status of Sayana Press registration globally.** Know that the safety, efficacy, and quality of this product have been thoroughly vetted. Understanding key facts about the product's regulatory history that the drug is approved in the United States and Europe, and that it is approved for self-injection by a stringent regulatory authority—can be useful for navigating introduction and scale-up.

- **Build flexibility into introduction plan timelines.** Registration is the manufacturer’s responsibility, and national processes are often unpredictable. National product registration processes often take much more time than expected.
- **Track the registration process and know what can be done to move introduction forward in the meantime.** While waiting for registration, it is helpful to stay in touch with key MOH staff and the manufacturer’s point person, in case questions or obstacles arise that require coordination. Introduction planning activities such as development/adaptation of the monitoring system, training curriculum, and communication campaigns can begin before registration is in hand.

QUANTIFICATION AND PROCUREMENT

- **Use the introduction plan to guide quantification.** Information from the introduction plan should inform the quantification exercise for initial procurement requirements. Key information includes the number, types, and locations of providers to be trained to administer the product and the timing of the trainings.
- **Consider data on doses administered per provider from similar delivery strategies.** PATH data from the pilot countries show a wide range of doses administered per provider, from 3 units per month administered by community providers in Senegal to 14 units per month administered by facility-based providers in Burkina Faso. Consider the ways these contexts vary to determine their relevance for quantification assumptions in new settings.
- **Use multiple sources to achieve accurate quantification.** In addition to service delivery and training inputs, the initial product quantification process requires considering the manufacturer’s planning horizons, product shelf life and expiry dates, country policies, and the timing for receipt of final formal registration.

TRAINING AND SUPERVISING PROVIDERS

- **Start by assessing who needs training on what topics throughout the family planning delivery system.** Do not overlook key players such as supervisors or outreach workers who might be women’s first point of contact with the system, even if they cannot administer injections.
- **For quick product uptake and rollout, implement a simultaneous training cascade.** This approach requires strong master trainers who are highly familiar with the product. Using a country’s existing government trainers will increase sustainability.
- **Design training for community health workers to meet their needs.** Community health workers (CHWs) in most settings are fully capable of administering Sayana Press in the context of informed choice. Ensure the curriculum covers all family planning content that is unfamiliar to them and meets them where they are, in terms of literacy, knowledge, and geography (to the extent possible).
- **Informed choice is always a priority in training and supervision, no matter what.** Emphasizing that Sayana Press is one option among many is especially important to counteract providers’ (often well-intentioned) excitement about a new product. Sayana Press will not be the right option for all, or even many, women. Address informed choice especially if your training only covers Sayana Press or injectable administration.
- **Design your curriculum to suit your context.** Adapt PATH’s field-tested curriculum as needed, considering whether it should cover Sayana Press or family planning comprehensively; also, consider the data you are expecting providers to collect.
- **Invest in high-quality supervision.** Supervision can help ensure that competencies transferred during group trainings are thoroughly mastered by each individual and that s/he can transfer them to the workplace. Plan for clear expectations



PATH/ Gabe Bienczycki

about who will conduct supervision, how often, and using what approaches.

GENERATING DEMAND

- **Use partner strengths and available evidence to select communications approaches.** In addition to traditional mass media, demand-generation strategies may include outreach to social and religious groups, development or modification of community theater dramas, and establishment of easy-to-access, confidential information sources such as toll-free hotlines and print materials that describe each contraceptive method in detail, including side effects.
- **Consider using radio and health workers for interpersonal communications.** Putting these channels to work requires the development of appropriate materials that support health workers to counsel their clients on family planning methods and side effects. Radio programs or “spots” should be developed to reach both men and women in a community or region with positive messages about family planning.
- **The timing and range of behavior change communications activities should align**

with the overall introduction or scale-up strategy. If a new product like Sayana Press is promoted before the product is available in local health facilities, clients may feel frustrated. If communications activities are delayed too long, project resources may be insufficient or campaigns may not have enough time to have a long-term impact, such as shifting social norms.

PRODUCT DISTRIBUTION

- **Invest in distribution systems to ensure Sayana Press will be consistently available.** Introduction of a novel technology shines a light on the strengths and weaknesses of existing distribution systems. An innovation’s potential to increase access is only as good as the distribution system that delivers it. Broader investments may be required for successful introduction—especially at the most peripheral levels (e.g., CHWs).
- **Map the supply chain.** Investigating and mapping the supply chain from the central warehouse all the way to the end user can help identify potential obstacles and identify the agencies and individuals who are responsible for various tasks.

- **Consider whether a “push” or a “pull” system is most appropriate for Sayana Press introduction and ongoing distribution.** Generally, push systems work well to minimize stockouts but are costly. They also tend to be less sustainable and require a complex transition if and when a product moves to scale. Most countries have pull systems, which may be more likely to experience stockouts that interrupt consumption. Working with these systems increases sustainability and minimizes costs.
- **Review monitoring data to assess the functioning of the distribution system.** A higher number of doses distributed than doses administered during a distinct time period indicates that the distribution system is functioning.
- **Account for shelf life of available Sayana Press units and product expiry.** Sayana Press has a three-year shelf life. Ensure that there is a plan for tracking product expiry and recapturing units in advance of their expiry. Sufficient stock should be distributed to the field in advance of product expiry.

MONITORING AND EVALUATION

- **Start early.** Designing the monitoring system should coincide with planning an introduction or scale-up strategy. Delays in implementing the monitoring system will likely result in missing information about the product’s impact.
- **Use consistent definitions.** Consistent and careful definition of indicators within and across countries can ensure they will provide meaningful information. Sometimes an absolute number is meaningful to get a sense of volume, but at other times a percentage calculation can provide richer information.
- **Keep the scale of data collection manageable** and only collect data you need. To avoid undue effort and expense, first ensure that all data are valuable and feasible to collect.
- **Budget adequately for data collection.** The time and financial resources needed to conduct monitoring well are often underestimated. Be sure to adequately prepare and finance the monitoring plan in advance.
- **Ensure the monitoring approach captures the contributions of more peripheral channels.** If community-based distribution (CBD) is introduced but data are rolled into the referral facility, the ability to measure the CBD contribution to a program is lost. When designing a monitoring system and forms, intentionally disaggregate data for any new delivery channels—such as CBD—to enable analysis of service innovations.
- **Train providers on monitoring tools and systems.** It is most cost-efficient and strategic to train providers on the monitoring tools at the same time they are trained on Sayana Press. Training on data collection through supervision is more costly and requires correcting already-established habits.
- **Consider whether evaluation or operations research activities are needed to provide additional information.** Monitoring data help understand numbers and trends, however some questions are best answered through in-depth qualitative or quantitative evaluation (e.g.; client or provider surveys) or operations research.

MOVING FROM INTRODUCTION TO SCALE

- **Consider options and requirements for vertical and horizontal scale.** To achieve vertical scale, does the product need to be integrated into any existing guidelines or policies (e.g., Essential Medicines Lists, other)? In terms of horizontal scale, does moving Sayana Press beyond facilities to the community level necessitate policy changes? Would moving to new geographies reach new groups with unmet need?
- **Work closely with the national MOH and other key groups to plan for scale.** National stakeholder engagement resulted in a relatively smooth and organic transition from pilot introduction to scale-up in all four countries. In addition, the fact that many groups were involved

and bought in meant that they were more likely to leverage existing family planning resources to support scale-up.

- **Scale may be possible before all the evidence is in.** In many of the pilot countries, decision-makers independently moved to scale up introduction based on monitoring data, before results of impact or cost-effectiveness analyses were available.
- **Remember that scale-up may not be the right outcome for every technology in every setting.** The Sayana Press pilot introductions in the first four pilot countries went very well, and global circumstances were also favorable.

Different contexts and experiences may result in different outcomes.

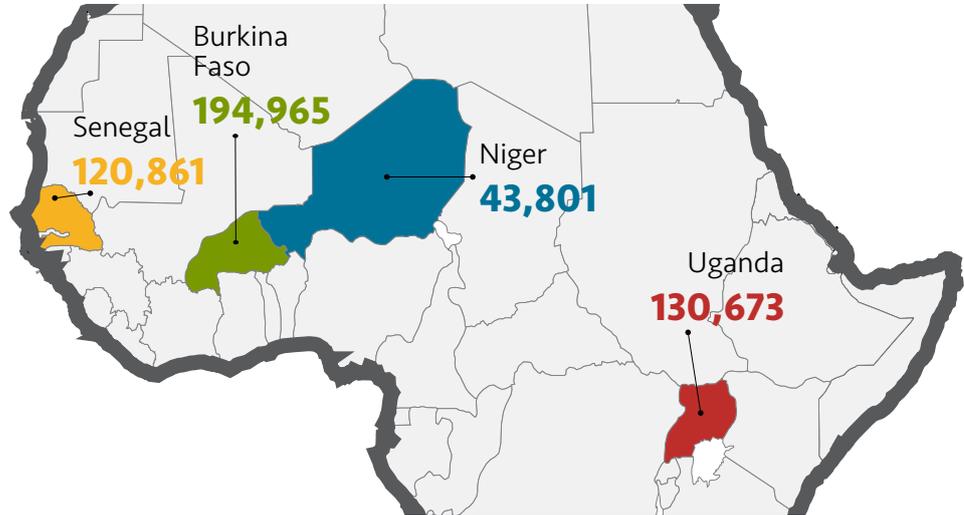
Following these recommendations will increase the likelihood of successful outcomes in countries that are introducing Sayana Press or scaling up use. Making this unique product available to CHWs and other providers will give many women, families, and communities, especially in remote regions, a new option for effective, convenient, and private contraception. Self-injection may prove especially valuable for overcoming access barriers and increasing women's ability to manage their reproductive health.

PATH SAYANA PRESS PILOT RESULTS



PILOT COUNTRIES

Burkina Faso
Niger
Senegal
Uganda



PILOT DURATIONS

July 2014–June 2016



LEAD PARTNERS

PATH
Ministries of health
United Nations Population
Fund (UNFPA)

Nearly half a million doses of Sayana Press administered across four pilot countries.



PILOT RESULTS

Total doses administered:	490,300
Proportion of doses administered to women under 25 years old:	44% (except Burkina Faso)
New users of family planning:	120,000
Proportion of doses administered to new users:	29%
Number of providers trained:	7,568
Switching from DMPA-IM:	11% (except Niger)
Proportion of injectables that were Sayana Press doses (community level): ..	75% (Senegal, Uganda only)
Proportion of injectables that were Sayana Press doses (all levels):	22% (Senegal, Burkina Faso only)



2 Background

The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 Sayana Press, a lower-dose formulation and “all-in-one” subcutaneous presentation of Depo-Provera®, can dramatically expand family planning access by increasing opportunities for lay health workers and even clients themselves to administer injections. Sayana Press is also known as DMPA-SC in Uniject.

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 Depo-Provera. 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, 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 Sayana Press was first presented as an option to the pilot countries prior to 2013, its price per dose was higher than the cost of depot medroxyprogesterone acetate (DMPA; the active ingredient in Depo-Provera) for intramuscular (IM) administration. While interested in the product's potential, international donor agencies and country governments were hesitant to invest in a more expensive presentation. Global interest in Sayana Press increased in 2014 when the product became available to qualified purchasers in the world's 69 poorest countries for 1 US dollar (USD) per

dose—much closer to the price of Depo-Provera (Novel agreement expands access to Pfizer's contraceptive, Sayana® Press [press release]. Available at www.pfizer.com/news/press-release/press-release-detail/novel_agreement_expands_access_to_pfizer_s_contraceptive_sayana_press_for_women_most_in_need_in_the_world_s_poorest_countries). 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).

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 FCFA (0.32 USD)		ANIMAS-SUTURA, CBD of SUTURA Press and partner pharmacies
Senegal	Product 200 XOF (0.32 USD) 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 center or franchise
		200 XOF (0.32 USD)	1,000 XOF (1.62 USD) for reinjection	Marie Stopes Ladies and mobile outreach
		200 XOF (0.32 USD)	Free	MSI youth centers
		Free	Free	ASBEF
		1,000 XOF (1.62 USD)	Free	Securil Press, sold in pharmacies
1,200 XOF (1.94 USD)	1,000 XOF (1.62 USD)			
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; FCFA, franc des colonies françaises d'Afrique; MS, ; 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.

DMPA-IM: Generic name for the intramuscular form of DMPA.

DMPA-SC: Generic name for the subcutaneous form of DMPA.

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 Limited brand of DMPA SC in the Uniject™ injection system.

PATH, ministries of health (MOHs), and partners have gained experience, knowledge, and resources on Sayana Press use through self-injection—and, eventually, introduction or scale-up of similar products. These can benefit donors, governments, and implementers who are working on Sayana Press 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 Sayana Press pilot introduction project.

ABOUT THE PRODUCT

Sayana Press is a unique three-month, progestin-only injectable contraceptive that combines the drug and needle in the Uniject 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. Sayana Press can improve access

SAYANA PRESS PROJECT

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 and partners are coordinating country-led pilot

PATH/Patrick Akkon

PRODUCT
in-one, three-month, injectable contraceptive product (IM) injection system. Each unit contains 150 mg of medroxyprogesterone acetate (DMPA) manufactured by Pfizer Inc. It is used in Sayana Press in the United States and in more than 25 countries in the world. The unit is used in Sayana Press in the United States.

It is used in Sayana Press in the United States.

It is used in Sayana Press in the United States.

SAYANA PRESS PROJECT

Sayana® Press Self-injection Research

In lower-income regions of the world, 225 million women want to avoid pregnancy but are not using contraception. Voluntary access to a range of safe and effective methods would help meet their needs.

PATH is working closely with the governments of Senegal and Uganda to conduct research on a potential new family planning option: self-injection of Sayana® Press.

At the end of 2015, early results from the first study in Uganda are promising: most women can competently self-inject after they are trained to do so.

ABOUT SAYANA PRESS
PATH's self-injection research complements its current work with the Ministries of Health and other partners in Burkina Faso, Niger, Senegal, and Uganda to introduce Sayana Press through existing service delivery channels. For more information on Sayana Press and PATH's pilot introduction work, visit <http://www.path.org/press>.

Sayana Press is a lower-dose presentation of the three-month injectable contraceptive Depo-Provera® in the Uniject™ injection system—a prefilled auto-disable device originally developed by PATH. Sayana Press contains depot medroxyprogesterone acetate (DMPA) and is administered via subcutaneous injection.

Sayana Press is small and easy to transport and administer. Sayana Press is approved by drug regulatory authorities in the European Union and more than 25 countries worldwide. The formulation of DMPA used in Sayana Press is also approved in the United States.

In 2015, the UK Medicines & Healthcare products Regulatory Agency authorized Sayana Press for self-injection in that country. The World Health Organization also recommends self-administration of Sayana Press "in contexts where mechanisms to provide the women with appropriate information and training exist, referral linkages to a healthcare provider are strong, and where monitoring and follow-up can be ensured."

PATH/Patrick Akkon

POTENTIAL FOR SELF-INJECTION OF SAYANA PRESS
Self-injection of Sayana Press could help overcome access barriers and increase women's ability to manage their health. PATH and partners in Senegal and Uganda will build on the ongoing introductions to explore feasibility and cost-effectiveness of self-injection through research.

Studies in higher-income settings, including the United States, indicate that self-injection of Sayana Press or similar products is both feasible and acceptable. Women and health workers in Ethiopia and Uganda have expressed strong interest in potential self-injection of Sayana Press.

Findings from Pfizer Inc.'s original clinical trials of Sayana® subcutaneous DMPA in a prefilled syringe and self-injection research in Florida, New York, and Scotland offer promising results.^{1,2,3} There were no pregnancies among women practicing self-injection in these studies, and nearly all reported it to be convenient and easy.

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

contraceptive use of estrogen is inappropriate or contraindicated.⁴

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 atrophy. 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 supported evaluation over a three-month period.⁴

women of five ethnic groups, ovulation suppression was 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.¹

The combined results of the Singapore and Los Angeles trials show no difference in suppressions 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

¹Depo-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.

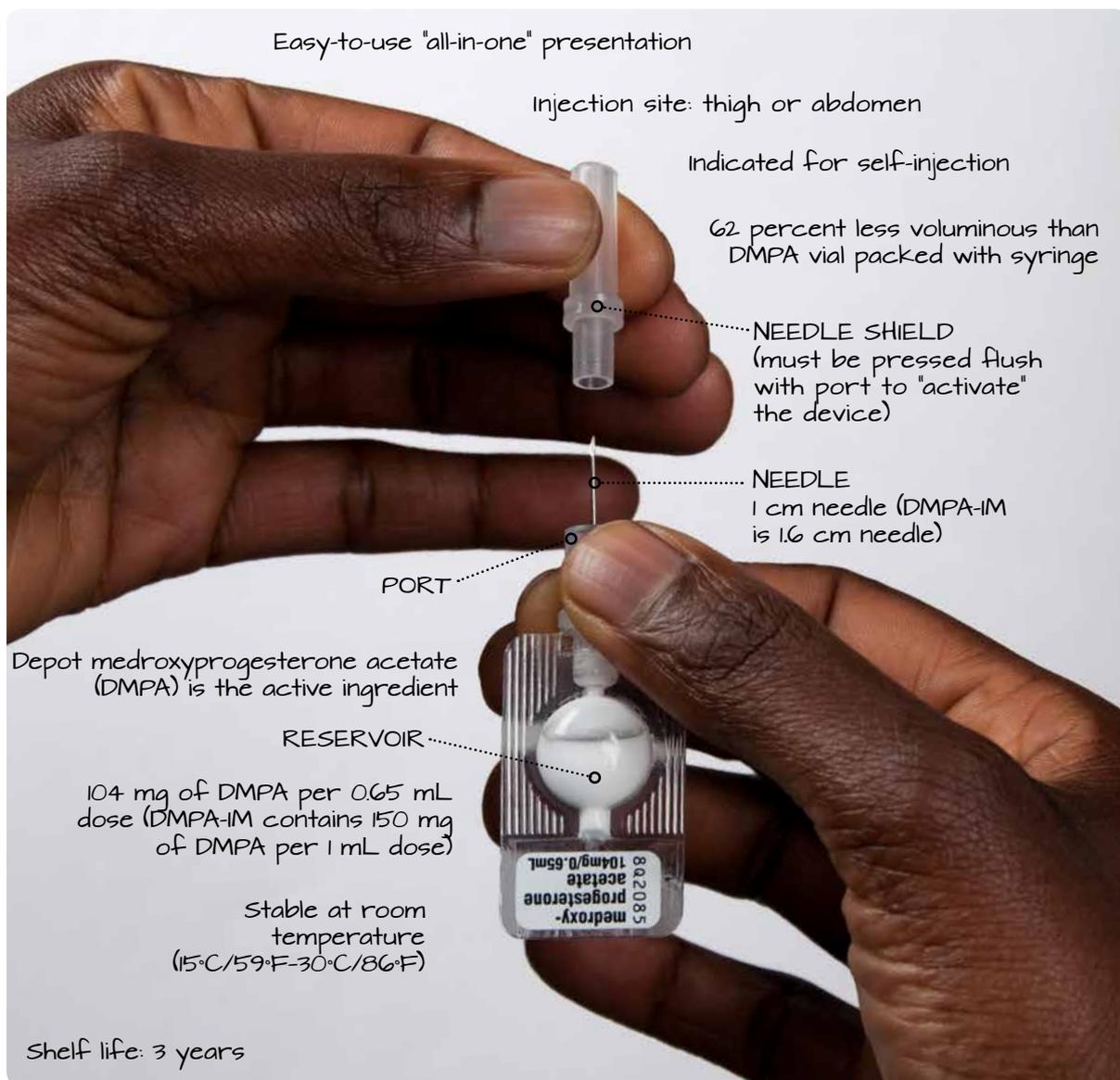
to a safe and effective contraceptive option, and increase women's autonomy, in the context of a full method mix.

Sayana Press 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

SAYANA® PRESS INTRODUCTION: PRACTICAL GUIDANCE FROM PATH

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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 Sayana Press introduction and research; these are available at sites.path.org/rh/?p=292#factsheets:

- Sayana Press: Product and Project Summary
- Sayana Press Clinical Brief
- Sayana Press Self-Injection Research
- 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 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 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 Sayana Press. 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 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 Sayana Press were administered by providers (see map). The total number of doses of Sayana Press that

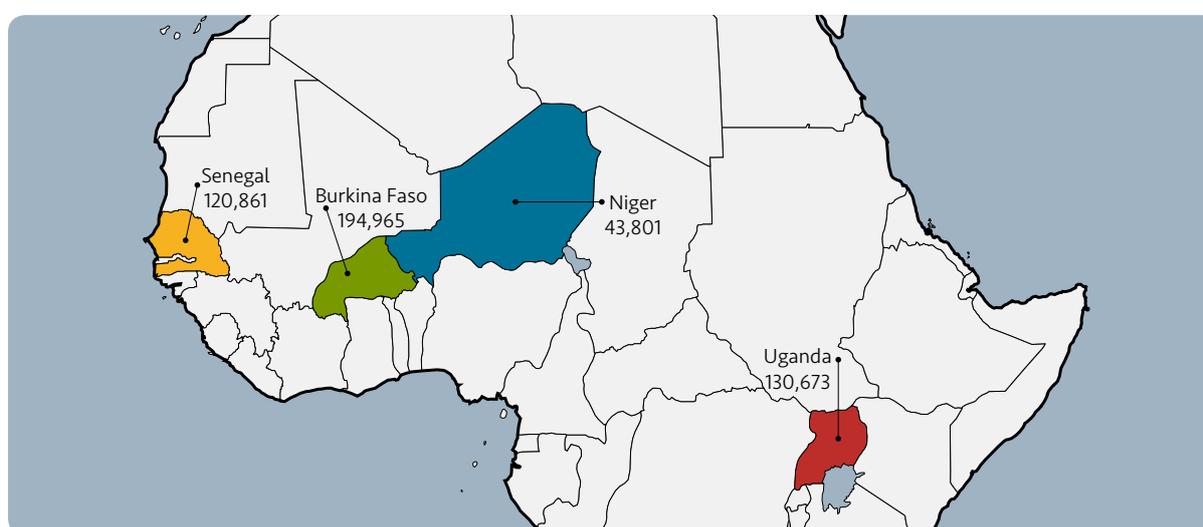
were administered increased steadily during the pilot.

- **Thousands of new users reached.** More than 120,000 women using modern family planning for the first time (“new users”) chose to use Sayana Press, indicating the product may help reduce unmet need and increase contraceptive prevalence (see bar graph).
- **Sayana Press 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).

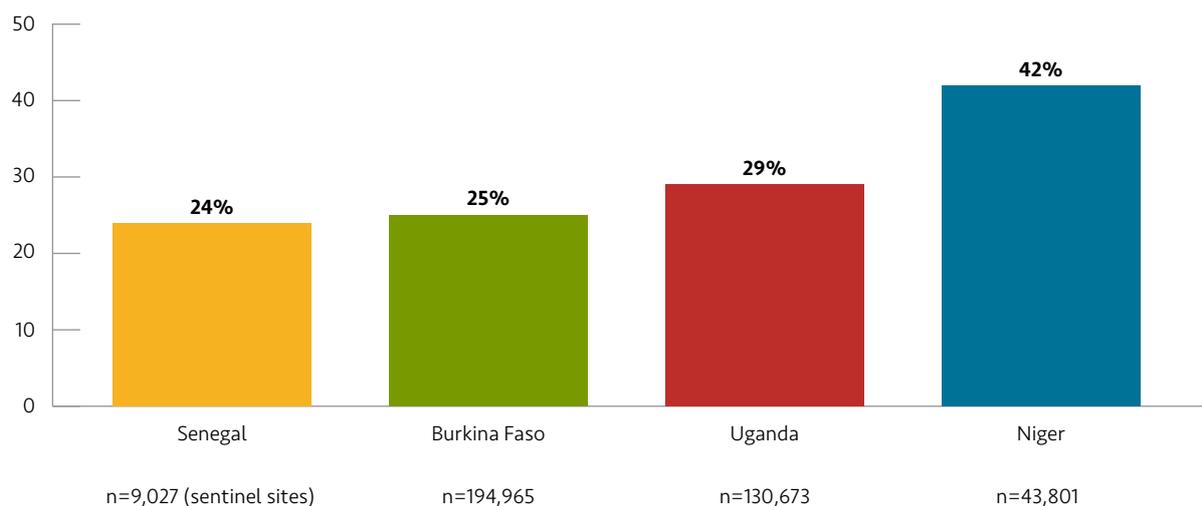
Highlights include:

- **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 Sayana Press at all levels of the

Total number of Sayana Press doses administered, by country (2014–2016)



Proportion of Sayana Press doses administered to new users, by country (2014–2016)



health system and train providers rapidly using a cascade approach.

- **Opportunities for task-sharing.** Sayana Press 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.
- **Switching was not widespread.** Cumulative proportions of doses administered to women switching from DMPA-IM to Sayana Press were not higher than 16 percent, allaying early concerns about wholesale replacement of DMPA-IM.

USING PRODUCT INTRODUCTION TO STRENGTHEN HEALTH SYSTEMS

Because of its ease of injection and delivery, Sayana Press 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.



Annet, a village health worker, decided to be the first woman in Uganda to receive Sayana Press 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.”

– Sayana Press client in Uganda, age 19

Introducing a new method like Sayana Press 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 Sayana Press 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

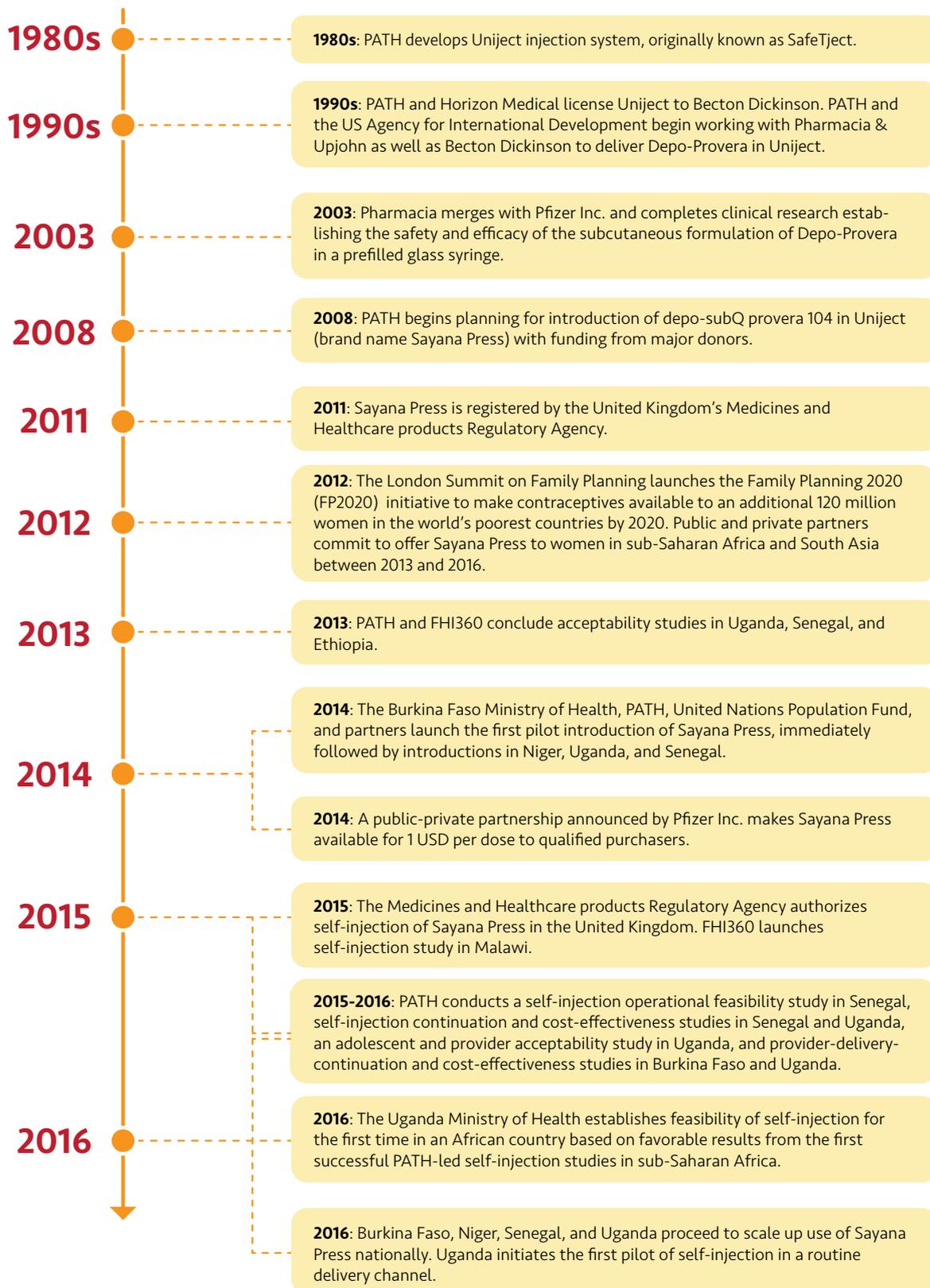
or unreliable. Studies to date suggest that self-injection of Sayana Press or similar products (e.g., DMPA-SC in a prefilled syringe) is both feasible and acceptable for many women.

Together with partners, MOHs and partners 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](http://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).

“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 Sayana Press Coordinator in Senegal

Milestones: A Short History of Sayana Press



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.



Sayana Press introduction and research: Expanding access and options web page. Available at sites.path.org/rh/?p=292. **Sayana Press 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 Sayana Press, including fact sheets, newsletters, blog posts, and research publications.



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.



The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **stakeholder engagement and coordination**.

COORDINATION AND ENGAGEMENT ENSURE PROGRESS

Product introduction is a complex process that involves many activities that are happening at the same time and that are being led by many different individuals and groups. Identifying key stakeholders and keeping them engaged throughout introduction ensured consistent progress and helped achieve the transition toward national scale in Burkina Faso, Niger, Senegal, and Uganda less than two years later. Stakeholders constituted a diverse array of individuals and groups in each country setting, ranging from ministry of health (MOH) officials to local nongovernmental organizations (NGOs) and civil society groups, from bilateral donors to health workers.

Engaging the MOH early in the introduction planning process was essential because public-sector delivery of health services is predominant in all of the pilot countries. In all four countries, the MOH establishes the national strategy for family planning and leads NGOs in implementing programs that support that strategy. PATH’s MOH engagement approaches through the product introduction included:

- **Briefing the MOH and partners on Sayana Press**, including evidence and information about the product and the unique opportunity it offers for expanding contraceptive access (see Section 2 Background). For example, country partners were very keen to understand how

the new product is different from DMPA-IM (generic name for the intramuscular form of depot medroxyprogesterone acetate) and how the two options should be positioned in the context of their family planning program. In some cases, these discussions also helped identify information gaps that needed to be filled by new monitoring and evaluation data or research studies. For example, would the product appeal to new family planning users, which would help to increase contraceptive prevalence and reduce unmet need in their countries?

- **Assessing government interest** in introducing a new contraceptive method and understanding family planning goals and priorities that would help to shape the product introduction strategy.
- **Identifying key champions** and supporters within the MOH to provide leadership in ensuring Sayana Press was integrated into strategy and planning documents and technical partners' meetings, and to support introduction technically and administratively.

The approach of private-sector businesses and social marketing agencies may be less dependent on obtaining governmental buy-in because these groups operate in ways that are often discrete from and complementary to public-sector services. While introductions of Sayana Press in the private sector may require less direct involvement with the government, private-sector and social-marketing agencies can likely benefit from exchange of information with the MOH and coordination with other NGOs.

THE VALUE OF CENTRALIZED, COUNTRY-LEVEL COORDINATION FOR MOVING FORWARD

During the pilot introductions of Sayana Press, the importance of country-level coordination of activities among stakeholders became keenly apparent. PATH hired a national coordinator in each country, and the role quickly became indispensable. In all four pilot countries, the coordinators ensured that partners moved in the same direction,

reached consensus, and leveraged other family planning initiatives. They also helped track other major health activities and the capacity of implementers (e.g., regional health teams and providers, NGOs) to implement activities on time. Over the course of the introduction, the coordinators achieved the following in each country:

- Shepherding the product introduction plans through the review and approval processes.
- Tracking Sayana Press product registration, identifying obstacles, and helping to ensure key questions were answered.
- Working with local experts to complete a quantification exercise for the first Sayana Press orders that took account of relevant evidence and information about the product.
- Integrating Sayana Press into the national family planning training curricula and ensuring high-quality training and supervision of health workers in Sayana Press administration and service delivery, enabling them to serve as experts on the product.
- Collecting monitoring data and entering it in a central global database that enabled comparative analysis and more timely review than most national systems.
- Coordinating the work of partners involved in Sayana Press introduction and obtaining technical guidance and approvals from the MOH during implementation.
- Overseeing any evaluation and research studies and ensuring they were aligned with overall introduction efforts.
- Facilitating discussions on the timing of, and funding sources for, moving the product to scale.



INTRODUCTION TIP

A national Sayana Press coordinator can keep introduction moving forward at all phases, from tracking registration to assisting with quantification, from ensuring high-quality training to overseeing data collection for monitoring or research.

CASE STUDY

PATH/Shirley Wood



PATH's role coordinating work to benefit all pilot countries

PATH staff filled leadership and technical roles at a global level and across all four pilot introduction countries. This included key work related to funding, procurement, product introduction, monitoring, and research.

Globally, leading up to and during the early phase of introduction, PATH regularly convened a consortium of funders and procurers of Sayana Press. The meetings helped to ensure alignment across organizations, track procurement and funding streams, update consumption estimates based on country introduction plans, and hone the research agenda. They also helped to define a critical path to country launches to coincide with country-level product registrations, ordering, and Pfizer's production schedule. In addition, PATH created a common monitoring system for analyzing data spanning all four countries.

PATH's coordination of efforts across countries resulted in a number of efficiencies and benefits. For example:

- Donor consortium members obtained standardized monitoring data across the pilot countries and tracked introduction progress.
- Country governments received common messaging about the objectives of the project, accurate clinical information about the product, and Sayana Press training materials that could be adapted to their unique contexts.
- The four pilot countries learned from each other and stayed apprised of introduction progress through PATH's regular updates as well as periodic midterm cross-country gatherings.
- PATH translated mounting interest in self-injection into a clear research agenda, initiated targeted studies to answer key questions, and publicly shared emerging evidence about the feasibility and acceptance of self-injection as it became available.

PATH also implemented country-level, cross-country, and global information dissemination and sharing during the pilots. This included publishing newsletters and monitoring briefs, posting online training materials for adaptation by each country, disseminating technical information such as fact sheets and conference presentations, and publishing research results in peer-review journals. These communications activities have not only facilitated evidence-based decision-making by donors but also enabled participating countries and programs and the family planning field at large to learn from the initiative.

In Burkina Faso, for example, the Sayana Press coordinator joined supervision visits for newly trained health workers and found that some providers mistakenly believed that Sayana Press would be available only for a very short time. As a result, they were reluctant to offer the method. The coordinator not only corrected their misunderstanding but also ensured that correct information was shared throughout the introduction regions.

In Niger, the Sayana Press coordinator worked to improve data quality in a health system with very weak infrastructure for monitoring data collection. By the end of the pilot, the project had almost two years of rich data from Niger, demonstrating that Sayana Press could reach new family planning users in remote settings where injectable contraception had not been previously available.

In Senegal, the Sayana Press coordinator realized during supportive supervision that a key contact point for women in clinics, family planning counselors, were not aware of Sayana Press. She sought permission from the MOH and then led training of these counselors in Senegal's introduction regions, which in turn helped increase awareness and boost use of Sayana Press.

Uganda's Sayana Press coordinator was directly involved in training community health workers and following up to provide supportive supervision. Through her coordinator role, she was also able to share details of what she heard from community health workers and family planning clients with government leaders at the MOH, as well as global donors and implementers in other countries. For example, she shared that communities in Uganda loved

the “all-in-one” presentation of Sayana Press and that women reported experiencing fewer side effects than they had when using DMPA-IM. These important real-life perspectives on the new product would not have been captured by monitoring systems or shared beyond these communities without established communication channels.

In Burkina Faso and Niger, the Sayana Press coordinators were based at the United Nations Population Fund (UNFPA), and in Senegal and Uganda, they were employed by PATH. In the case of Burkina Faso, UNFPA placed a project point person at the MOH offices, who was supervised by and remained in constant contact with the UNFPA-based Sayana Press coordinator. This formula worked well, particularly in planning for meetings or for facilitating approvals for coordinated trips to the field for trainings, supervision visits, and collection of monitoring data. Proximity of the Sayana Press point person to key Division of Family Health staff helped the MOH assimilate and take ownership of the Sayana Press pilot. Designating an MOH point person or seconding the coordinator to sit at the MOH may be an effective approach that some countries can consider to ensure forward movement on Sayana Press introduction.



INTRODUCTION TIP

Designating an MOH point person or seconding the coordinator to sit at the MOH may be an effective approach that some countries can consider to ensure forward movement on Sayana Press introduction.

“A clear, centralized coordination mechanism is ideal to avoid leadership conflicts between the government and all organizations involved. This can harmonize efforts and avoid the program being implemented as several discrete projects. Appointing both a central coordinator and a focal point for each partner agency is one way to create linkages between partners without risking disagreement among lead groups.”

– Alain Kaboré, United Nations Population Fund Sayana Press Coordinator in Burkina Faso

MAXIMIZING LEARNING AND INFORMATION EXCHANGE TO IDENTIFY NEW OPPORTUNITIES

A component of PATH's global coordination role was to maximize learning and information-sharing among partners such as UNFPA, the MOH, and implementing NGOs. PATH worked with country partners to maintain open lines of communication within and among the four pilot countries. Some of these efforts were ongoing, and others were short-term based on a specific need. For example, PATH helped connect social marketing agencies in Niger and Senegal with each other and with the product manufacturer to help address major questions about the process of overbranding Sayana Press with a local or national brand name for successful marketing.

For coordination to be most effective during the introduction of a new contraceptive method, it is important to hold regular implementation meetings that include all parties. During the pilot introductions for Sayana Press, in some cases PATH leveraged pre-existing technical working groups, such as Senegal's MOH-led Family Planning Technical Working Group. In other settings, this meant creating a pilot project steering committee, as in Niger. In some settings, both approaches were used. For example, in Uganda, PATH represented Sayana Press work in the existing monthly Maternal and Child Health Cluster

meetings and quarterly Family Planning Working Group meetings convened by the MOH, and PATH also convened a monthly Sayana Press Partners Group meeting of NGO implementing partners. These groups all played a key role in scale-up decisions in late 2015 and early 2016.

In addition to ongoing efforts to share information and build communication networks in each country, PATH organized several cross-country events focused on maximizing learning and exchange. After the first full year of implementation, PATH brought together key staff from the four pilot countries for a project review meeting in Dakar in June 2015. This allowed for sharing of information among key project staff about approaches and learnings to date and peer feedback on the activities conducted in each country.

In September 2016, PATH worked with the Ouagadougou Partnership to organize a study tour to Uganda for key stakeholders in several countries interested in Sayana Press self-injection and community-based distribution (CBD) programs. Delegations from Benin, Burkina Faso, Niger, and Senegal traveled to Uganda for one week to observe the self-injection research studies and CBD program, meet with Village Health Team members, and exchange information with government and NGO partner counterparts. Each country team developed an action plan related to self-injection and CBD.

"At the one-year project review meeting in Dakar, I gained a fuller understanding of how the pilots in West Africa differed from my own country. There were some similarities in our approach with the Niger pilot, as it was community-based, and the other countries were intrigued to hear about Uganda's communication campaign, monitoring approach, and way of interacting with the MOH, given that it is not the same as how things are done in the francophone settings. We each returned to our countries with new ideas to try out, such as the Husbands' Schools in Niger and the regional data validation workshops in Burkina Faso."

– Fiona Walugembe, PATH Sayana Press Coordinator in Uganda

“Creating a favorable environment for self-injection is one of the five priority actions identified by Senegal’s Family Planning Division to meet 2018 national goals. The Uganda study tour helped clarify how to make this vision a reality. The concept was presented to the Minister of Health following the tour, and was met with approval. The MOH now plans to develop self-injection programming over the next year.”

– Marguerite Ndour, PATH Sayana Press Coordinator in Senegal

CLEARLY DEFINING PARTNER ROLES TO IMPROVE COORDINATION AND ACCOUNTABILITY

PATH conducted initial landscape assessments to identify the best partners for various product introduction areas—for example, product distribution, training, and communication or demand generation—based on each institution’s strengths. In some cases, as budget allowed, PATH subcontracted specific scopes of work to partner agencies with strong experience in a given technical

area or presence in a particular geographic area (see table).

Subcontracting helped to ensure accountability because organizations were contractually obligated to share relevant data and meet deliverables to receive payments. PATH also collaborated with a number of introduction partners more informally. In most of those informal partnerships, communication and data-sharing worked well. That said, busy implementers are universally more likely to prioritize contractual obligations than informal ones. And in

Examples of work subcontracted by PATH

WORKSTREAM	AGENCY SUBCONTRACTED	MAIN ROLE
Product distribution in Uganda	UHMG	Because of constraints at the national medical stores, PATH contracted with UHMG to distribute Sayana Press due to its specialized work in receiving, storing, and distributing contraceptive supplies (see Section 9: Product distribution for case study on UHMG).
Training in Senegal	ChildFund IntraHealth International	ChildFund trained community health agents working at health huts, and IntraHealth International trained facility-level health providers in the pilot intervention areas.
Demand-generation communication in Uganda	CDFU	CDFU developed and implemented a behavior change communications strategy in support of the work of VHTs in mostly rural communities in 10 target districts over two years. CDFU’s campaign created awareness and promoted uptake of family planning methods, including Sayana Press, among communities in the participating districts through a wide range of media and interpersonal approaches (see Section 8: Generating demand for case study on CDFU).

Note: CDFU, Communication for Development Foundation Uganda; UHMG, Uganda Health Marketing Group.; VHT, Village Health Team

almost all cases, there was some turnover among staff at implementing agencies for the pilot introduction. In cases where PATH had subagreements in place, the terms of collaboration were clearly laid out in a contract and not tied to the relationship with one individual. However, managing subcontracts demands significant administrative, financial, and technical oversight to ensure the quality of work and respect of deadlines.



PATH/Gabe Blenczycki

RECOMMENDATIONS: STAKEHOLDER ENGAGEMENT AND COORDINATION

PATH/Will Boase



- **Build relationships with ministry of health counterparts.** Building and nurturing active, strong, two-way relationships with MOH counterparts will help ensure a smooth transition toward scale-up.
- **Designate an individual or agency responsible for coordinating stakeholders and their activities.** A well-defined lead person or agency can keep activities moving forward, assist in sharing of information and resources, and serve as a clear point for communications among all partners, including the MOH and donors.
- **Define partners' roles and mechanisms for coordinating introduction in a written plan.** Given the complexity of new product introduction, there is a great risk that planning and implementation will be stalled in the absence of a clear plan for engagement and coordination among the MOH and civil society organizations.
- **Widely share experience and results from product introduction.** Subnational, national, regional, and international stakeholders will all benefit from learnings on Sayana Press introduction and may identify exciting new opportunities for the product to increase women's contraceptive access.

RESOURCES



PATH initial country assessments for DMPA-SC. Available at www.path.org/publications/detail.php?i=1952. These executive summaries reveal findings and recommendations from initial assessments conducted in Bangladesh, Ethiopia, Kenya, Malawi, Nigeria, Pakistan, Rwanda, and Senegal. PATH evaluated these settings in 2009 in terms of service delivery, supply systems, and stakeholder perspectives with respect to the feasibility and appropriateness of introducing DMPA-SC in Uniject.



Advocacy materials on Sayana Press. Available by April 2017 at www.rhsupplies.org. This set of advocacy materials provides tools for researchers and program implementers working to increase access to injectable contraception and specifically use of DMPA-SC.



4 Planning the country introduction strategy

The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **planning the country introduction strategy**.

INTRODUCTION PLANNING PROVIDES A ROAD MAP

Introduction of Sayana Press can increase contraceptive access for women and adolescent girls. Traditionally, injectable contraception has been most widely available in clinics. Because administration of Sayana Press requires minimal training, it is especially suitable for use in more remote settings and community-based distribution (CBD).

At the beginning of PATH's coordinated pilot introduction efforts in Burkina Faso, Niger, Senegal, and Uganda, each country developed a Sayana Press introduction plan to harness this product's potential. These plans served as road maps, providing an overview of each country's

family planning goals and a corresponding approach to integrating the product in their program. The introduction plans generally included:

- Overview of the country's family planning landscape and goals.
- Country need or rationale for Sayana Press introduction.
- Description of introduction strategy, including:
 - » Service delivery channels (e.g., public or private sector, clinics, communities, or pharmacies).
 - » Geographic area for introduction.
 - » Partners and their roles.

- » Distribution plans.
- » Training plan: number of providers to be trained, approach, timeline.
- » Approach to demand generation and communications.
- » Monitoring plan: indicators, reporting system.
- Product registration status and procurement plans.
- Description of any research or evaluation activities.
- Plans for scaling up.



INTRODUCTION TIP

The key components of a Sayana Press introduction plan are also applicable to a scale-up plan. Some introduction plans may include budget provisions or sources of financing.

Developing the Sayana Press introduction plans with national partners and validating the plans with a broader set of national family planning stakeholders helped generate buy-in and support, as well as a common vision. Each country's Sayana Press coordinator was responsible for shepherding the plan to completion. National family planning partners reviewed the introduction plans in a workshop or meeting forum, and the national ministry

of health (MOH) validated the plans before introduction got under way.

The planning phase is an opportunity to carefully think through a monitoring and evaluation approach for pilot introduction. The approach should consider what results are expected or hoped for, and what systems and resources are available to measure those results. During the pilot introductions, all countries elected to initiate use of Sayana Press in limited geographic areas, moving to scale after about a year of successful implementation. Collecting and reviewing monitoring data were essential to scale-up decisions in the pilot countries. In addition, the data can inform programmatic improvements even when scale-up is already assured (see Section 10: Monitoring and evaluation).

DESIGNING THE INTRODUCTION STRATEGY TO ACHIEVE DESIRED RESULTS

During the pilot phase, how and where each country chose to introduce Sayana Press depended on the country's family planning program goals. All countries aimed to increase their contraceptive prevalence rate and reduce unmet need for contraception, but each strategy was also driven by more particular priorities (e.g., expanding coverage or reaching more new family planning users). Analysis



PATH/WILL BOASE



PATH/Patrick McKern

Respective roles of Sayana Press and DMPA-IM

When Sayana Press was first presented as an option to the pilot countries prior to 2013, its price per dose was higher than that of DMPA-IM (generic name for the intramuscular form of depot medroxyprogesterone acetate). International donor agencies such as the United States Agency for International Development, United Nations Population Fund, and the World Bank, which often procure contraceptives on behalf of country governments, were wary of replacing DMPA-IM with a more costly presentation. Country governments were similarly hesitant to invest in a more expensive product. In November 2014, a public-private partnership made Sayana Press available for 1.00 USD per dose to qualified purchasers; DMPA-IM is generally available for about 0.70–0.80 USD per dose. This significantly reduced donors' and countries' concerns about pricing and helped pave the way for decisions to scale up the product in the pilot countries. Given the near price comparability, concerns about replacement were largely alleviated during the past two years.

Sayana Press was not intended to replace DMPA-IM in any pilot setting. Most countries expressed interest in enlarging their family planning method mix and envisioned Sayana Press attracting new clients through nonclinic channels, including outreach and community-based distribution, while satisfied DMPA-IM clients would continue with this method. Some degree of switching was expected, but it was impossible to predict how much. Monitoring data reveal that, cumulatively, the share of doses administered to women switching from DMPA-IM to Sayana Press ranged from 7 percent in Burkina Faso to 16 percent in Uganda.

In some instances, provider bias for one product or the other may have influenced Sayana Press uptake. For example, early on in introduction, many providers across country settings misunderstood that Sayana Press was to replace DMPA-IM, which resulted in higher proportions of doses administered to women switching from DMPA-IM (ranging from 16 percent in Burkina Faso to 51 percent in Senegal). This was quickly addressed during supervision, and switching declined sharply at first then continued to gradually decline over time. In contrast, early on at some sites in Burkina Faso, providers were hesitant to initiate women on Sayana Press because they had surmised that “pilot project” meant a short-term or temporary offer of the method. Supervisors had to remind these providers that Sayana Press would continue to be available long-term because the term “pilot” referred to the limited geographic area for initial introduction.

The approach to introduction depends on each country's goals, which may include co-delivery of both injectable presentations, eventual replacement of DMPA-IM, or targeted offering of Sayana Press in specific channels. If volumes of Sayana Press administered continue to increase in the coming years across geographies, and if and when self-injection becomes more widely available, conversations among international family planning donors, ministries of health, implementing agencies, and the product manufacturer about these two products will undoubtedly continue and evolve.

of pilot introduction monitoring data from Burkina Faso, Niger, Senegal, and Uganda helps to illustrate how different Sayana Press introduction strategies may achieve varied family planning outcomes, as outlined below.

Introducing Sayana Press at many delivery points and higher levels of the health system achieves large volumes.

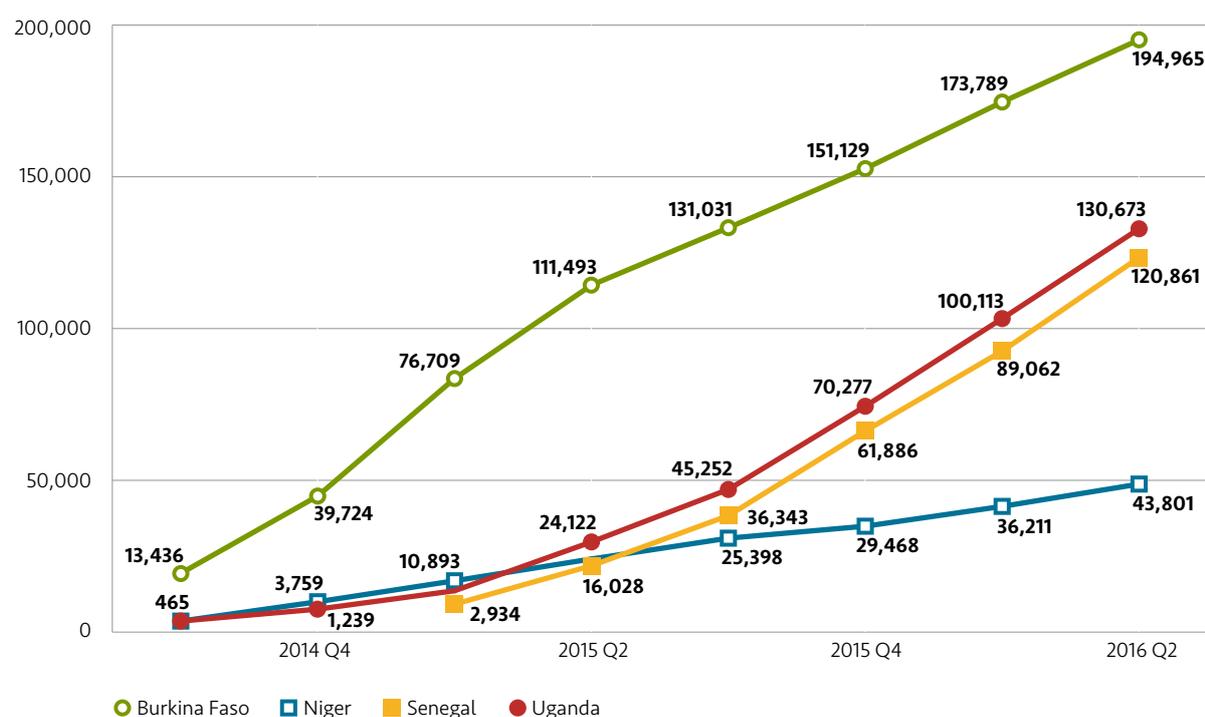
- **Approach:** Senegal and Burkina Faso introduced Sayana Press through delivery points at all levels of the health system, alongside DMPA-IM. They also implemented the pilots in four regions with the greatest population and highest rates of intention to use family planning, based on data from national Demographic and Health Surveys.
- **Results:** Volumes of Sayana Press distributed and administered were high in both countries, because the product

was available in every type of health facility—including clinics (see graph). Higher volumes of Sayana Press distributed can help inform global conversations about product supply and demand. Ideally, higher demand will result in more supply and more availability of the product for women—including those with an unmet need for family planning.

Introducing Sayana Press in more peripheral channels reaches higher proportions of new family planning users.

- **Approach:** Given Niger’s high fertility rate (7.6 percent) and low level of unmet need (16.0 percent) due to the desire for large families, the MOH wanted to reach and attract new users of family planning and expand geographic access for women living in remote or rural areas. They elected to introduce Sayana Press as the first offer

Total cumulative number of Sayana Press doses administered by quarter, by country (2014–2016)



of injectables only at the most peripheral facilities in two districts, and through CBD of socially marketed product at the village level in two districts. In other words, women in Niger who previously only had access to pills and condoms were provided with an entirely new contraceptive option. Given how new the injectable offer was at these outlets, Niger elected to pilot in only four districts, with the intention to move swiftly to national scale if the first year of the pilot was successful.

- Results:** Of the four countries, Niger reached the highest cumulative proportion of new users (44 percent of doses were administered to new users overall for the entire pilot period). From the beginning, demand among new users was clear: in the first full quarter of introduction in Niger (October through December 2014), the percentage of Sayana Press doses administered to new family planning users was an astounding 70 percent. The proportion of all doses administered to new users decreased and leveled off

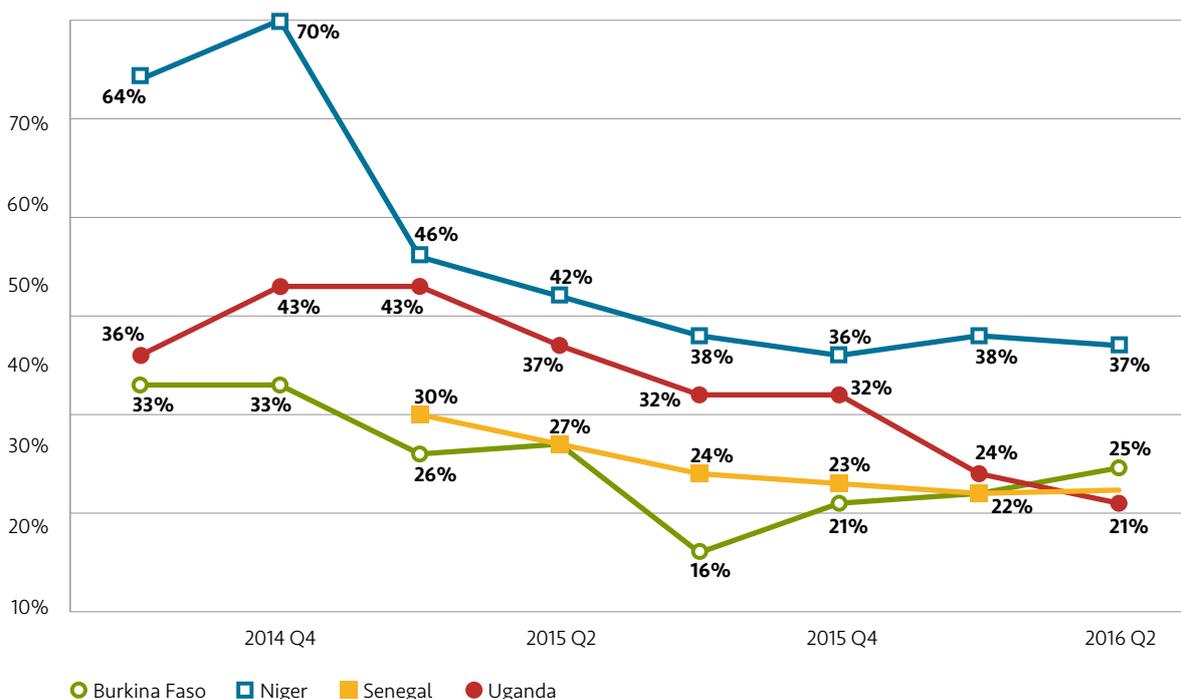
over time as more clients came back for reinjections (see graph).

Introducing Sayana Press through community-based distribution will likely result in the product outpacing DMPA-IM in these channels (see graph on following page).

- Approach:** Planning for Sayana Press introduction in Senegal was concurrent with a successful pilot study of CBD of DMPA-IM. A full policy shift at the outset of Senegal’s introduction enabled community health workers (CHWs) called *matrones* to offer both Sayana Press and DMPA-IM.

Uganda was the only pilot introduction country that already had a policy supporting CBD of DMPA-IM when Sayana Press introduction began. The Uganda MOH and implementing partners desired to expand task-sharing through community-based service provision, selecting 28 districts where Village Health Teams (VHTs) were functional but not offering

Proportion of Sayana Press administered to new users by country, by quarter (2014–2016)



injectables consistently. The pilot trained VHTs in family planning, including administration of both Sayana Press and DMPA-IM.

- **Results:** When offered side-by-side at the community level in both countries, Sayana Press volumes far outpaced DMPA-IM volumes. CHWs and their clients may be more comfortable with Sayana Press due to its ease of use or may prefer subcutaneous injection over intramuscular injections. For example, in Senegal, the proportion of Sayana Press administered relative to DMPA-IM was 72 percent at rural community health huts compared to only 14 percent at upper-level facilities. Similarly, in Uganda, Sayana Press constituted 75 percent of injectables administered by VHTs where both methods were available.



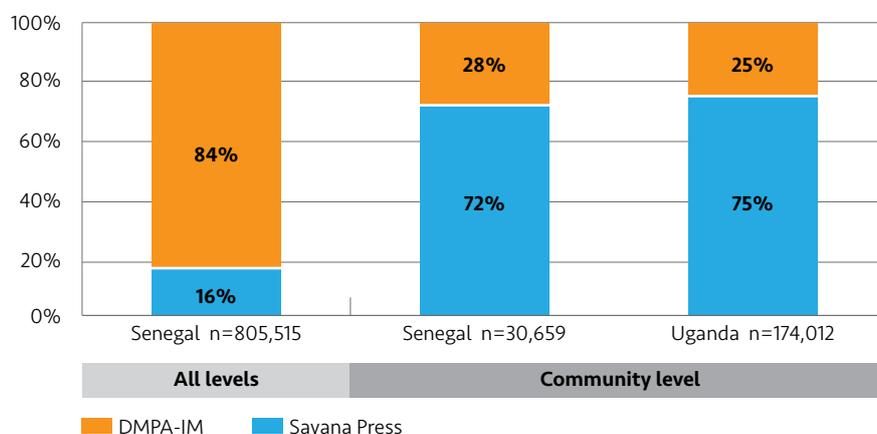
INTRODUCTION TIP

Sayana Press seems to be highly preferred by community health workers and their clients, and may help advance task-shifting and task-sharing.

Introducing Sayana Press may help reach more young women with contraception.

- **Approach:** Uganda expressly aimed to reach young women and adolescent girls through the pilot introduction of Sayana Press, and it revised the national training curriculum and developed communication strategies accordingly. The training curriculum includes specific sessions designed to reduce resistance to provision of family planning to adolescents, and radio spots targeted to a younger audience were developed.
- **Results:** In Uganda, monitoring data from the second quarter of 2015 showed that 41 percent of Sayana Press clients were under the age of 25 years. By way of comparison, the Demographic and Health Survey (2011) found that only 26 percent of injectable users were under the age of 25 years. Because the Demographic and Health Survey data on injectable users were collected prior to Sayana Press introduction, they represent DMPA-IM clients. Although the Demographic and Health Survey data are several years old, it is encouraging to see that a higher proportion of women under age 25 years accessed Sayana Press compared to the previously available DMPA-IM. This may indicate that Sayana Press is an attractive option for younger

Relative proportions of DMPA-IM and Sayana Press administered by country, by level—Senegal and Uganda (2014–2016)



women. It is not possible to conclude whether the product itself, specific training and communication approaches, the community-based delivery channel, or the demographics of the pilot areas may have driven these results. In Niger, the proportion of doses administered to women under 25 years was even higher (52 percent).

DISTRIBUTION THROUGH THE PRIVATE SECTOR

Sayana Press introduction in these first four countries primarily took place in the public sector, where most women access contraception (particularly injectable contraception). In each country, private, nonprofit implementers also introduced Sayana Press in a small number of outlets. In Burkina Faso, for example, PATH's monitoring data from the first 18 months of pilot introduction reveal that while the relatively small-scale nongovernmental-organization (NGO) sector distribution represented only 6 percent of overall doses administered, it

reached a higher proportion of new users (39 percent) compared with the public sector (25 percent). Additionally, fewer doses were administered to women switching from DMPA-IM and other methods in the private sector. This may be partly attributable to NGO delivery channels like mobile outreach, community distribution, youth centers, and pharmacies. Much remains to be learned from settings where Sayana Press is distributed through the private, commercial sector. In some of the pilot countries, private-sector implementers faced delays getting started because of procurement challenges and the need to obtain permission to overbrand the product for social marketing. Examples of private-sector introductions are outlined below:

- **Association Nigérienne de Marketing Social (ANIMAS-SUTURA).** A local social marketing agency, ANIMAS-SUTURA, was contracted by the United Nations Population Fund (UNFPA) to distribute an overbranded product called “SUTURA Press” at the community level through a network

Marie Stopes complements public-sector introduction in Burkina Faso

Marie Stopes Burkina Faso (MSBF) integrated Sayana Press into its package of family planning services at various service delivery points, including three clinics, five mobile teams, and one youth counseling center in the four pilot regions. MSBF trained 31 health providers as well as 32 social marketing agents who provide information and refer clients to MSBF's service delivery points. In collaboration with health district management teams, MSBF conducted behavior change communications and media activities (such as radio talk shows and spots, and referral education) that reached an estimated 223,000 people. One unique activity was the engagement of women's and men's associations, such as hair dressers and taxi drivers, to serve as client referral networks. MSBF also trained 140 cotton-farming group leaders to refer family planning clients to MSBF's service delivery points. During the project, MSBF administered more than 3,500 doses of Sayana Press, including approximately half of these to first-time users of modern contraception.



PATH/Anna Stout



of 100 trained community health agents in Madarounfa and Mayahi, two districts of Maradi Region that have distributed nearly 4,000 doses (9 percent of total doses administered in pilot introduction in Niger). In addition, in March 2015, the project trained 151 staff from private pharmacies and clinics in Niamey in promotion and sales (no distribution data available).

- **Agence pour le Développement du Marketing Social (ADEMAS) in Senegal.** Promoting an overbranded product called “Securil Press,” the social marketing agency ADEMAS trained 164 pharmacists in the pilot regions to counsel clients about injectable contraception and sell the product. Clients needed to take the product to a different trained provider for the actual injection. More than 9,000 doses were sold to pharmacies through June 2016.
- **Marie Stopes Burkina Faso (MSBF).** MSBF integrated Sayana Press into its package of family planning services at fixed and mobile clinics, trained health providers and social marketing agents, and led behavior change communications activities (see text box on page 37).
- **Marie Stopes Senegal (MSS).** After overcoming significant challenges in product procurement, MSS trained staff

and began offering Sayana Press through a clinic and a youth center in Dakar in May 2016. By June, MSS began offering the product through all their distribution channels nationwide except in one region; these distribution channels included mobile outreach teams, social marketing agents called “MS Ladies,” youth centers, and a social marketing franchise network of 55 affiliated private health centers.

- **National affiliates of International Planned Parenthood Federation (IPPF) in Burkina Faso** (Association Burkinabe pour le Bien-Être Familial, or ABBEF), Senegal (Association Sénégalaise pour le Bien-Être Familial, or ASBEF), and Uganda (Reproductive Health Uganda, or RHU). ABBEF introduced Sayana Press through 11 clinics, 3 mobile clinics, 2 youth counseling centers, and more than 600 community-based health distribution agents. In fact, the first four women in Africa to receive Sayana Press in a normal clinic delivery setting were clients at an ABBEF clinic in Burkina Faso in June 2014. In Senegal, ASBEF introduced Sayana Press nationwide in 8 clinics and through CBD programs in 17 cities and towns across the country. In Uganda, RHU integrated Sayana Press into one of its urban clinics in Gulu District. Two years later, RHU is integrating Sayana Press into its contraceptive offerings across the country.

EXPANDING INJECTABLE ACCESS IN: **BURKINA FASO**

BURKINA FASO PILOT INTRODUCTION BY THE NUMBERS: JUNE 2014–JUNE 2016

1,908

Number of providers trained in pilot

194,965

Doses administered during pilot

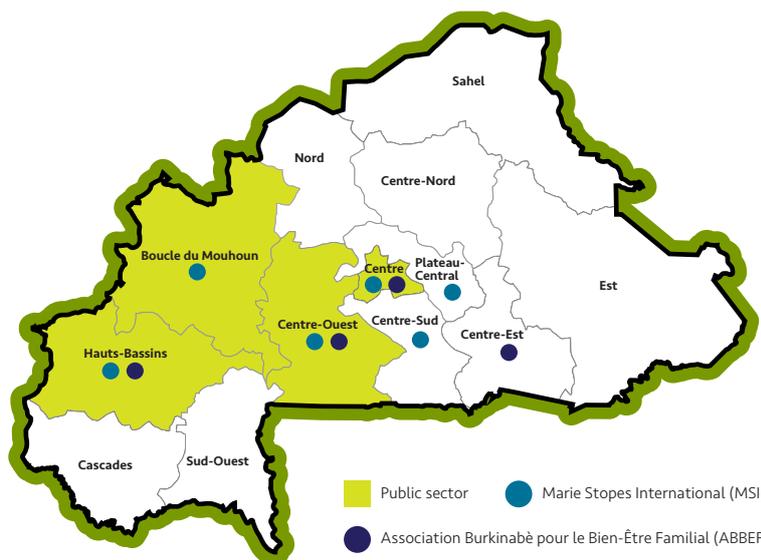
25%

Proportion of doses administered to new users



COUNTRY OVERVIEW

- Contraceptive prevalence rate, modern methods, all women: 16%
- Injectables as proportion of method mix, married women: 31%
- Most popular method: implants (45%)



GEOGRAPHIC SCOPE OF PILOT

Over 680 public-sector facilities across the 4 most populous regions and 23 districts participated in the pilot. Sayana Press was offered alongside DMPA-IM at all levels of the health system. Clinic and mobile outreach was offered by nongovernmental organization partners.



INNOVATIVE DELIVERY

Sayana Press pilot introduction represents the first time injectables are offered through outreach directly in communities. Outreach workers based at the most peripheral health centers—already active in routine vaccination campaigns—offer Sayana Press during monthly community visits.



SCALE-UP

Decision to move to scale made in November 2015. National pool of 35 master trainers from 9 regions trained in May 2016, followed by simultaneous cascade training of providers across 9 additional regions and 47 districts by end June 2016.



STATUS OF SELF-INJECTION

Label change pending. No self-injection research currently under way. Interest in self-injection pilot emerging.



PARTNERS

Ministry of Health, United Nations Population Fund (UNFPA), Marie Stopes Burkina Faso (MSBF), Association Burkinabè pour le Bien-Être Familial (ABBEF), Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)

Sources: Demographic and Health Surveys, Performance Monitoring and Accountability 2020 (PMA2020) country reports, PATH's Monitoring Sayana Press Pilot Introduction: Final Pilot Project Results

EXPANDING INJECTABLE ACCESS IN: NIGER

NIGER PILOT INTRODUCTION BY THE NUMBERS: SEPTEMBER 2014–JUNE 2016

371

Number of providers trained in pilot

43,801

Doses administered during pilot

42%

Proportion of doses administered to new users

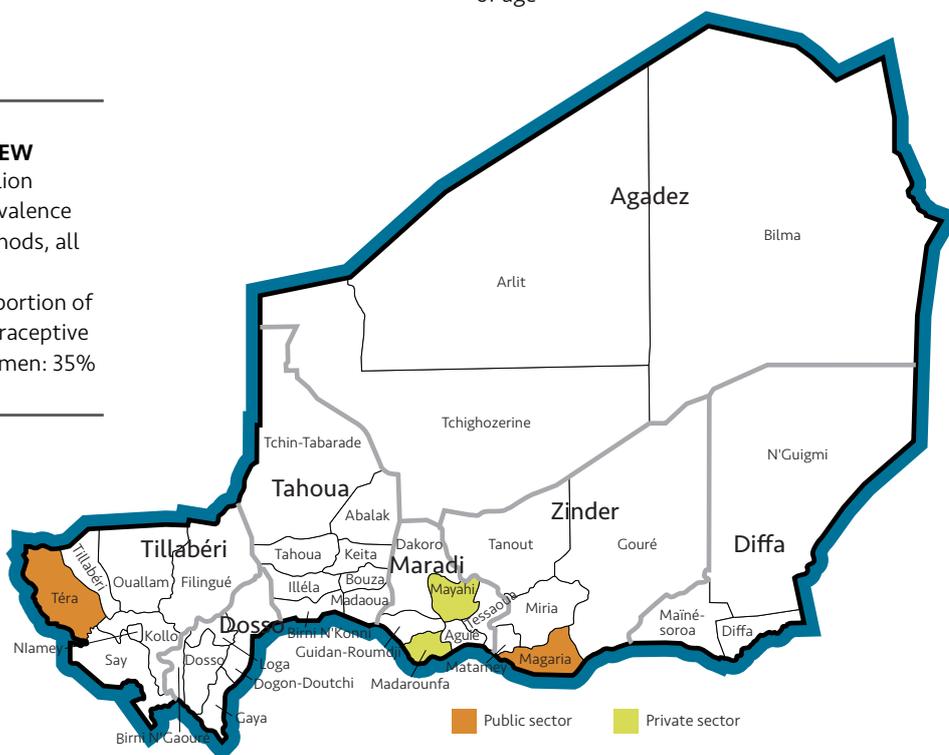
50%

Proportion of doses administered to users under 25 years of age



COUNTRY OVERVIEW

- Population: 17 million
- Contraceptive prevalence rate, modern methods, all women: 11%
- Injectables as proportion of method mix, contraceptive users, married women: 35%



GEOGRAPHIC SCOPE OF PILOT

211 public-sector community health huts in 2 districts (Téra and Magaria) of 2 regions (Tillabéri and Zinder). ANIMAS-SUTURA distributed socially marketed brand SUTRA Press through community-based distribution in 50 villages of 2 districts (Madarounfa and Mayahi) of Maradi Region and in pharmacies and private clinics around Niamey.

INNOVATIVE DELIVERY

Sayana Press pilot introduction represents the first offer of injectables in public-sector health huts, the most peripheral level of Niger's health system.

SCALE-UP

Decision to move to scale was made in June 2015. Partners, including Pathfinder and EngenderHealth, trained health workers in an additional 661 health huts beyond the 211 huts involved in the pilot introduction, out of 2,500 total across the country.



STATUS OF SELF-INJECTION

Label change was approved to indicate self-injection in June 2016. The status of future introduction or research is unknown.

PARTNERS

Ministry of Health, United Nations Population Fund (UNFPA), Association Nigérienne pour le Bien-Etre Familial (ANBEF), Association Nigérienne de Marketing Social (ANIMAS-SUTURA)

Sources: Demographic and Health Surveys, Performance Monitoring and Accountability 2020 (PMA2020) country reports, PATH's Monitoring Sayana Press Pilot Introduction: Final Pilot Project Results

EXPANDING INJECTABLE ACCESS IN: SENEGAL

SENEGAL PILOT INTRODUCTION BY THE NUMBERS: JANUARY 2015–JUNE 2016

2,023

Number of providers trained in pilot

120,861

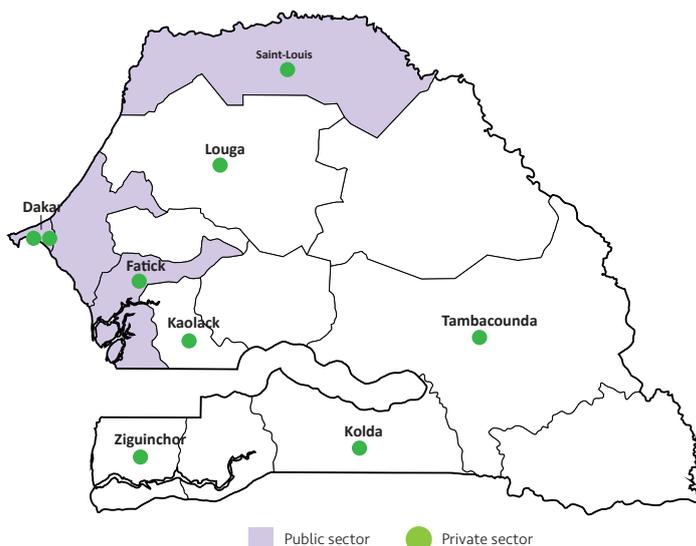
Doses administered during pilot

24%

Proportion of doses administered to new users

34%

Proportion of doses administered to users under 25 years of age



COUNTRY OVERVIEW

- Population: 14 million
- Contraceptive prevalence rate, modern methods, married women: 22.3%
- Injectables as proportion of method mix, married women: 39% (most popular method)



GEOGRAPHIC SCOPE OF PILOT

268 facilities and 637 health huts across the 4 most populous regions, across all levels of the public sector and alongside DMPA-IM. Marie Stopes Senegal offered Sayana Press through a network of 55 clinics and mobile outreach teams in pilot areas, and Association Sénégalaise pour le Bien-Etre Familial (ASBEF) worked through 8 clinics and community distribution in 17 towns and cities nationwide. Agence pour le Développement du Marketing Social (ADEMAS) distributed an overbranded product, Securil Press, for sale in pharmacies.



INNOVATIVE DELIVERY

Both Sayana Press and DMPA-IM were introduced at the health-hut level for the first time during the pilot.



SCALE-UP

Decision to move to scale was made in March 2016. Regional supervision teams were trained in May and June 2016. Progressive rollout of provider training in 10 nonpilot regions began in June 2016, continuing into early 2017.



STATUS OF SELF-INJECTION

A self-injection operational feasibility study was completed in June 2016. Continuation/cost-effectiveness studies will be completed in 2017. Label change is pending. Clear intention to pilot self-injection.



PARTNERS

Ministry of Health and Social Action, ChildFund International, IntraHealth International, Agence pour le Développement du Marketing Social (ADEMAS), Marie Stopes Senegal (MSS), Agence Sénégalaise pour le Bien-Etre Familial (ASBEF).

Sources: Demographic and Health Surveys, Performance Monitoring and Accountability 2020 (PMA2020) country reports, PATH's Monitoring Sayana Press Pilot Introduction: Final Pilot Project Results

EXPANDING INJECTABLE ACCESS IN: UGANDA

UGANDA PILOT INTRODUCTION BY THE NUMBERS: OCTOBER 2014–JUNE 2016

2,284

Number of providers trained in pilot

130,673

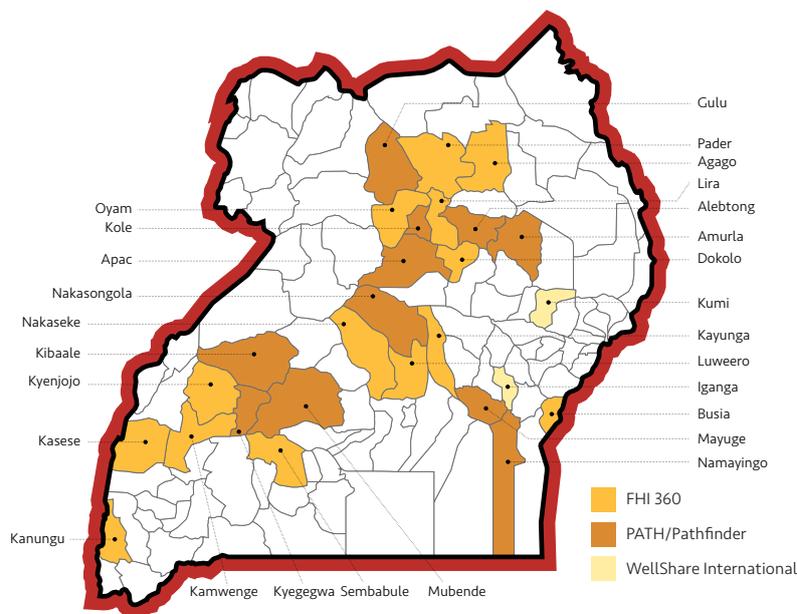
Doses administered during pilot

29%

Proportion of doses administered to new users

44%

Proportion of doses administered to users under 25 years of age



COUNTRY OVERVIEW

- Total population: 36 million
- Contraceptive prevalence rate, modern methods, all women: 21%
- Injectables as proportion of the method mix, married women: 56%



GEOGRAPHIC SCOPE OF PILOT

Community-based distribution by Village Health Teams in 28 out of 112 districts: 10 were managed by PATH and Pathfinder, 16 by FHI 360; and 2 by WellShare International. Reproductive Health Uganda (RHU) reached youth through their nongovernmental-organization clinic site in Gulu, northern Uganda.



INNOVATIVE DELIVERY

The pilot introduction expanded on Uganda's commitment to task-sharing by training many community health workers, Village Health Teams, to administer Sayana Press and DMPA-IM.



SCALE-UP

In April 2016, the Ministry of Health signaled its commitment to national coverage of Sayana Press. By the end of the year, several implementers had launched training in more districts and a coordinated national plan was under development.



STATUS OF SELF-INJECTION

Self-injection operational feasibility studies were completed in December 2016. Continuation/cost-effectiveness studies will be completed in mid-2017. In late 2016, self-injection of Sayana Press was piloted in Uganda's Mubende District—the first time the practice has been available in sub-Saharan Africa outside of a research setting. Label change is pending.



PARTNERS

Ministry of Health, Pathfinder International, WellShare International, FHI 360, Uganda Health Marketing Group (UHMG), Communication for Development Foundation Uganda (CDFU), Reproductive Health Uganda (RHU), Makerere University

Sources: Demographic and Health Surveys, Performance Monitoring and Accountability 2020 (PMA2020) country reports, PATH's Monitoring Sayana Press Pilot Introduction: Final Pilot Project Results

RECOMMENDATIONS: PLANNING THE COUNTRY INTRODUCTION STRATEGY

PATH/Will Boase



- **To reach large volumes, introduce Sayana Press at all levels of the public sector (or public-private) in large geographies.** Do not discount the potential for more remote and community-level channels to achieve large volumes as well.
- **To reach the largest number of new users, prioritize community-level delivery and offer injectables where previously unavailable.** Increasing the number of new family planning users can contribute to reducing unmet need and increasing contraceptive prevalence.
- **Expect high volumes of Sayana Press compared to DMPA-IM in community-level delivery channels.** Data from the pilot introduction reinforce early research data on acceptability of and preference for Sayana Press among community-level providers and their clients.
- **Consider opportunities for Sayana Press to increase access for young women.** Explore a variety of public and private delivery channels and consider what additional training, supervision, and communications activities are needed to support and sustain access for young women and adolescent girls.
- **Invest in total market introduction from the origins of introduction planning and beyond.** There are still limited data on Sayana Press introduction in private-sector channels, but the limited data available indicate that private-sector outlets hold great potential to increase access.



Uganda Sayana Press Introduction Plan Summary. Available at sites.path.org/rh/recent-reproductive-health-projects/sayanapress/sayanapress-resources/#uganda. This executive summary outlines the core elements of Uganda’s pilot introduction plan, including the country’s family planning goals, product registration process, Sayana Press partners and their roles, geographic coverage, and plans for training, end-user communications, and monitoring.



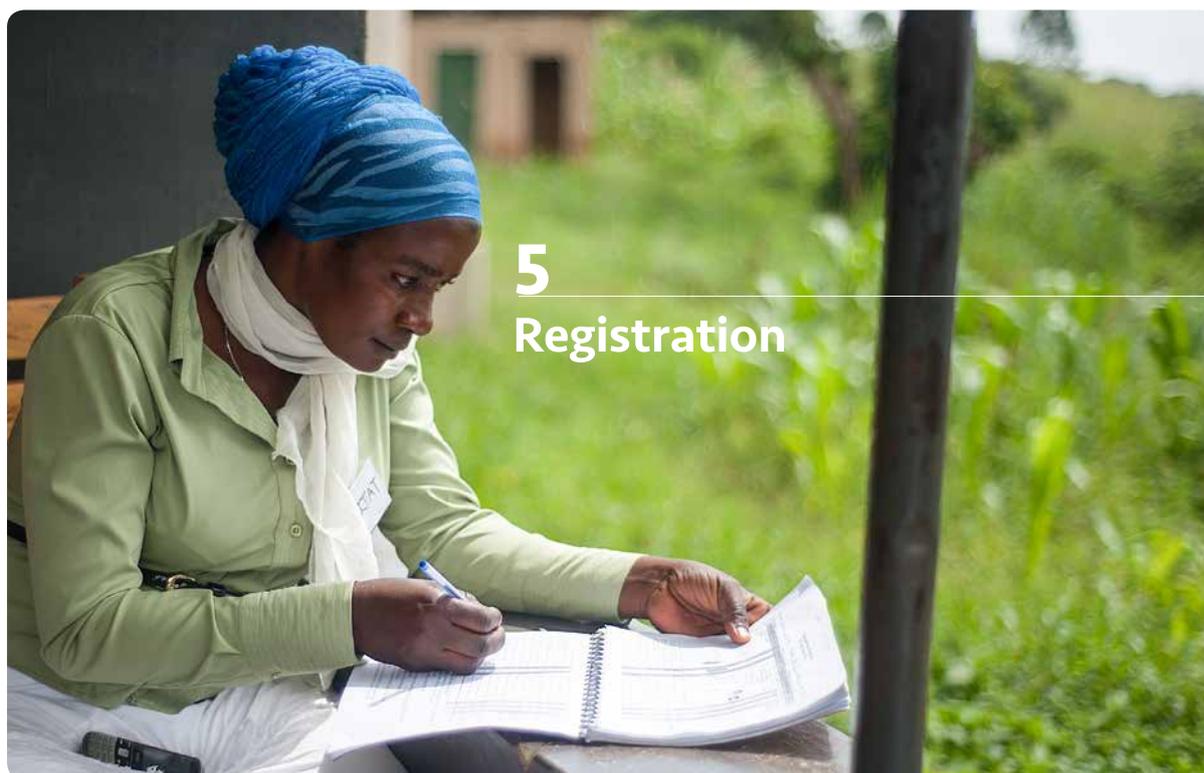
Provision of Injectable Contraception Services through Community-Based Distribution. Available at www.fhi360.org/resource/provision-injectable-contraception-services-through-community-based-distribution. Produced by FHI 360 and Save the Children USA, this step-by-step guide explains how to introduce injectable contraceptives — such as DMPA-SC— into an existing community-based distribution program.



Community-Based Access to Injectable Contraceptives Toolkit. Available at www.k4health.org/toolkits/cba2i. This comprehensive resource is a platform for agencies and organizations working to plan, implement, evaluate, promote, and scale up programs for community-based access to injectables and to advocate for changes to national policy and service delivery guidelines.



Community-Based Health Workers Can Safely and Effectively Administer Injectable Contraceptives: Conclusions from a Technical Consultation. Available at www.who.int/reproductivehealth/publications/family_planning/WHO_CBD_brief.pdf. This four-page summary presents the conclusions of a technical consultation of technical experts in 2009. The group reviewed extensive evidence and recommended that community-based provision of injectable contraceptives by trained community health workers is safe and effective. The document highlights program guidance and operational issues as well as priorities for new research.



The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **product registration**.

PERMISSION TO BUY, IMPORT, AND USE PRODUCT IN A COUNTRY

Registering a new product like Sayana Press with a country’s relevant drug regulatory authorities is essential for introduction. The national medicines regulatory authority is often a division of the ministry of health (MOH) established to ensure the safety of all medicines on the market. This group monitors the quality and efficacy of all medicines as a public health responsibility; oversees the licensing, trade, and advertising of medicines; and ensures conformity to international legal standards pertaining to the regulation of medicines.

REGISTRATION PROCESSES AND RESPONSIBILITY

Registration influences many ensuing steps in the introduction process. In most cases, a country’s regulatory authority examines available clinical data to evaluate the safety, efficacy, and quality of the product. When review is complete, it issues authorization to import and distribute the product. Registration is required for product procurement and importation, and it drives subsequent modifications to how the product is used.

As the product’s manufacturer, Pfizer is responsible for Sayana Press registration. In other words, Pfizer must prepare, submit, and track regulatory submissions; determine in which markets the product should (or can

feasibly) be registered, factoring in global health priorities and country demand; and assess how many registration dossiers can be prepared, submitted, and tracked in a given time period. The company must weigh the costs required to register a product like Sayana Press in a new market against the advantages, which are measured in terms of revenue, profit, competitive position, and/or potential benefit to, and demand from, women.



INTRODUCTION TIP

The product manufacturer, Pfizer Inc., leads registration of Sayana Press.

Sayana Press received stringent regulatory approval in 2011 from the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) (see Sayana Press registration milestones box). Stringent regulatory approval is the registration of a new product with one or more regulatory authorities recognized globally as having high standards, such as the UK MHRA, the US Food and Drug Administration, or the drug regulatory authorities of several other European countries as well as Japan and

Australia. The UK MHRA was a critical reference point for the national registration processes in the pilot introduction countries—Burkina Faso, Niger, Senegal, and Uganda.



INTRODUCTION TIP

Sayana Press has stringent regulatory approval from the United Kingdom—including for self-injection—that serves as a key reference point for registrations in other countries.

One question that arose often from global and national stakeholders during the pilot phase is whether Sayana Press should be prequalified by the World Health Organization (WHO). Like stringent regulatory approval, WHO prequalification can sometimes help streamline national registration processes. Reproductive health procurement agencies do not typically require the products that have been approved by an internationally recognized stringent regulatory authority to also be prequalified by WHO.

In some cases, as an alternative to official registration, Sayana Press has been made available in a country based on a waiver. A

Sayana Press and the World Health Organization Collaborative Registration Procedure

In 2016, Pfizer worked through the WHO Collaborative Registration Procedure to facilitate rapid review and approval of Sayana Press, including labeling for self-injection in multiple countries. The process requires working closely with WHO to submit the multiple dossiers required. Concurrently, Pfizer submitted individual dossiers in some markets. Through this process, it is possible that up to 18 countries (see below) may approve Sayana Press, including the self-injection indication by early 2017. This time frame contrasts sharply with the lengthy time frame that is typical during a standard country approval process. All country standards for review of the regulatory submission are maintained, while WHO's involvement ensures a consistent, expedited review. The WHO Collaborative Registration Procedure has been used for many products that already have WHO prequalification, including oral contraceptive pills. The process also is being explored as an option for products that have been approved by a stringent regulatory agency but are not prequalified, such as Sayana Press. The 18 countries participating are Burkina Faso, Burundi, Cameroon, Cote d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, Madagascar, Malawi, Mozambique, Niger, Nigeria, Senegal, Sierra Leone, Tanzania, Uganda, and Zambia.

Sayana Press registration milestones

Since 2007, the safety, efficacy, and quality of Sayana Press and the drug contained in Sayana Press (DMPA-SC [generic name for the subcutaneous form of depot medroxyprogesterone acetate]) have been thoroughly vetted through multiple steps in the registration process.

- **2007: Sayana receives stringent regulatory approval from the UK MHRA.** Sayana is the same drug that is used in Sayana Press, but it is packaged in a glass, prefilled syringe for administration by a health worker. Pfizer's approved registration with the MHRA permitted additional country registrations in Europe through a "cascade" to other European Union countries that have a mutual recognition agreement for drug regulatory approvals with the MHRA.
- **2011: Sayana Press receives stringent regulatory approval from the UK MHRA,** based on an amendment to the original Sayana registration. The amendment requested regulatory approval of a container change: Sayana in the Uniject injection system (formerly known as depo-subQ in Uniject, now known as Sayana Press).
- **2013–ongoing: Sayana Press receives national regulatory approval in Burkina Faso, Niger, Senegal, and Uganda and beyond.** With stringent MHRA approval of Sayana Press in place, Pfizer filed for regulatory approval in more individual countries, including the four pilot countries. The submission requirements, timelines, and processes for review and approval in each country varied.
- **2015: Sayana Press self-injection approved by the UK MHRA.** Based both on commercial and global health interest, Pfizer prepared additional regulatory documentation on the safety and efficacy of self-injection, referencing studies undertaken in the United States and UK. Pfizer submitted a new application to the MHRA to update the Sayana Press label to include self-injection as an additional route of administration, which was approved in 2015.
- **2016–ongoing: Sayana Press self-injection label approved by national regulatory authorities in Niger, Uganda, and beyond.** The MHRA's approval of Sayana Press for self-injection is now facilitating submission, review, and approval of a set of country-level applications for label updates. Niger was the first country to have national regulatory approval for the new product label.

waiver is a type of interim regulatory approval granted for a limited time frame concurrent with the full regulatory approval process. Waivers are often requested for a specific purpose such as a small pilot or trial. For example, Sayana Press was initially made available via the waiver process in Malawi, for the purposes of a self-injection study, and in the Democratic Republic of the Congo because of complexities and lengthy timelines associated with country-level regulatory approval.



INTRODUCTION TIP

Waivers are an option if country registration processes might delay product introduction substantially.

UNPREDICTABILITY OF REGISTRATION TIMELINES

Product registration for the first four Sayana Press pilot introductions was complex and time-consuming. Because the registration application process is driven by Pfizer and depends on country regulatory processes, it is the part of the introduction process over which implementing organizations have the least control. Preparation for regulatory submissions alone can require considerable resources. For example, after the July 2012 London Summit on Family Planning and the commitment of donor resources to Sayana Press pilot introduction, it took about six months for Pfizer to prepare multiple, simultaneous regulatory submissions for diverse country systems. National regulatory submissions were made in Burkina Faso, Niger, Senegal, and Uganda in early 2013.



INTRODUCTION TIP

While implementers are not directly involved in product registration, they can check with authorities and see how it is going. On occasion, implementers may be able to assist in resolving problems that stakeholders or regulators are not aware of.

In the four pilot countries, the time from Pfizer's regulatory submission to national regulatory approval varied from just six weeks to more than a year. If effective coordination mechanisms are in place, planning for introduction can proceed while product registration is in process. For example, PATH continued to revise and review Sayana Press training curricula with the MOHs and engaged local partners to plan provider training and behavior change communication

activities. In addition, PATH Sayana Press coordinators and key ministry representatives helped track each step of the registration process, identify bottlenecks, and keep the process moving, to a certain extent.

Still, final implementation of certain country-level activities was delayed given uncertainty about the timing of the product's arrival in country. Flexibility in developing work plans and perseverance are keys to successful project implementation. For example, provider training was planned but not scheduled until the product was in country and available for distribution. Launch events were planned with official dates on hold pending final regulatory approval and certainty of the product's arrival in the country. Success in navigating these unpredictable timelines during the pilots reflects the value of coordination to keep stakeholders informed and activities moving forward.

RECOMMENDATIONS: REGISTRATION

PATH/Gabe Blenczycki



- **Get up to speed on the status of Sayana Press registration globally.** Know that the safety, efficacy, and quality of this product have been thoroughly vetted. Understanding key facts about the product’s regulatory history—that the drug is approved in the United States and Europe, and that it is approved for self-injection by a stringent regulatory authority—can be useful for navigating many steps in the introduction process.
- **Build flexibility into introduction plan timelines.** Registration is the manufacturer’s responsibility, and national processes are often unpredictable. National product registration processes often take much more time than expected.
- **Track the registration process and know what can be done to move introduction forward in the meantime.** While waiting for registration, it is helpful to stay in touch with key MOH staff and the manufacturer’s point person, in case questions or obstacles arise that require coordination. Introduction planning activities such as design of the monitoring system, revision or development of a provider training curriculum, and conceptualization of communication campaigns can begin before registration is in hand.



WHO's Essential Medicines and Health Products Information Portal.

Available at apps.who.int/medicinedocs/en/. This website portal serves as a repository for full-text articles about all aspects of international drug and health product registration.



Access to Medicines and Drug Regulation in Developing Countries: A Resource Guide for DFID.

Available at apps.who.int/medicinedocs/documents/s18246en/s18246en.pdf. This paper provides an overview of the debate about how developing-country drug-regulation agencies are funded and the extent to which they should build local capacity or rely on regulatory bodies in developed countries.



WHO Launches the PQP Collaborative Registration Procedure.

Available at apps.who.int/medicinedocs/en/d/J/s21317en/. This concise summary of WHO's Collaborative Registration Procedure describes the advantages of this program as well as experiences and lessons learned during the launch of the activity in 2012.



WHO Collaborative Registration Procedure for Medicines in Developing Countries. Master's Dissertation.

Available at dgra.de/media/pdf/studium/masterthesis/master_haas_s.pdf. This thesis provides an in-depth review of key WHO-led procedures for registering medicines in developing countries, including prequalification, the concept of essential medicines, and collaborative registration.



The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **quantification and procurement**.

PURCHASING THE RIGHT AMOUNT OF PRODUCT

Procurement is the process of purchasing or ordering a commodity; an essential step in that process is quantification, or estimating the amount of product to procure. Quantification includes forecasting (estimating the quantity of produce to be consumed) and supply planning (developing order quantities and delivery schedules to meet these needs while accounting for various stock/supply factors). Regular quantification exercises for estimating commodity requirements for family planning are generally led by the ministry of health (MOH) with input from partners and donors. Quantification is not a one-time event but rather an ongoing process that requires updating to adjust for new information such

as consumption data, changes in introduction plans, and shifts in timing or quantity of product shipments. The results feed into each country’s ongoing or periodic commodity procurement process. PATH and partners undertook a version of this quantification exercise for the Sayana Press pilot introductions in Burkina Faso, Niger, Senegal, and Uganda to be consistent with country processes, fulfill donor procurement requirements, and provide an estimate of initial product needs based on assumptions about product use. As the first introduction of Sayana Press in nonresearch settings, these quantification exercises were somewhat unique, but they ultimately merged into each country’s procurement process. Quantification for any new contraceptive product ideally integrates into existing

programs and systems to become part of routine mobilization of funds and commodity orders.

PATH and the country partners—most centrally, the MOH, as these first introductions were largely public-sector endeavors—worked closely with the country offices of the primary procurement agency partner, United Nations Population Fund (UNFPA), to develop the first Sayana Press quantifications. Relevant MOH partners in each country reviewed, refined, and approved the proposed quantifications for the initial Sayana Press orders before officially submitting them to UNFPA headquarters in Copenhagen to kick off procurement.

The introduction plans developed for each of the four pilot introduction countries specified the pilot's geographic locations, service delivery channels, and training plans (see Section 4: Planning the country introduction strategy). This information was key to each country's quantification of its initial Sayana Press order. Additional factors beyond the introduction plan itself that were relevant to product quantification included:

- **Timing of country registration.** Each country's introduction plan and quantification reflected assumptions about the date when official country registration would be in hand. Shifts in registration timelines in each country led to shifts in assumptions about product uptake and quantification (see Section 5: Registration).
- **Product manufacturing dates and shelf life.** Sayana Press is authorized for a three-year shelf life. Some units that Pfizer had available for pilot introduction were manufactured as early as 2012. Because the pilot introductions did not begin until 2014, after the product was registered, the shelf life of each available product batch had to be matched with the projected schedule of training rollout and uptake, and influenced the final quantification. Countries are now supplied with newly manufactured product and stock closer to full shelf-life; however, this unique consideration for the pilot had to be accounted for to try to prevent stock expiring in country, which would require additional orders.

- **Country policies.** Each country had a different policy indicating the minimum remaining shelf life for products procured for public-sector family planning programs. These policies were factored into the quantification process. For example, Senegal requires medicines to have at least 66 to 80 percent of product shelf life remaining upon delivery in country. PATH worked with country partners to document these policies as inputs to the quantification process.



INTRODUCTION TIP

Determine the minimum remaining shelf life of a product required by the country government and the procurement agency, such as the United Nations Population Fund or United States Agency for International Development.

QUANTIFICATION PROCESS: HOW MUCH PRODUCT IS NEEDED FOR PILOT INTRODUCTION?

Sayana Press was a new product in the four pilot introduction countries and had no historic consumption information available to inform initial estimates for quantification. However, data on historic and current use of other injectable contraceptives—notably, DMPA-IM (generic name for the intramuscular form of depot medroxyprogesterone acetate)—are highly relevant for estimating potential Sayana Press consumption. PATH and partners started the process by consulting available technical resources and reviewing injectable contraceptive use data for each country. These resources helped to frame PATH's thinking about the variables to be considered in estimating consumption and quantification for Sayana Press.

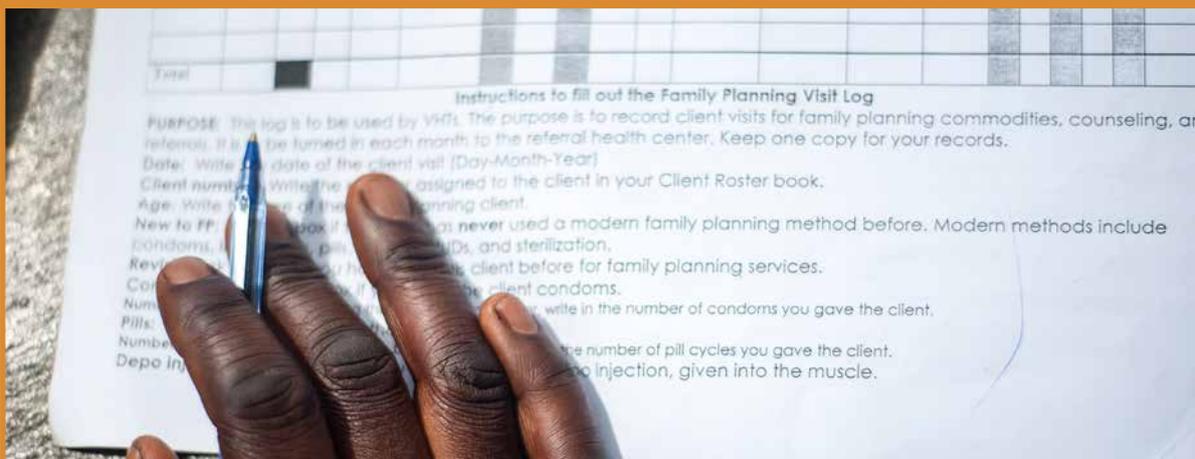


INTRODUCTION TIP

Review data on injectable contraception use to help inform Sayana Press quantification.

CASE STUDY

PATH/Will Boase



Consumption estimated for quantification versus actual consumption in Uganda

PATH modeled Sayana Press consumption in Uganda to prepare the quantification estimate. The model reflected the pilot introduction strategy of introducing Sayana Press in 28 districts through Village Health Teams (VHTs) consisting of volunteer community-based health workers. PATH's model incorporated training details from the institutions designated at that time to train participating VHTs: Pathfinder International, FHI 360, and PATH.

Additional assumptions incorporated estimates of:

- Numbers of new and continuing clients.
- Rates of retention of VHTs in the pilot program by quarter.
- Switching from DMPA-IM (for VHTs already trained to deliver DMPA-IM).
- The maximum number of new clients for any VHT.

The model then projected how Sayana Press uptake would increase over time based on the number of VHTs trained per quarter. It assumed that 2,300 VHTs would be trained and that all training would be completed in 2014. The initial estimate based on forecasting was that 298,860 units of Sayana Press would be needed through the fourth quarter of 2015, and an order was placed for 331,000 doses. The actual consumption of Sayana Press in Uganda as of the fourth quarter of 2015 was 68,909. Thus, actual consumption was well below the estimate. There are a few reasons for this disparity:

- Timing of trainings. Provider training started later and took longer than the quantification model assumed; as a result, uptake increased later and more slowly than expected.
- VHT capacity. The modeled assumptions about client ramp-up and retention proved to be inaccurate. The models assumed that each VHT would have 22 to 27 Sayana Press clients per quarter. Results from PATH's monitoring data show that an average of 18 doses were administered per quarter per VHT in Uganda, as of mid-2016. Thus, each VHT has had fewer Sayana Press clients on average than originally estimated.

Despite the significant disparity between the forecast estimate and actual consumption numbers in Uganda, the country has not been overstocked with the product. Consumption rose steadily over the course of the two-year pilot. As of mid-2016, most of the original 331,000 units ordered for Uganda had been consumed or distributed to service delivery points in the field, and based on the subsequent quantification exercise, a new order of 548,000 units arrived in June 2016.

PATH supported the quantification exercises differently in each country depending on the context. In Burkina Faso and Niger, the UNFPA country programs were already working closely with the MOH to support overall contraceptive commodity estimation, including quantification for Sayana Press pilot introduction. In these two cases, the country partners developed their initial quantification of Sayana Press based on the introduction plans and submitted them to UNFPA headquarters. PATH supported the Burkina Faso and Niger processes by tracking and aggregating the four-country quantifications and coordinating multicountry communication with UNFPA headquarters, specifically the procurement unit in Copenhagen.

For Senegal and Uganda, PATH developed models in Excel for estimating Sayana Press consumption as a key input to country quantification. These consumption models were built from “the bottom up,” incorporating information about:

- Numbers of health workers to be trained, training locations, geographic coverage, and expected timeline for trainings.
- Estimates of Sayana Press units that each trained health worker would be expected to administer to women each quarter (see box on page 55).

- Assumptions about the number of reinjecting clients, new clients, and dropouts.
- Estimates of the number of women using Sayana Press each quarter (i.e., estimated number of Sayana Press units to be consumed) based in part on data from prior acceptability studies.

Such information was more readily available in Uganda, where community-based distribution (CBD) of injectables was already under way, but was scarce in Senegal, which had limited experience with CBD of injectables. The resulting output was a modeled estimate of product consumption over time that could be modified as assumptions and timelines shifted. These consumption estimates formed the basis of the Senegal and Uganda quantifications.

Consumption patterns form the basis for quantification exercises, which in turn form the basis for procurement orders. The first order for Sayana Press units placed by each pilot country varied by country setting, specifically, 100,000 doses in Niger; 250,000 doses in Burkina Faso; 331,000 doses in Uganda; and 448,600 in Senegal. Subsequent orders were made semiannually based on emerging consumption data and remaining stock available in each country.

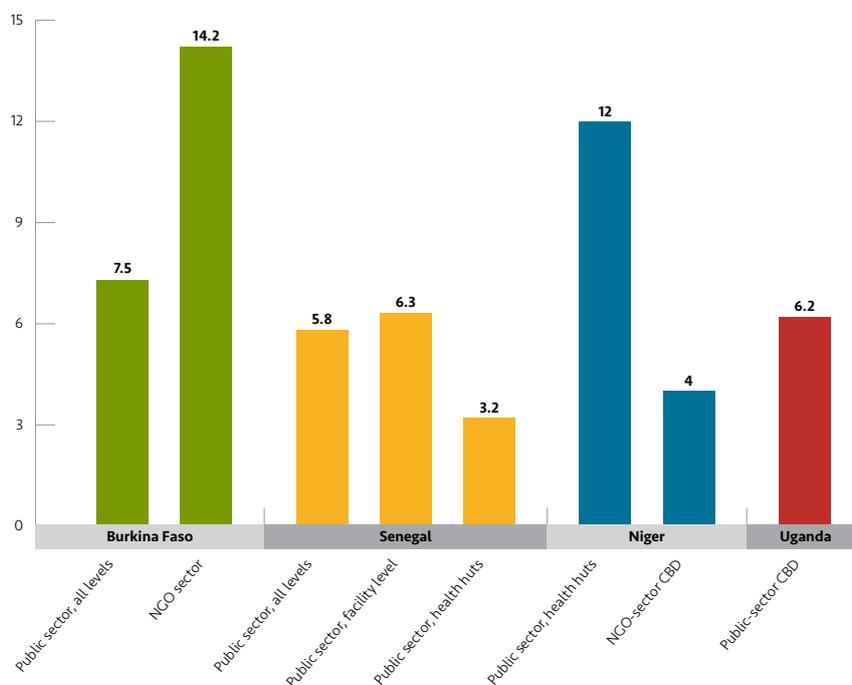


PATH/Siri Wood

How many units did health workers administer per month during the pilot introductions?

PATH developed estimates of the average number of Sayana Press doses administered per trained health provider, by month, across different delivery channels in the four countries. After provider training was completed, the number of doses administered per trained provider generally increased gradually over time as introduction progressed, or fluctuated due to stockouts. The graph below features the month with the highest number of doses administered per trained provider from each country and delivery channel, representing the maximum monthly number of doses administered per trained provider during pilot introduction. The graph reflects the potential number of doses administered per trained provider, per month, in the absence of contextual challenges, such as stockouts. The month with the maximum number of doses administered per trained provider varied across settings, falling between March 2015 and May 2016. These data may help to inform new quantifications in countries planning Sayana Press introduction strategies similar to those of Burkina Faso, Niger, Senegal, or Uganda.

Maximum monthly number of Sayana Press doses administered per trained health provider during pilot introduction—Burkina Faso, Senegal, Niger, & Uganda (2015–2016)



Due to wide variation in country settings and introduction strategies, it is not feasible to directly compare the number of doses administered per trained provider across countries without carefully considering context. The high number of doses attributed to Marie Stopes International and Association Burkinabè pour le Bien-Être Familial providers in Burkina Faso's nongovernmental organization (NGO) sector, for example, is likely due to their intensive focus on outreach. In another instance, because Niger is the only country that did not introduce Sayana Press alongside DMPA-IM, it makes sense that providers at public-sector health huts administered a higher number of doses compared to providers at public sector health huts in Senegal, where DMPA-IM was also readily available. These and other factors—such as the proportion of injectables in the method mix or location of service delivery points (e.g., community versus facility level)—make it more useful to consider the potential number of doses administered per trained provider in a month for individual introduction strategies given the local context (see Section 4: Planning the country introduction strategy).

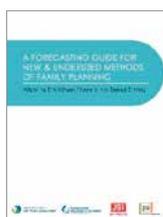
Note: CBD, community-based distribution; NGO, nongovernmental organization.

RECOMMENDATIONS: QUANTIFICATION AND PROCUREMENT

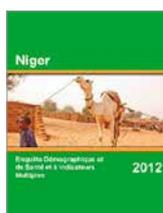
PATH/Siti Wood



- **Use the introduction plan to guide quantification.** Information from the introduction plan should inform the quantification exercise for initial Sayana Press procurement requirements. Key information includes the number, types, and locations of providers to be trained to administer the product and the timing of the trainings.
- **Consider data on doses administered per provider from similar delivery strategies.** PATH data from the pilot countries show a wide range of doses administered per provider, from 3 units per month administered by community providers in Senegal to 14 units per month administered by facility-based providers in the NGO sector in Burkina Faso. Consider the ways these contexts vary to determine their relevance for quantification assumptions in new settings.
- **Use multiple sources to achieve accurate quantification.** In addition to service delivery and training inputs, the initial product quantification process requires considering multiple other variables, including the manufacturer's planning horizons, product shelf life and expiry dates, country policies, and the timing for receipt of final formal registration. All of these factors affect the quantification and procurement process as well as the date when the product first becomes available to clients.



A Forecasting Guide for New and Underused Methods of Family Planning. Available at www.k4health.org/toolkits/NUMs-forecasting-guide. This resource offers a framework and guidance to program managers involved in forecasting for new contraceptive technologies or underused methods that are moving to scale. The guide identifies common pitfalls in forecasting and recommends strategies to avoid them.



Demographic and Health Surveys (DHS) Program. Available at www.dhsprogram.com/. The DHS Program disseminates data collected from large, household surveys conducted regularly in more than 80 countries. Data are available in country reports, as well as in mobile applications, a spatial data repository, and STATcompiler, a program that allows users to make custom tables based on thousands of demographic and health indicators.



Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement. Available at www.jsi.com This guide was developed to assist technical advisors, program managers, warehouse managers, procurement officers, and service providers in estimating the total commodity needs and costs for successful implementation of national health program strategies and goals. The guide also helps these individuals to identify funding needs and gaps for procuring the required commodities, and plan procurements and shipment delivery schedules to ensure a sustained and effective supply of health commodities.



The Reproductive Health Supplies Coalition publications web page. Available at www.rhsupplies.org/activities-resources/publications/. The website is a repository for many resources including the Reducing Stockouts Impact Calculator, Strategic Pathway to Reproductive Health Commodity Security, Optimizing Supply Chains for Improved Performance, Contraceptive Stockouts: A Review of the Published and Grey Literature, and Building a Strong Supply Chain Workforce: The Role of Pre-Service Training.



7 Training and supervising providers

The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **training and supervision**.

TRAINING AND SUPERVISION ENSURE QUALITY IN SERVICE DELIVERY

Training of health providers and follow-up supervision and support are at the heart of any product introduction process. These activities contributed to successful introductions in the Sayana Press pilot countries. The quality of training and supervision strongly influence whether and how a product or innovation reaches users. Effective training and supervision require sufficient planning, committed personnel, and financial resources, all of which are integral to a program's success. Efforts to train providers who will teach women to self-inject are just beginning in a few countries, but many of the same high-level issues will apply.

During the pilot introductions, PATH and partners trained more than 7,500 individuals in the administration of Sayana Press and DMPA-IM (generic name for the intramuscular form of depot medroxyprogesterone acetate). The cadre of providers trained and the approach to training were unique to each country setting, but in all cases they reinforced the philosophy of informed choice and a client's right to select the family planning method that best meets her needs.

Based on the diverse approaches taken to implementing provider training across the pilot settings, PATH and partners reaped significant learning about various aspects of training and supervision—including how to

Factors to consider when planning to train providers

During the pilot introduction planning process, PATH worked closely with the Ministry of Health (MOH) in each country to conduct a needs assessment and strategize the best approach for provider training. The assessment identified the following:

- Which entities would fund training.
- Which entity would lead training (provide trainers)—whether the MOH or nongovernmental organizations (NGOs).
- The number and type(s) of providers to be trained and at what level, and how much family planning training these providers had already received.
- Training approaches and timelines.
- Procurement of adequate product and supplies for training/injection practice.
- The topics that provider training would cover.
- The process for and timing of adapting Sayana Press training materials to the local context and integrating them into existing family planning training curricula.

effectively begin offering a new method in the context of informed choice.

ASSESSING TRAINING NEEDS

In most settings, PATH and partners conducted training needs assessments to inform training strategies and plans. PATH worked with MOHs and NGO partners to determine which providers needed training on what topics, their level of education, their background, and the family planning training they had previously received. Skilled family planning providers only needed training in Sayana Press and an injectable contraception refresher. Lower cadres of workers, such as Uganda's community health workers (Village Health Team [VHT] members), needed comprehensive training on informed choice counseling and all available family planning methods.

The training needs assessments were thorough and informative, but flexibility in implementation was helpful as new needs were identified during or after trainings. For example, as the pilot introduction began in Uganda, community-based distribution (CBD) of injectables was an approved national policy. PATH expected that many VHTs would already have strong family planning experience and know how to administer DMPA-IM. As VHT trainings

started, however, PATH found that many new VHTs had no experience providing any contraception at all. This necessitated taking more time during the training to ensure that all VHTs were fully equipped to provide high-quality services and a range of methods, including oral contraceptives and male and female condoms, as well as both intramuscular and subcutaneous injections. In Senegal, after training was thought to be complete, the introduction team discovered that there was a cadre of family planning counselors at many facilities who were clients' first points of contact but who did not know about Sayana Press. PATH, the MOH, and regional teams organized a second round of trainings to ensure that these counselors would include Sayana Press in the method mix during initial family planning counseling sessions with clients.



INTRODUCTION TIP

Train more than one provider per site whenever possible so clients will have continuity of service if a provider is absent or transfers to another facility.

TRAINING DRIVES INTRODUCTION RESULTS

Introduction or scale-up strategies, including the delivery channels and types of providers being trained, will drive training strategies, which will, in turn, drive results. For example, the MOHs in Burkina Faso and Senegal implemented an efficient training approach that worked well for introducing Sayana Press at all levels of the health system and in relatively large geographies. The governments organized centralized trainings for national master trainers, then regional trainings-of-trainers, followed by a simultaneous cascade approach to train district providers in each pilot introduction region. In Burkina Faso and Senegal, all trainings of providers with prior injection

and a practicum. NGOs trained their own providers. This approach enabled the training of a large number of health workers in the shortest time possible, and product use began to increase in these two countries relatively quickly after trainings began (see Senegal graph).



INTRODUCTION TIP

Work with existing regional or district MOH trainers to increase cost-effectiveness and sustainability of training.



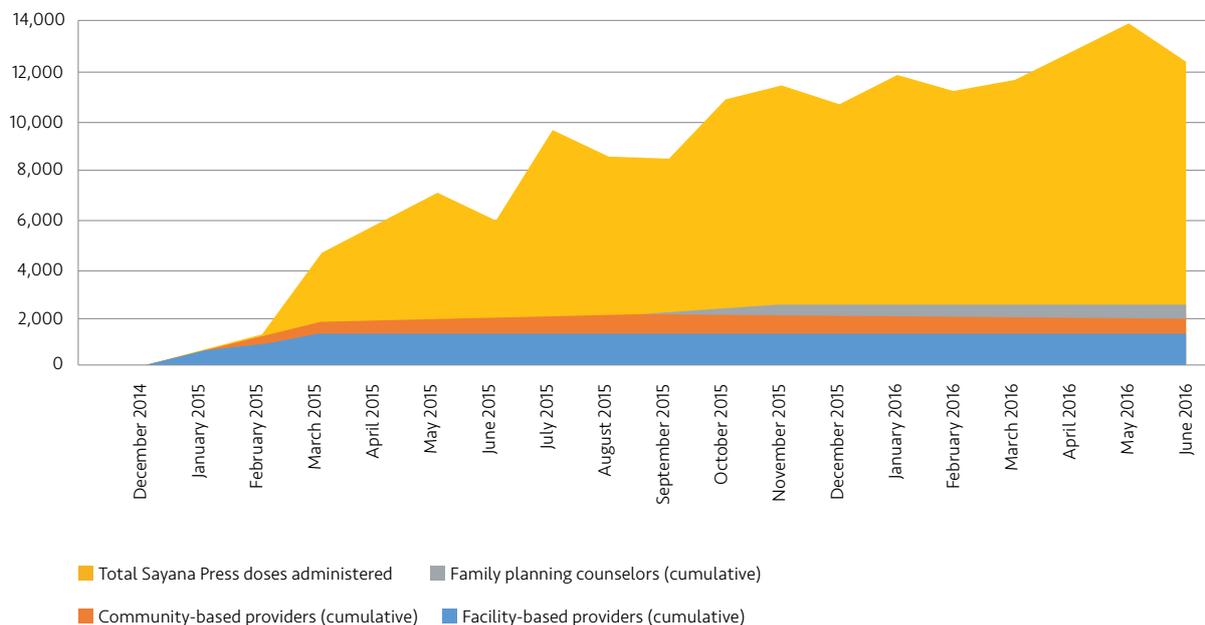
INTRODUCTION TIP

A cascade training approach necessitates strong master trainers with a thorough understanding of Sayana Press.

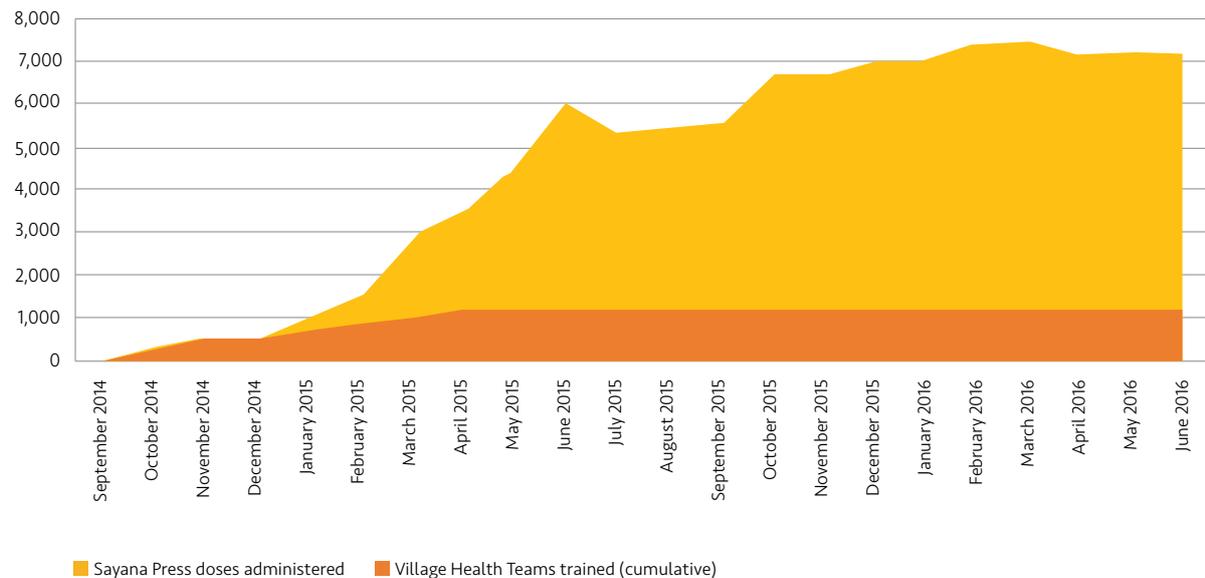
By contrast, training in Uganda was led by NGOs and involved a district-by-district approach spanning nearly 30 districts. Uganda's introduction was exclusively through community health workers, and their training was longer (seven days) and conducted in less-centralized locations (see text box on training community health workers [CHWs]). Uganda trained the largest number of individuals to administer Sayana Press—2,100 VHTs—over about an eight-month period. Consumption increased gradually as trainings rolled out over a longer period of time (see Uganda graph).

experience covered the administration of DMPA-IM and Sayana Press, lasted for two days, and included theory, practice on injection models,

Cumulative number of providers trained, by type, and total number of Sayana Press doses administered, by month—Senegal



Cumulative number of providers trained and total number of Sayana Press administered, by month—Uganda



Tips for training community health workers

Introducing Sayana Press presents many countries with the opportunity to strengthen and expand CBD of contraception. When training at the community level, country teams learned that the need for more comprehensive, more extensive training for CHWs may require more resources or a more gradual approach to training. In addition, because CHWs are often dispersed in remote locations, considerable travel time for both trainers and CHWs is required. Different approaches included:

- **Taking the time needed for comprehension and mastery.** The MOHs in both Niger and Senegal called for a four-day Sayana Press training for community health agents, including two days of theory and two days of practicum. In Uganda, VHTs received a seven-day comprehensive family planning training with four days of theory and three days of practicum.
- **Spreading out trainings to minimize confusion and time away from service delivery.** Senegal conducted trainings on DMPA-IM and Sayana Press in two discrete sessions separated by two months to avoid confusion concerning the two types of injection techniques.
- **Maximizing convenience for CHWs.** PATH also found in Uganda and other settings that on-site/residential training helped trainees concentrate and perform better than when they commuted daily from their homes to a training site. Additional costs to cover accommodation and per diems for trainees were offset by efficiency and time savings (e.g., ability to begin the day earlier and avoid lateness/absences).

CHWs, such as VHTs in Uganda and facility-based outreach workers in Burkina Faso, who are experienced in conducting immunization campaigns and administering vaccines adapted to administering Sayana Press very quickly. This cadre can move to different areas in the community and can be supported at minimal cost, such as by allocating transport fees.

CURRICULUM AND CONTENT DECISIONS

Countries introducing Sayana Press can choose to train providers on just the one method, or on contraception more broadly. For example, new product introduction can provide programs with the opportunity to revisit and update their overall family planning training curriculum as well as offer refresher trainings for existing cadres of health workers. This depends on the time and resources available, as well as the country context. There may be trade-offs to consider: a more comprehensive training requires more time and funds but reinforces informed choice by strengthening provider counseling for all contraceptive methods.

When the MOH introduced Sayana Press in Uganda, the PATH-developed training materials (see text box) were adapted and integrated into the existing ten-day MOH family planning training for VHTs. The ten-day training curriculum was then revised, condensed to seven days, and enhanced with a module on youth-friendly services. Burkina Faso, Niger, and Senegal adapted the PATH Sayana Press training materials to the country context and simply trained existing cadres of

health workers on the new method only. In Senegal and Burkina Faso, partners integrated Sayana Press training into the national family planning training curriculum only after the pilot phase was completed and the MOH decided to scale up Sayana Press nationally.

Regardless of whether the training was narrow or broad, PATH and partners emphasized that Sayana Press is intended to expand the range of methods available to women and should be offered as one new option in the context of informed choice. Sayana Press is not intended to replace or supersede other family planning methods. In most pilot settings, Sayana Press was offered side by side with DMPA-IM. In the case of Niger, Sayana Press was the only form of injectable contraceptive available at health posts, but providers were trained to administer DMPA-IM as a back-up method in case of Sayana Press stockouts.

Some health workers may be inclined to promote or have a bias toward Sayana Press over other options for various reasons, such as their excitement about a new product or a misunderstanding that they should specifically promote Sayana Press. In addition, lower-skilled health workers, such as CHWs, may be more

Sayana Press training curriculum available online

PATH's Sayana Press training materials (sites.path.org/rh/?p=436#training) were first used in 2012 to train facility- and community-based health service providers on the use of Sayana Press (formerly known as depo-subQ in Uniject) in acceptability studies led by PATH and FHI 360 in Senegal and Uganda. Those studies revealed that the curriculum enabled providers to deliver Sayana Press safely and effectively, even community-based health workers who had never given injections. The materials were then updated with information from the studies and modified for training outside a research context.

Available in both French and English, the materials address essential content for instructing providers on Sayana Press delivery, including a comprehensive overview of the product and its administration, as well as client screening and counseling skills. Training methodologies include presentations, role-playing, discussions, and hands-on practice. The Sayana Press training is intended to take one to two days, though this may vary depending on context and the training participants' background and experience.

PATH's training materials are designed for adaptation to the local context and integration into a country program's broader training curriculum for family planning providers. To date, the materials have been adapted and used in at least eight countries. The materials were used to train more than 7,500 family planning providers in Sayana Press administration—including nearly 600 providers who serve as trainers, master trainers, or supervisors—across the four initial pilot countries.

“Outreach workers [*agents itinérant de santé* or AIS] don’t traditionally provide family planning services, and for most of them it was their first time to be trained on contraceptives. Since we don’t want to promote Sayana Press specifically, it is important to train the AIS to speak about all methods during counseling and education sessions.”

– Alain Kaboré, United Nations Population Fund Sayana Press Coordinator in Burkina Faso

comfortable administering a subcutaneous injection rather than intramuscular injection because of ease of administration. For these reasons, it is important during initial training to emphasize the full range of methods available and teach counseling techniques that support clients’ informed choice.



INTRODUCTION TIP

Trainers can familiarize themselves with the pre- and posttraining evaluation to ensure they repeatedly reinforce key issues during Sayana Press training.

EVALUATING PROVIDER COMPETENCY AFTER TRAINING

Sayana Press training in the four pilot countries included theory, hands-on practice administering injections on a prosthetic model, and a supervised field practicum in which training participants gain real-world experience working with family planning clients. PATH and partners evaluated both theoretical knowledge and contraceptive delivery skills to determine provider competency. Sayana Press theoretical knowledge generally included how to initiate the contraceptive method, contraindications, side effects, reinjection timing, and injection safety; it was evaluated through a pre- and posttraining evaluation (available in PATH’s Sayana Press online training materials at sites.path.org/rh/?p=436#eval).

Injection technique generally takes practice and supervision to master, both during training and the practicum. During injection practice on prosthetic models, participants’ injection technique was evaluated using an observation checklist to determine competency (see example, next page). Participants were encouraged to practice as many times as necessary to master the technique and gain confidence in their skill. After successful completion of theoretical training and injection practice, participants took a field practicum. Practicum requirements varied by country context, depending on the type of providers being trained, the contraceptive methods covered, and specific training objectives (see text box).

Posttraining evaluation: How good is good enough?

Generally, only trainees who passed the Sayana Press theoretical exam would go on to practice administering the method and then take the practicum. The initial recommended passing score on the posttraining evaluation was 80 percent or higher. In practice, however, not all trainees attained 80 percent or better on the posttraining evaluation. As a result, countries adapted their own minimum passing requirements according to the provider cadre and local context. In Uganda, for example, some trainees who demonstrated promise as VHT members did not achieve a minimum score of 80 percent. PATH instead evaluated the extent to which VHT members improved their score from baseline. Any VHT members struggling with content were given the opportunity to move to practice but were supervised more closely during the practicum.

Sayana Press



Checklist for Sayana[®] Press Injection Practice

Trainers and trainees can use this checklist during injection practice on nonhuman models. Trainers can also use it when evaluating whether a trainee can give a Sayana[®] Press injection according to the performance standards. At the end of the training lesson, each trainee must demonstrate to the trainer that they can competently administer a Sayana Press injection.

Steps	Observations		
	1	2	3
1. Places safety box and cotton swabs (optional) within arm's reach.			
2. Washes hands (during the training, this step may be stated aloud or mimicked rather than actual handwashing).			
3. Selects the injection site (and cleans if needed).			
4. Opens the Uniject [™] injection system pouch by tearing the notch.			
5. Checks the expiration date and makes sure the DMPA is at room temperature.			
6. Holds the Uniject by the port while mixing.			
7. Mixes the DMPA by shaking it vigorously for 30 seconds.			
8. Checks to make sure the DMPA is mixed and there is no damage to the Uniject.			
9. Holds the Uniject with the needle pointing upward during activation.			
10. Holds the Uniject by the port while activating.			
11. Pushes the needle shield and port together to fully activate the Uniject for use.			
12. Pinches the "skin" of the model to form a tent.			
13. Holds the port of the Uniject while inserting the needle.			
14. Inserts the needle into the tent of "skin" between the thumb and forefinger.			
15. Inserts the needle at a downward angle.			
16. Inserts the needle completely so that the port is in full contact with the injection model.			
17. Moves fingers from the port to the reservoir while still pinching the skin.			
18. Squeezes the reservoir slowly to inject the contraceptive—taking about 5–7 seconds.			
19. Removes the Uniject from the injection model.			
20. Releases the fingers used to pinch the skin and create the tent.			
21. Places the used Uniject immediately into a safety box without replacing the needle shield.			

Key

√ = Satisfactory	U = Unsatisfactory (attempted but not to standard)	NA = Not applicable (e.g., handwashing, cleaning site)
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Sayana Press is a registered trademark of Pfizer, Inc. Uniject is a trademark of BD.

Injection technique: Practice makes for excellence



During the practicum phase, training participants generally administer injectable contraception under the supervision of a qualified provider to clients who have selected that method through informed choice counseling. Participants' injection technique is again evaluated using the same observational checklist, with supervisors helping them to master their technique. During the pilots, the number of supervised practicum injections required before providers were certified to inject independently varied by country. In Uganda, a minimum of five successful injections of both Sayana Press and DMPA-IM were required during practicums. In other countries, and in trainings for qualified providers with previous injection experience, a smaller number of successful client injections was required.

In the case of Uganda's VHTs, participants had to master their technique on an injection model before moving on to the practicum. To complete their practicum, VHTs were stationed at health facilities, where under the supervision of a trained provider (usually a nurse or midwife), they were then required to lead a community health talk, provide general family planning counseling to clients, and correctly administer five injections each of Sayana Press and DMPA-IM, following the observational checklist, before they were certified to offer family planning in their community.

When training was first initiated in Burkina Faso, the number of participants in each district training session was too high (averaged 30). As a result, many of them were unable to practice a sufficient number of injections during the practicum phase because it was difficult to mobilize enough clients to enable trainees to gain practical experience administering Sayana Press. Other countries encountered similar challenges in matching trainees' needs to master injection technique with client volume.



INTRODUCTION TIP

Plan practicum sessions during times of high client volume at facilities to ensure that trainees can gain sufficient injection experience in the allotted time frame.

Plan ahead to ensure sufficient Sayana Press units are available for training and practice injections

Ensuring that sufficient Sayana Press units are available for practice injections is crucial for successful training. During product procurement planning, staff should anticipate the quantity of units needed for training as well as for administering injections to clients. Although several trainings during the pilot introductions used water-filled Uniject injection systems, PATH now recommends using actual Sayana Press units for this purpose. Procuring water-filled devices (e.g., from Becton Dickinson [BD], the Uniject manufacturer) may be expensive and require an additional quantification, procurement, and distribution exercise that can complicate planning. In addition, the saline solution does not have the same appearance and viscosity (thickness) as DMPA, so it must be manipulated carefully to avoid product leakage. Providers will be better prepared to administer injections if they have practiced using the actual product during training. Because some trainers or providers may be hesitant to “waste” actual product while practicing, all should be encouraged to use the product only as many times as needed to achieve competence.



INTRODUCTION TIP

Given the expense and complication of obtaining placebo units, use actual Sayana Press units for provider and self-injection trainings.

TRAINING PROVIDERS TO COLLECT DATA

Because this was a pilot project, PATH trained all providers to complete monitoring data collection forms that were collected and entered into a centralized database to track results (see Section 10: Monitoring and evaluation). The quality of program monitoring data depended on the quality of provider training on data collection as well as posttraining supervision. In all settings, it proved most effective to train health workers in collection and management of monitoring data at the same time as training on counseling and administration of Sayana Press. Data collection was a discrete training module.

To ensure good data quality, it was necessary to devote adequate time to this topic to allow for theory, as well as time for providers to practice using the monitoring tools through role-playing. When training participants are swept up in the excitement of learning to administer a new product, monitoring can fall to the wayside. Furthermore, training curricula are often designed with monitoring modules toward the end, so any delays in the

training schedule can potentially impinge on the time allocated to cover monitoring. Investments by PATH and partners in training providers to become familiar with filling in monitoring forms—especially CHWs who did not have extensive experience with these forms—increased the project’s ability to obtain high-quality data in a timely manner.



INTRODUCTION TIP

Devote sufficient time during initial provider training to cover the collection and management of monitoring data to ensure these topics are not overlooked.

SELF-INJECTION: TRAINING PROVIDERS TO BE TRAINERS

Sayana Press injections are mainly available from trained providers at present, but self-injection is under regulatory, policy, and programmatic consideration in an increasing number of countries. PATH’s self-injection research to date indicates that thorough training of providers and clients will enable

women to self-inject correctly and remember their reinjection dates using reminder tools.

To train health providers to counsel and train their clients in Sayana Press self-injection, PATH developed a training module for providers. This lesson takes approximately two hours to facilitate and includes a presentation, participant role-playing, and hands-on practice using a highly visual client instruction booklet (see image). The client self-injection booklet is designed to be used by women as a visual and written memory aid when injecting at home. It is available in English, French, and several national languages spoken in Senegal and Uganda. The booklet is available online at sites.path.org/rh/recent-reproductive-health-projects/sayanapress/home-and-self-injection-with-sayana-press/. It is part of PATH's Sayana Press training curriculum, designed for adaptation and integration into family planning provider training programs.

In PATH's self-injection operational feasibility studies in Uganda and Senegal, about 98 percent of women felt that the one-on-one training with practice on a model adequately prepared them to self-inject independently. During the feasibility studies, study nurses trained women using the instruction booklet, evaluated clients' competence using the checklist during practice injections, and then supervised self-injection. On average, women practiced about three times before self-injecting for the first time. In Uganda, for example, the nurses later followed up with

clients to determine whether they could demonstrate correct self-injection technique three months later, and whether they self-injected independently within one week of their scheduled reinjection date. In Uganda, 96 percent of women used the booklet to assist with their independent self-injections and 88 percent demonstrated competent injection technique three months posttraining. A total of 95 percent injected on time, remembering their reinjection date using calendar and reminder tools given to them by the provider.



INTRODUCTION TIP

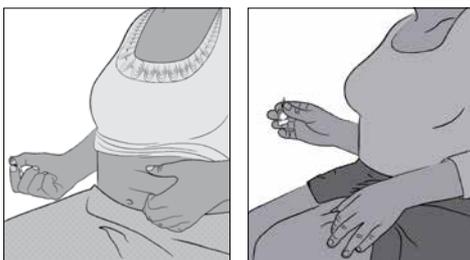
Family planning clients required three practice injections on average before achieving mastery in PATH's self-injection feasibility studies.

PATH's current self-injection training module is modeled on this approach. It instructs providers to meet individually with each client to orient her on how to administer an injection and calculate her reinjection date, using the booklet and a calendar. More research and evaluation activities are under way to assess whether it will be feasible to streamline approaches to self-injection and still achieve the key outcomes of injection competence, acceptability, and accessibility for most women.

Excerpt from illustrated client self-injection booklet

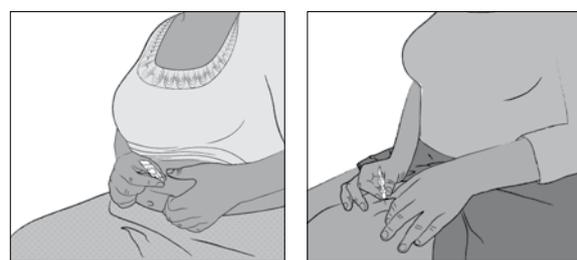
STEP 7: Gently pinch the skin at the injection site.

- This creates a "tent" for inserting the needle.



STEP 8: Insert the needle at a downward angle

- Continue to hold the device **by the port** and insert the needle straight into the skin at a downward angle.
- The port should touch the skin completely to ensure the needle is inserted at the correct depth.



Correct Sayana Press injection technique entails a few crucial steps

PATH's experience with training across multiple country settings shows that providers and clients with varying levels of education and literacy can be trained to successfully administer Sayana Press. Although the length of training varies based on the trainees' experience and proficiency, there are five critical injection steps that must be executed for successful administration:

1. Select an appropriate injection site and clean if needed.
2. Mix the liquid by shaking the device vigorously (about 30 seconds).
3. Push the needle cap and port together to activate the device.
4. Pinch the "skin" at the injection site to form a tent.
5. Squeeze the reservoir slowly to inject—taking about 5 to 7 seconds.

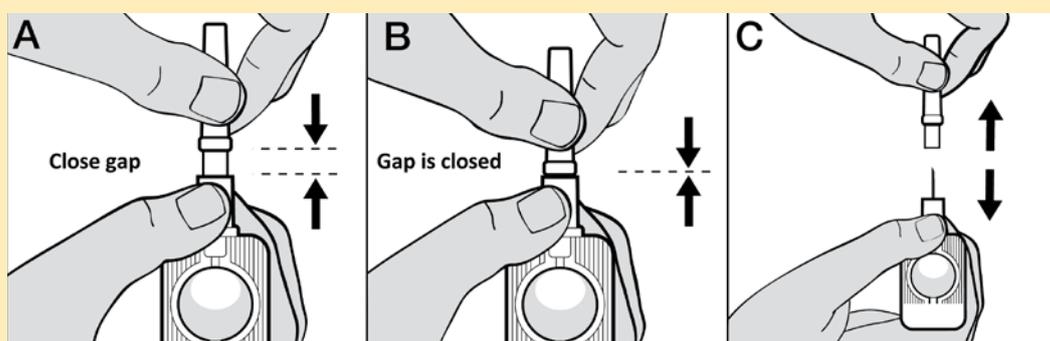
Steps that have been shown in research to be most prone to error are mixing the solution, activating the device, and pressing the reservoir slowly. All of these steps should be emphasized and practiced during training sessions for all providers and users. For more information, visit sites.path.org/rh/?p=436#training.



INTRODUCTION TIP

Verify that all Sayana Press providers or self-injectors learn the five critical steps, and ensure that trainers emphasize the importance of activation. Even highly qualified physicians overlook this step if they are not trained well.

Activate the Uniject



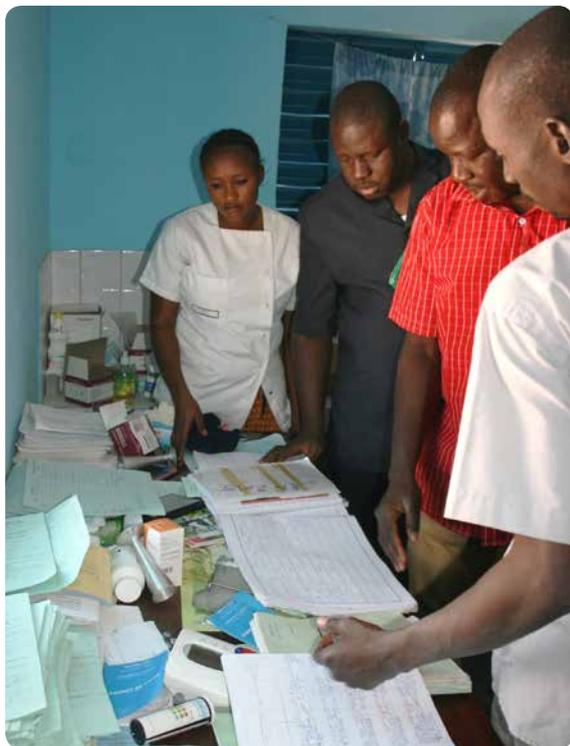
THE VALUE OF SUPERVISION AFTER TRAINING

During the pilot introductions, not surprisingly, posttraining supervision was as important as initial provider training to ensure high-quality service delivery. In particular, supportive supervision approaches that emphasize teamwork, two-way communication, and skill-building ensured informed choice in counseling and good injection technique, corrected misunderstandings, and supported providers in capturing service delivery data and managing stock. Regular and hands-on

supervision was particularly important to provide support in settings like Uganda where many CHWs were offering injectables (and contraception) for the first time. Key learnings from the pilots on supervision included:

- Look for efficient approaches to provider supervision, which can be costly: In Uganda and Senegal, PATH staff linked supervision visits with the collection of monitoring data. This strategy conserved resources by allowing staff to both pick up data regularly and follow up with providers.

In Burkina Faso and Niger, MOH staff integrated Sayana Press into the existing



system of periodic supervision from the region to district and from the districts to facilities. Sayana Press coordinators in both countries periodically joined supervision visits to help reinforce lessons learned from the project.

The need for frequent supervision decreases over time. Regular supervision was especially important in the early phase of the pilot effort while dedicated resources were available to solidify provider knowledge and skills. PATH found that it was ideal to start with more intensive joint supervision schedules and then scale back, gradually transitioning to a sustainable system led by the MOH.

- Check whether providers are offering women informed choice among a wide range of products. During supervision visits, PATH found that many providers tend to prefer Sayana Press because of its ease of use, so it was important during post-training supervision visits to emphasize that they should promote the full range of methods. Provider bias can affect the

method mix being offered to clients. This can sometimes be detected by reviewing monitoring data and examining trends of product uptake, or simply by speaking with providers during supervision visits and reviewing their patient registers. Early on during introduction in Burkina Faso, for example, supervisors found by reviewing data and talking with providers that some incorrectly believed that Sayana Press was being introduced to replace DMPA-IM. Other providers were not including Sayana Press in their counseling because they thought it would only be available for a short time during the “pilot” approach to the introduction.

- Include supervisors themselves in initial training. To provide on-the-job training to health workers, supervisors themselves must be well informed and well trained. Most countries elected to invite supervisors to one day of the provider training so that they were informed and could assist in filling out monitoring forms, respond to technical questions such as the reinjection window, and review the status of product stock during site visits. Active involvement of the family planning focal persons (e.g., Uganda) or the reproductive health regional coordinators (e.g., Senegal) during training enabled them to provide continuous supportive supervision for CHWs. In Uganda, for example, PATH staff met with both supervisors (focal persons) and CHWs during visits to reinforce the relationship between the supervisors and supervisees and to facilitate collaborative problem-solving.



INTRODUCTION TIP

Encourage and support strong linkages between CHWs and health facilities to foster effective communication and collaboration and a team approach to task-sharing between providers at fixed facilities and in communities.

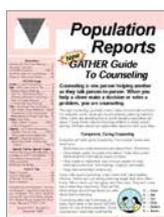
Beyond a project's life cycle, the long-term capacity of a government to provide ongoing supervision is often unknown. This is particularly true in a setting such as Uganda where the government is considering changing the community health program

to include a smaller number of paid health extension workers instead of volunteer CHWs. It is unclear how such evolutions will affect the trajectory of product introduction and mainstreaming.

RECOMMENDATIONS: TRAINING AND SUPERVISING PROVIDERS

- **Start by assessing who needs training on what topics throughout the family planning delivery system.** Do not overlook key players such as supervisors or outreach workers who might be women's first point of contact with the system, even if they cannot administer injections.
- **For quick product uptake and rollout, implement a simultaneous training cascade.** This approach requires strong master trainers who are highly familiar with the product. Using a country's existing government trainers will increase sustainability.
- **Design training for community health workers to meet their needs.** CHWs in most settings are fully capable of administering Sayana Press in the context of informed choice. Ensure the curriculum covers all family planning content that is unfamiliar to them and meets them where they are, in terms of literacy, knowledge, and geography (to the extent possible).
- **Informed choice is always a priority in training and supervision, no matter what.** Emphasizing that Sayana Press is one option among many is especially important to counteract providers' (often well-intentioned) excitement about a new product. Sayana Press will not be the right option for all, or even many, women. Address informed choice especially if your training only covers Sayana Press or injectable administration.
- **Design your curriculum to suit your context.** Adapt PATH's field-tested curriculum as needed, considering whether it should cover Sayana Press or family planning comprehensively; also, consider the data you are expecting providers to collect.
- **Invest in high-quality supervision.** Supervision can help ensure that competencies transferred during group trainings are thoroughly mastered by each individual and that s/he can transfer them to the workplace. Plan for clear expectations about who will conduct supervision, how often, and using what approaches. Consider combining supervision with other activities or integrating it into existing systems.

RESOURCES



GATHER Guide to Counseling. Available at www.k4health.org/sites/default/files/j48.pdf. The GATHER model of family planning counseling has been successfully used for nearly two decades, and is based on the elements described in this seminal publication that includes tips, illustrations, techniques, technical information, and charts.



Training for Mid-Level Managers (MLM). Module 4: Supportive Supervision. Available at www.who.int/immunization/documents/MLM_module4.pdf. This resource is part of a World Health Organization series of modules on immunization training. Supportive supervision involves supervisors and health workers working together to solve problems and improve performance. The module outlines key steps and practical implementation strategies.



The Balanced Counseling Strategy Plus: A Toolkit for Family Planning Service Providers Working in High HIV/STI Prevalence Settings. Available at www.popcouncil.org/research/the-balanced-counseling-strategy-plus-a-toolkit-for-family-planning-service. This toolkit is comprised of a trainer's manual, user's guide, counseling cards, and other clinical-based resources that provide information and materials that health care providers need to offer high-quality family planning counseling to clients living in areas with high rates of HIV and sexually transmitted infections.



The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **demand generation**.

CREATING DEMAND FOR A NEW CONTRACEPTIVE OPTION

Behavior change communication is a process that motivates people to adopt healthy behaviors or lifestyles. Because family planning choices are made in a broader context of social and gender norms, outreach to audiences requires more than just information, education, and communication. Encouraging women to access family planning and building a supportive social and cultural environment are both important components of a communication and demand-generation strategy for product introduction or scale-up. Strong communication, outreach, and awareness-raising about a new product can help to increase the use of modern contraceptives, including Sayana Press. Communication can also foster understanding and dialogue within

communities, improving trust in health interventions and preventing the spread of misinformation.

Communication activities may be broad in scope to encourage women's access to family planning and social and cultural support. They may also be product-specific and more informational or promotional in nature. Both types of communication are ideal to expand public awareness about Sayana Press as a new contraceptive option and to correct myths and misinformation. Method-specific communication materials can help women continue using their chosen method by explaining normal side effects and responding to frequently asked questions. Many of the behavior change strategies during the pilot introductions focused on

promoting a lifestyle that involves modern family planning methods as the preferred alternative to traditional practices or nonuse of contraception when women want to delay or space their pregnancies. When materials and messages were specific to Sayana Press, they were integrated into overarching strategies for promoting family planning services in general.

When used strategically, mass media such as radio and TV programming can reach large numbers of people with crucial information and persuasive messages. Interactive communication approaches such as home visits, community theater, and group discussions can foster dialogue within communities to influence social norms, garner support from trusted and influential leaders, and pave the way for broader family planning access. Interactive approaches in particular allow messages and information to be tailored to the specific needs of the end user.



INTRODUCTION TIP

Frequent radio spots were associated with relatively high levels of new family planning users seeking Sayana Press in Niger and Uganda.

Overall, the Sayana Press introduction project did not have an extensive budget to support communication and demand-generation activities in the pilot countries. Each country set its own communications goals and objectives for introduction and determined how best to achieve its goals. PATH found that it was most useful for each communications partner agency to assess its programs and decide what methods and channels would be most effective for the country context. A range of examples illustrates how demand-generation work played out during the pilot introductions. In Burkina Faso, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) received funding to implement extensive communications activities to generate demand for family planning services and increase awareness of Sayana Press in the pilot regions (see box). Similarly, in Uganda, PATH contracted CDFU

CASE STUDY



Creating demand in Burkina Faso: GIZ

During the first two years of Sayana Press introductions, GIZ led a project to develop and implement multifaceted mass media and interpersonal communication activities across the four pilot regions to generate demand for the product. Key highlights of the project's communications campaign include:

- Conducted 38,511 educational group discussions, estimated to have reached nearly a million people.
- Organized 1,083 film viewings, 387 interactive theater presentations, and 12,609 home visits, which together reached more than 320,600 people.
- Broadcast 4,312 radio and 860 TV spots, reaching nearly 4 million listeners and viewers.

GIZ's project also built the capacity of local nongovernmental organizations (NGOs) implementing family planning advocacy and education activities through intense training and supervision. The project materials included messages targeting men as key supporters of family planning and highlighted referral systems so community members would know where and how to access services.

“My wife and I made the decision to use family planning because it was difficult for me to provide basic needs to my children like education, clothing, and food. One day, my wife and I were listening to the radio and we heard a radio spot about Sayana Press on Divine FM. The spot said it’s easy and safe to use, and they referred people to the nearest VHT. We went to see him, and he gave us more information and counseling on Sayana Press. My wife made up her mind, and she started using it.”

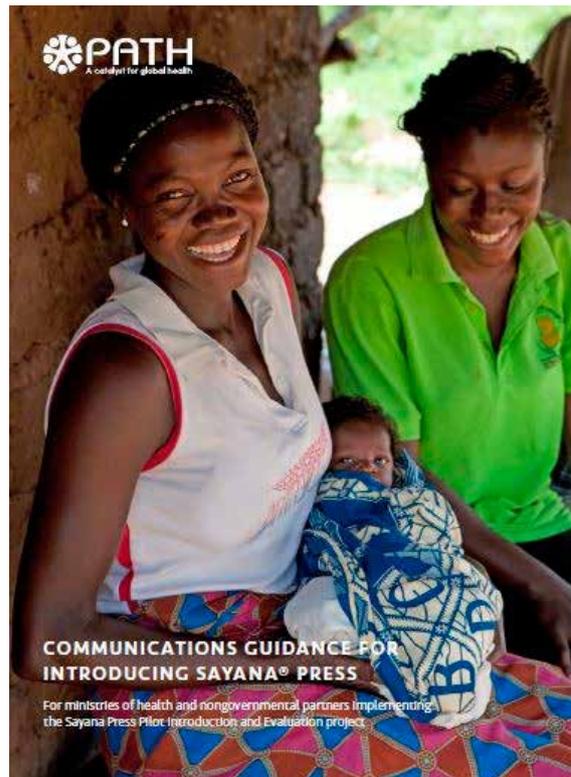
– Husband of Sayana Press client in Uganda

to implement a comprehensive campaign in a selection of the pilot districts (see box on page 75). PATH and partners in all countries used a mixture of mass media and interpersonal communication strategies, and targeted different audience segments.

In many countries, it is not permitted by law to do brand-specific promotion of pharmaceutical products using mass media. Determining what types of product promotion are allowed in each country was challenging. In Niger, the United Nations Population Fund (UNFPA) worked with district Ministry of Health officials to determine how to mention Sayana Press in radio campaigns as one of the family planning options available to women at local health posts. This was acceptable to the government partners because it was not simply brand promotion, and the campaigns were in limited pilot areas. In Senegal, PATH and other NGOs that implement family planning benefitted from a national family planning campaign with the slogan *Moytu Nef*, which translates to “avoid closely spaced births.”

COMMUNICATIONS GUIDANCE FOR SAYANA PRESS PARTNERS

PATH developed a comprehensive guidance document to support implementing partners as they developed communications strategies and activities related to the introduction of Sayana Press. *Communications Guidance for Introducing Sayana® Press* was published in 2014. Available in French and English at <http://sites.path.org/rh/?p=436>. It is based on a comprehensive review of the literature on communications and behavior change strategies

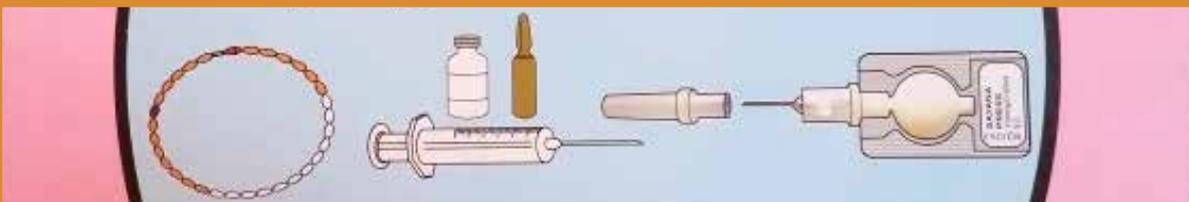


to increase use of family planning methods, with an emphasis on injectable contraceptives and the four pilot countries.

The guidance document provides background information on Sayana Press and the pilot introduction efforts and outlines communication strategies, audiences, and key messages recommended for successful introduction. It also recommends the use of specific communication channels based on previous success. GIZ used the document as a foundation for its behavior change communications strategy for Sayana Press introduction in Burkina Faso. Likewise, CDFU used the document to guide behavior change activities in support of introduction. The document’s suggestions include focusing on

CASE STUDY

PATH/ShirWood



Multiple-channel communication campaign on Sayana Press in Uganda

In Uganda, Communication for Development Foundation Uganda (CDFU) helped to raise awareness of family planning and the new option of Sayana Press in selected pilot introduction districts. Their strategy was designed to help increase knowledge of the availability of injectable contraceptives from Village Health Teams (VHTs).

CDFU implemented a wide variety of communication activities between 2014 and 2016, including:

- Held provider trainings on VHTs' role in education and outreach, beyond just contraceptive service provision.
- Trained existing family planning hotline counselors to answer questions about Sayana Press.
- Conducted more than 150 community dialogues on contraception, Sayana Press, and myths and misconceptions, reaching over 3,000 people.
- Broadcast 42 interactive radio talk shows and 4,680 radio spots.
- Produced and distributed more than 2,000 posters for health facilities/communities and 5,000 leaflets targeted to opinion leaders.
- Conducted an endline evaluation of their communication campaign.

What worked? Community members, including women using Sayana Press, were most likely to report hearing about the new product from radio or VHTs. As one young woman in Apac District reported, "I started using Sayana Press after hearing about it from Voice of Lango FM... I have used it for nine months now." At the same time, VHTs clearly played a critical role. Another youth in Kyegegwa District shared, "The VHTs have made tremendous efforts to meet people in their youth groups during meetings, and sometimes having a one-on-one session to talk about family planning."



INTRODUCTION TIP

Community health workers in Uganda were a trusted source of information, beyond a source of products and services.

Although it is resource-intensive to reach large numbers of people through a community dialogue strategy, it is possible that these activities helped prevent major opposition to the new option or to contraception training for VHTs. The community dialogues were a key mechanism, for example, for engaging men and religious leaders and fostering exchange about their role in supporting family planning.

CDFU's hotline received between 81 and 326 calls about contraception per quarter, and the number of questions about Sayana Press varied. Interestingly, most calls were from men. In some cases, VHTs themselves—who were trained to publicize the hotline to their clients—used the hotline as an information resource.

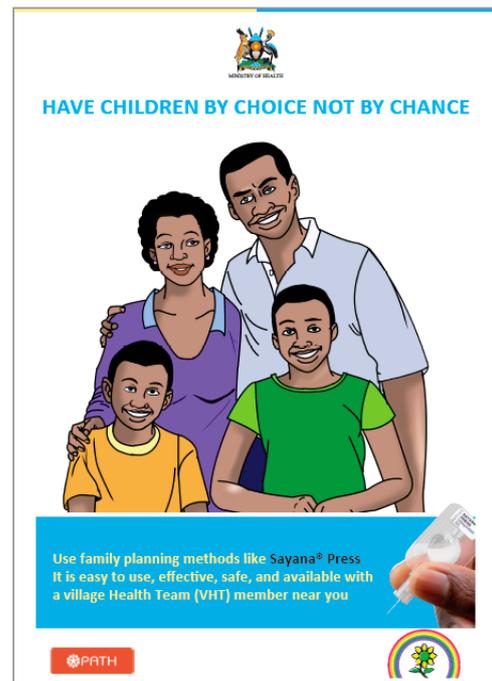
Consumption of Sayana Press increased steadily throughout the pilot introduction period. It is difficult to assess the contributions of various demand-generation activities to the monitoring results.

changing behavior, not just providing information; identifying the needs of end users; and addressing family planning needs generally, not just targeting one method (see example of CDFU poster).



INTRODUCTION TIP

Even if outreach is specific to Sayana Press, make sure it reinforces the importance and benefits of contraception overall.



CASE STUDY

PATH/Siri Wood



Recruiting new users in rural Niger

Early in the Sayana Press pilot in Niger, UNFPA worked with district health authorities in the two pilot zones to launch intense awareness-raising activities. These included:

- Using “information caravans” in dozens of villages, which included theater skits, discussion groups, and debates. Theater troupe performers were trained in family planning and supervised by the district health management teams.
- Training announcers at seven community radio stations and one private station, reaching 161 villages in Téra District to broadcast messages about family planning and Sayana Press in particular. Messages were broadcast three times a day in five national languages for more than six months.
- Conducting a radio campaign through five community radio stations in Magaria District and training two broadcasters per station, who then engaged with surrounding communities to produce and air a series of 20 “magazine” radio shows.
- Contracting with the Niger Office of Radio and Television’s theater group in Zinder Region to lead 40 village visits across eight communes in Magaria District.
- Conducting community mobilization and door-to-door visits by Ecoles des Maris (Husbands’ Schools) in Magaria District and in the areas around Goundey, Dargol, and Chatoumane in Téra District.

Radio is extremely popular in rural Niger. More than half of Niger’s households own a radio, and more than a third of Niger’s population reports that they listen to the radio at least once a week. Although no evaluation data are available to prove association, it is plausible that the intense and prolonged radio campaigns in Téra and Magaria contributed to many women learning about and seeking Sayana Press in local health posts. As reflected in the project monitoring data, the percentage of new users reached in Niger was significantly higher than in other countries.

RECOMMENDATIONS: GENERATING DEMAND

PATH/Siti Wood



- **Use partner strengths and available evidence to select communications approaches.** Communications partners should assess their existing communications programs and decide which methods and channels are most effective in their context. In addition to traditional mass media, demand-generation strategies that may merit an investment of time and resources include outreach to social and religious groups, development or modification of community theater dramas, and the establishment of easy-to-access, confidential information sources such as toll-free hotlines and print materials that describe each method in detail, including side effects.
- **Consider using radio and health workers for interpersonal communications.** Evidence suggests that two channels are most effective when generating demand for family planning services: (1) interpersonal communication between health workers and patients and (2) radio dramas and programs targeting both men and women. Putting these channels to work requires the development of appropriate materials that support clinic- and community-based health workers to counsel their clients on family planning methods and side effects. And radio programs (i.e., call-in programs or short public service announcements) should be developed to reach both men and women in a community or region with positive messages about family planning.
- **The timing and range of behavior change communications activities should align with the overall introduction or scale-up strategy.** If a new product like Sayana Press is promoted before the product is available in local health facilities, clients may feel frustrated. If communications activities are delayed too long, project resources may be insufficient or campaigns may not have enough time to have a long-term impact, such as shifting social norms.

RESOURCES



Communications Guidance for Introducing Sayana® Press. Available at <http://sites.path.org/rh/?p=436>. PATH developed this publication in early 2014 to support partners in developing-country settings working on communication activities supporting Sayana Press introduction. The document includes recommended strategic and tactical approaches, guidance to identify high-priority audiences, suggested key messages, and choose communication channels.



A Field Guide to Designing a Health Communication Strategy. Available at ccp.jhu.edu/documents/A%20Field%20Guide%20to%20Designing%20Health%20Comm%20Strategy.pdf. This comprehensive guide is an A-to-Z resource for developing and implementing a health communications strategy, replete with tools, examples, case studies, and worksheets.



9 Product distribution

The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **product distribution**.

MOVING THE NEEDLES

Product distribution refers to the process of moving commodities from a central storage facility all the way through the health system supply chain. The purpose of distribution is to make products widely available to consumers—in the case of Sayana Press, getting the unit in the hands of the person who will ultimately administer the injectable (e.g., a health worker or a family planning client herself, in the case of self-injection).

Family planning practitioners and public health experts leading product introduction efforts may not always be familiar or comfortable with the logistics systems associated with product distribution—but it is a critical “behind-the-scenes” function that ensures women’s and adolescent girls’ ongoing access to new

contraceptive products. There are distribution and logistics experts in every country who can and should be engaged in Sayana Press introduction.

For example, it can be helpful to budget for health worker training on Sayana Press distribution and supply management, or conduct a dedicated training on this topic for the relevant point people (e.g., logisticians)—not just at the central level, but in district or regional warehouses and/or at the facilities that serve as key delivery and distribution points. During the pilot phase, implementers in Niger and Burkina Faso organized discrete one-day trainings for individuals responsible for logistics and contraceptive stock management. Without this orientation, logisticians and pharmaceutical store managers would not have been familiar with the Sayana Press package

and required storage conditions, supply chain monitoring tools, and geographic destination in the pilot regions.



INTRODUCTION TIP

Consider training needs for supply management among health workers and logisticians as part of introduction planning.

During the initial assessment phase, PATH carefully studied the existing distribution system and identified any additional measures needed to ensure the maximum potential for sustainability and supply security. Developing a map of each country's supply chain was a valuable element of this assessment; the map helped to reveal which agency or individual is responsible for movement of the product at different points, and when and where data are collected and transferred.

EFFECTS OF PRODUCT DISTRIBUTION APPROACHES ON PROGRAM COSTS AND RESULTS

Countries use a “push” or “pull” distribution system or, more often, some combination of the two, depending on their needs. In the

pull system, lower-level facilities send stock requests to the central level based on actual (not forecasted) demand. This requires expertise and resources at the lower-level facilities to actively track stock and calculate needs in advance. Sometimes, in a pull system, the central level coordinates and pays for transport, while in other cases the lower level does. In a push system, especially where capacity and personnel are limited, products are actively transported from the central level to peripheral facilities during a defined time frame or in a situation of urgency based on a forecast determined by historical consumption data. Because Sayana Press is a new product, in most health systems it can be difficult to implement a pull system with no trends or data on prior use. However, data on use of existing injectable products, or data from similar countries, might help inform projections if a pull system is preferred.

During the pilot introductions, Sayana Press was distributed through the most appropriate mechanisms in each country. During the pilots, distribution involved three distinct approaches:

- Integration of Sayana Press into the existing public-sector national distribution system from the outset (Burkina Faso pull systems, see box on page 82).

Public-sector distribution chain for Sayana Press in Senegal



“Introduction of a new contraceptive method such as Sayana Press can present a needed opportunity to invest in training or retraining staff who are handling stock inventory at all levels. Particularly in a pilot introduction scenario or when conducting operational research, it is important to invest in strengthening the supply chain so that stockouts don’t negatively bias program results.”

– Sara Tift, PATH Sayana Press Project Director

CASE STUDY

PATH/Siri Wood



Burkina Faso relies on national distribution system from the outset

Burkina Faso began integrating Sayana Press into the national contraceptive distribution system from the start of the pilot. In the first quarter, the Sayana Press coordinator attended a workshop with the Ministry of Health (MOH) and DELIVER PROJECT of the US Agency for International Development on contraceptive supplies logistics and information systems. This allowed stakeholders to validate the integration of Sayana Press into the existing tools for contraceptive supply chain security data collection and supervision. And in addition to training providers in Sayana Press administration, the United Nations Population Fund (UNFPA) supported the MOH to integrate Sayana Press into a broader workshop on management of essential reproductive health commodities using CHANNEL web-based software. This training benefited individuals working in the supply chain in the national and regional medicines storehouses (Centrale d'Achat des Médicaments Essentiels Génériques et des Consommables médicaux).

In the first nine months of Burkina Faso's pilot introduction, the supply of Sayana Press to the pilot areas was consistent. This was followed by a period of decreased consumption when supplies were not delivered from the central to the regional level and on to district facilities in a timely manner. Over the course of the pilot period, stockouts occurred in up to 67 percent of facilities, compromising the product's potential to increase access. For example, because of Sayana Press stockouts, providers prioritized remaining stocks for continuing injectable users—therefore decreasing the number of doses available for new users.

Another factor contributing to supply challenges in Burkina Faso was the fact that the initial Sayana Press stock that was imported in late 2013 had been manufactured in 2012, with a three-year shelf life. Since training was not complete until July 2014, there was only a year left before product expiry. Stockouts in Burkina Faso were also exacerbated by general weaknesses in the national stock surveillance system for reproductive health commodities, which contributed to stockouts of a number of products. Stockouts impact client and provider confidence in the continued availability of contraceptive products, which is often reflected in a slow return to prior levels of product use or proportions of new user recruits following a period of stockouts.

When national stakeholders convened in November 2015 and decided to offer Sayana Press nationally, they identified a number of prerequisites for effective scale-up: notably, that the MOH should continue to include Sayana Press in the country's existing essential medicines procurement and distribution cycles, conduct weekly surveillance of reproductive health commodities, and actively monitor the pharmacovigilance tracking system. To ensure supply chain security, stakeholders also insisted on close involvement of Centrale d'Achat des Médicaments Essentiels Génériques et des Consommables médicaux agents, particularly at regional meetings.

CASE STUDY

PATH/Breanne Crady



Alternative distribution system in Uganda

In Uganda, the MOH advised early on that Sayana Press would need to be distributed through the Uganda Health Marketing Group's (UHMG's) alternative, private distribution system. This was in part due to the narrow geography of the pilot (28 of 112 districts) and the fact that the product was not on the national Essential Medicines List.

PATH funded distribution in 10 of the 28 pilot districts through a subagreement with UHMG, which incurred additional project costs as compared to integrating the product directly into the national distribution system. UHMG distributed Sayana Press from its national warehouse all the way to facilities; the facilities then managed the final distribution step to the community health workers/Village Health Teams. Other partners such as FHI 360 and WellShare International were included on a list of partners permitted to pick up product from UHMG, and they managed their own distribution in the other 18 districts with their donor funding. The primary advantage of UHMG's private distribution was that it minimized stockouts. Monitoring data from Uganda reflect steady increases in consumption. The key drawback was the cost.

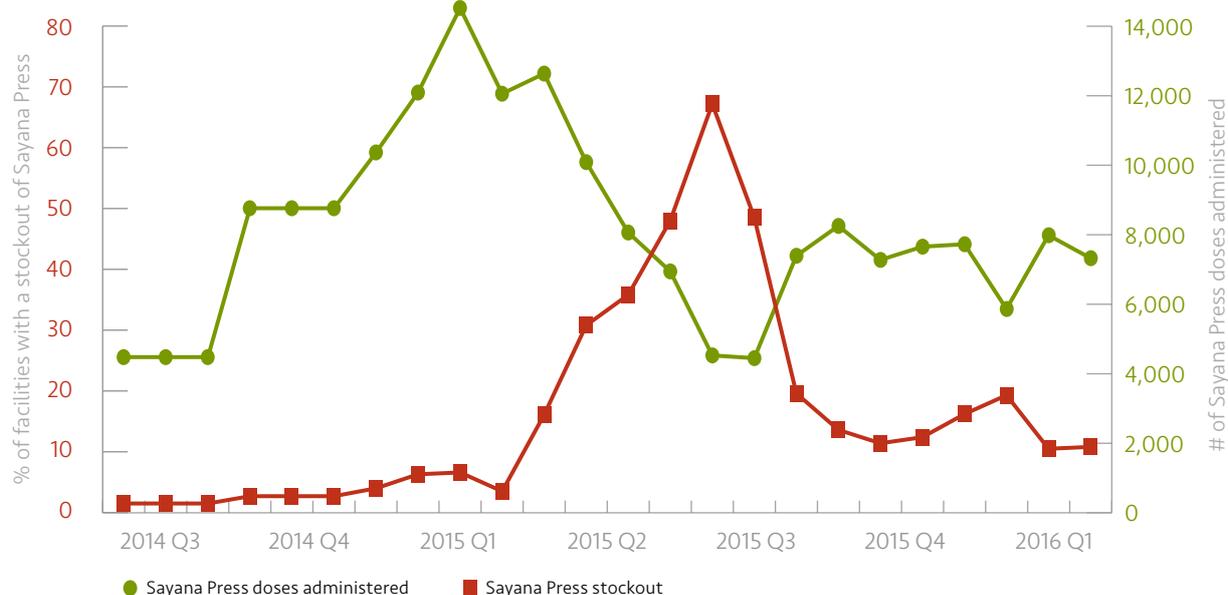
In 2016, when the Ugandan government approved additional provider trainings in a move toward scale, resources were insufficient to continue the alternative distribution at the facility level. However, Uganda was not yet ready to include the product in the national system given that the geographic scope was still limited. As an intermediate step, PATH funded distribution to the district level and worked with district leadership to include Sayana Press in established district distribution systems. PATH also worked with the distributor to train logistics leads in each district on supply management and distribution for the new product. A clear end date of March 2017 was established for this parallel system. To prepare for the transition, PATH, UNFPA, and the MOH worked together to get the product on the Essential Medicines List and integrated into the National Medical Store.

- Integration of Sayana Press into a donor-funded initiative to improve distribution of contraceptive supplies and reduce stockouts, called the Informed Push Model (IPM; Senegal, push system) (see box page 85).
- Establishment of a parallel distribution system with donor funding, using a private distributor approved by the MOH as an alternative to the public-sector system (Uganda, push system). In this case, the National Medical Stores in Uganda could

not distribute the product to a subset of select districts or before the product was on the national Essential Medicines List (see box above).

Every country setting has unique characteristics that affect product distribution. In general, the push systems in Senegal and Uganda minimized stockouts but were more costly relative to the pull systems in Burkina Faso and Niger. Consumption trends are also affected by the nature of the

Proportion of facilities with Sayana Press stockout and number of Sayana Press doses administered, by month—Burkina Faso (2014–2016)



Note: Q, quarter.

Using data on average monthly consumption

Beyond PATH’s project monitoring, some global donors and family planning supply experts also track distribution by monitoring “average monthly consumption” (AMC) through national, ministry-led information systems. AMC tracks the average number of contraceptive units dispensed in a month, usually based on quantities dispensed over a six-month period. When a product is newly introduced and demand is changing, the average may be calculated more frequently (e.g., quarterly). Although it employs the term “consumption,” AMC measures doses distributed from central medicine stores to regional and district depots, not doses administered to clients. The AMC over a period of time should generally be higher than the number of actual doses administered during the same period, as tracked through service delivery data. This indicates that the distribution system is working properly (i.e., there should be limited stockouts in this scenario). Collecting data on indicators like AMC or total doses administered helps identify problems with the distribution system and areas where course corrections are needed.

supply chain. Burkina Faso and Niger rely on existing national distribution systems; they experienced stockouts beginning in the second quarter of 2015 in Burkina Faso and in the fourth quarter of 2015 in Niger. In these countries, stockouts resulted from the lack of timely and accurate requests coming to the central level from peripheral districts, which led to a sharp decline in use of Sayana Press (see graph above). Meanwhile, Uganda

and Senegal have privately funded parallel distribution systems and experienced very limited stockouts. While a reinforced system such as the IPM in Senegal nearly eliminates stockouts (less than 2 percent during the pilot), the model may not be sustainable if it relies on outside donor funding (see text box on page 85).

Informed Push Model in Senegal reduces stockouts



IntraHealth International, in collaboration with Senegal's MOH, has led introduction of the IPM to reduce contraceptive stockouts. IPM reinvests proceeds from clients' contraceptive purchases back into the public contraceptive supply system to ensure the constant flow and availability of products. The model makes a wide range of family planning commodities available, allowing women to more freely choose the methods they want at affordable prices.

Through this model, trained logisticians deliver supplies to points of sale on a regular schedule, restocking where necessary and recording quantities of products sold. With a professional logistician managing stock and deliveries, the health facilities no longer need to place and pick up orders.

When IPM was introduced into health centers, stockouts of contraceptive pills, injectable contraceptives, implants, and intrauterine devices were completely eliminated at the 14 public health facilities in Pikine during the six-month pilot phase. The government subsequently expanded IPM to all 140 public facilities in the Dakar region; six months later, stockout rates throughout the region dropped to less than 2 percent. Partners are currently expanding IPM nationally to improve the family planning supply chain in Senegal's public sector.

A donor-subsidized model such as IPM is effective at reducing stockouts but is challenging to sustain and scale up to the national level. To ensure financial sustainability of the IPM, Senegal's government is evaluating different scenarios, and IPM design will remain flexible to respond to the most cost-effective and politically viable option. A number of strategies to maintain funding for the IPM at national scale are under consideration: for example, using revenue from contraceptive and other product sales, including a government budget line item for product distribution, and collaborating with other donors and multilateral programs to support product distribution.

TRACKING DISTRIBUTION TO IDENTIFY AND ADDRESS PROBLEMS

At the outset of the pilot introductions, the number of doses distributed and the number and percentage of facilities with stockouts were identified as priority indicators by the global donor consortium and national family planning leaders. PATH tracked and reported on these

indicators throughout the pilot introduction (see Section 10: Monitoring and evaluation).

Governments and partners that are managing distribution more closely are also likely to track central inventory stock reports that cover opening balance, closing balance, batch number, date of manufacture, date of expiry per quarter, as well as supply/resupply

distribution reports that cover geographies/facilities resupplied and the number of units (if any) returned due to impending expiry. For example, UHMG reported these details to PATH on a quarterly basis as part of its Sayana Press inventory management activities during the pilot introduction.

SUPPLIES: IT IS NOT JUST ABOUT SAYANA PRESS

During the pilot introductions, PATH found that it was important to consider and plan for a number of supplies in addition to Sayana Press. These included sharps disposal boxes, units for practice injections during trainings, condoms

for dual protection, and pregnancy tests for use when initiating women on the injectable. Program planners needed to ensure timely and effective procurement of these supplies for introduction to proceed smoothly; this becomes even more crucial when transitioning to scale. When self-injection of Sayana Press is offered, there will also be implications for distribution, such as determining how many units each client will be given to take home, ensuring that clients are given units that still have sufficient shelf life, and providing guidelines to clients regarding storage and disposal at home. PATH plans to explore these operational considerations as self-injection is offered outside of research for the first time in Uganda as of late 2016.

RECOMMENDATIONS: PRODUCT DISTRIBUTION

PATH/Siri Wood



- **Invest in distribution systems to ensure Sayana Press will be consistently available.**

Introduction of a novel technology shines a light on the strengths and weaknesses of existing distribution systems. An innovation's potential to increase access is only as good as the distribution system required to deliver it. Broader investments may be required for successful introduction—especially at the most peripheral levels (e.g., community health workers).

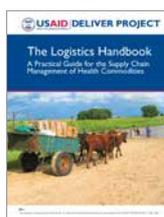
- **Map the supply chain.** Map the supply chain from the central warehouse all the way to the end user to identify potential obstacles. This exercise will identify the agencies and individuals who are responsible for various tasks in the supply chain.

- **Consider whether a “push” or a “pull” system is most appropriate for Sayana Press introduction and ongoing distribution.**

Generally, push systems require external funding and may not be responsive. They work well to minimize stockouts but are costly. They also tend to be less sustainable and require a complex transition if and when a product moves to scale. Most countries have pull systems, which may be more likely to experience stockouts that interrupt consumption. Working with these systems increases sustainability and minimizes costs.

- **Review monitoring data to assess the functioning of the distribution system.** The number of doses distributed or the average monthly consumption should generally be higher than the number of doses administered during a period of time, indicating that the distribution system is functioning.

- **Account for shelf life of available Sayana Press units and product expiry.** Sayana Press has a three-year shelf life. Ensure that there is a plan for tracking product expiry and recapturing units in advance of their expiry. Sufficient stock should be distributed to the field in advance of product expiry.



The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Available at www.deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LogiHand.pdf. This resource offers practical guidance for program managers who design, manage, and assess logistics systems for health commodities and programs. In addition, policymakers and stakeholders working in logistics will find it helpful as a system overview and overall approach. It includes detailed information about the design and implementation of logistics management information systems and inventory control systems.



Essential Medicines and Health Products Information Portal. Available at apps.who.int/medicinedocs/en/. This portal supports efforts to improve access to essential medicines and health products by making publications available online. It includes 5,604 medicines—and health products—related publications from the World Health Organization, other United Nations partners, global nongovernmental organizations, development agencies and their partners, countries, and academics. The portal is updated monthly.



The Reproductive Health Supplies Coalition publications web page. Available at www.rhsupplies.org/activities-resources/publications/. The website is a repository for many resources including the Reducing Stockouts Impact Calculator, Strategic Pathway to Reproductive Health Commodity Security, Optimizing Supply Chains for Improved Performance, Contraceptive Stockouts: A Review of the Published and Grey Literature, and Building a Strong Supply Chain Workforce: The Role of Pre-Service Training.



The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **monitoring and evaluation**.

INFORMING DECISIONS AND MEASURING RESULTS

Monitoring involves collecting, storing, and analyzing data from ongoing programs to inform decisions and help improve implementation. Monitoring data can provide insights into what is working well or not in a given program, without the added cost of evaluation. Careful analysis of monitoring data from the Sayana Press pilot introductions helped PATH and partners assess whether the project was functioning as expected, identify where technical or programmatic course corrections were needed, and summarize project results. PATH worked with partners to develop indicators that linked directly to project goals and desired outcomes. The monitoring data ultimately helped measure the effect of introducing Sayana Press as a new contraceptive

product in each country’s method mix and family planning program.

At the outset of pilot introductions, PATH collaborated with local and global stakeholders to build consensus on a set of global indicators across Burkina Faso, Niger, Senegal, and Uganda. Working with each national system, PATH developed a multicountry monitoring approach for these indicators and a central web-based system for entering and managing



INTRODUCTION TIP

Plan the introduction monitoring approach early and thoroughly, and include a session on data collection for monitoring purposes in the provider training.

data. Each country's introduction plan included a section describing the monitoring system. Defining the monitoring approach early on ensured that data collection could begin as soon as provider training and service delivery were under way in each country.

SELECTING AND DEFINING INDICATORS

PATH selected global indicators based on key interests of national stakeholders and donors to make decisions regarding scale-up and future investments in Sayana Press. In addition

to tracking volumes of doses administered, PATH's approach to monitoring Sayana Press pilot introductions measured indicators related to new family planning users, youth, and switching to Sayana Press from other methods, especially DMPA-IM (generic name for the intramuscular form of depot medroxyprogesterone acetate).

During the design of the monitoring system, PATH paid careful attention to defining indicators consistently within each country, as well as globally. Harmonizing indicators across all countries allowed the team to conduct a cross-country analysis of monitoring data, which

Global indicators for Sayana Press pilot introduction

PATH tracked the list of indicators shown below across all countries for donor-reporting and decision-making purposes; each pilot introduction country tracked a longer list of indicators. The service delivery and logistics indicators were compared across all four pilot countries to illuminate results of various introduction approaches. Training indicators provided a framework for tracking implementation progress and contextualizing product uptake.

Service delivery

- Number of doses of Sayana Press administered to clients, by service delivery channel.
- Number (and percent) of Sayana Press doses administered to new users of modern contraception.
- Number (and percent) of Sayana Press doses administered to users under age 20 years, ages 20 to 24 years, and ages 25 years and older (not available for Burkina Faso).
- Number (and percent) of Sayana Press doses administered to users who switched from DMPA-IM (not available for Niger), and from other methods (not available for Niger and Uganda).
- The relative proportion of Sayana Press and DMPA-IM doses administered, where both methods are offered side-by-side.

Logistics

- Number of doses of Sayana Press distributed to health facilities.
- Number (and percent) of facilities with a stockout of Sayana Press.

Training

- Number of training sessions held.
- Number of providers trained, by level/type.
- Number (and percent) of trained providers achieving competency in injectable administration (Sayana Press and/or DMPA-IM).

Average monthly consumption, as described in the section on product distribution, is an additional indicator of keen interest to global donors and national family planning stakeholders. PATH did not track this indicator specifically because data on the number of doses administered to clients were more accurate measures of consumption for the pilot phase.

provided rich information on the outcomes of different training and introduction approaches (see Section 4: Planning the country introduction strategy). PATH found early on, however, that indicators were interpreted or defined in different ways by partners in different countries. For example, the definition of “new user of family planning” was debated in each setting. It could refer to a client trying a particular method for the first time, to a client who had used family planning in the past but had discontinued and was restarting anew, or to a client who had never before used any modern method of contraception. Ultimately, all four countries reached consensus consistent with the final definition and revised existing data collection tools as needed to reflect this understanding.

In addition, given that Sayana Press is expected to increase access through more remote delivery channels, PATH found that it was important to determine how to break down (or disaggregate) data in ways that allowed for analysis by different channels (e.g., community based-distribution [CBD], mobile outreach, different types of facilities; see box).

It was also important to assess the degree of difficulty of, and value in, collecting each indicator. PATH linked each indicator to the project goals and desired outcomes and limited indicators to those essential for project

monitoring and decision-making. In other words, only collect the data that you need. The most essential information can get lost in monitoring plans attempting to track a large number of indicators. At the country level, a process of negotiation among stakeholders was necessary to refine indicator lists. To separate the “nice to know” from the “need to know,” PATH and partners applied criteria such as how feasible it would be to collect the data and how important



INTRODUCTION TIP

To avoid undue effort and expense, only collect data on monitoring indicators that are really needed, ensuring that all data are valuable and feasible to collect.

the data would be for decision-making.

Some common family planning indicators have been defined and asserted by international agencies, such as Family Planning 2020 or the Reproductive Health Supply Coalition’s Take Stock campaign, to track progress toward international family planning commitments (see resources at the end of this section). These indicators can serve as a reference for nongovernmental organizations (NGOs) and ministries of health (MOHs) in

Monitoring community-based distribution

Existing monitoring systems may not be equipped to collect and report data on CBD. Data may be rolled up together for an entire district, for example, with no information about which data come from community health workers (CHWs) and which data come from facilities they may be affiliated with (i.e., where the CHWs receive supervision, pick up products, and turn in data). To discern the contribution of a CBD program, it is necessary to break out service delivery data from CHWs. Where there are limited systems to collect data at the community level, this requires:

- Extending the existing monitoring system to the community level.
- Training CHWs in data collection. During training, special care should be taken to ensure that CHWs understand monitoring indicator definitions and how to apply them consistently.
- In the case of national scale, adapting the health information system (HIS) to account for CBD of contraceptives to truly understand the contribution of Sayana Press.

countries introducing Sayana Press, where a multicountry monitoring system is not needed.

THE NEED FOR A MONITORING PLAN AND RESOURCES FOR IMPLEMENTATION

Once indicators were finalized, PATH developed comprehensive country monitoring plans to map out how data would be collected in each country, at what level, data sources (including data collection tools), reporting frequency, and parties responsible for data collection and reporting. The plan for each country was unique and tailored to leverage existing systems (see graphic). PATH also developed data flow diagrams and standard operating procedures for data collection, which helped to define roles and responsibilities.



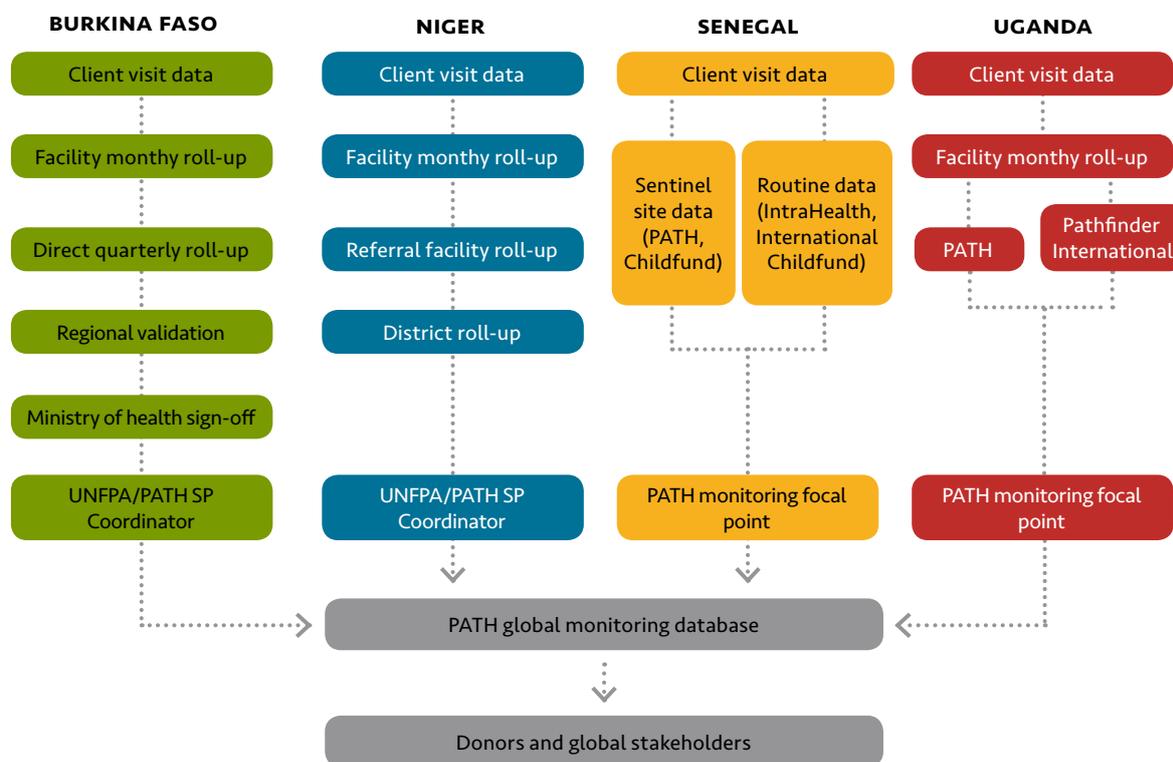
INTRODUCTION TIP

Develop standard operating procedures, particularly if multiple organizations are collecting data.

To develop the monitoring plans, PATH reviewed and assessed existing national HISs to determine how data collection for global indicators could be integrated into existing systems and what new systems would be needed. The PATH team visited health facilities at various levels to review data collection tools and HIS reporting forms. Modifications were sometimes as simple as training health workers to write in the method name (Sayana Press or DMPA-IM) rather than simply writing “injectable” or ticking a box for injectables.

More complicated changes involved adding additional columns to family planning registers, or creating entirely new forms. For example, PATH found itself stretched to allocate sufficient human resources and budget for data collection in Senegal and Uganda, where Sayana Press could not be integrated fully into the national system. PATH staff needed to pick up data at the district level on a quarterly basis in both countries because data flowing through the national system only reached the central level every six months and did not include the full range of

Data collection and reporting pathways



Note: SP, Sayana Press; UNFPA, United Nations Population Fund.



PATH/WILL BOASE

“The women coming for family planning are the last to be seen at the clinic so they go home late. It can take three hours to be seen. For many, it takes two to three hours to get here because there are no nearby health centers. Most women are farmers or businesswomen and need to work. We sometimes have stockouts of the needles, so we prefer that the device is together. There are 35 women enrolled in the Sayana Press self-injection study here. Most of the women are impressed and excited after their first injection because it’s small and not painful.”

– Susan Palma Anek, Sayana Press study nurse in Uganda

product indicators. This approach yielded high-quality data but was costly and time intensive. For maximum efficiency, both teams combined data collection missions with supervision visits. Fortunately, at the end of the pilot, the HIS in each country was revised to include Sayana Press.



INTRODUCTION TIP

Combine monitoring data collection and provider supervision visits to minimize costs.

METHODS FOR DATA COLLECTION AND REPORTING

The most appropriate data collection system will depend on what is currently in place in the country setting, as well as the available budget. PATH used existing paper-based data collection

and reporting systems in the four introduction countries. Where electronic health records and data collection systems are already established, Sayana Press could be integrated. Projects with well-resourced monitoring budgets may wish to explore the use of mobile data collection and reporting. Regardless of the system, introducing or modifying data collection tools requires pilot-testing the tools to verify health worker comprehension, appropriateness to context, and efficacy of reporting mechanisms. Several rounds of revision may be needed before tools are ready for implementation.



INTRODUCTION TIP

Pilot-test monitoring tools to make sure providers understand them and that they work within systems.

Sayana Press project coordinators intervened at the district level to pick up data and entered these data into a centralized web-based SharePoint database to facilitate timely access to project data for decision-making and donor reporting. Having data from all four countries in one database facilitated cross-country analysis. Where Sayana Press is introduced on a pilot basis, some form of parallel system may be required to collect data for key indicators needed for decisions about future scale. Where Sayana Press is introduced at national scale, however, the national HIS should be adapted to accommodate Sayana Press as well as any new delivery channels.



INTRODUCTION TIP

Wherever possible, Sayana Press should be integrated directly into the national health information and data collection system.

EVALUATING SAYANA PRESS INTRODUCTION: UNDERSTANDING COST, CONTINUATION, AND IMPACT

While monitoring provides data to help understand trends, evaluation helps understand why certain results are obtained and can be very useful to inform decisions about how to revise program implementation. Some questions cannot easily be answered through the analysis of monitoring data and may merit more in-depth program evaluation or operational research. For example, in the four Sayana Press pilot introductions, it was not possible to track how long each woman who received Sayana Press continued using the method, and whether those women tended to keep using this new method longer than other existing methods. Most country systems do not follow and report on individual clients over time through the HIS because it is difficult to do so accurately. Numerous unanswered questions about Sayana Press among donors, country governments, and family planning implementers can only be answered through careful evaluation, ideally timed to coincide with product introduction. For example:

- Will Sayana Press introduction result in increased injectable use and a higher

contraceptive prevalence rate? For example, does Sayana Press contribute to improved continuation rates for injectable clients compared with the alternative DMPA-IM? What about when it is administered by providers versus self-injected?

- Will Sayana Press contribute to reducing unmet need for family planning? Will it draw new users of modern family planning methods to initiate and/or continue using contraception? What about young women and adolescent girls?
- What is the cost of adding Sayana Press to the method mix, and how does that cost compare with the cost of offering DMPA-IM?
- How cost-effective is Sayana Press (from providers or self-injected) compared to provider-administered DMPA-IM? What is its relative contribution to preventing unintended pregnancies and their health consequences for women and children?

Evaluators and researchers should also consider using qualitative methods in Sayana Press introduction. Qualitative approaches can help program teams to understand stakeholder, community, and women's attitudes toward Sayana Press, or injectables in general, prior to introduction and can provide important clues about introduction approaches that may work best in a particular context. In addition, qualitative methods can be very helpful during the introduction of a new technology like Sayana Press by uncovering provider and client attitudes and beliefs about the product, illuminating health system issues such as monitoring data collection flow or stockout problems, and providing rich information about the impact of the introduction on women, couples, families, and communities.

When the pilot introductions began in 2014, PATH developed a research agenda to begin answering some of the key questions above and began to explore the feasibility and acceptability of self-injection with Sayana Press—an emerging priority. Research studies began about a year after the pilot introduction phase began, building on stakeholder, provider, and client familiarity with the product to maximize success. This research agenda was developed in consultation with country stakeholders, MOHs, and global donors.

PATH's Sayana Press research portfolio

Ongoing research studies on Sayana Press continue to augment the growing evidence base for understanding the potential of this product, particularly for self-injection. Research conducted in prior years included a review and assessment of needs related to home administration in low-resource settings, provider and client product acceptability studies in Senegal and Uganda, a preference study among HIV-positive women in Uganda, and qualitative research on home and self-injection in Ethiopia, among other works. Many of these resources can be accessed at: [sites.path.org/rh/recent-reproductive-health-projects/sayanapress/sayanapress-resources/](https://www.path.org/rh/recent-reproductive-health-projects/sayanapress/sayanapress-resources/). PATH and country governments are currently conducting research to address information gaps and better understand operational and programmatic considerations related to self-injection in sub-Saharan Africa. Launched in 2015, the studies are outlined below.

Study topic	What we learned/will learn (outcomes)	Countries
Self-injection stakeholder perspectives	<p>Results of the study in Senegal and Uganda helped inform the operational feasibility study design (see Stakeholder Views on Self-Injection of DMPA-SC in Senegal and Uganda. Available at www.path.org/publications/detail.php?i=2688).</p> <p>Analysis enabled PATH to tailor advocacy and communications about self-injection based on country readiness.</p>	<p>Uganda</p> <p>Senegal</p> <p>Burkina Faso</p> <p>Niger</p>
Self-injection operational feasibility	<p>Most women can competently and independently self-inject.</p> <p>One-on-one training and a client instruction booklet seem to help maximize injection competence.</p> <p>Innovative approaches are still needed for efficient training, support, and product waste management in self-injection programs. See results of Uganda study published in "A prospective cohort study of the feasibility and acceptability of depot medroxyprogesterone acetate administered subcutaneously through self-injection." Available at http://www.contraceptionjournal.org/article/S0010-7824(16)30459-0/pdf.</p>	<p>Uganda</p> <p>Senegal</p>
Self-injection acceptability	<p>Adolescent girls found Sayana Press easy to use, and many of them (but not all) could envision trying self-injection themselves.</p> <p>Providers were quite positive about self-injection as an option for women and adolescent girls (but not unanimously).</p> <p>Training, including advice on storage and disposal, and follow-up were identified as critical elements for the design of a future self-injection program.</p>	<p>Uganda</p>
Self-injection continuation and cost-effectiveness	<p>Whether self-injection contributes to longer continuation, relative to DMPA-IM administered by providers.</p> <p>Cost-effectiveness of self-injected Sayana Press compared with DMPA-IM from providers.</p> <p>Results anticipated late 2017.</p>	<p>Uganda</p> <p>Senegal</p>
Provider-administered continuation and cost-effectiveness	<p>Whether Sayana Press administered by a CHW contributes to longer continuation and is cost-effective, relative to DMPA-IM.</p> <p>Whether Sayana Press administered at a clinic or via outreach contributes to longer continuation and is cost-effective, relative to DMPA-IM.</p> <p>Results anticipated mid-2017.</p>	<p>Burkina Faso</p> <p>Uganda</p>

Beyond PATH's research portfolio and studies led by FHI 360 or other international institutions, MOHs and implementing partners in countries that are introducing Sayana Press may choose to explore a wide range of research topics and lines of inquiry to generate additional evidence. Examples of research topics that could be explored in future Sayana Press introduction programs include:

Contraceptive continuation

- How long do women who self-inject continue with this method?
- What factors predict how long women will continue injecting?
- What kinds of programs lead to higher continuation rates?
- Do women who discontinue self-injection shift to other methods, return to provider-administered injection, or stop contraception?

Impact

- How successful is the program in reaching new family planning users?
- What impact does the program have on the contraceptive prevalence rate?
- Do rural women have increased access to contraception?

Implementation science

- What kinds of training formats are most cost-effective?
- What delivery channels work best to reach the most women?
- What health system factors influence program success?
- What delivery channels work to reach different segments of women (younger or older, married or unmarried, etc.)?



PATH/Siri Wood

RECOMMENDATIONS: MONITORING AND EVALUATION

- **Start early.** Developing key indicators and designing the monitoring system should coincide with planning an introduction or scale-up strategy. Delays in implementing the monitoring system will translate to delays in data collection and reporting and will likely result in missing information about the product's impact.
- **Use consistent definitions.** Consistent definition of indicators within and across countries is critical to obtain meaningful results. Indicators should be carefully crafted to ensure they will provide meaningful information. Sometimes an absolute number is meaningful to get a sense of volume, but at other times a percentage calculation can provide richer information.
- **Keep the scale of data collection manageable** and only collect data you need. To avoid undue effort and expense, first ensure that all data are valuable and feasible to collect.
- **Budget adequately for data collection.** Despite the high value of monitoring data, the time and financial resources needed to conduct monitoring well are often underestimated. Be sure to adequately prepare and finance the monitoring plan in advance. Until a new product like Sayana Press is integrated into a country's HIS (after the pilot phase), it may be necessary to plan and budget for separate data collection in the field. For maximum cost-efficiency, data collection missions can be combined with supervision visits.
- **Ensure the monitoring approach captures the contributions of more peripheral channels.** If CBD is introduced but data are rolled into the referral facility, the ability to measure the CBD component of a program is lost. When designing a monitoring system and forms, it is ideal to intentionally disaggregate data for any new delivery channels—such as CBD—to enable analysis of service innovations.
- **Train providers on monitoring tools and systems.** It is most cost-efficient and strategic to train providers on the monitoring tools at the same time they are trained on Sayana Press. This approach has potential to improve data quality and reduce gaps in data collection. Training on data collection through supervision is more costly and requires correcting already-established habits.
- **Consider whether evaluation or operations research activities are needed to provide additional information.** Monitoring data help understand numbers and trends, however some questions are best answered through in-depth qualitative or quantitative evaluation (e.g., client or provider surveys) or operations research.



Monitoring Sayana Press Introduction: Final Pilot Project Results.

Available at www.path.org/publications/detail.php?i=2551. PATH produced semiannual summaries of monitoring data compiled through a global data base during pilot introductions. This brief summarizes the final cumulative analysis of data collected during the pilots and published in late 2016.



Key Indicators for Community-based Access to Injectable

Contraception Pilot Studies. Available at www.k4health.org/sites/default/files/Key%20Indicators%20for%20CBA2I%20Final%20with%20Branding.pdf This document presents potential process and outcome indicators organized according to phases of CBD pilots along with related evaluation questions, data sources, and measurement tools. The list can be adapted to the local context and program goals to assess a pilot's progress toward intended outputs and achievement of goals.



PATH Sayana Press Global Indicator Guide. Available at www.path.org/publications/detail.php?i=2551. This resource regroups indicators that PATH found particularly relevant during the pilot introduction of Sayana Press when monitoring data were generated and analyzed across a number of countries.



11

Moving from introduction to scale

The introduction of Sayana® Press (DMPA-SC in Uniject™) 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 discusses results and lessons learned during introduction pilots in four countries and provides recommendations to guide future efforts by ministries of health and implementing partners related to **moving from introduction to scale**.

INCREASING IMPACT THROUGH SCALE

The World Health Organization WHO defines scaling up as “deliberate efforts to increase the impact of successfully tested health innovations so as to benefit more people and to foster policy and program development on a lasting basis.” Scale-up strategies can include different types of scale. Vertical scale generally refers to integrating a product in an existing health system: the policy, political, legal, regulatory, budgetary, or other changes needed to institutionalize the innovation at national or subnational level. Horizontal scaling up is perhaps more commonly used and refers to replicating an innovation in new geographies or service delivery points.

FACTORS DRIVING DECISION-MAKING ON SCALE-UP

At the outset of the four Sayana Press pilot introductions, scale-up was not a given. However, between 12 and 18 months after Sayana Press was introduced in their countries, all four governments reviewed evidence from



INTRODUCTION TIP

Review of at least one year of implementation data in a given country setting may provide sufficient evidence and learning to make a decision about scale-up.

the pilot and declared their intention to scale up the innovation. In each case, the decision to move to scale hinged on a combination of evidence, partner coordination, availability of funding, and political vision.

Evidence from the pilot introduction experiences shed light on some of the early, unanswered questions about Sayana Press. For example, monitoring data from all four countries demonstrated steady increases in consumption of Sayana Press in pilot introduction areas. In particular, promising proportions of doses administered to new users and women under age 25 years indicated that Sayana Press held potential to reduce unmet need (see Section 2: Background). At the same time, no major problems with the product itself were reported by stakeholders, providers, or users. In some settings, especially communities in Uganda, providers and users even reported an experience of reduced side effects relative to DMPA-IM (generic name for the intramuscular form of depot medroxyprogesterone acetate)—a finding not backed up by clinical evidence but conceptually reasonable due to the lower dose.

Scale-up decisions are not just driven by the innovation itself but also by the external environment. Decisions by country governments and procurement agencies to support scale were made based on the product's 1 USD unit price established in late 2014. In addition, around the time the pilot introductions launched, there was an increased emphasis by major donors on accelerating the timeline for self-injection. Self-injection was approved by a stringent regulatory authority during the pilot phase, in 2015 (see Section 5: Registration). This powerful differentiating aspect of Sayana Press therefore became more tangible during the pilot phase.

FOUR DISTINCT NATIONAL SCALE-UP DECISIONS

Because the Sayana Press pilot introductions were country-led and co-designed with ministries of health (MOHs), the movement to scale was relatively smooth in all four countries. PATH shared and reviewed

monitoring data with country leaders at regular reproductive health and family planning technical meetings on an ongoing basis, resulting in few surprises by the end of the pilot period. The decision to expand or move to national scale was made in response to presentation of data and experience from the pilot introduction.



INTRODUCTION TIP

Showing up regularly at existing family planning meetings to share introduction results can pave the way for scale-up.

In all four pilot countries, the decision to scale up was made at a meeting of family planning technical partners led by MOH representatives (see table). In Uganda, initially there was some concern about a large surplus of DMPA-IM in the national warehouse that might go to waste if it were displaced by Sayana Press. A few months later, however, there were indications that there was less DMPA-IM in the country than had been understood, and the government shifted to a position of supporting national scale.

In the four countries, actual training of additional providers as part of a scale-up strategy began relatively quickly after the decisions were made—about three to six months later. In Burkina Faso and Niger, the governments leveraged and mobilized existing family planning funding. This also happened in Senegal to some extent, but there were still gaps that needed to be filled by additional funding. In Uganda, the global donor Children's Investment Fund Foundation made a grant to PATH to support additional trainings. Shortly after that, additional agencies like the United Nations Population Fund, Uganda Health Marketing Group, Reproductive Health Uganda, and the local Population Services International (PSI) affiliate, PACE, began planning to integrate Sayana Press into their family planning projects, which were funded by other donors. This reflected Uganda's overall less-centrally driven family planning training system, which is generally driven by individual grants to a

“We have an arsenal of human resources, which has not yet been used. We need to take Sayana Press to the most hard-to-reach villages. We have networks of community relays [community health workers, or CHWs] that are not fully optimized. We can train them, strengthen their skills, teach them about family planning. Every village can have one or two CHWs from whom women can get contraceptives. During community discussions, women can come see the CHW and even get Sayana Press without anyone knowing. Why don’t we do that next?”

– Member of regional health team in Niger

Summary of scale-up process and timeline in each country.

Scale-up variable	Burkina Faso	Niger	Senegal	Uganda
Time frame between pilot launch and scale-up decision	17 months (July 2014–November 2015)	12 months (July 2014–June 2015)	13 months (January 2015–February 2016)	12 months (September 2014–October 2015)
Who made the decision, and where?	MOH and key family planning stakeholders, by unanimous vote at midterm Sayana Press review meeting	MOH and key family planning stakeholders at Reproductive Health Supply Security Committee meeting	MOH and key family planning stakeholders at national Family Planning Technical Working Group meeting	Initial indication by MOH and key stakeholders at a monthly meeting of the Maternal and Child Health Cluster; decision expanded 6 months later at MOH/PATH Sayana Press dissemination meeting
Scale-up approach	Expand provider training in remaining 9 regions; integrate product in normal distribution, supply surveillance, and logistics planning mechanisms; conduct BCC activities; hold on-site training of providers	Expand Sayana Press provision to all health huts in all health districts that can mobilize technical and financial support beginning in July 2015, and to all health huts across the country in 2016. Implement communications/ BCC and monitoring	Expand Sayana Press provision to all levels of facilities in the remaining 10 districts; start with PATH/MOH-led orientations in each region and then implement a provider training cascade	Introduce Sayana Press at health facilities in a subset of the initial 28 introduction districts only, due to concerns about DMPA-IM replacement; later shift to offer Sayana Press nationally and at all levels
Initial budget estimate	~1 million USD	~1.2 million USD	~300,000 USD	~US\$1 million for initial expansion only; more resources needed for national scale
When did scale-up training actually start?	Q2 2016	Q3 2015	Q2 2016	Q2 2016
Who funded?	BMGF, CIFF	USAID, UNFPA	MOH/regions/ implementing partners	CIFF, TBD

Note: BCC, behavior change communication; BMGF, Bill & Melinda Gates Foundation; CIFF, Children’s Investment Fund Foundation; MOH, ministry of health; Q, quarter; TBD, to be determined; UNFPA, United Nations Population Fund; USAID, US Agency for International Development; USD, US dollar.

“In Niger, we are working to scale up Sayana Press in a number of ways: Health authorities are considering the most strategic and effective way to initiate community-based distribution and eventually self-injection, yes, but we can’t put the cart before the horse. First, we need to expand geographically to more regions. Second, we want to offer Sayana Press at the integrated health centers. That’s the most logical next step, because health providers at the integrated health centers are already trained as supervisors, are familiar with Sayana Press, and are demanding the product.”

– Dr. Daouda Sidjo, United Nations Population Fund Sayana Press Coordinator in Niger

variety of family planning nongovernmental organizations or implementing partners. PATH is working with the MOH in Uganda to develop an overall coordinated strategy for national scale.

Reviewing pilot introduction monitoring data and planning for national scale-up may also present opportunities to expand access through community-based distribution (CBD), even if CBD was not part of the original Sayana Press introduction strategy. In Burkina Faso, the successful pilot of Sayana Press offered through outreach spurred an official task-sharing pilot for community health workers to offer injectable contraception and initial prescriptions for oral contraception in three regions for the first time.

TRUE SCALE WILL REQUIRE A LOT MORE WORK—IN THESE FOUR COUNTRIES AND BEYOND

By the end of 2016, the move to national scale in all four countries was still in process. The fact that initial trainings have been undertaken is very promising, but there is still a lot of work to be done in the area of vertical scale—integrating Sayana Press sustainably in each country’s training, distribution, and monitoring systems. The pace of horizontal and vertical scale-up is variable in each country setting, and depends on factors such as implementation capacity, political commitment, resources, and timing. In late 2016, for example, Uganda became the first of the four countries to integrate Sayana Press in

its Essential Medicines List, a key milestone for integrating the product into ongoing commodity procurement and distribution. Also in late 2016, Senegal agreed to integrate Sayana Press indicators—including self-injection—and age-disaggregated data for all methods in the next scheduled update of all national family planning tools, registries, and data collection forms.



INTRODUCTION TIP

Assess whether Sayana Press needs to be integrated into a country’s Essential Medicines List as part of planning for introduction and scale.

In addition, a new set of decisions and plans will be required to support a potential offer of self-injection in each country. Initial evidence from feasibility studies in Senegal and Uganda indicates that women are capable of competent, on-time reinjection three months after a single, one-on-one training session. That said, the approach in the research was rigorous and driven by requirements of global/national ethics review boards. Work is ongoing to design an approach to integrating self-injection in family planning programs that is scalable.

Also, there are a number of ongoing evaluations and research activities that could shift the landscape yet again (see Section 10:

Monitoring and evaluation). For instance, the global community is still waiting to learn:

- What is the impact/cost-effectiveness of Sayana Press (including self-injection) relative to DMPA-IM? Research results are forthcoming in 2017. Donors and country leaders made the move to scale before that evidence was available.
- What happens to DMPA-IM when you take Sayana Press to scale?

- What is a cost-efficient approach to providing women with training and ongoing support, including support for managing side effects and self-injection? How can the practice be monitored to document impact? How should the product be disposed?

In other words, the unique story of Sayana Press scale-up, and how to leverage this innovation to improve access for as many women as possible, is only just beginning.

Evidence-based decision to move to national scale in Senegal

In early 2016, Senegal had a full year of pilot implementation data in hand, demonstrating successful integration of Sayana Press into the contraceptive method mix and in the family planning program overall in the country's four pilot regions. Demand had increased steadily during the first year of the pilot, and 62,000 doses had been administered by the end of 2015. Fewer than 2 percent of facilities experienced stockouts during the pilot period. A review of PATH's sentinel site monitoring data revealed that 25 percent of Sayana Press users were new to family planning (higher at the community level), and Sayana Press was available at all levels of the health system side-by-side with DMPA-IM. PATH's data also showed that switching from DMPA-IM to Sayana Press, while common in the first quarter (51 percent), had leveled out at a reasonable 12 percent by the last quarter of 2015. Sayana Press had not "overtaken" DMPA-IM as some may have feared.

During a quarterly performance review in March 2016 led by the MOH's Director of Reproductive Health and Child Survival, stakeholders reviewed data and decided to initiate the move to national scale. The MOH requested that the remaining ten regions submit scale-up plans and begin exploring funding possibilities among donor partners for training public-sector providers in each region (see illustrative timeline for scale-up activities). PATH financed an initial round of regional and district orientation sessions on Sayana Press and worked with the MOH to seek funding for the subsequent rounds of cascade training of providers in the remaining regions.

Illustrative example of scale-up planning schedule

Planned activities	Implementation timeline (in weeks)												
	1	2	3	4	5	6	7	8	9	10	11	12	
Develop presentations of pilot results to share with stakeholders	■												
Present pilot results, lead discussions, and make decisions regarding scale-up of Sayana Press during MOH-led meeting		■											
Disseminate scale-up action plan and budgeting template to all regions		■											
Issue formal ministerial approved letter supporting scale-up and request action plans from all regions			■										
Compile synthesis of needs from all regions in terms of number of providers to be trained, funding partners identified, budget gaps, and projected timeline				■	■								
Finalize budgeted national scale-up plan						■	■						
Organize a workshop to validate national scale-up plan if needed								■					
Pursue fundraising to fill budgetary gaps, if needed									■	■	■	■	
Initiate series of 1-day Sayana Press orientation sessions with regional and district medical teams in each scale-up region											■	■	
Meet regularly with MOH and key partners to track implementation progress related to scale-up plan (ongoing)													■

RECOMMENDATIONS: MOVING FROM INTRODUCTION TO SCALE

PATH/SiriWood

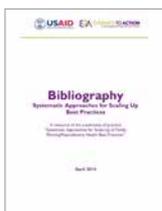


- **Consider options and requirements for vertical and horizontal scale.** What is required for vertical scale? For example, does the product need to be integrated into any existing guidelines or policies (e.g., Essential Medicines Lists, other)? In terms of horizontal scale, does moving Sayana Press beyond facilities to the community level necessitate policy changes? Would moving to new geographies reach new groups with unmet need (e.g., adolescent girls and young women)?
- **Work closely with the national MOH and other key groups to plan for scale.** National stakeholder engagement can be a painstaking process and may not move in sync with original project or donor timelines. However, investing in that work up front resulted in a relatively smooth and organic transition from pilot introduction to scale-up in all four countries. In addition, the fact that many groups were involved and bought in meant that they were more likely to leverage existing family planning resources to support scale-up.
- **Scale may be possible before all the evidence is in.** In some settings, stakeholders may choose to not wait for all the evidence to be available and for every question to be answered before deciding on scale-up. In many of the pilot countries, decision-makers independently moved to scale up introduction based on monitoring data, before results of impact or cost-effectiveness analyses were available.
- **Remember that scale-up may not be the right outcome for every technology in every setting.** The Sayana Press pilot introductions in the first four pilot countries went very well, and global circumstances were also favorable. Different contexts and experiences may result in different outcomes.

RESOURCES



Evidence to Action (E2A) scaling up best practices web page. Available at www.e2aproject.org/what-we-do/scaling-up.html. ExpandNet is a network organization that supports a methodology for ensuring systematic attention to scaling up at the stage of planning pilot projects or when the testing of interventions has been completed. The network runs a community of practice and has published numerous resources.



Bibliography: Systematic Approaches for Scaling Up Best Practices. Available at www.e2aproject.org/publications-tools/bibliography-systematic-scale-up.html. This bibliography is a selection of published articles and other reports that address systematic approaches to scaling up.



Nine Steps for Developing a Scaling-Up Strategy. Available at www.who.int/reproductivehealth/publications/strategic_approach/9789241500319/en/. This guide for program managers, researchers, and technical support agencies aims to facilitate systematic planning for scaling up health service innovations that have been tested in pilot projects or other field tests and proven successful.



Idea to Impact: A Guide to Introduction and Scale. Available at www.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.



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