PATH/Will Boase

SETTING THE STAGE FOR EXPANDED CHOICE

In a groundbreaking initiative coordinated by PATH, subcutaneous DMPA (DMPA-SC, brand name Sayana® Press) 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. The subcutaneous DMPA product used in pilot introductions and referred to in this guidance document is Sayana® Press.

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 DMPA-SC 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 DMPA-SC (brand name Sayana Press), a lower-dose formulation and "all-in-one" presentation of the traditional intramuscular DMPA (DMPA-IM, brand name 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 DMPA-SC in the four pilot countries. They can also help stakeholders in other settings make informed decisions about

The DMPA-SC product introduced in pilots was Sayana Press.
Sayana Press is a registered trademark of Pfizer Inc. Uniject is a trademark of BD.

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 DMPA-SC 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 DMPA-SC 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 DMPA-SC compared to DMPA-IM in community-level delivery channels.** Data from the pilot introductions reinforce early research data on acceptability of, and preference for, DMPA-SC among community-level providers and their clients.
- **Consider opportunities for DMPA-SC 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 DMPA-SC 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 the nongovernmental-organization 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 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 DMPA-SC 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 DMPA-SC is one option among many is especially important to counteract providers' (often well-intentioned) excitement about a new product. DMPA-SC will not be the right option for all, or even many, women. Address informed choice especially if your training only covers DMPA-SC or injectable administration.
- **Design your curriculum to suit your context.** Adapt PATH's field-tested curriculum as needed, considering whether it should cover DMPA-SC 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

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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.

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 DMPA-SC 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.

SUPPLY CHAIN MANAGEMENT

- **Invest in distribution systems to ensure DMPA-SC 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 how DMPA-SC can most efficiently be integrated into the existing supply chain for family planning commodities.** To the extent integration in the national system is possible, this approach will minimize additional investments and position the product to move to scale. Consider targeted investments to strengthen reporting, logistics management and minimize stockouts.
- **Review key logistics data points such as AMC and MOS to ensure sufficient supply of the product at each supply chain level.** AMC and stock status will inform resupply orders at the facility level and procurement plans at the national level.
- **Account for shelf life of available DMPA-SC units and product expiry.** DMPA-SC 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 DMPA-SC. 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 DMPA-SC 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

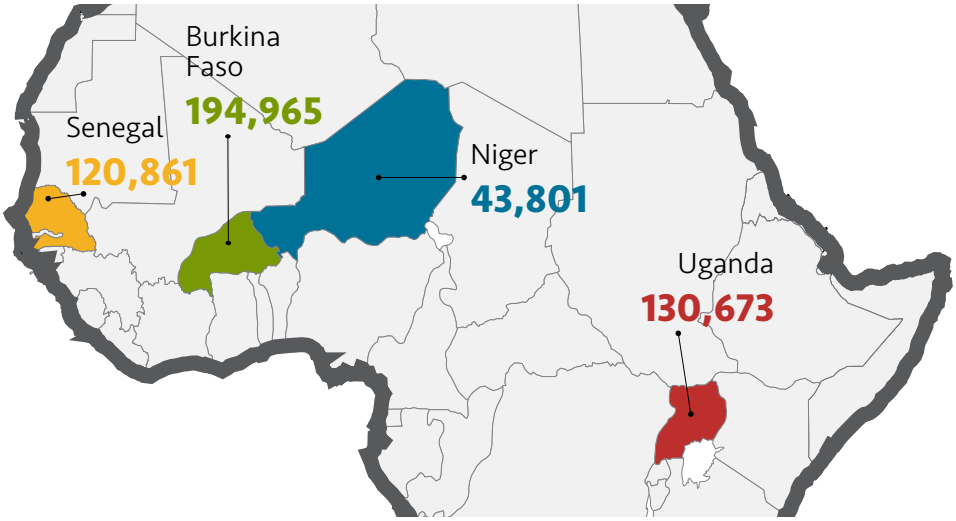
likely to leverage existing family planning resources to support scale-up.

- **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 DMPA-SC 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 DMPA-SC 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 DMPA-SC 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 DMPA-SC 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:	**135,000**
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 DMPA-SC doses (community level):	**75%** (Senegal, Uganda only)
Proportion of injectables that were DMPA-SC doses (all levels):	**22%** (Senegal, Burkina Faso only)

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