11 Moving from introduction to scale

PATH/Will Boase

The introduction of Ssubcutaneous DMPA (DMPA-SC, brand name Sayana® Press) promises to expand women's access to family planning options by increasing opportunities for lower-level health workers and even clients themselves to administer injectable contraceptives. Insights from the first introductions can help inform new country experiences and transitions, whether small pilots or scaled delivery. This section 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 into 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 DMPA-SC pilot introductions, scale-up was not a given. However, between 12 and 18 months after the DMPA-SC product was introduced in their countries, all four governments reviewed evidence from the pilot

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.

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

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. The DMPA-SC product currently available and used in pilot introductions was Sayana Press.

Evidence from the pilot introduction experiences shed light on some of the early, unanswered questions about DMPA-SC. For example, monitoring data from all four countries demonstrated steady increases in consumption of DMPA-SC in pilot introduction areas. In particular, promising proportions of doses administered to new users and women under age 25 years indicated that DMPA-SC 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 intramuscular DMPA (DMPA-IM)—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 US$1 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 of the DMPA-SC product, Sayana Press, was approved by a stringent regulatory authority during the pilot phase, in 2015 (see Section 5: Registration). This powerful differentiating aspect of DMPA-SC therefore became more tangible during the pilot phase.

FOUR DISTINCT NATIONAL SCALE-UP DECISIONS

Because the DMPA-SC 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 DMPA-SC. 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 (see box on page 105). 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 (CIFF) made a grant to PATH to support additional trainings. Shortly after that, additional agencies like the United Nations Population Fund (UNFPA), Uganda Health Marketing Group (UHMG), Reproductive Health Uganda (RHU), and the local Population Services International affiliate, PACE, began planning to integrate DMPA-SC into their family planning projects, which were funded by other donors. This reflected Uganda's overall less centrally driven family planning

"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 DMPA-SC 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 DMPA-SC 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 DMPA-SC 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 DMPA-SC provision to all levels of facilities in the remaining 10 regions; start with PATH/MOH-led orientations in each region and then implement a provider training cascade	Introduce DMPA-SC at health facilities in a subset of the initial 28 introduction districts only, due to concerns about DMPA-IM replacement; later shift to offer DMPA-SC nationally and at all levels
Initial budget estimate	~US$1 million	~US$1.2 million	~US$300,000	~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.

"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 Siddo, United Nations Population Fund DMPA-SC Coordinator in Niger

training system, which is generally driven by individual grants to a variety of family planning nongovernmental organizations (NGOs) 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 DMPA-SC introduction strategy. In Burkina Faso, the successful pilot of DMPA-SC 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 DMPA-SC 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 DMPA-SC 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 DMPA-SC indicators—including self-injection—and age-disaggregated data for all methods into the next scheduled update of all national family planning tools, registries, and data collection forms.

INTRODUCTION TIP

Assess whether DMPA-SC 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 into family planning programs Work is ongoing to design a scalable approach to integrating self-injection into family planning programs.

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 DMPA-SC (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 DMPA-SC 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 DMPA-SC 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 DMPA-SC into the contraceptive method mix and into 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 DMPA-SC users were new to family planning (higher at the community level), and that DMPA-SC 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 DMPA-SC, while common in the first quarter (51 percent), had leveled out at a reasonable 12 percent by the last quarter of 2015. DMPA-SC 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 DMPA-SC 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 DMPA-SC 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 DMPA-SC 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/Siri Wood

- **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 DMPA-SC 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 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.

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.

From Pilot to Practice: Lessons on Scale, Institutionalization and Sustainability from the (in progress) Journey of the SC4CCM Project. Available at: http://sc4ccm.jsi.com/wp-content/uploads/2016/07/Pilot-to-Practice-Brief.pdf This document summarizes implementation lessons from JSI's 5-year Supply Chains for Community Case Management Project in Malawi, Rwanda and Ethiopia. The resource describes three distinguishable stages of implementing systemic supply chain improvements, providing country examples and key messages relevant to each stage.