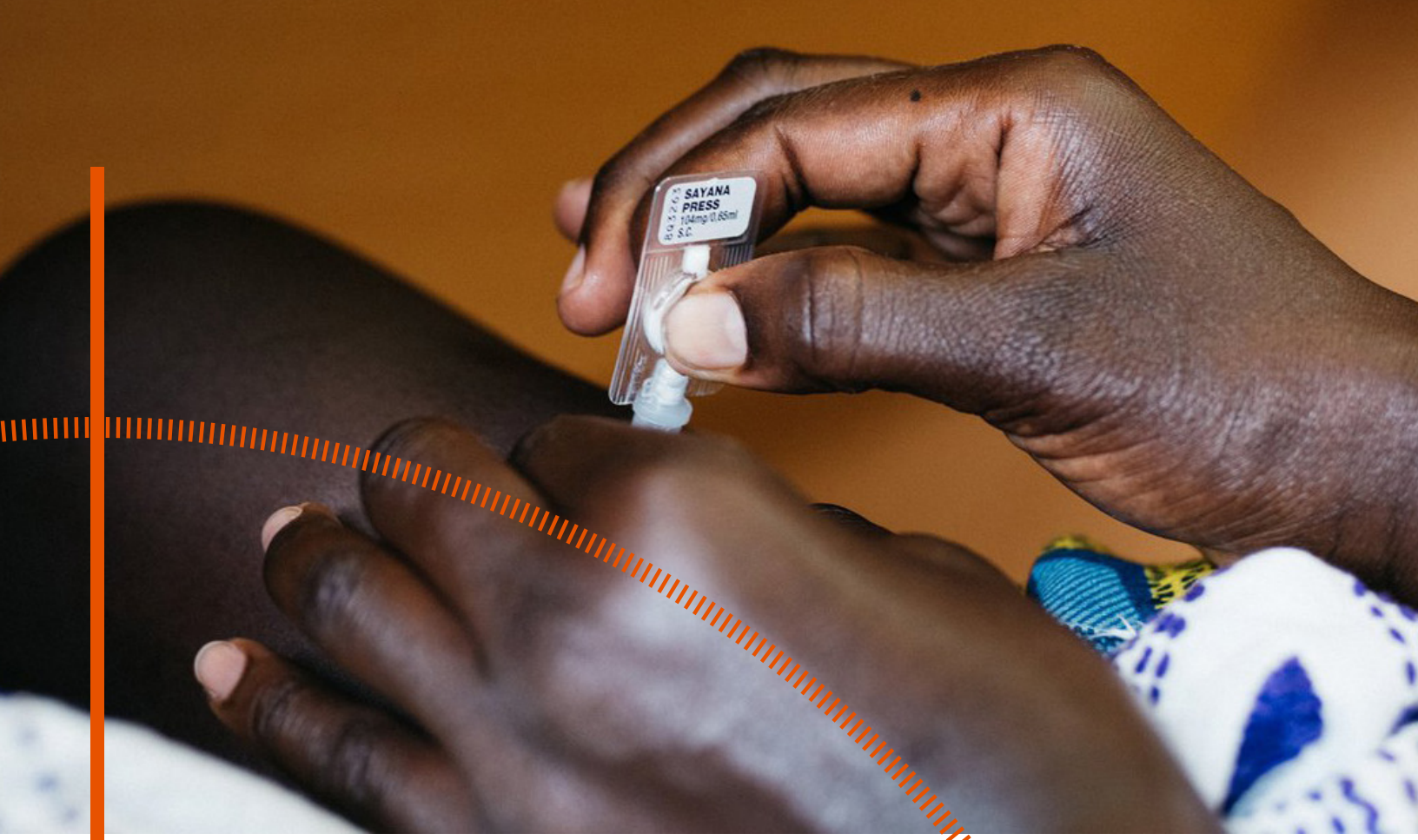

Source: PATH/Gabe Bienczycki

Scaling Life-Saving Interventions Faster
Case Studies Series

Sayana® Press (DMPA-SC)

Sayana® Press (SP) is an easy-to-administer three-month injectable contraceptive (depot-medroxyprogesterone acetate, DMPA-SC) that has been hailed as a game changer in family planning. An estimated 190 million women around the world have an unmet need for contraceptives—with the introduction of Sayana® Press, accessible, affordable, and easy-to-use contraceptives are now available closer to home via self-injection. The following case study highlights key elements that determined the pace of development and uptake of Sayana® Press.

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This case study is part of a series that explores pathways and important factors that contribute to the development and uptake of global health interventions—from proof of concept to scale-up.

LAUNCH & SCALE SPEEDOMETER

Duke GLOBAL HEALTH Innovation Center

LAUNCH & SCALE SPEEDOMETER

Sayana® Press (DMPA-SC)

Photo from PATH/Patrick McKern

An easy-to-administer three-month injectable contraceptive (depot-medroxyprogesterone acetate, DMPA-SC) administered into the fat below the skin.

GLOBAL BURDEN: 190 MILLION WOMEN WITH UNMET NEEDS FOR CONTRACEPTION[1]

TIME FROM PRODUCT IDEATION TO FIRST IN COUNTRY LAUNCH: 19 YEARS

TOTAL DISTRIBUTION : AVAILABLE IN > 30 FAMILY PLANNING 2020 COUNTRIES (2019)[2]

PRICE: $0.85 USD PER DOSE FOR QUALIFIED BUYERS (FAMILY PLANNING 2020 COUNTRIES) FROM MAY 2017 TO 2022[3]

9 YEARS

1995
IDEATION
Effort to deliver DMPA in disposable, single dose syringe begins[4]

2005
PROOF OF CONCEPT
DMPA-SC demonstrated effective as a contraceptive method[4]

2011
REGULATORY AUTHORITY APPROVAL
UK Medicines and Healthcare Products Regulatory Agency (MHRA)[5]

2014
FIRST COUNTRY LAUNCH
Sayana® Press launched for commercial use in Burkina Faso[6,7]

2015
WHO POLICY
Recommendation of DMPA-SC for use as a contraceptive[8]

An estimated 190 million women in low- and middle-income countries (LMICs), have unmet needs for contraception despite the availability of a wide range of options.[1] This unmet need is due to a variety of factors that affect women in LMICs differently than in other parts of the world. Many women in LMICs cite the great distances they must travel to clinics, stock shortages at facilities, and a lack of support in their family planning decisions as barriers to accessing contraception.[9]

Injectables are a popular contraceptive choice in LMICs. In Sub-Saharan Africa (SSA), 47% of modern contraceptive users choose injectables.[10] Unfortunately, access to these injectables is plagued by many of the aforementioned barriers. The most common injectable is depot medroxyprogesterone acetate or DMPA. Traditionally, DMPA required the services of a healthcare provider, who had access to the necessary vials, syringes and needles, and was trained to do the intramuscular injection.[11] This meant

that women had to find transportation to clinics multiple times a year. Not surprisingly, this proved to be a difficult task.[12]

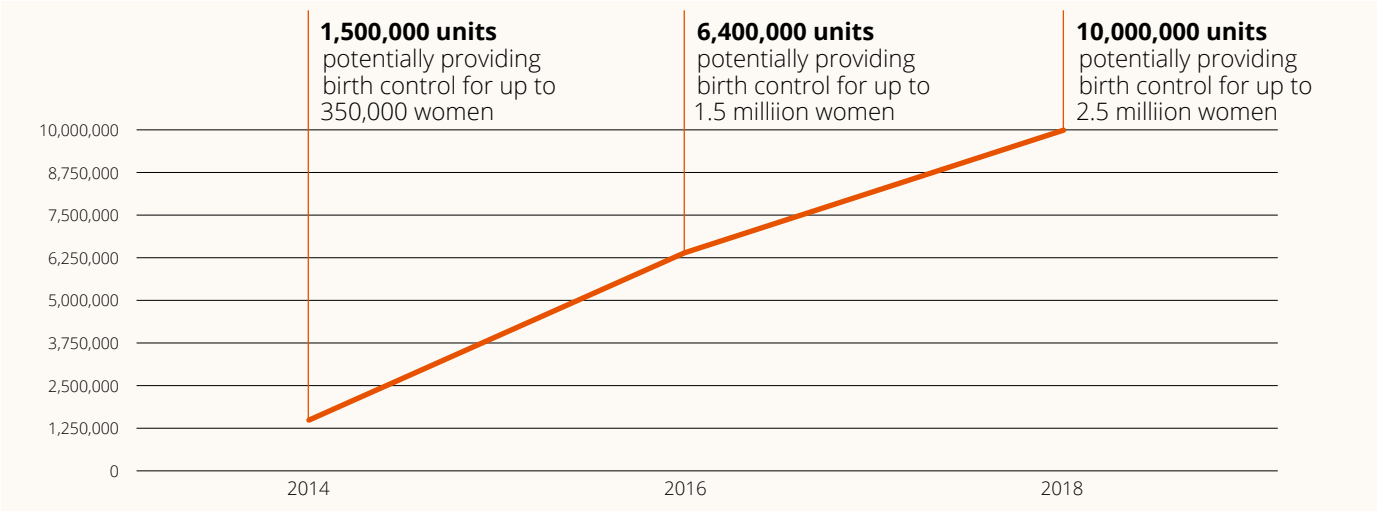
This challenge led PATH and partners to champion development of DMPA-SC under the brand name Sayana® Press (SP). SP can be injected subcutaneously with the BD Uniject™, a single-use, prefilled injection system named for licensee Becton Dickson & Company.[13] With little training, physicians, nurses, community health workers (CHWs), pharmacists, and even the women themselves (in countries where self-injection is approved) can administer the correct dose to prevent pregnancy for at least three months. Because CHWs and women can administer the contraceptive, SP is a game changer that has brought injectables from "the clinic to the home."[14] The injectable is safe, effective, and it affords women full access to birth control, while preserving their choice and privacy.[6,4]

SP's story began in the 1980s when PATH developed the uniject system it then licensed in the 1990s to Becton Dickson and Company (BD), a global medical technology company. That same decade, PATH partnered with USAID and Pfizer Inc. in an effort to deliver DMPA in the all-in-one injectable system. This partnership combined BD's expertise in medical technology and Pfizer's expertise in pharmaceuticals and product commercialization.[6] Pfizer completed clinical trials to prove the efficacy of SP in the mid-2000s.[6] In 2011, the contraceptive received regulatory approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).[4,5,6]

The following year, FP2020, a public-private partnership began funding efforts to provide 120 million more women in 69 countries with access to contraceptives.[15] This global consortium was aimed at focusing the family planning agenda and supporting the fertility rights of women and girls. It became a critical enabler of the scale-up of Sayana® Press. Pfizer committed to manufacturing SP and registering it in various markets, while FP2020 partners (PATH, UNFPA, DFID and USAID) would be in charge of in-country distribution and implementation.[16,17] These partners committed to launching SP in sub-Saharan Africa and South Asia, and to disperse 12 million doses of SP by 2020.[18]

In 2013, acceptability studies began in Ethiopia, Uganda, and Senegal, and pilot projects introduced the contraceptive in Burkina Faso, Niger, Uganda, and Senegal in 2014.[6,19] PATH led some of these efforts with funding from USAID, UNFPA, BMGF, and others.[20] The pilot projects, which focused on CHW administration of SP, were done in partnership with the ministries of health in each country.[11] This led to a smooth transition to scale a year to 18 months after the contraceptive was introduced, highlighting

Figure 1 **Sayana® Press Scale: Units shipped to 20 LMICs since pilot introductions in 2014**



Data for chart from sources 21, 24

the importance of country-level coordination and buy-in. Additionally, the introduction and delivery of SP marked a change in policy and scope/norms of practice with non-clinical CHWs becoming key providers of SP and bringing contraceptives closer to home.[11] SP also showed promise among new contraceptive users and young women (women and girls < 25 years) with uptake ranging from 30% to 70%, amount to 44 % of all doses.[11] During this time, researchers also explored the feasibility of self-injection.6 In 2016, a label update for self-injection was approved by the MHRA. Now, self-injection is permitted in 20 FP2020 countries.[6,2]

From 2014 through 2018, "10 million units of Sayana Press were shipped to 20 developing world countries, potentially reaching more than 2.5 million women" (See figure 1 for SP scale over the years).[21] This meant a 614% increase in four years and amounted to 83% of the 12 million dose commitment with two years to spare.[18,21] In 2017, the Access Collaborative (BMGF, Pfizer, and the Children's Investment Fund Foundation), negotiated a lower price for qualified buyers at $0.85 USD per dose (from $1 USD), which made the cost competitive with intramuscular forms of DMPA.3 In 2019, SP was available in nearly half (>30) of the FP2020 focus countries.[2]

Despite continued success, the introduction and implementation of SP has not been without challenges. Part of the problem is fear of side effects and the issue of who delivers the injections.[22,23] Some governments are hesitant to change norms or policies about who can administer contraceptives for fear that the injections will not be done correctly or safely, that follow-up will be more difficult.[23] These reasons are why only 20 out of 30+ countries where SP is available have approved self-injection.

Overall, SP has expanded access to contraceptive methods available to women in LMICs (especially among young women and new users).[11] In places where women lack empowerment to make their own family planning decisions, this discrete contraceptive gives them the ability to decide if, when, and how many children to have. Getting SP into women's hands for self-injection de-medicalizes family planning and will ultimately lead to healthier and more prosperous families and communities.

KEY INSIGHTS TO LAUNCH AND SCALE

Sayana Press (SP) is a game changer in family planning, shifting care from clinics to community and homes and in so doing, "de-medicalizing" family planning. Furthermore, with the approval of self-injectable SP, for the first time in history, women themselves have effective control of their reproductive decisions.

Approval of self-injection in more countries is essential for more women to access SP. SP helps address the challenges (distance to health facilities, lack of family or partner support) underlying unmet needs for contraception.

SP provides an opportunity to task share with community providers and reduces the burden on medical facilities, while it also shifts FP care to non-clinical settings and the homes of women themselves.

There is growing evidence that self-injection may help decrease the rates of discontinuation among young women.

Organizational partnerships and a global consortium made the development, financing and scaling of SP possible.

Collaborative partnership between profit and nonprofit companies with different areas of expertise (global health research, medical technology, pharmaceuticals and product commercialization) were essential for the development and advancement of SP. One company (PATH) also played a pivotal brokering role, bringing the companies together, and then obtaining the financial support of a FP global champion and investor, USAID.

Another trajectory-changing public-private partnership, the FP2020 Global Consortium was largely responsible for setting a global agenda, catalyzing funding, and negotiating lower prices to assure access to SP in nearly 70 countries

Division of roles enabled the Consortium to utilize their diverse strengths to advance development, funding, distribution and uptake – to achieve clear distribution goals by 2020

However, a note of caution: over-reliance on global champions can mean that global health issues or products not in the "initiative spotlight" may have difficulty attracting funding and attention

Country uptake was accelerated by support from both public and private sectors.

Simultaneous with product development and efforts to gain regulatory approval, acceptability and research pilot studies were undertaken in conjunction with Ministries of Health in multiple countries, thus preparing their health systems, policies and providers for rapid implementation

Global organizations championed the use of SP and advocated for low-price agreements, as well as providing funding for research, and advocating for policy changes

Partnerships with Ministries of Health shaped introduction and scale strategies making it easier to integrate SP into the public supply chain and eased the transition from pilots to scale.

COVID-19 IMPACT

Concerns over the spread of COVID-19, have led to decreased access to health services like family planning as many women in LMICs are under lockdown or quarantining and have limited access to healthcare providers. Self-injection or CHW provided injection is possible even in these extreme circumstances. Ironically, the COVID-19 crisis may increase the demand for Sayana® Press.

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