

## Sayana<sup>®</sup> 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<sup>®</sup> 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://sites.path.org/rh/?p=292>.

Sayana Press is a lower-dose presentation of the three-month injectable contraceptive Depo-Provera<sup>®</sup> in the Uniject<sup>™</sup> injection system—a prefilled autodisable 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 woman with appropriate information and training exist, referral linkages to a healthcare provider are strong, and where monitoring and follow-up can be ensured.”<sup>1</sup>



PATH/Will Boase

*There are barriers to contraceptive use. Those include cost of travel, possibility of not finding health workers, long waiting times, stockouts; and if women can self-inject, all of these barriers would be overcome. – Ministry of Health representative, Uganda*

### 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<sup>2</sup> and Uganda<sup>3</sup> have expressed strong interest in potential self-injection of Sayana Press.

Findings from Pfizer Inc.'s original clinical trials of Sayana<sup>®</sup> (subcutaneous DMPA in a prefilled syringe) and self-injection research in Florida, New York, and Scotland offer promising results.<sup>4,5,6,7</sup> There were no pregnancies among women practicing self-injection in these studies, and nearly all reported it to be convenient and easy.

To date, no studies have involved home-based self-injection in low-resource settings. Two small studies in Bangladesh (S. Hossain, unpublished data, 2012) and Brazil<sup>8</sup> involved supervised self-injection in a clinic. Neither study permitted women to take the product home to self-inject independently.

### WHAT DO WE NEED TO LEARN ABOUT SELF-INJECTION?

While Sayana Press self-injection studies have been promising, more information is needed to support women to self-inject Sayana Press safely and effectively across a range of settings. For example, what is the most effective approach to train women in Senegal, Uganda, and similar contexts to self-inject independently, without direct supervision of a trained health worker?

Ministries of health also need to know whether self-injection can improve family planning outcomes—for example, whether self-injection will make it easier for women to continue using the method for a longer period, should they wish to do so.

### PATH'S SELF-INJECTION RESEARCH

PATH and country governments are conducting research to address information gaps and begin building an evidence base for self-injection in Senegal, Uganda, and similar settings. This work is funded by the Bill & Melinda Gates Foundation and Children's Investment Fund Foundation.

#### Operational feasibility: Senegal and Uganda

Operational feasibility studies, designed with inputs from key family planning stakeholders in each country, have been the first to involve Sayana Press self-injection in sub-Saharan Africa. Launched in 2015, the studies are:

- Assessing feasibility of self-injection as demonstrated by competent and timely self-injection.
- Identifying operational considerations, such as approaches to health worker and client training and support, reminder systems, and waste disposal.
- Identifying characteristics of women for whom self-injection is acceptable or not acceptable.

Early results from the Uganda study indicate that most Ugandan women readily attain proficiency at self-injection after a single one-on-one training session—retained even three months later when they are reinjecting on their own. A similar feasibility study in Senegal will finish in mid-2016.

#### Effectiveness and cost-effectiveness: Senegal and Uganda

Effectiveness and cost-effectiveness studies in Senegal and Uganda in 2016–2017 will assess whether women who self-inject with Sayana Press continue using injectable contraceptives longer than women who receive intramuscular DMPA (DMPA IM) injections from a provider. This information, along with data that measure the relative costs of these two approaches, will be analyzed to establish the effectiveness and cost-effectiveness of self-injected Sayana Press compared to provider-administered DMPA IM.

#### Provider and youth acceptability: Uganda

A 2015 acceptability study in Uganda's Gulu district assessed the interest of younger women in injectable contraception and in self-injection specifically, including perceived benefits and barriers. The study also explored family planning providers' attitudes regarding injectable contraception for young women and self-injection for women of all ages. Analysis is ongoing and results are forthcoming in early 2016. The study involved no administration of product.

### REFERENCES

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