

# ADVANCING PARTNERS & COMMUNITIES SAYANA® PRESS EVALUATION



## BACKGROUND

Injectable contraceptives are among the most popular family planning options. They are safe, effective and discreet, but in many countries not widely available outside clinic settings. Women in rural and remote communities often travel long distances to reach clinics that offer injectable contraceptives.

Sayana® Press is a lower-dose formula and presentation of the popular injectable contraceptive, Depo-Provera®, and provides three months of safe, effective pregnancy prevention with a single injection. It is easy to transport, and easy to use with minimal training—ideal for community-based health workers and potentially for women themselves to administer.

The Malawi Ministry of Health and USAID/Malawi requested that FHI 360, through USAID's Advancing Partners & Communities (APC) project, assess home and self-injection of Sayana® Press to inform their decision making for its procurement and distribution through the national health system in Malawi.

## STUDY DESCRIPTION

A one-year, randomized clinical trial with 734 women who opt into the study after seeking family planning services at Malawi Ministry of Health clinics and who are at least 18 years old. Women will receive, at random, either Sayana® Press from providers including community health workers, or training on how to self-inject Sayana® Press and the opportunity to self-inject at home. Quarterly visits are conducted after each reinjection date to assess continuation rates, acceptability, and adverse events. Pregnancy will be assessed at the last visit. In-depth interviews will be conducted with a random sample of participants in the self-injection group to understand participants' strategies for remembering when to reinject, adherence to the injection procedures, safe injection practices and storage and waste disposal procedures. FHI 360 will also conduct interviews with a random sample of family planning providers to describe their techniques and recommendations for training and supporting women to self-inject Sayana® Press.



The primary objective is to compare continuation rates between women who self-inject Sayana® Press and women who receive the Sayana® Press injection from a provider.

The study will also:

- ▶ Compare reported side effects between the two study groups
- ▶ Compare pregnancy rates between the two study groups
- ▶ Describe experiences of women who self-inject Sayana® Press
- ▶ Describe experiences and recommendations of family planning providers who train women to self-inject Sayana® Press

Findings from this study will inform decision making for procurement and distribution of Sayana® Press while also informing and refining self-injection training materials, messaging for clients and providers and scale-up. Additionally, the study findings may lead to increased access to family planning methods for women of reproductive age.

A 12-month open-label randomized controlled trial to evaluate Sayana® Press suitability for at home subcutaneous self-injection procedures in adult women

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