Depot medroxyprogesterone acetate (Depo-Provera®; DMPA) is a widely used injectable contraceptive given by the intramuscular (IM) route. A subcutaneous formulation has been developed by Pfizer and is marketed in the United States, Europe and a number of other countries globally in a preloaded glass syringe under that trade name Sayana® or Depo-SubQ. Through the collaborative efforts of PATH, Becton Dickenson and Pfizer, this subcutaneous DMPA has been formulated in the Uniject, which is expected to be more appropriate for low resource settings. The Uniject is a prefilled, auto-disabled injection system that was developed to meet persistent logistics, safety and cost-effectiveness challenges posed by widespread distribution of vaccines and other injectable medications in low-resource settings.

The addition of this method is anticipated to aid in improving provision of family planning services in low-resource settings. This outcome hinges on the method being affordable and acceptable to in-country decision makers, family planning (FP) providers, and clients.

This study will assess acceptability of Depo-subQ in Uniject among family planning providers and clients, and offer recommendations for the introduction of this method. This study will be conducted in two countries in Sub-Saharan Africa: Uganda and Senegal. The Uganda Ministry of Health invited FHI 360, through its PROGRESS project, to undertake this study, which is funded by the United States Agency for International Development (USAID).

The primary objectives are:
1) Measure the acceptability of Depo-subQ in Uniject among DMPA IM family planning clients;
2) Measure the acceptability of Depo-subQ in Uniject among family planning providers (both clinic-based and CHWs);
3) Assess family planning providers’ (clinic-based and CHWs) training materials.

The primary endpoints are:
1) The percent of participants who declare they would select Depo-subQ in Uniject for their next injection if this drug product was available
2) Qualitative summary of family planning providers’ (clinic-based and CHWs) acceptability of Depo-subQ in Uniject and preference for administering Depo-subQ in Uniject relative to the typical DMPA intramuscular injection.
3) Feedback on the family planning providers’ (clinic-based and CHWs) training materials that can be used to revise the materials for future trainings.

While the study procedures and instruments will be the same for each country, the type and number of study participants will be tailored to the specific family planning situation in each country. In Uganda the acceptability study will be done in the context of Community Health Workers (CHWs), while in Senegal the study will be conducted both in family planning clinics and in the context of CHWs.

In Uganda, five health facilities (total) were selected from Mubende and Nakasongola Districts, where family planning services are offered and have established CBD programs with CHWs who are already providing DMPA to their clients.

In Uganda, a total of 210 participants will be involved in this study:
- 40 CHWs will be trained to give Depo-subQ in Uniject, asked to complete an evaluation questionnaire at the end of the training, and participate in an interview about their experience providing the method.
- 120 current DMPA clients who seek re-injection of DMPA from CHWs and agree to participate in the acceptability study will be enrolled into the study. Participants will be between the ages 18-40 years, have been using DMPA for at least six months continuously, and received their last injection no more than 13 weeks prior to enrollment in the study.
- Up to 50 current DMPA IM clients who meet the inclusion/exclusion criteria but do not want to receive the injection with Depo-subQ in Uniject, will be invited to complete a short questionnaire.

The total study duration will be approximately eight months in the field: four months for participant recruitment, and three months of follow up for each participant. The results should be available in the second half of 2013.

*Uniject photo credit: PATH/Patrick McKern