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Original research article

Women's satisfaction, use, storage and disposal of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) during a randomized trial☆

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ABSTRACT

Objective: To describe women's experiences with subcutaneous depot medroxyprogesterone acetate (DMPA-SC) to inform scale-up of self-administered DMPA-SC.
Study design: We conducted a 12-month randomized controlled trial in Malawi to measure DMPA-SC continuation rates. A total of 731 women presenting at six Ministry of Health clinics or to community health workers (CHWs) in rural communities were randomized to receive DMPA-SC administered by a provider or be trained to self-inject DMPA-SC. Data collectors contacted women after the reinjection window at 3, 6 and 9 months to collect data on satisfaction and use; self-injectors were also queried about storage and disposal of DMPA-SC. We compared frequencies of injection experiences and satisfaction by study group and over time.
Results: Ninety-two percent of women who self-injected felt it was easy to do the first time. Women in the self-administered group primarily gave themselves the injection versus having someone else inject them; stored DMPA-SC mostly in bags, often in ways to keep the product away from others; and properly disposed of DMPA-SC in pit latrines. Women in both groups used printed calendars to remember when to get/be given their next injection. Both groups reported high satisfaction with DMPA-SC.
Conclusions: Women in low-resource settings can be successfully trained by public sector CHWs and clinic-based providers to self-inject and to appropriately store and dispose of DMPA-SC. DMPA-SC and self-injection are acceptable and feasible in a low-resource setting.
Implications: Self-administered and provider-administrated DMPA-SC should be scaled up, and the lessons learned during our trial should be applied to future scale-up efforts.

1. Introduction

More than 40 million women worldwide use injectable contraceptives, and in many low- and middle-income country (LMIC) settings, injectables account for at least one half of modern contraceptive method use [1]. The subcutaneous formulation of depot medroxyprogesterone acetate (DMPA-SC) in the prefilled Uniject™ injection system, commercially known as Sayana® Press, is gaining popularity among family planning providers and women. For example, providers in Senegal and Uganda preferred DMPA-SC over the intramuscular (IM) formulation; they felt that it was easier and faster to administer the injection, would decrease stockouts (as a prefilled, single injection instead of separate vial and syringe) and would be preferred by women because it was less painful [2,3].

Interest in DMPA-SC self-administration is growing. A randomized trial of self- versus clinically administered DMPA-SC conducted in New York City, USA, showed that 63% of women approached for the study were interested in self-administration, and nearly all eligible women successfully self-injected [4]. All participants who attempted self-injection of DMPA-SC in a recent randomized trial conducted in three Planned Parenthood clinics in Texas and New Jersey could self-inject successfully, and at 12 months, 87% reported that they were satisfied with the method [5]. Research in Uganda and Senegal has also found DMPA-SC self-injection acceptable and feasible [6,7]. Given the advantages and demand for DMPA-SC self-injection, the experiences of self-injectors should be used to inform plans for scale up of the practice.

We conducted an open-label randomized controlled trial in Malawi from September 2015 to February 2017 in Ministry of Health (MOH) family planning clinics and established community-based distribution programs where community health workers (CHWs) provided DMPA-

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IM. The primary objective was to compare the continuation rates of women who self-injected DMPA-SC to those of women who received DMPA-SC from a provider, including CHWs. We found significantly higher continuation rates among women in the self-administration group compared to women in the provider-administered group [8]. Here, we describe the experiences of trial participants to inform development of training and communication materials that will optimize delivery and scale-up of self-administered DMPA-SC. We also make recommendations for scale-up of DMPA-SC in both self- and provider-administrated contexts.

2. Material and methods

The design, eligibility criteria and other trial information are detailed elsewhere [8]. In brief, women ages 18–40 were recruited during their routine family planning visit at six participating MOH clinics or while receiving family planning services from participating CHWs in communities located in Mangochi District, Malawi. In addition to family planning, the CHWs (also called health surveillance assistants) provide maternal health, newborn care, child health and nutrition, tuberculosis, HIV/AIDS, malaria and WASH services to approximately 1000 people and are the lowest level of paid government health workers. They must have completed secondary school and a 12-week training.

A total of 731 women were enrolled into the study — 364 randomized to the self-administered group and 367 to the provider-administered group. One participant was not able to self-inject at enrollment after being trained by the provider and was discontinued at month zero. The other 730 women received DMPA-SC at enrollment. Crossover was not permitted.

Providers instructed women that DMPA-SC injections should be given in the abdomen or thigh every 13 weeks but could be given up to 1 week early and 1 week late (12 to 14 weeks). Women in the self-injection group who successfully self-injected at enrollment were given three doses of DMPA-SC to take home for subsequent self-injections and written instructions to remind them of the injection procedures. Self-injectors could ask the provider to train a trusted person to give them DMPA-SC at home. Providers were trained to instruct women to store DMPA-SC in a safe place out of reach of children or animals, and away from direct sunlight and extreme heat or cold temperatures. Self-injectors were instructed to dispose of used DMPA-SC units by first putting the unit in a puncture-proof container with a lid for safe transport and then throwing the unit out into the pit latrine; alternatively, they could give it to a health worker to be put in a safety box at a clinic.

To mimic normal service delivery procedures, participants in both study arms were not reminded of scheduled reinjections. However, unlike normal service delivery procedures, all participants were given a written note with their three future injection dates (every 13 weeks) and a calendar at enrollment to assist them in remembering when to reinject or return for reinjection. Once the 14-week reinjection window elapsed, all participants were assessed by data collectors every 3 months through their fourth injection at 9 months. Women were deemed to have discontinued DMPA-SC if they had not received an injection within the allowable window. No additional follow-up were scheduled after DMPA-SC discontinuation. Follow-up interviews were conducted in a private setting at a study clinic or at a private location of the woman's preference.

We compared injection experiences and satisfaction by visit and study group. These were measured through variables such as injection site location (back of the upper arm, thigh or abdomen); person administering the injection (e.g., self, provider, family member); methods used to keep track of injections; concerns about DMPA-SC; choice between DMPA-SC self-injection, DMPA-SC provider-administered and provider-administered DMPA-IM; and future willingness to self-inject DMPA-SC.

Self-injectors' experiences were described by tabulating answers to three questions regarding storage, disposal and ease of administration. Specifically, respondents were asked to select from prespecified options to indicate where they disposed of DMPA-SC after the last injection (12 response options including "other," "don't know," and "no response") and to describe ease of administration of the injectable (ranging from 1 for "very easy" to 5 for "very difficult", with options for "don't know" and no response); the question regarding self-injectors' place of choice for storing DMPA-SC was open-ended. Responses for the place of disposal (i.e., "other" responses) and the place of storage were recorded by data collectors in raw text form and were then assigned into common categories by research staff prior to analysis. Frequency of answers to these questions was summarized for each group at 3, 6 and 9 months.

3. Results

Women in both groups had similar demographic characteristics [8]. Over 70% were enrolled by a CHW. The mean age was 27 years. Seventy-five percent had no schooling or did not complete primary school. Over half were of Muslim faith. Almost all were married or had a sexual partner, and 20% said that their husband or partner did not know about their appointment to receive family planning. Almost all had previously given birth and had three living children, on average. Ninety-three percent had previously used contraception, primarily injectables (90%). One quarter did not want additional children.

Of those reporting having received an injection prior to each interview, over 94% of women in the self-administered group administered the injection themselves at the 3-, 6-, and 9-month interviews (Table 1). The other injections were given by the women's husbands/partners, friends, CHWs or family members. Almost all in the provider-administered group reported that a study provider administered their last injection; however, one woman at 3 and 9 months and two women at 6 months reported self-injection, and another reported that her husband/partner injected her at 9 months.

At least 89% of self-injectors injected into the thigh at any reinjection time point; the few injections in the arm and stomach decreased over time. At least 87% of provider-administered injections at any time point were in the back of the upper arm, but some were given in the thigh.

At least 50% of women in both groups used calendars to remember when to get/be given their next injection. Other strategies included appointment/reminder card (given at enrollment), health passport (a patient-held, small paper booklet distributed by MOH which collects an individual's medical information, including contraceptive services provided), memorizing dates, counting days/months, study staff reminders and being reminded by a partner or someone else. Women in the provider-administered group were more likely to report using health passports, whereas self-injectors were more likely to report using calendars, appointment/reminder cards and being reminded by a partner or someone else.

Very few women had any concerns about DMPA-SC. When asked the open-ended question, "What concerns, if any, do you have about your most recent injection?" 94% percent of women at 3 months, 97% at 6 months and 99% at 9 months had no concerns about DMPA-SC, with little differences observed between groups (data not shown). Of the few who expressed concerns, fear of side effects was most common, but this decreased from 4% at 3 months to less than 1% at 9 months. Concerns about DMPA-SC did not appear to differ by group (data not shown).

Willingness to self-administer DMPA-SC was high at 3 months and increased over time (Table 2). Among women in the provider-administered group, 70%, 75% and 78% at 3, 6 and 9 months, respectively, said that they would be moderately or very willing to self-inject in the future. Among self-injectors, 93%, 96% and 98% said that they would be moderately or very willing. When asked, "If you were given the choice between DMPA-SC to be injected at home, DMPA-SC injected by a provider, or DMPA-IM injected by a provider, which would you choose?" at 3 months, over 70% of women, including 50% in the

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