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Original research article

Continuation of subcutaneous or intramuscular injectable contraception when administered by facility-based and community health workers: findings from a prospective cohort study in Burkina Faso and Uganda☆

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ABSTRACT

Objective: The aim of this study was to examine continuation of subcutaneous and intramuscular depot medroxyprogesterone acetate (DMPA-SC and DMPA-IM) when administered by facility-based health workers in Burkina Faso and Village Health Teams (VHTs) in Uganda.

Study design: Participants were family planning clients of health centers (Burkina Faso) or VHTs (Uganda) who had decided to initiate injectable use. Women selected DMPA-SC or DMPA-IM and study staff followed them for up to four injections (providing 12 months of pregnancy protection) to determine contraceptive continuation. Study staff interviewed women at their first injection (baseline), second injection, fourth injection and if they discontinued either product.

Results: Twelve-month continuation in Burkina Faso was 50% for DMPA-SC and 47.4% for DMPA-IM (p=.41, *N*=990, 492 DMPA-SC and 498 DMPA-IM). Twelve-month continuation in Uganda was 77.8% for DMPA-SC and 77.4% for DMPA-IM (p=.85, *N*=1224, 609 DMPA-SC and 615 DMPA-IM). Reasons for discontinuation of DMPA across groups in Burkina Faso included side effects (90/492, 18.3%), being late for injection (68/492, 13.8%) and refusal of spouse (51/492, 10.4%). Reasons for discontinuation in Uganda included being late for injection (65/229, 28.4%), received from non-VHT (50/229, 21.8%) and side effects (34/229, 14.8%). Increased age (adjusted hazard ratio=0.98, p=.01) and partner acceptance of family planning (adjusted hazard ratio=0.48, p<.001) had protective effects against discontinuation in Burkina Faso; we did not find statistically significant variables in Uganda.

Conclusions: There is no difference in 12-month continuation (through four injections) between DMPA-SC and DMPA-IM whether from facility-based health workers in Burkina Faso or VHTs in Uganda. Continuation was higher through community-based distribution in Uganda than health facilities in Burkina Faso.

Implications: The subcutaneous formulation of depot medroxyprogesterone acetate (DMPA-SC) is increasingly available in Family Planning 2020 countries. Use of DMPA-SC does not appear to change continuation relative to traditional intramuscular DMPA. Growing evidence of DMPA-SC's suitability for community-based distribution and self-injection may yield indirect benefits for contraceptive continuation and help reach new users.

1. Introduction

Injectable contraceptives are among the world's most widely used methods for preventing pregnancy, offering women safe and effective protection, convenience and privacy [1]. Depot medroxyprogesterone acetate (DMPA) is the most commonly used injectable contraceptive; health care providers customarily administer the drug intramuscularly

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(DMPA-IM; brand name: Depo-Provera®, by Pfizer Inc.). However, a new, lower-dose, subcutaneous version of DMPA (DMPA-SC) is increasingly available [2]. Countries in Europe and several Family Planning 2020 (FP2020) countries are currently introducing DMPA-SC. Sayana® Press, packaged in the BD Uniject™ injection system which combines the needle and drug reservoir in a single device, is the branded DMPA-SC product available to FP2020 countries. Because of the simplified injection system, a wide range of health workers — including community health workers (CHWs) — can readily administer Sayana Press to clients, and women can administer it themselves through self-injection [3–6].

Burkina Faso and Uganda are among several countries that have recently introduced DMPA-SC. The contraceptive prevalence rate in Burkina Faso is low (around 15% of women of reproductive age are using contraceptive methods) and has been slow to increase [7]. Of the women using modern contraception, 32% use injectables [8]. The total fertility rate remains high with important disparities between rural and urban areas (respectively, 6.7 children per woman vs. 3.9 children per woman), and the maternal mortality rate is among the highest in the world (341 per 100,000 alive newborns) [7]. In order to improve reproductive health outcomes in the country, the government set the status of women as a priority intervention in the national health policy and, in 2013, adopted a plan for continued repositioning of family planning. Sayana Press received regulatory approval in 2013, and health facilities introduced it across four regions [9]. In 2016, the introduction moved to national scale-up.

Contraceptive use is higher in Uganda (30% prevalence), with injectables being the most commonly used method among married and unmarried women [10]. In response to WHO task sharing guidance, the Ministry of Health authorized CHWs called Village Health Teams (VHTs) to provide family planning products, including DMPA injections, to women in their communities in 2013. Following this agreement and national regulatory approval of Sayana Press, and building on the Ugandan government's goal to expand contraceptive access into rural communities, the Ministry of Health introduced VHT-delivered DMPA-SC in 28 districts in September 2014. Programmatic results (Fredrick Mubiru, written communication, April 2018) have shown that VHTs can effectively administer the injectables with minimal challenges and that uptake of injectables was 11% higher in areas where community-based distribution occurred compared to areas where only facility-based administration was available. Currently, national scale-up of DMPA-SC is under way. Program monitoring data from Uganda's introduction found that health workers administered 29% of DMPA-SC doses to new users of family planning, thereby helping to address unmet need [11].

Addressing unmet need for family planning requires supporting women to continue using contraception for as long as they wish to do so, in addition to reaching new users of contraception [12]. Method-related concerns, primarily side effects or myths and rumors, are a predominant reason for discontinuation, especially among those with unmet need for contraception [13]. The two studies described in this article intended to explore whether DMPA-SC could help to address unmet need by reducing discontinuation of injectable contraception relative to DMPA-IM. PATH and partners conducted two contraceptive continuation studies from December 2015 through April 2017 to determine DMPA-SC and DMPA-IM contraceptive continuation over four injections (approximately 12 months) when each product was delivered by facility-based health workers in Burkina Faso or VHTs in Uganda. These studies therefore present the first comparison of 12-month continuation rates for DMPA-SC and DMPA-IM when administered by health workers and, as a secondary objective, present reasons for discontinuation for each product.

2. Methods

2.1. Study population and design

In Burkina Faso, we conducted the study in four regions (Centre, Centre-Ouest, Boucle du Mouhoun and Hauts-Bassins). Study participants were newly initiating injectable contraceptive users from 10 participating health facilities in each of the 4 regions. Of 40 participating facilities, 31 were Centres de Santé et de Promotion Sociale, the most peripheral level of medical care available, serving the most remote areas of Burkina Faso and covering a population of 8000 to 15,000. Seven facilities in the study were nongovernmental organization (NGO) family planning clinics administered by either Marie Stopes Burkina Faso or L'Association Burkinabè pour le Bien-Être Familial and located in the larger cities of Ouagadougou, Bobo Dioulasso and Koudougou. The remaining two study sites were larger medical centers.

In Uganda, we implemented the study through VHTs (and their associated government health center or NGO) in six districts (Busia, Mubende, Gulu, Mayuge, Kayunga and Oyam). A total of 27 health facilities participated (one NGO facility; the remaining, government facilities), with the affiliated VHTs recruiting community-based clients who were newly initiating injectable contraception into either the DMPA-SC or DMPA-IM group.

In both study settings, we carried out a prospective cohort study. Women seeking injectable contraception at a participating site self-selected DMPA-SC or DMPA-IM. All health workers involved in the study counseled women on both injectables and provided DMPA-SC or DMPA-IM based on the client's preference; study staff provided additional training and supervision to minimize the potential for provider bias. After giving the injectable contraceptive to the woman, the health worker asked her interest in participating in the study using a recruitment script and eligibility checklist. A woman was eligible if she was 18 to 49 years old (15 to 49 in Uganda), had no contraindications to DMPA, was newly initiating the injectable at the time of enrollment (either a new user of injectables or a woman who had used injectables in the past but had stopped), planned to reside in the area for the 12 months, expressed a desire to prevent pregnancy for at least 12 months and provided informed consent. Study staff noted the injection schedule for each woman so that research assistants could plan to return to interview the women at specific time points. Research assistants then followed up with eligible women who had indicated a willingness to participate, explained the study further, and enrolled them as a DMPA-SC or DMPA-IM user in the study if they agreed to participate. Enrollment in both studies began in December 2015 and continued through April 2016.

Research assistants followed participants for up to four injections (providing approximately 12 months of pregnancy protection), concluding in April 2017. We describe more information on follow-up procedures in Section 2.4.

2.2. Ethics approvals

The Ministry of Health Comité d'Ethique pour la Recherche en Santé approved the Burkina Faso study on October 7, 2015. The Higher Degrees, Research and Ethics Committee of Makerere University College of Health Sciences School of Public Health and the Uganda National Council for Science and Technology approved the Uganda study on November 2, 2015.

2.3. Sample size

We calculated sample sizes with the intent to observe whether or not there was a significant difference in 12-month injectable continuation use between DMPA-IM and DMPA-SC users. The target sample size for the Burkina Faso study (483 women per group) assumes a statistical power of 90%, a significance level of .05 and a 10-percentage-point difference in continuation rates between DMPA-IM users (an estimated 72% [7]) and those receiving DMPA-SC from a facility-based health worker. We used a 20% loss to follow-up rate.

The target sample size for the Uganda study (604 women per group) assumes a statistical power of 87%, a significance level of .05 and a 10-percentage-point difference in continuation rates between DMPA-IM users (54% continuation in Uganda, based on 2011 Demographic and

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