Contraception

Contraception 89 (2014) 361 – 367

Original research article

Observational study of the acceptability of Sayana® Press among intramuscular DMPA users in Uganda and Senegal☆

Holly M. Burke[a,*], Monique P. Mueller[a], Brian Perry[a], Catherine Packer[a], Leonard Bufumbo[b], Daouda Mbengue[c], Ibrahima Mall[c], Bocar Mamadou Daff[d], Anthony K. Mbonye[e]

[a]FHI 360, Durham, NC, USA
[b]FHI 360, Kampala, Uganda
[c]Centre de Formation et de Recherche en Santé de la Reproduction (CEFOREP), Senegal
[d]Ministry of Health and Social Action, Senegal
[e]Ministry of Health, Uganda

Received 14 September 2013; revised 17 January 2014; accepted 25 January 2014

Abstract

Background: Sayana® Press (SP), a subcutaneous formulation of depot medroxyprogesterone acetate (DMPA) in Uniject™, has potential to be a valuable innovation in family planning (FP) because it may overcome logistic and safety challenges in delivering intramuscular DMPA (DMPA IM). However, SP's acceptability is unknown. We measured acceptability of SP among DMPA IM users.

Study design: This open-label observational study was conducted in clinics in three districts in Senegal and community-based distribution services in two districts in Uganda. Experienced DMPA IM users were offered SP by community health workers (CHWs) or clinic-based providers. SP decliners were asked to discuss their reasons. Those who received SP were interviewed pre- and postinjection and 3 months later, when they were asked if they would select SP over DMPA IM if it were available.

Results: One hundred twenty women in Uganda and 242 in Senegal received SP (117 and 240 were followed up, respectively). Nine Ugandan and seven Senegalese SP decliners were interviewed. Three months after receiving SP, 84% [95% confidence interval (CI)=75%–93%] of Ugandan participants and 80% (95% CI=74%–87%) of Senegalese participants said they would select SP over DMPA IM. Main reasons for selecting SP were fewer side effects, liking the method, fast administration, less pain and method effectiveness. Thirty-four adverse events were reported but were not serious. No pregnancies were reported.

Conclusion: Current DMPA IM users in Senegal and Uganda accepted SP, and most preferred SP over DMPA IM. SP can be safely introduced into FP programs and administered by trained CHWs, with expectation of client uptake.

Implications: We found SP acceptable and safe in diverse settings among current intramuscular DMPA users, including those who received SP from CHWs. This provides evidence that SP would be used and could therefore reduce unmet family planning needs if introduced into family planning programs.

Keywords: Depot medroxyprogesterone acetate; Subcutaneous injection; Contraception; Community health worker

1. Introduction

Depot medroxyprogesterone acetate 150 mg/mL (DMPA; Depo-Provera®) is a widely used injectable contraceptive given intramuscularly (DMPA IM). Sayana® Press (SP) is a lower-dose subcutaneous (SC) formulation (104 mg/0.65 mL) of DMPA delivered in Uniject™, a prefilled, autodisabled injection system developed to meet logistical and safety challenges in distributing injectable medications in low-resource settings.

Acceptability studies using Uniject with other drugs found that most users preferred the Uniject over disposable or reusable syringes [1–3]. Clinical trials of subcutaneous DMPA administered via syringe (DMPA-SC), not Uniject, demonstrated safety, efficacy, user satisfaction and immediacy of

☆ Registration number: The trial was registered on Clinicaltrials.gov under the FHI 360 Protocol Record NCT01667276.

* Corresponding author. Social and Behavioral Health Sciences, 359 Blackwell Street, Suite 200, Durham, NC 27701, USA. Tel.: +1 919 544 7040x11469.

E-mail address: hburke@fhi360.org (H.M. Burke).

0010-7824/$ – see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.contraception.2014.01.022

onset equivalent to DMPA IM [4,5]. Adverse events (AEs) were similar other than more injection site reactions in the DMPA-SC group, although all were mild to moderate [5]. SP (with Uniject) administered in the abdomen and thigh provides comparable blood levels of medroxyprogesterone acetate (MPA) and similar safety and tolerability as syringe [6]. DMPA-SC injection in the upper arm, a site likely to be preferred among clients in developing countries, provided sufficient MPA levels for contraceptive protection for 3 months [7]. However, SP's acceptability is unknown.

Injectables are the most common contraceptive in Uganda and Senegal among currently married women [8,9]. Unmet need for family planning is high, 34% of currently married women in Uganda and 29% in Senegal, with the greatest need in rural areas. However, like many countries, Uganda and Senegal suffer from a shortage of health workers, especially in rural areas. To address this situation, lay community health workers (CHWs) have successfully been trained to provide contraceptives and, in Uganda, to administer DMPA IM [10,11]. However, some continue to have concerns about CHWs' ability to safely administer injectable contraceptives.

SP's prefilled, SC design could increase CHW provision of injectables and reduce unmet need for family planning. However, the ultimate success of SP hinges on acceptability. The primary objective of this study was to measure acceptability of SP among DMPA IM users in Uganda and Senegal; a secondary objective was to assess safety.

2. Materials and methods

This open-label observational study was conducted in Ministry of Health family planning clinics in three districts in Senegal and within community-based distribution services in two districts in Uganda. Study providers had at least 6 months' experience providing contraceptives and were literate. Ugandan providers included 35 CHWs with previous experience providing DMPA IM in nonclinic settings. Senegalese providers included 20 clinic-based providers (nurses and midwives) with DMPA IM experience and 32 CHWs with limited to no DMPA IM experience. Ugandan providers recruited clients within their communities, whereas Senegalese providers recruited in study clinics.

The planned enrollment was 360 clients seeking reinjection with DMPA IM. Up to 100 eligible women who declined SP and agreed to discuss their reasons could have been interviewed.

Sample size was based on achieving a desired precision for estimating the primary endpoint. From other Uniject studies, we anticipated that a high proportion of clients would choose SP. Assuming that 80% of current DMPA IM clients would select SP and a 3% intraclass correlation among clients clustered within provider, a sample of 120 clients in Uganda would give a precision of 7.5 percentage points around the point estimate [e.g., 95% confidence interval (CI)=72.5%–87.5%]. Under similar assumptions, 240 clients in Senegal (120 to clinic-based providers and 120 to CHWs) would give a precision of 5.5 percentage points.

Providers were trained in Good Clinical Practice, human research ethics, recruitment and consent processes, and to counsel on and administer SP using materials developed for this study [12]. Participants were told that SP is not available in their country yet; SP is injected under the skin with a short needle, instead of into muscle like DMPA IM; SP contains less medicine than DMPA IM; injections under the skin require less medicine than injections into the muscle; SP is delivered in the Uniject injection system which is prefilled and can only be used one time; SP provides the same safety and effectiveness at preventing pregnancy as DMPA IM; SP provides 3 months of pregnancy prevention like DMPA IM; SP has similar side effects to DMPA IM; and there is a small chance of skin reaction at the SP injection site. Senegalese participants were also told if they receive SP from a CHW that this person may not have as much practice giving injections as their regular provider. All Uganda CHWs had previous experience providing DMPA IM to clients.

Providers assessed participants' eligibility. Women were eligible if they were aged 18–40, had self-reported good health, sought reinjection of DMPA IM, used DMPA IM continuously during the previous 6 months, received the most recent injection no more than 15 weeks prior to enrollment and from a Ugandan study provider or at a Senegal study clinic, were willing to adhere to study requirements and provided informed consent. Clients were excluded if they planned to become pregnant in the next 3 months; were less than 6 weeks postpartum and breastfeeding; had contraindications to continuing DMPA IM, including current pregnancy; using aminoglutethimide (Cytadren); or had a known MPA sensitivity.

Eligible women received a single injection of SP in their choice of the upper arm, anterior thigh or abdominal wall. Structured questionnaires were administered preinjection, postinjection and at 3 months. Participant characteristics (e.g., demographics, contraceptive history, perceptions of DMPA IM and SP) were also collected. Another structured questionnaire was administered to consenting eligible women who chose to continue using DMPA IM rather than switch to SP (SP decliners). All interviews were conducted by trained staff other than SP providers to minimize social desirability bias. Responses were recorded on personal digital assistants. AEs and pregnancies, if any, were followed by the providers throughout the 3-month period and recorded on standard clinical data collection forms.

The planned primary endpoint was the percentage of participants (with 95% CI) who at 3 months after receiving the SP injection would choose SP (vs. any other response) if, hypothetically, both SP and DMPA IM were available at their next family planning appointment.

All analyses were adjusted for clustering of clients within provider and were conducted separately by country. Missing data (which were minimal) were treated as missing

at random. Primary endpoint CIs were Wald CI for proportions (SAS System PROC SURVEYFREQ) [13]. Change over time in this percentage (immediately post-injection versus 3 months postinjection) was also evaluated using a generalized linear mixed model with binary outcome and logit link, with random effects to account for repeated measures across participants and clustering of participants within providers.

To help inform future programs, differences in baseline characteristics of women who preferred versus did not prefer SP at 3 months were explored using χ^2 (categorical variables) and univariate regression (continuous variables). The p values in this underpowered, hypothesis-generating work were not adjusted for multiple analyses.

Safety, the secondary endpoint, was evaluated by the number of participants reporting AEs coded using MedDRA version 15.1.

The study received ethical approval from FHI 360's Protection of Human Subjects Committee; PATH's Research Ethics Committee; Ugandan National Council for Science and Technology; and Comité National d'Éthique pour la Recherche en Santé, Senegal. We obtained approval from the Ugandan National Drug Authority and Direction des Pharmacies et des Laboratoires, Senegal, to import the study product, which was donated by Pfizer. Pfizer also reviewed and approved the study.

3. Results

Recruitment began July 2012 (Uganda) and August 2012 (Senegal) and ended November 2012 in both countries. A total of 120 clients in Uganda and 242 in Senegal received SP. Nine of 15 Ugandan and 7 of 10 Senegalese SP decliners were interviewed about their reasons for declining. Five Ugandan (one who had declined SP) and five Senegalese participants were found to be ineligible. One Senegalese client discontinued before receiving SP for reasons unrelated to the study. Follow-up was very high (117 out of 120 in Uganda, 240 out of 242 in Senegal) returning at 3 months. Follow-up ended February 2013 (Uganda) and March 2013 (Senegal).

3.1. Characteristics of participants

The mean age of participants who received SP was 28 in Uganda (n=120) and 30 in Senegal (n=242). More Ugandans had attended school (89% Uganda; 58% Senegal). Sixty-four percent of Ugandans and 88% in Senegal said their husbands/partners approved of family planning, with more Senegalese husbands/partners knowing about the current appointment (40% Uganda; 84% Senegal).

Almost all had given birth. Fifty-nine percent of Ugandans and 39% of Senegalese participants reported that their last

Table 1
Selected baseline characteristics of those who used vs. declined Sayana Press (SP)

	Uganda (n=129)		Senegal (n=247)	
	Users (n=120)	Decliners (n=9)	Users (n=242)	Decliners (n=5[a])
Mean age in years (SD)	27.9 (6.1)	29.6 (6.4)	29.8 (5.9)	31.4 (5.6)
Ever attended school	89.2% (107)	77.8% (7)	57.9% (140)	80.0% (4)
Among those who attended school, highest level completed				
Primary	74.8% (80)	85.7% (6)	73.6% (103)	100% (4)
Secondary	24.3% (26)	14.3% (1)	23.6% (33)	0% (0)
Postsecondary	0.9% (1)	0% (0)	2.9% (4)	0% (0)
Married	80.8% (97)	88.9% (8)	97.1% (235)	100% (5)
Husband/partner's approval of family planning				
Disapproves	29.2% (35)	44.4% (4)	8.7% (21)	20.0% (1)
Approves	64.2% (77)	55.6% (5)	87.6% (212)	80.0% (4)
Don't know	3.3% (4)	0% (0)	2.9% (7)	0% (0)
Missing	3.3% (4)	0% (0)	0.8% (2)	0% (0)
Husband/partner knows that you had family planning appointment				
No	56.7% (68)	55.6% (5)	15.3% (37)	60.0% (3)
Yes	40.0% (48)	44.5% (4)	83.5% (202)	40.0% (2)
Don't know	0% (0)	0% (0)	0.4% (1)	0% (0)
Missing	3.3% (4)	0% (0)	0.8% (2)	0% (0)
Ever given birth	96.7% (116)	88.9% (8)	99.6% (241)	100% (5)
Among those who gave birth, at time of last pregnancy				
Wanted pregnancy then	40.5% (47)	62.5% (5)	60.6% (146)	40.0% (2)
Wanted pregnancy later	26.7% (31)	12.5% (1)	29.5% (71)	60.0% (3)
Did not want to have any (more) children	32.8% (38)	25.0% (2)	7.5% (18)	0% (0)
Don't know	0% (0)	0% (0)	2.1% (5)	0% (0)
Missing	0% (0)	0% (0)	0.4% (1)	0% (0)
Mean months of continuous DMPA IM use (SD)	15.8 (14.8)	12.1 (6.1)	19.1 (15.7)	18.0 (13.4)

[a] Only five of the seven decliners in Senegal had useable data.

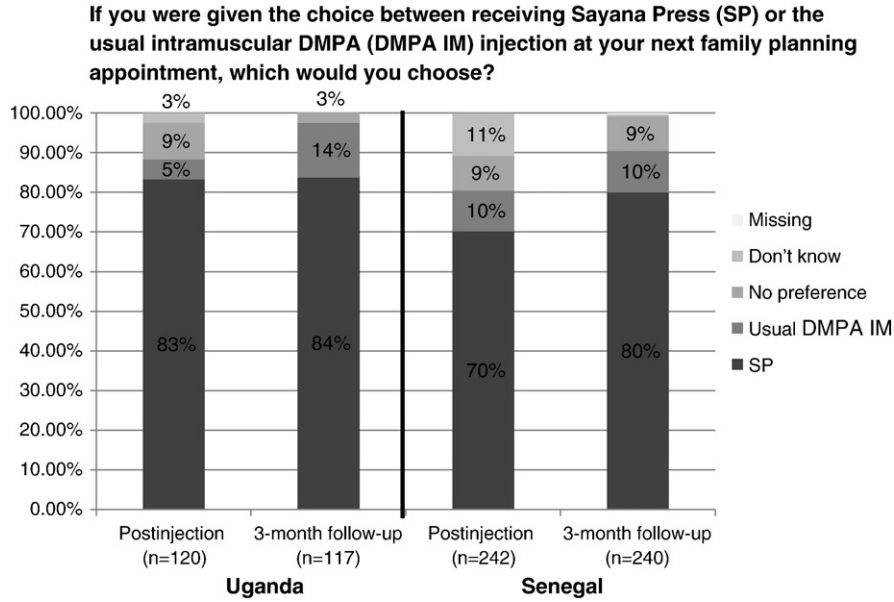

Fig. 1. Client acceptability of Sayana Press (SP).

pregnancy was unintended. Prior to enrollment, participants had been continuously using DMPA IM on average for 16 months in Uganda and 19 months in Senegal. Fourteen percent and 19% of Ugandan and Senegalese participants, respectively, had previously used and discontinued DMPA IM prior to their most recent use of the method (data not shown). Mean time of noncontinuous DMPA IM use was 29 months in Uganda and 27 months in Senegal. Nearly all (90% Uganda; 98% Senegal) chose to receive SP in the upper arm.

The Ugandan SP decliners had similar demographics to those who tried SP (Table 1). In Senegal, a higher proportion of decliners had attended school or reported their husbands/partners did not know about the current appointment. The main reasons for declining were because SP was new or fear of possible side effects (data not shown), though samples are small.

3.2. Primary endpoint: client acceptability

Three months after the SP injection, 84% (95% CI= 75%–93%) of Ugandan participants and 80% (95% CI= 74%–87%) of Senegalese participants said they would select SP if both DMPA IM and SP were available. Preference for SP immediately postinjection was also high (>70%) (Fig. 1 and Table 2). Ugandan participants' main reasons for choosing SP at 3 months included fewer side effects, general statements about liking SP, less pain and beneficial effects on menstruation (regulates or decreases bleeding). Senegalese participants' main reasons were similar but also included fast administration and method effectiveness (data not shown).

In Uganda, preference for SP was uniformly high at postinjection and 3-month follow-up [83% vs. 84%, odds ratio (OR)=1.1, 95% CI=0.5–2.2, p value=.86, two-tailed]. In Senegal, the percentage increased from 70% postinjection to 80% at 3 months (OR=1.7, 95% CI=1.1–2.6, p value=.02, two-tailed).

3.3. Secondary endpoint: safety

A total of 34 AEs—28 in Uganda, 6 in Senegal—were reported by 25 participants (19/117=16% Uganda; 6/240= 3% Senegal). Only one AE (malaria) was serious but unrelated to SP. Ten AEs (nine in Uganda, one in Senegal) were possibly or definitely related to SP but were not serious and only mild or moderate in severity. Three of these (two in Uganda, one in Senegal) were related to skin irritation at the injection site, a known issue with subcutaneous injections, and all resolved without sequelae. The other seven (all in Uganda) are known side effects of DMPA IM (data not shown). No pregnancies were reported.

Table 2
Primary end point: client acceptability of Sayana Press (SP)

If given the choice, would select SP (versus DMPA IM, no preference, don't know)	Uganda		Senegal	
	Percent (*n*/*N*)	95% CI[a]	Percent (*n*/*N*)	95% CI[a]
Postinjection	83% (100/120)	76%–91%	70% (170/242)	64%–77%
3-month follow-up[b]	84% (98/117)	75%–93%	80% (192/240)	74%–87%

[a] Adjusted for clustering of clients within providers.
[b] Primary client acceptability endpoint.

Table 3
Comparison of Sayana Press (SP) and intramuscular DMPA (DMPA IM)[a]: post SP injection

Which injection caused more:	Uganda (n=120)			Senegal (n=242)		
	SP % (n)	DMPA IM % (n)	No difference % (n)	SP % (n)	DMPA IM % (n)	No difference % (n)
Nervousness prior to injection	19.2% (23)	34.2% (41)	46.7% (56)	22.7% (55)	28.9% (70)	47.9% (116)
Pain during injection	14.2% (17)	50.0% (60)	35.0% (42)	17.4% (42)	46.7% (113)	35.5% (86)
Pain after injection	8.3% (10)	44.2% (53)	47.5% (57)	10.8% (26)	45.0% (109)	43.6% (105)
Skin irritation	5.0% (6)	23.3% (28)	69.2% (83)	9.9% (24)	27.3% (66)	62.4% (151)
Soreness	5.0% (6)	19.2% (23)	73.3% (88)	11.6% (28)	44.6% (108)	43.0% (104)

Total percentages below 100% are the result of missing data (n=2) or don't know (n=12) responses.
[a] Referring to most recent DMPA IM injection received 3 months prior to study enrollment.

3.4. Exploratory analyses

Immediately postinjection, participants were asked to compare their experience with SP against their most recent DMPA IM injection 3 months earlier (Table 3). Nearly half in both countries reported no difference in how nervous they felt prior to injection. Approximately half felt DMPA IM was more painful during the injection, while most felt that either pain after the injection was higher with DMPA IM or there was no difference. Many (69% Uganda; 62% Senegal) found no difference in skin irritation. Over 70% of Ugandan participants observed no difference in soreness, but 45% in Senegal reported DMPA IM caused them more soreness and 43% reported no difference.

At 3 months, most (≥76%) reported no pain, irritation or soreness at the injection site, and the majority indicated that side effects had not interfered with their activities or relationships (data not shown). Almost all (97% Uganda; 94% Senegal) planned to continue using injectable contraception. Four Ugandan and 14 Senegalese women planned to discontinue injectable use. The most common reasons included side effects (n=5), desire for pregnancy (n=3), husband/partner disapproval (n=2) and wants a more effective method (n=2).

After receiving SP, participants were asked about their willingness to receive SP at home by a family member or other trusted person, or to self-inject (Table 4). Ugandan participants were more willing than Senegalese participants to receive SP at home (53% vs. 19% moderately or very willing) and to self-inject SP (45% vs. 22% moderately or very willing).

Table 4
Client acceptability of home and self-injection of Sayana Press (SP): post SP injection

Willingness	Uganda (n=120)		Senegal (n=242)	
	Home injection % (n)	Self-injection % (n)	Home injection % (n)	Self-injection % (n)
Not at all	18.3% (22)	26.7% (32)	61.6% (149)	59.1% (143)
Very little	23.3% (28)	26.7% (32)	7.0% (17)	11.6% (28)
Little	5.8% (7)	0.8% (1)	11.2% (27)	7.0% (17)
Moderate	18.3% (22)	8.3% (10)	6.2% (15)	6.2% (15)
Very much	34.2% (41)	36.7% (44)	12.8% (31)	15.3% (37)
Don't know	0.0% (0)	0.8% (1)	1.2% (3)	0.4% (1)
Missing	0.0% (0)	0.0% (0)	0.0% (0)	0.4% (1)

Baseline characteristics between women who did versus did not prefer SP at 3 months were generally similar. Based on review of descriptive statistics of approximately 100 baseline variables, characteristics that may be informative for future programs were selected for statistical testing. These characteristics (Table 5) did not differ significantly except for one nominally statistically significant result in each country: SP preference was associated with no previous experience of side effects from injectables in Uganda (p=.0033, two-tailed) and a longer history of continuous DMPA IM use in Senegal (p=.0037, two-tailed).

4. Discussion

Current DMPA IM clients accepted SP, with a high percentage (≥80%) preferring SP over DMPA IM. Participants' main reasons for this preference included fewer side effects, liking SP, fast administration, less pain and method effectiveness. SP was generally safe and well tolerated in the populations studied. No pregnancies were reported.

Our findings were both consistent and inconsistent with findings from previous studies. Like other Uniject studies, we found that clients preferred delivery via Uniject over standard syringe. However, many participants perceived fewer side effects from SP compared to DMPA IM, though previous safety and effectiveness trials have not demonstrated this difference [4,5]. One possible explanation may be that participants in our study did not report side effects they were accustomed to or which had diminished over time as they had been using DMPA IM for at least 6 months. The participants had also been told that SP is a lower-dose formulation, and this may have influenced their perceptions. A previous trial reported higher rates of injection-site irritation for DMPA-SC compared to DMPA IM [5]. Our study found only three minor AEs related to the injection site which all resolved without sequelae.

A possible explanation for the higher adverse event rate in Uganda compared to Senegal may be shorter travel distances between the Uganda CHWs and their client participants who live in the same community compared to the Senegal study clinics and their participants. This difference may have made it easier for the providers and participants to encounter each other more frequently in

Table 5
Sayana Press (SP) preference at 3 months by selected preinjection (baseline) client characteristics (exploratory)

	Uganda (n=117)		Senegal (n=240)	
	Prefers SP (n=98) % (n)	Does not prefer SP (n=19) % (n)	Prefers SP (n=192) % (n)	Does not prefer SP (n=48) % (n)
District (Uganda/Senegal)				
Nakasongola/Mbour	35.7% (35)	57.9% (11)	33.9% (65)	39.6% (19)
Mubende/Tivaouane	64.3% (63)	42.1% (8)	30.7% (59)	27.1% (13)
Thies	–	–	35.4% (68)	33.3% (16)
Client received SP injection from CHW	100% (98)	100% (19)	47.9% (92)	52.1% (25)
Mean age in years (SD)	28.2 (6.1)	27.3 (5.8)	29.7 (5.8)	30.5 (6.4)
Mean months of continuous DMPA IM use (SD)	15.6 (14.3)	17.6 (18.4)	20.4 (16.4)*	13.9 (10.7)
Ever used method besides injectables	16.3% (16)	10.5% (2)	18.8% (36)	31.3% (15)
Ever experienced side effects from injectables	57.1% (56)*	89.5% (17)	29.7% (57)	39.6% (19)
Experienced side effects at last DMPA IM injection	44.9% (44)	57.9% (11)	20.8% (40)	27.1% (13)

Based on review of descriptive statistics of approximately 100 baseline variables, characteristics that may be informative for future programs were selected for statistical testing. The table includes only participants who completed the 3-month follow-up questionnaire. Results within the full baseline sample do not materially differ.

* $p<.05$, two-tailed, not adjusted for multiple analysis.

Uganda and potentially resulted in a higher rate of reporting minor events by participants.

We measured acceptability from responses regarding a hypothetical situation. A stronger measure would have been to offer an actual choice between DMPA IM and SP after 3 months. We increased the robustness of our design within our constraints by (a) including current DMPA IM clients who could reflect on recent DMPA IM experiences; (b) assessing preferences at both minutes after and 3 months after receiving SP; and (c) while meeting Good Clinical Practice, we maintained most real-world conditions to minimize bias to the primary outcome — acceptability. Our results indicate that most DMPA IM clients preferred SP over DMPA IM at both time periods. The consistency of these findings, along with high retention and therefore no differential dropout, increases our confidence in the results.

Our findings may be generalized only to current DMPA IM users. That said, our study in East and West African contexts, in community-based and clinic-based service delivery settings, and with providers with and without previous DMPA IM experience expands the generalizability of our findings to many settings that could benefit from a new contraceptive added to the method mix.

This study provides evidence that SP can be safely introduced into family planning programs and demonstrated that trained CHWs can safely administer SP. The findings support the feasibility of community-based distribution of SP and thereby increasing women's access to family planning.

From participant responses, we recommend that introduction efforts emphasize that SP can be quickly administered with less pain compared to DMPA IM. As with other DMPA formulations, we recommend that the safety and effectiveness of SP be highlighted.

Almost all participants selected the upper arm as the injection site, which is not included on Pfizer's label. It is unknown whether clients will still prefer SP if injections in the arm are prohibited. We recommend that the arm be approved for the label.

Ugandans were more willing than Senegalese participants to receive SP at home or to self-inject, possibly because Ugandan participants are accustomed to receiving DMPA IM from CHWs, while Senegalese participants receive DMPA IM in clinics from nurses or midwives. Home injection and self-injection of SP are areas for future research.

Opportunities for future research of SP will expand when it is a registered product. Although demonstration of SP acceptability was a critical first step, important questions remain to be answered. Beyond those areas already mentioned, given the anticipated higher cost of SP relative to DMPA IM, which could impede access from the national to individual level, a better understanding of SP's potential to reduce unmet need is essential. Future research on SP should also include new contraceptive users, youth and clients who obtain contraceptives from the private sector. Finally, it will be important to investigate the cost-effectiveness of offering SP and DMPA IM under various scenarios to determine the most efficient and effective way to distribute SP.

Acknowledgment

This work was made possible by the generous support of the American people through the US Agency for International Development (USAID). The contents are the responsibility of FHI 360 and do not necessarily reflect the views of USAID or the US Government. Financial assistance was provided by USAID under the terms of Cooperative Agreement GPO-A-00-08-00001-00, the Program Research for Strengthening Services (PROGRESS) project. FHI 360 collaborated with the Uganda Ministry of Health and Senegal Ministry of Health and Social Action, with additional support from PATH and Pfizer and technical

support from the Bill & Melinda Gates Foundation. Pfizer donated the study product but provided no monetary support; they reviewed the publication for unprotected inventions and were able to provide comments, but authors were under no obligation to incorporate any Pfizer suggestions.

The FHI 360 project team included Dr. Vera Halpern and Dr. David C. Sokal as the medical monitors, Ms. Anja Lendvay and Ms. Sarah Mullins as clinical research managers and monitors, Ms. Lisa Saylor as data manager, Mr. Justin Dash as programmer, Ms. Debra Weiner and Ms. Alissa Berholc as biostatisticians, Mr. Thomas Grey as programmer/analyst and Dr. Lakshmi Venkatakrishnaiah as regulatory liaison. Drs. Jeff Spieler, Laneta Dorflinger, John Stanback, Cindy Geary, Donna McCarraher and Aida Cancel advised on this study. In addition, special acknowledgment goes to the staff supporting this study through the FHI 360 Uganda office, FHI 360 Senegal office and Centre de Formation et de Recherche en Santé de la Reproduction (CEFOREP).

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.contraception.2014.01.022.

References

[1] Bahamondes L, Marchi NM, de Lourdes Cristofoletti M, Nakagava HM, Pellini E, Araujo F, et al. Uniject® as a delivery system for the once-a-month injectable contraceptive Cyclofem® in Brazil. Contraception 1996;53:115–9.

[2] Sutanto A, Suarnawa IM, Nelson CM, Stewart T, Soewarso TI. Home delivery of heat-stable vaccines in Indonesia: outreach immunization with a prefilled, single-use injection device. Bull World Health Organ 1999;77(2):119–26.

[3] Tsu VD, Sutanto A, Vaidya K, Coffey P, Widjaya A. Oxytocin in prefilled Uniject™ injection devices for managing third-stage labor in Indonesia. Int J Gynecol Obstet 2003;83(1):103–11.

[4] Jain J, Jakimiuk AJ, Bode FR, Ross D, Kaunitz AM. Contraceptive efficacy and safety of DMPA-SUBQ. Contraception 2004;70:269–75.

[5] Kaunitz AM, Darney PD, Ross D, Wolter KD, Speroff L. Subcutaneous DMPA vs. intramuscular DMPA: a 2-year randomized study of contraceptive efficacy and bone mineral density. Contraception 2009; 80(7–17):1–2.

[6] Pfizer. A randomized, open label, parallel group study of the pharmacokinetics of medroxyprogesterone acetate in healthy female volunteers following subcutaneous injection with the Uniject ™ delivery system or the currently marketed pre-filled syringe. Pfizer Inc Protocol A6791030; 2010.

[7] Halpern V, Combes SL, Dorflinger LJ, Weiner DH, Archer DF. Pharmacokinetics of subcutaneous depot medroxyprogesterone acetate injected in the upper arm. Contraception 2014;89(1):31–5.

[8] DHS. Uganda demographic and health survey 2011. Kampala, Uganda and Calverton, Maryland: 2012.

[9] DHS. 2010-11 Senegal demographic and health and multiple indicators survey: key findings. Calverton, Maryland: 2012.

[10] WHO, USAID, FHI. Community-based health workers can safely and effectively administer injectable contraceptives: conclusions from a technical consultation. Research Triangle Park, North Carolina: World Health Organization (WHO), United States Agency for International Development (USAID), Family Health International (FHI), 2009.

[11] Stanback J, Mbonye AK, Bekiita M. Contraceptive injections by community health workers in Uganda: a nonrandomized community trial. Bull World Health Organ 2007;85(10):768–73.

[12] Burke HM, Perry B, Packer C, Mueller MP, Bufumbo L, Mbengue D. Training family planning providers to administer Depo-subQ in Uniject (Sayana® Press) — an evaluation. Research Triangle Park, NC: FHI 360; 2013.

[13] SAS statistical software, Version 9.3. Cary, NC: SAS Institute Inc.; 2002–2010.