



Original Research Article

A prospective cohort study to assess the acceptability of Sayana Press among 18–49-year-old women in Nepal



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ABSTRACT

Objective: We compared acceptability and continuation of Sayana Press, a subcutaneous formulation of depot-medroxyprogesterone acetate (DMPA) in a Uniject injection system, to intramuscular (IM) DMPA, among both current users of DMPA-IM and new users in Nepal.

Study Design: We recruited women seeking injectable contraception at 14 public health facilities in Nepal selected for geographic diversity. We enrolled women who self-selected either Sayana Press or DMPA-IM and used structured interviews to obtain baseline demographics and assess satisfaction and continuation rates at 1, 3, and 6 months.

Results: Seven hundred ninety-four women (71%) selected and received Sayana Press, while 318 women (28.6%) selected and received DMPA-IM. One hundred and seventy-eight (48%) women continuing Sayana Press injection reported that they experienced “no possible side effects” compared to 29 (22%) among DMPA-IM selectors during the previous 6 months. The continuation rate of Sayana Press at 6 months was higher than DMPA-IM (Sayana Press 46.5% vs DMPA-IM 34.4%; $p < 0.001$). Selection of Sayana Press method (OR_{adj} : 1.74; 95% confidence interval 1.32–2.3) and approval from husband (OR_{adj} : 1.59; 95% confidence interval 1.21–2.09) were associated with injection continuation.

Conclusion: Sayana Press is acceptable to women in Nepal with the preference for Sayana Press over DMPA-IM (higher proportion chose the method when counseled and given the option, better continuation).

Implications: The potential for self-injection with Sayana Press® may have implications for continuation and opportunity for future research and strategies to roll out this innovative technology must be explored.

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1. Introduction

Contraceptives are highly cost-effective public health investments which could globally prevent 170,000 maternal deaths and around 1.6 million newborn deaths each year [1]. In Nepal, among the currently married women aged 15 to 49, female sterilization is the most used family planning (FP) method (14.7%) followed by injectable contraceptives (8.9%), respectively. Pills and condoms each accounted for 4.6% and 4.2%, while IUDs (1.4%) and implants

(3.3%) continue to have low uptake in the overall picture of contraceptive use mix in the country [2]. While the use of any modern method has plateaued for last 15 years, traditional method use has increased from 4% to 10% between 2006 and 2016 [2]. A follow-up study of married women, who had participated in the Nepal Demographic and Health Survey, aged 15 to 39 revealed several access-related barriers to commodity-based methods, including geographic inaccessibility, limited or inconsistent provider operating hours, and a small number of method types locally available [3].

Innovative, next-generation products like DMPA-SC (depot-medroxyprogesterone acetate-Subcutaneous, brand name Sayana Press) that increase opportunities for provision by lay health care workers or self-care have the potential to dramatically expand FP access and uptake. Sayana Press+ (DMPA-SC) is similar in

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formulation to the intramuscular injectable contraceptive depot-medroxyprogesterone acetate (DMPA-IM) but contains 30% lower dose (104 mg of DMPA-SC vs 150 mg of DMPA-IM) and is administered subcutaneously using prefilled single-use syringe. The method can also be self-injected by women themselves. Sayana Press can be provided in low-resource, non-clinic settings because of its unique method with alternative route of delivery requiring less trained providers and the product being compact, discreet, and easily transportable [4–6], potentially transforming the way in which women can access and receive their preferred method of contraception [7]. Sayana Press is approved by regulatory authorities in more than 40 countries across the world [8]. However, selection of contraceptive methods may be experienced differently by women in Nepal due to women's social status [9].

We conducted a study to assess acceptability and continuation of Sayana Press vs DMPA-IM among women requesting injectable contraception in public health facilities of Nawalpur and Sindhuli districts, Nepal. The primary objective of the study was to assess acceptability of Sayana Press by women in Nepal as a viable option for family planning and continuation of use. The self-injection option is not available in Nepal yet but may offer benefits for continuation and should be studied.

2. Material and methods

2.1. Study design

We conducted a prospective cohort study at 14 public health facilities of Nawalpur and Sindhuli districts of Nepal, selected to represent the diversity of the population in the plainlands and hill areas, to determine the acceptability and continuation of Sayana Press vs DMPA-IM. We collected data from September 2019 through July 2020. We received approval from the Ethics Committee of Nepal Health Research Council and permission from provincial health directorates of Gandaki and Bagmati provinces and local governments. See Supplemental Table 1 for the list of study sites.

2.2. Training of providers

We trained 28 family planning service providers from 14 public health facilities on Sayana Press®, including counseling about the method, potential side effects, correct administration, and waste management. Training also emphasized all other family planning methods to reduce provider bias. In Nepal, there is a regulation limiting the provision of family planning injectables to trained service providers.

We trained 17 field researchers for 5 days on research objectives, research ethics, introduction to contraceptives including Sayana Press, recruitment and follow up process.

2.3. Sampling procedures

A trained health worker provided information on all family planning methods, including the latest addition, “Sayana Press,” and its dose and expected side effects to all women visiting the sampled health facility for FP services. FP clients providing written informed consent to participate in the interviews and follow-ups were enrolled. All women below 18 years or above 49 years of age or who reported not planning to reside in the current place of residence for at least seven months from the date of enrolment were excluded from the study.

After injecting the preferred injectable contraceptive method (Sayana Press or Depo Provera), the health providers administered the FP client screening form to determine study eligibility based on age. The form contained information such as the name and age of the FP client and the type of injection received. The health

providers referred all FP clients between 18 and 49 years who selected and received injectable contraceptives (Sayana Press or Depo Provera) and expressed their willingness to participate in the study for interviews.

2.4. Data collection method

After confirming consent and explaining the nature of the follow-up study, the female interviewers administered a structured questionnaire to those meeting eligibility criteria. We conducted a private face-to-face interview in the local Nepali language. The questionnaire included age, education and caste/ethnicity of women, mode of transportation used to visit a health facility, previous and current use of FP methods, duration of counseling, types of contraceptive methods included in counseling, reasons for accepting the method, and whether the chosen method would be recommended to others.

We conducted the 3 months and 6 months follow-up interviews at the health facility during the woman's visit for her next injection. In the follow-up questionnaire, we assessed for continuity of the selected method along with the 6-month follow-up. We assessed the level of satisfaction, intention to continue the method, and preference to self-administer the Sayana Press. Women who returned for their injections at 3 months and 6 months postinjection completed a survey at the health facility during these visits. Women who did not return for a repeat injection at >13 weeks after the previous injection completed a phone or home-based survey. Injectable users switching to other methods were interviewed at the health facility when they sought advice on another method. We validated the numbers with facility logbooks.

2.5. Sample size

We recruited injectable contraceptive method (Sayana Press or Depo Provera) selectors during the initial three months of implementation. The total sample size required for the study was 1114 women, assuming a statistical power of 80%, a significance level of 0.05 and 10-percentage-point difference in continuation rates between Sayana Press and DMPA-IM users. We collected information using android smart tablets. Data were uploaded to the server every day.

The primary outcome was to assess acceptability of the method based on individual adherence to the method, self-reported individual perception, and experiences at 6 months among those continuing with injection. The secondary outcome was continuity of injection by women who selected either a Sayana Press or DMPA-IM.

2.6. Statistical analysis

We analyzed data using R 3.5.3. [10]. Sociodemographic and basic characteristics of women choosing either Sayana Press or DMPA-IM were compared and tested using χ^2 method and Fisher's exact test for proportions. A p -value of <0.05 was considered significant. We expected a 30% loss to follow up rate.

Sayana Press or DMPA-IM selectors continuing their injectable method was “continuers” users. Those switching to other methods or not appearing for repeat injection at >13 weeks interval was considered “discontinuers”.

To identify predictors of injection continuation, we used a logistic regression model including continuation of injectable method at 6 months as the dependent variable and the following characteristics as independent variables: age, site, education, distance to facility, method type and approval from husband/partners to use FP services. Any independent variable with an adjusted odds ratio

Table 1
Baseline data comparing sociodemographic variables and basic characteristics of women selecting a Sayana Press® or DMPA IM in Nepal, 2019.

	Sayana Press® N = 794	DMPA-IM N = 318	p value ^a
Age group-			0.25
<25-year-old	236 (29.7%)	83 (26.1%)	
≥25-year-old	558 (70.3%)	235 (73.9%)	
Highest level of school completed-			<0.001
No school	155 (19.5%)	97 (30.5%)	
Primary (1st-5th grade)	214 (33.5%)	94 (42.5%)	
Secondary (6th-10th grade)	322 (50.4%)	101 (45.7%)	
College or higher (11th grade and higher)	103 (16.1%)	26 (11.8%)	
Distance to the health facility-			0.01
<15 min	327 (41.2%)	115 (36.2%)	
15 min–1 h	345 (43.5%)	130 (40.9%)	
>1 h	122 (15.4%)	73 (23%)	
Time spent by provider counseling-			0.002
<5 mins	348 (43.8%)	105 (33%)	
5–15 min	342 (43.1%)	153 (48.1%)	
>15 min	104 (13.1%)	60 (18.9%)	
Side effects experienced from a previous contraceptive method			0.002
Yes	347 (43.7%)	123 (38.7%)	
No	352 (44.3%)	174 (54.7%)	
Did not respond	95 (12%)	21 (6.6%)	
Someone had used the method previously-			< 0.001
sister	22 (2.8%)	81 (25.5%)	
friends	29 (3.7%)	22 (6.9%)	
other FM	6 (0.8%)	18 (5.7%)	
neighbors	29 (3.7%)	25 (7.9%)	
Did not respond	708 (89.2%)	172 (54.1%)	
Approval required from Husband/partners to use FP services			0.31
Yes	551 (69.4%)	231 (72.6%)	
No	243 (30.6%)	87 (27.4%)	

^a Pearson χ^2 , unless any cell has <5 participants, in which case Fisher's Exact Test was used.

statistically significant ($p < 0.05$) at 95% confidence intervals (95% CI) were considered a predictive factor for injection continuation.

3. Results

Between September and December 2019, 1184 FP clients received an injectable contraceptive method (Sayana Press or Depo Provera). We recruited only 1112 injectable contraceptive method (Sayana Press or Depo Provera) selectors who met the eligibility criteria. We excluded the remaining 54 women (4.5%) who did not plan to reside in the area and 18 women (1.5%) who did not meet the age criteria. Of the 1112 women, 794 women (71.4%) selected and received Sayana Press, while 318 women (28.6%) selected and received DMPA-IM (Table 1). There were differences observed in sociodemographic and basic characteristics among Sayana Press and DMPA-IM selectors. More than two-thirds of both Sayana Press and DMPA-IM selectors stated that they require husband/partners approval to use the selected FP method.

Of 794 women selecting Sayana Press, 569 women had switched from DMPA-IM, 95 were new users, and 130 had switched from other methods (69 pills, 27 condoms, 18 withdrawal, 5 implant, 3 IUCD, and 1 emergency contraception). Similarly, out of 318 women selecting DMPA-IM, 281 were continuous users of DMPA-IM, 21 were new users, and the remaining 16 had switched from other methods. Six hundred and sixty-eight (60%) women travelled on foot to get to the closest health facility for either Sayana Press or DMPA-IM.

Table 2 shows the experiences of women selecting either a Sayana Press or DMPA-IM at the health facility and their preferred product attributes at 6 months. Compared to DMPA-IM, close to half of FP clients selecting Sayana Press experienced “no possible side effects” during the previous 6 months. A 1-year increase in

age was associated with 5% increase in the odds of experiencing “no possible side effects” (OR_{adj}: 1.05; 95% CI: 1.02–1.09) (Table not shown).

Table 3 displays the reasons stated by injectable contraceptive method (Sayana Press or Depo Provera) selectors for discontinuation of Sayana Press or DMPA-IM at 3 months and 6 months follow-up at home or phone interviews, respectively. The most common reason for Sayana Press discontinuation was “could not access due to COVID-19 lockdown” and “husband away from home”. For DMPA-IM, the main reasons for discontinuation were “decided on a different method” and “could not access due to COVID-19 lockdown”. Two hundred twenty-seven women selecting either a Sayana Press or DMPA-IM were unable to receive their third injection due to lockdown. Of those, 214 (166 Sayana Press and 48 DMPA-IM) users stated that they would continue the method in the post lockdown period. The remaining 13 chose not to continue their current method.

The continuation rate of injectable contraceptive method (Sayana Press or Depo Provera) users selecting a DMPA-IM or Sayana Press by health facilities are presented as supplementary information S1 Table 1. In all the 14 public health facilities, the number of women seeking Sayana Press was higher than DMPA-IM. Compared to all other facilities, Maternal and Child Health (MCH) clinic located within the premises of district hospital had the highest proportion of injectable contraceptive method (Sayana Press or Depo Provera) users. There was a difference with a higher continuation rate of Sayana Press than DMPA-IM for the second injection (Sayana Press 72.9% and DMPA-IM 54.4%, $p < 0.001$) and third injection (Sayana Press 46.4% and DMPA-IM 34.5%, $p < 0.001$). At 6 months, older and better educated women were more likely to state a preference for self-administration.

Table 2Experiences of women selecting a Sayana Press® or DMPA IM after the 3rd injection at the health facility at 6 months in Nepal, 2020.

	Sayana Press (n = 369)	DMPA-IM (n = 110)
No possible side effects	178 (48.2%)	29 (26.4%)
Husband/partner likes method	17 (4.6)	8 (7.3%)
More widely available	10 (2.7)	39 (35.5%)
Small and short needle	6 (1.6)	3 (2.7%)
Contains lower doses than depo	9 (2.4)	0
Effective & Reliable in preventing pregnancy	0	4 (3.6%)
Do not know/Refused	149 (40.5)	27 (24.5%)
Total	369	110

Table 3

Reasons for discontinuation of Sayana Press® or DMPA IM stated by women at the 3- or 6-month follow-up at home or phone interviews in Nepal, 2020.

Reasons for discontinuation	at the 3- or 6-month follow-up	
	Sayana Press	DMPA-IM
Unpleasant side effects	13 (3%)	11 (5.2%)
Decided on a different method	63 (14.8%)	75 (36%)
Husband/partner did not want me to get another injection	13 (3%)	8 (3.8%)
First injection was too painful	1 (0.2%)	4 (1.9%)
Trying to get pregnant	21 (4.9%)	2 (0.9%)
Became pregnant (method failure)	0	0
Health facility too far for the preferred method	14 (3.2%)	2 (0.9%)
Preferred method not available	5 (1.1%)	0
Provider was not available at the time of visit	2 (0.4%)	0
Irregular menstruation	3 (0.7%)	7 (3.3%)
Husband away	91 (21.4%)	35 (16.8%)
Myself away from home	14 (3.2%)	3 (1.4%)
Pain at the injection site	3 (0.7%)	0
Planning to use permanent method	3 (0.7%)	3 (1.4%)
Could not access due to lockdown	174 (40.9%)	53 (25.4%)
Other (death of husband, health problem)	5 (1.1%)	5 (2.4%)
Total	425	208

Table 4

Adjusted odds ratio of socioeconomic variables and FP method use to predict injection continuation with Sayana Press® or DMPA IM over 6 months follow-up in Nepal (2020) using logistic regression.

	Adjusted OR (95% CI)	p-value
Injectable:	Ref	<0.001
Depo	1.74 (1.32, 2.3)	
Sayana Press		
Age in years cont.	1.02 (1, 1.04)	0.04
Location:		0.98
Rural Municipality	Ref	
Urban Municipality	1.0 (0.7, 1.3)	
Education		0.83
No School	Ref	
Primary (1–5th grade)	0.92 (0.64, 1.31)	
Secondary (6–10th grade)	0.84 (0.58, 1.22)	
College or higher (11+)	0.91 (0.56, 1.49)	
Distance to health facility		0.58
<15 mins	Ref	
15 min–1 h	0.94 (0.72, 1.24)	
h >1 h	0.82 (0.57, 1.19)	
Approval from husband/partner to use FP services		<0.001
No	Ref	
Yes	1.59 (1.21, 2.09)	

DMPA IM, depot-medroxyprogesterone acetate-intramuscular; FP, family planning.

As reported in Table 4, selection of Sayana Press method (OR_{adj} 1.74; 95% CI 1.32–2.3) and approval from husband (OR_{adj} 1.59; 95% CI 1.21–2.09) was associated with injection continuation. All other variables, age, location, education, distance to health facility did not result in statistically significant impact on injection continuation.

4. Discussion

Over two thirds of women selected Sayana Press rather than DMPA-IM when the option to select the preferred method was made available to them. Close to half of Sayana Press selectors reported having experienced "no possible side effects" compared to

less than a quarter among DMPA-IM in the previous 6 months. The continuation of Sayana Press at 6 months was higher than DMPA-IM.

The findings in this study are like previous acceptability studies of Sayana Press and DMPA-IM with preference of Sayana Press over DMPA-IM [11–13]. A large number of referrals tell us that women's contraceptive decision is socially informed. In Nepal, among women, there is a tendency to trust the experiences of people close to them; they typically do not trust information received from people who are not close to family members or neighbors. Continuation of injection at 6 months was higher among Sayana Press selectors, however this study also highlighted certain form of status quo regarding method approval required from husband or partners for continuation. The information on husband or partners approval of contraception use was acquired through the injectable contraceptive method (Sayana Press or Depo Provera) users. Therefore, further study is required to directly assess men's attitude toward contraceptive use. We found that close to half of the women selecting Sayana Press reported experiencing no possible side effects compared to a quarter among DMPA-IM selectors. In the present study, two thirds of women selecting Sayana Press had previously used DMPA-IM, therefore it can be speculated that Sayana Press method selectors may have compared their current experiences with previous DMPA-IM injection.

Contrary to a study from Malawi [14], Sayana Press selectors opting for future self-injection option was higher in Nepal among women with a college or higher education. Research on the determinants of contraceptive choice in Nepal has also shown that an additional year of schooling increased the probability of choosing an injectable by 0.7 percentage points for women in Nepal [9]. Likewise, other research has also shown that higher education helped to change attitudes and practices towards family planning [15].

The major reasons for Sayana Press injection discontinuation at 3 months and 6 months were husband's absence and COVID-19 lockdown. Evidence from Nepal and elsewhere has also shown that women with migrant husbands feel internally stigmatized and were less likely to access FP methods in the absence of husband [16,17] due to existing social contexts [16]. Further, national trends in injection use appear to be decreasing likely due to COVID-19 restrictions [18].

Taken all together, these results indicate that Sayana Press is acceptable to women in Nepal, with the preference for Sayana Press over DMPA-IM as higher proportion chose the method when counseled and given the option, better continuation, provided important information to the government to pave the way for introduction as well as to consider future self-injection research.

Declaration of Competing Interest

The authors have no conflicts of interest to disclose.

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