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An implementation project to expand access to self-administered depot medroxyprogesterone acetate (DMPA) ☆,☆☆

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ABSTRACT

Objective: To describe the implementation and results of a proactive patient outreach project to offer self-administered, depot medroxyprogesterone (DMPA) subcutaneous (SC) to interested patients at a California safety-net clinic following expanded state Medicaid coverage.
Study design: We contacted non-pregnant patients at an urban, safety-net hospital-based primary care clinic who had been prescribed DMPA intramuscular (IM) in the past year to gauge interest in self-administered DMPA-SC. Interested patients received a prescription for DMPA-SC and a telehealth appointment with a clinic provider to learn self-injection. We recorded patient interest in DMPA-SC, completed appointments, and completed first injections. We conducted initial outreach in May, 2020 and recorded appointment attendance and completed injections through August, 2020.
Results: Of 90 eligible patients (age 17–54), we successfully contacted and discussed DMPA-SC with 70 (78%). Twenty-six (37%) patients expressed interest in DMPA-SC and scheduled telehealth appointments to learn to self-administer the medication. Fifteen (58%) of those interested (21% of the total) successfully self-injected DMPA-SC. Of the 44 (63%) patients not interested in DMPA-SC, the three most common reasons were fear of self-injection (n = 23 [52%]), wanting to stop DMPA (n = 11 [25%]), and satisfaction with DMPA-IM (n = 6 [14%]).
Conclusion: There is interest in and successful initiation of self-administered DMPA-SC among patients at an urban safety net hospital-based primary care clinic who have used DMPA-IM in the last year.
Implications: Our data provide evidence for the interest and successful first injection rate after offering self-administered DMPA-SC to patients on DMPA-IM. Expanding coverage of self-administered DMPA-SC could increase patient-centeredness and accessibility of contraception as well as reduce patient anxiety around COVID-19 transmission without losing contraceptive access.

1. Introduction

Depot medroxyprogesterone acetate (DMPA) is a progestin-only, injectable contraceptive administered every three months either intramuscularly (IM) or subcutaneously (SC). DMPA-SC and IM are equally safe and effective; however, DMPA-SC offers potential advantages over IM administration [1,2]. DMPA-SC was initially designed with the possibility for self-administration, with a smaller needle and with one-third the volume of medication administered compared to DMPA-IM. In global settings, these differences in formulation and administration mechanism contribute to equal or reduced pain and side effects with DMPA-SC [2–5]. Furthermore, self-administration offers greater autonomy and reduced barriers to care by removing the necessity of returning to a clinic every three months. Global and US data potentially reflect these benefits, showing improved continuation rates of self-administered DMPA-SC relative to clinic administered DMPA-IM and DMPA-SC [5,6].

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DMPA-SC has the potential to satisfy a significant interest in self-administered, reversible, injectable contraception in the US [7]. Currently, DMPA-SC is approved by the United States Food and Drug Administration (FDA) for administration by a healthcare professional only. Additionally, many public and private insurers either do not cover it as a pharmacy benefit or place utilization requirements like prior approval upon its use, creating barriers to access [8].

Due to the novel Coronavirus 2019 (COVID-19) presenting emergent public health risks, the Centers for Medicare & Medicaid Services (CMS) issued waivers under section 1135 of the Social Security Act to facilitate local health departments' responses to the pandemic [9]. California's public health insurance program (Medi-Cal) utilized the 1135 waiver to approve DMPA-SC as a pharmacy benefit without prior approval as of April 2020 [10]. This change also extended to patients who receive their contraceptive coverage through California's Medicaid expansion program, Family Planning, Access, Care and Treatment (Family PACT), which provides comprehensive family planning services to eligible low income (under 200% federal poverty level) residents. Enabled by this policy change, we describe the initial implementation project aimed at offering self-administered DMPA-SC to current or historical DMPA-IM users at an urban, California, primary care clinic. We include both the process of changing from clinic administered DMPA-IM to pharmacy supplied DMPA-SC as well as interest in DMPA-SC and success of first injection to offer insight to implementation in other settings.

2. Materials and methods

Our population included all non-pregnant patients who received DMPA-IM for contraception within the prior 9 months at an urban, hospital-based safety-net primary care clinic in San Francisco. Almost all the patients who receive care at our clinic are eligible for Medi-Cal or Family PACT.

We searched our electronic health record (EHR) for patients who received DMPA-IM from August 2019 to May 2020, with August 2019 corresponding to our transition to EHR. We developed a patient-centered contraceptive counseling script (online Appendix A) to call patients and assess their interest in self-administered DMPA-SC. In May 2020 (approximately one and a half months after the implementation of city and state-wide shelter-in-place orders), a team of five medical and pharmacy students contacted these patients and offered the DMPA-SC formulation. We used phone interpreters for non-English speaking patients and called all patients a maximum of three times without receiving a response before leaving a general voice message with clinic contact information.

Upon reaching patients, we confirmed their identity with name and date of birth and verified past or present DMPA-IM use. We then described the new availability of DMPA-SC and its similarities and differences from DMPA-IM, after which we asked about interest in use of this method. For patients interested in DMPA-SC, we ordered prescriptions to their pharmacy of choice and scheduled telehealth appointments with a provider at the clinic (their primary care physician, resident or attending physician, pharmacist, or advanced care practitioner) to teach them how to self-inject. Additionally, we instructed those interested patients more than 15 weeks from the last DMPA injection and who had been sexually active to perform a home urine pregnancy test prior to DMPA-SC injection. We instructed patients who had been sexually active within two weeks prior to DMPA-SC injection to repeat pregnancy testing two weeks after their injection (and four weeks after the sexual encounter). If the patient could not afford an at home pregnancy test, we offered the option to come to the clinic for a point-of-care pregnancy test that would be paid for by their insurance.

Providers performed telehealth appointments using video or telephone, depending on patient preference. They discussed the differences between DMPA-SC and DMPA-IM and instructed patients how to administer the injection and dispose of the needle. Providers had access to the materials in Appendix B for their own education and to share with patients. We offered observed first injection during the telehealth visit but did not require it. If the patient planned on having a family member or community healthcare worker (HCW) administer the injection, we recommended, but did not require, that person to attend the telehealth visit. If patients injected DMPA-SC at a date later than their appointment, we followed up to confirm successful injection for the purposes of data collection; however, it was not a part of the provider workflow. We reached out to patients who missed their appointments for follow up. If we could not reach the patient for follow up, we monitored their EHR to check for new appointments and contraception use. We collected data on appointments and injections that occurred through August 2020.

For patients not interested in self-administered DMPA-SC, we asked an optional open-ended question about reasons for lack of interest. For analysis, we sorted these responses into four predetermined categories which fit all of the data: fear of self-injection, wanting to stop all DMPA, being satisfied with their current method, and not having the time to think about their contraception at the time. Patients interested in contraceptive counseling for any reason received telehealth appointments with a clinic provider. If the patients' insurer rejected the prescription claim at the pharmacy, a pharmacist or pharmacy student contacted the pharmacy to provide information and guide them through successfully processing the prescription claim through insurance.

We collected this data as part of outreach to facilitate routine care to provide patients with increased contraceptive options in the context of a pandemic. The Institutional Review Board at University of California San Francisco reviewed our plan and provided exempt status for our study.

3. Results

Of the 90 patients who fit our criteria, we successfully contacted 72 (80%), 70 (97%) of whom were willing to speak to us about their birth control. Table 1 depicts the characteristics of our study cohort. Fig. 1 presents the number of patients who expressed interest in DMPA-SC, those who went on to successfully inject DMPA-SC, and the contraceptive outcomes of those who did not take up DMPA-SC.

Table 1
Demographic characteristics of patients who had received intramuscular depot medroxyprogesterone acetate from August 2019 to May 2020.

Patient characteristic	*n* (%) or median (range)
Age, years	32 (17–54)
Race/Ethnicity[a]	
Hispanic/Latinx/Spanish	39 (56%)
Black/African American	17 (24%)
White	6 (9%)
Asian	5 (7%)
American Indian/Alaska Native	3 (4%)
Preferred language	
English	36 (51%)
Spanish	32 (46%)
Vietnamese	2 (3%)

[a] Racial identifiers and terminology were extracted directly from the electronic health record and are not self-reported.

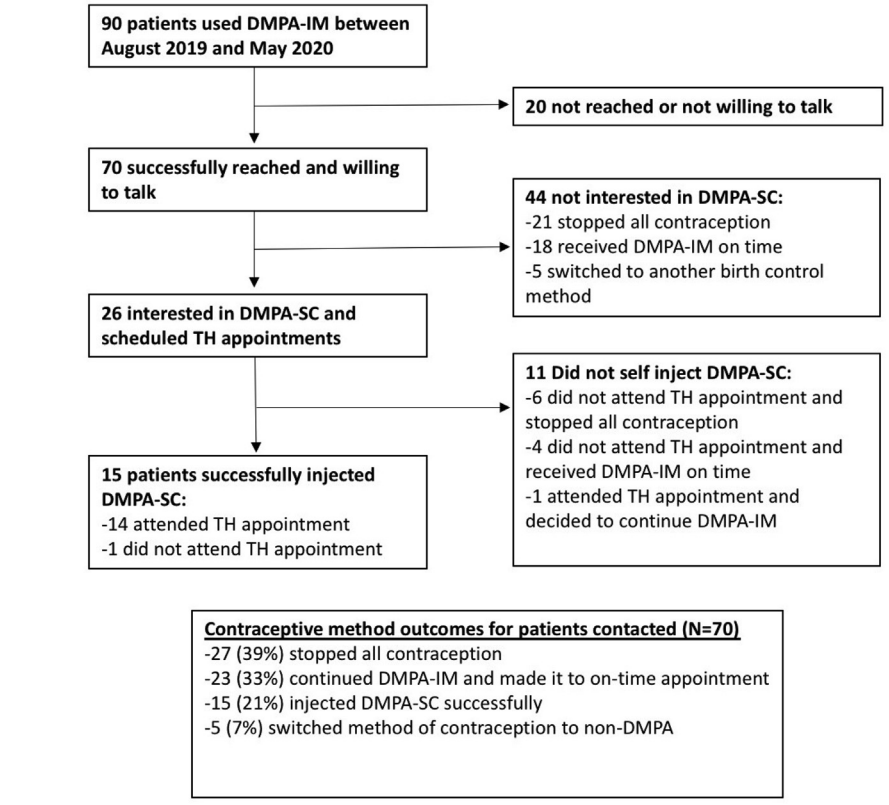

Fig. 1. Patient recruitment, interest in subcutaneous depot medroxyprogesterone acetate, and contraceptive outcomes for patients who had received intramuscular depot medroxyprogesterone acetate from August 2019 to May 2020. *DMPA: Depot medroxyprogesterone acetate; IM: intramuscular; SC: subcutaneous; TH: telehealth.

Of the 70 patients we contacted, 26 (37%) expressed initial interest in DMPA-SC. While we did not ask patients why they were interested in DMPA-SC as a part of our data collection, many spontaneously offered their motivations. Some patients cited the extenuating circumstances of COVID-19 as an influence to start self-administration of the subcutaneous formulation. Patients commonly expressed that they had cancelled, or were planning to cancel, their DMPA-IM appointments because of COVID-19 and were grateful for another method of DMPA administration that did not require entering a healthcare facility. Other patients provided non-COVID-19 related motivations such as difficulty attending regular DMPA-IM clinic appointments due to work and childcare obligations.

Of the 44 (63%) patients not interested in DMPA-SC, a plurality cited fear of self-injection (n = 23 [52%]) as their reason. The next most common reason for lack of interest was wanting to stop all forms of DMPA (n = 11 [25%]) for a variety of reasons, including no longer desiring any form of contraception and side effects of DMPA. Six patients (14%) were satisfied with clinic-administered DMPA-IM and did not want to change their method of contraception and four patients (8%) cited not having the time to think about contraception.

Fifteen patients (21% of those contacted and 58% of those interested in DMPA-SC) successfully injected. Five patients had a friend, family member or community HCW provide the injection. Of the 26 patients interested in DMPA-SC, 11 (42%) did not initiate. When we followed up with these patients about the reasons that they did not complete the injection, they cited a multitude of intertwining factors including changing their mind about self-injection, moving home location, a desire to stop all birth control, clinic miscommunication, and pharmacy and insurance delays.

4. Discussion

Over one-third of patients who currently or recently used DMPA-IM at an urban, hospital-based primary care clinic expressed interest in home-administered DMPA-SC in the context of state and local shelter-in-place orders and other social distancing guidelines in response to COVID-19. Those who declined DMPA-SC primarily cited an aversion to self-injection, satisfaction with DMPA-IM, or a desire to stop all DMPA. Many, but not all, cited COVID-19 as a motivating factor to switch to home-administered DMPA-SC. This interest in home-administered, injectable contraception in a safety-net setting is consistent with prior studies demonstrating interest in self-injectable contraception for the general population. One multi-site survey of family planning clinics and abortion clinics in the US found that 21% of participants expressed interest in self-administered injectable contraception, with greater interest among those who faced increased barriers to care [7]. Multiple factors might explain our higher initial interest rate. As our sample population contained only current or past users of DMPA-IM, our population may have been more likely to consider an injectable method of contraception and the specific side effects of DMPA acceptable. Additionally, we conducted our project during a peak in COVID-19 infections, with many of our patients citing the pandemic as a barrier to accessing clinical care.

In addition to interest, our data indicate appreciable uptake of home-administered DMPA. We believe this success was due to the person-centered approach we employed in offering this recently-covered contraceptive method in the context of COVID-19 related barriers to accessing clinical care. Additionally, supporting administration by a family or community member seemed to

contribute to successful initiation. This is consistent with other studies examining the acceptability of DMPA-SC in the global setting, which included administration by a community member as an option to facilitate contraceptive accessibility and patient comfort [4,5]. Future DMPA-SC implementation efforts might mention community member administration to prospective patients more uniformly during outreach and contraceptive counseling.

Patients who expressed initial interest, but did not successfully inject DMPA-SC, encountered barriers to receiving their teaching at the telehealth visit or obtaining their medications due to clinic miscommunication, prior approval requirements, or losing health insurance entirely. In some cases, patients were unable to obtain their prescription from their pharmacy without direct advocacy from our team. These logistical barriers undermined patients' desire to trial a new method, especially when layered on fears of self-injection. Future DMPA-SC outreach requires further education of all health care team members about the coverage and feasibility of home-administration of DMPA-SC in order to minimize these logistical barriers.

We attempted to minimize bias during outreach and data collection by offering self-administered DMPA-SC without advocating for it in order to elicit patient preferences without coercion. Limitations of the study included the small sample size and single-site approach. While this implementation project provided additional information about contraceptive preferences and the logistics of uptake for a primarily low-income population, patients in this cohort had previously used DMPA-IM, limiting generalizability to patients without a history of injectable contraception use or contraception with similar side effect profiles. While patients cited factors outside of COVID-19 as reasons for switching to DMPA-SC, it is unclear whether patient interest and uptake would be similar in an environment with reduced risk of COVID-19 transmission in public spaces. Future research might examine continuation rates of patients who initiated DMPA-SC during COVID-19 and examine patient experiences of DMPA-SC home-injection over time to determine whether public coverage of home-administered, injectable contraception has the potential, even outside of a pandemic, to expand access and increase patient-centeredness of contraceptive care. Nonetheless, the interest and uptake we found in home-administered DMPA-SC among current DMPA-IM users provides support for state and federal policy efforts to expand the availability of home-administered DMPA-SC. For home-administration of DMPA-SC to continue after the current pandemic, barriers to access including the FDA-mandated healthcare professional-only administration, utilization limits, and insurance denials must be removed.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.contraception.2020.09.001.

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