PROTOCOL TITLE: Continuation Rates of Self-administered Subcutaneous Depot Medroxyprogesterone Acetate and Provider-administered Intramuscular Depot Medroxyprogesterone Acetate in Patients Seeking Post-abortion Contraception

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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	Subcutaneous depot medroxyprogesterone acetate 104 mg, intramuscular depot medroxyprogesterone acetate 150 mg
IND / IDE / HDE #	NA
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☒ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	588
Funding Source	Society of Family Planning
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

OBJECTIVES:

The primary objective of the proposed project is to determine whether continuation rates for self-administered subcutaneous depot medroxyprogesterone acetate (DMPA-SC) and provider-administered intramuscular depot medroxyprogesterone acetate (DMPA-IM) differ for patients seeking abortion services. We hypothesize that, similar to prior research investigating

continuation rates in populations primarily seeking contraceptive services[1–4], patients using self-administered DMPA-SC will have higher continuation rates than patient using provider-administered DMPA-IM. Secondary objectives of the project will include identifying which demographic and clinical factors are associated with continuation of DMPA and whether patient satisfaction differs between the two methods. We hypothesize that older age, private insurance, higher income, higher education level, medication as opposed to surgical abortion, higher parity, and prior use of DMPA will be associated with higher continuation rates. We hypothesize that patients will report higher satisfaction with self-administered DMPA-SC than with provider-administered DMPA-IM.

BACKGROUND:

Depot medroxyprogesterone acetate (DMPA) is an effective and popular contraceptive method. Perfect use failure rate is 0.2% and typical use failure rate is 4%[5]. While only the seventh most used form of contraception in the United States, its users are more likely to be teenagers, identify as black, have lower income, and have lower educational attainment[6,7]. DMPA is available in both intramuscular (DMPA-IM) and subcutaneous (DMPA-SC) formulations with dosing of 150 mg and 104 mg, respectively and must be administered every 11-15 weeks. DMPA-SC, which was first approved by the FDA for use as a contraceptive in 2004, is uniquely suited to self-administration[8]. Although both DMPA-IM and DMPA-SC are only FDA approved for administration by a health care provider, the 2021 update to the CDC Selected Practice Recommendations advises that DMPA-SC be made available for self-administration[9].

Multiple studies have compared self-administered DMPA-SC with provider-administered DMPA-SC as well as self-administered DMPA-SC with provider-administered DMPA-IM and found that self-administration of DMPA-SC is safe, acceptable to patients, and cost-effective. A prospective cohort study comparing self-administered DMPA-SC to provider-administered DMPA-IM in patients seeking DMPA at clinics in Uganda found that pregnancy rates did not differ between the two groups[1]. Multiple studies have demonstrated lower or similar rates of adverse effects with self-administration of DMPA-SC compared to provider-administered DMPA-SC or DMPA-IM[1–3]. Patients have positive experiences with self-administration of DMPA with over 90% of patients reporting that self-administration was easy and 87% reporting that they would recommend self-administration to a friend[4,10,11]. Patients feel that self-

administration saves them time and money and rates of patient satisfaction were not significantly different than for provider-administered DMPA[10–12]. Cost-effectiveness analyses have shown that self-administration of DMPA-SC could save from 84,000-1,000,000 USD on a societal level through prevention of unintended pregnancies[13,14].

Research has also compared continuation rates for self-administered and provider-administered DMPA. While some studies have shown no significant difference in continuation rates[12,15] other studies have shown higher continuation rates with self-administration. A randomized controlled trial of patients requesting DMPA at Planned Parenthood clinics in Texas and New Jersey found that continuation rates at 1 year were 69% for self-administered DMPA-SC compared to 54% for provider-administered DMPA-SC[4]; a randomized controlled trial in Malawi found continuation rates of 73% for self-administered DMPA-SC and 54% for provider-administered DMPA-SC[2]; a prospective cohort study in Senegal found continuation rates of 80% for self-administered DMPA-SC and 70% for DMPA-IM[3]; and a prospective cohort study in Uganda found continuation rates of 81% for self-administered DMPA-SC and 65% for DMPA-IM[1]. Self-administration of DMPA-SC reduced risk of discontinuation more for younger patients compared to older patients[1,16].

Thus far, research investigating continuation rates of self-administered DMPA-SC has primarily focused on patients presenting for contraceptive services. Self-administered DMPA-SC has not been widely studied in patients presenting for abortion services and has also been more extensively studied in international settings than in the United States. Prior research has shown that continuation rates for DMPA in patients receiving abortion services are much lower than in patients seeking contraception, with continuation rates of approximately one-fifth to one-quarter of patients[17]. Further research is needed to describe continuation rates for self-administered DMPA in patients seeking abortion services, as well patient satisfaction with this method. Data addressing these questions will help inform decisions by abortion providers to prescribe DMPA-SC for the purpose of self-administration and to offer patient education on self-administration of DMPA-SC. This will also help inform decisions regarding insurance coverage and reimbursement rates for DMPA-SC as well as pharmacy stocking of DMPA-SC.

STUDY ENDPOINTS:

Study participants will be followed for a total of 6 months after enrollment in the study at the time of initiation of either self-administered DMPA-SC or provider-administered DMPA-IM.

The primary endpoint will be continuation of either self-administered DMPA-SC or provider-administered DMPA-IM at 3 months and 6 months, corresponding to second and third subsequent doses of DMPA after the initial dose of DMPA at the time of study enrollment.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

Study participants will receive their initial dose of either DMPA-IM 150 mg via provider administration or DMPA-SC 104 mg via patient self-administration at the study location. The study team will procure initial doses of DMPA-IM and DMPA-SC from the drug manufacturer, Pfizer. These doses will be stored in a secure location at the study location per manufacturer guidelines and will be labeled to identify them for use only in study participants. Patients receiving DMPA-SC via self-administration will be provided with patient education on self-injection of DMPA-SC by study team members and will be directly observed self-administering their initial dose of DMPA-SC. Patients receiving DMPA-IM via provider-administration will receive DMPA-IM from a health care provider at the study location accordingly to the location's routine clinical practice. Study participants will be provided with prescriptions for a year's worth of subsequent doses of either DMPA-IM or DMPA-SC. Although study participants will only be followed by the research team for 6 months after enrollment, providing a year's worth of birth control is considered standard of care. They will fill these prescriptions at a pharmacy of their choice. Study participants receiving DMPA-IM will receive their subsequent doses either at the study location or at a different health care provider of their choosing. Study participants receiving DMPA-SC will self-administer their subsequent doses. Both DMPA-IM and DMPA-SC are FDA-approved for use in humans and therefore do not have an IND or IDE. Both drugs are FDA-approved for administration by a health care provider. DMPA-SC is not FDA-approved for self-administration by patients, however the 2021 update to the CDC Selected Practice Recommendations advises that DMPA-SC be made available for self-administration[9]. Self-administration of DMPA-SC in this research study should be considered exempt from IND requirements under Category #1 - Lawfully Marketed Drugs (21 CFR 312.2(b)(1)) or Biologics, because a) it is lawfully marketed in the United States; b) the research is not intended to be reported to the FDA in support of a new indication for use nor intended to be used to support any other significant change in labeling for the drug; c) the research is not intended to support a significant change in advertising for the drug; d) the research does not involve a route of administration, dosage level, use in a patient population, or other factor that significantly

increases the risk (or decreases the acceptability of the risks) associated with the use of the drug; and e) the research is conducted in compliance with the marketing limitations described in 21 CFR §312.7. In particular, as outlined above, extensive data exists documenting that self-administration of DMPA-SC is associated with similar or lower rates of adverse effects compared to health care provider-administration of DMPA.

PROCEDURES INVOLVED:

The study will be a prospective cohort study of patients at a free-standing abortion clinic in Chicago, IL, Family Planning Associates. Patients who indicate during the counseling and intake process for abortion services that they desire DMPA for post-abortion contraception will be approached for participation in the study. Patients who consent to participate in the study will choose either provider-administered DMPA-IM or self-administered DMPA-SC. In their current clinical practice, Family Planning Associates only offers DMPA-IM and does not offer DMPA-SC to patients seeking post-abortion contraception. Therefore, administration of DMPA-SC to patients seeking post-abortion contraception at Family Planning Associates will be study driven, as patients will only receive DMPA-SC if they participate in the research study. However, both DMPA-IM and DMPA-SC are considered standard of care for patients seeking long-term injectable contraception and both are approved for use in humans by the FDA. DMPA-SC has been shown to be as safe and effective as DMPA-IM and is routinely provided to patients seeking contraception. Patients in both groups will complete a baseline survey that will collect demographic and clinical characteristics, as well as patient values regarding contraceptive decision-making. Study participants who choose self-administered DMPA-SC will receive self-injection teaching from study staff and will self-inject their first dose of DMPA-SC in the clinic (see patient education materials). They will receive a sharps box to take home, as well as a link to an online video which provides patient education on self-administration of DMPA-SC (https://www.youtube.com/watch?v=tFcff27k320). Study participants who choose provider-administered DMPA-IM will receive their first dose of DMPA-IM in the clinic, administered by clinic staff according to their routine clinical practice. Although Family Planning Associates clinic staff will administer DMPA-IM to patients who have chosen this as their desired method of contraception, this is not a study-driven activity, because this is how patients requesting DMPA for post-abortion contraception receive DMPA according to Family Planning Associates current clinical practice. Only Northwestern University study personnel will complete study-

driven, research activities including recruitment, informed consent, education on DMPA-SC self-injection, and survey administration. Both groups of patients will be directly observed receiving their first dose of DMPA, such that any immediate adverse reaction, e.g. anaphylaxis, would be identified. Both groups will receive a prescription for the subsequent doses of DMPA and will receive an injection calendar, indicating the timing of their subsequent doses. Study participants will receive a reminder prior to the start of the injection window for their subsequent doses. This reminder will be primarily via secure text messaging application with phone calls, email, and mail reserved for patients who cannot or prefer not to be contacted via text message. Participants in the self-administered DMPA-SC group will administer their dose at home. Participants in the provider-administered DMPA-IM group will receive their dose at a clinic of their choosing. After the injection window for each subsequent dose closes, participants will complete a follow up survey. These surveys will assess whether patients received the subsequent doses of DMPA, reasons for discontinuing DMPA for patients who did not receive a dose, pregnancy status, patient satisfaction with DMPA use and education on DMPA-SC self-administration, and any adverse reactions to DMPA. Follow up for survey administration will be primarily via text message with phone, email, and mail as secondary contact methods, as outlined above. Members of the study team will follow up with study participants who are identified by survey results to be having any adverse reaction to DMPA and who desire to be contacted by the study team regarding this, and will offer referral to a family planning or Ob/Gyn clinic if study participants desire further follow up for their adverse reaction. At the time of enrollment, all study participants will be provided with contact information for the study team, so that they can report any adverse reaction to DMPA prior to completing a follow up survey and receive an appropriate referral for evaluation of their adverse reaction if needed or desired.

SHARING RESULTS WITH PARTICIPANTS

Study results will be reported in aggregate and submitted for publication to one or more peer-reviewed medical journals and to conferences of relevant professional organizations. Because the study does not investigate diagnostic tests or generate test results for study participants, study results will not be shared with participants.

STUDY TIMELINES

We estimate that we will need to recruit for 8 months in order to enroll 653 participants. Follow up will be conducted over 6 months following enrollment, corresponding to 2 subsequent

doses of DMPA after the initial post-abortion dose at the time of enrollment in the study. Enrollment will occur from April 2022 through October 2022 and 6-month follow up of the last participants to be enrolled will be completed in April 2023. Data analysis and manuscript preparation will take place from May 2023 through June 2023.

INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria for the study will be patients presenting to the study location who request DMPA for post-abortion contraception. Given that the study's population is patients seeking post-abortion contraception it will include pregnant women. Exclusion criteria will include patients who are under age 18, who do not speak and read English, and who do not have access to a phone for follow up. The study will also exclude adults who are unable to consent and prisoners. Screening for eligibility will take place during the study location's routine counseling and intake process for patients presenting for abortion services. Patients indicate their preference for post-abortion contraception during this process. Exclusion criteria based on age and primary language are also gathered as part of the study location's routine intake process.

VULNERABLE POPULATIONS

For patients seeking a surgical termination of pregnancy, the recruitment and consent processes will take place prior to their abortion, because patients routinely receive sedation or anesthesia during abortion procedures. DMPA administration will take place after their abortion is complete. After undergoing a pregnancy termination, study participants are, by definition, no longer pregnant. A pregnancy test will not be administered after a participant's abortion prior to DMPA administration to confirm that participants are not pregnant, because this is not considered to be appropriate medical care. A pregnancy test would be expected to be positive immediately after an abortion because pregnancy hormone levels do not fall to a negative level until weeks after an abortion. For patients seeking a medical termination of pregnancy, recruitment, consent, and DMPA administration will take place before their abortion is complete, because medication abortions are completed at home by patients self-administering misoprostol. This is standard practice for DMPA administration for patients undergoing medication abortion. Although study participants will be pregnant at the time of study enrollment, they will not be pregnant during the subsequent follow up period. Given that study participants are presenting for pregnancy termination independent of study enrollment, participation in the study will not

affect the pregnancy or fetus. No inducements, monetary or otherwise, will be offered to terminate a pregnancy and the study team will have no part in any decisions regarding the timing, method, or procedures used to terminate a pregnancy.

PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local			
Study-wide	Pregnant Women	1,950	588
Total:			

RECRUITMENT METHODS

The study population will be recruited from patients presenting for abortion services at the study location, Family Planning Associates. Patients who request DMPA for post-abortion contraception during the counseling and intake process for abortion services will be approached for participation. Recruitment will take place at the study location before patients receive their abortion services. The study location serves a diverse patient population. All patients presenting to the study location who meet inclusion and exclusion criteria will be recruited using the same methods, to ensure that the study population is inclusive and representative of the general patient population at the study location. Patients will be recruited verbally (see recruitment script) during the counseling and intake process. Written recruitment materials (e.g. fliers) will not be used, as we do not wish to influence the decisions of the study location's general patient population to use DMPA vs. an alternative form of contraception.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Study participants will receive their initial dose of DMPA free of charge at the time of study enrollment and will be compensated for their time upon completion of the baeline survey at the time of study enrollment and follow up surveys at 3 and 6 months. Participants will be compensated $20 for completion of the baseline survey and $15 for each of the two follow up

surveys. Total compensation for completion of all study activities will be $50. Payment will be provided in the form of a Stored Value VISA card. As outlined above, study results will not be shared with study participants as the study does not involve diagnostic tests for the participants.

WITHDRAWAL OF PARTICIPANTS

Study participants who enroll in the study during the abortion counseling and intake process and then do not follow through with pregnancy termination will be withdrawn from the study, as the objective of the study is to determine continuation rates in patients using DMPA for post-abortion contraception. If study participants become pregnant during the follow up period, this data will be reflected in the study results, however they will not participate in further study follow up. If a study participant withdraws after enrollment, no further follow up or data collection will be pursued for that study participant, however any data previously collected will be maintained as part of the study records if the participant consents to this. Study participants will be withdrawn from the study without their consent if they have a severe adverse reaction to the study intervention, i.e. anaphylaxis to DMPA.

RISKS TO PARTICIPANTS

The main risks of participation in the study include risks related to DMPA use and risks related to inadvertent disclosure of participant PHI. Possible risks related to DMPA use include injection site reaction, irregular or heavy menstrual bleeding, anemia, and anaphylaxis. A randomized controlled trial of 401 women in the US comparing self-administered DMPA-SC and provider-administered DMPA-IM reported no serious adverse events[4]. A randomized controlled trial of 731 women in Malawi comparing self-administered and provider-administered DMPA-SC reported only 2 serious study-related adverse events, specifically heavy menstrual bleeding and anemia requiring hospitalization[2]. Given that study participants are presenting for pregnancy termination independent of study enrollment, participation in the study will not pose a risk to the pregnancy or fetus. We do not anticipate any psychological, social, economic, or legal risks to participants.

POTENTIAL BENEFITS TO PARTICIPANTS

Study participants who choose to receive self-administered DMPA-SC will benefit from having access to a contraceptive method that is not otherwise offered at the study location. Self-administration of DMPA-SC may offer them greater convenience and ease in following up for

subsequent doses of this contraceptive method, which will facilitate them achieving their reproductive goals. Study participants who choose self-administered DMPA-SC will also receive the benefit of patient education on self-injection. This skill set will be potentially useful to them for the remainder of their reproductive years. There will be no direct benefits to patients receiving provider-administered DMPA-IM as this is the standard practice at the study location for patients requesting DMPA for post-abortion contraception.

DATA MANAGEMENT AND CONFIDENTIALITY

In order to detect a 10% difference in continuation rates between patients receiving self-administered DMPA-SC and provider-administered DMPA-IM at a power of 80%, an alpha error of 0.05, and an enrollment ratio of 0.94 for self-administered DMPA-SC to provider-administered DMPA-IM, 588 patients will need to complete the study. Accounting for an estimated 10% loss-to-follow up based on prior studies[4, 17], we will need to enroll 653 participants in order for 588 participants to complete all study follow up. In prior studies the minimum difference in continuation rates detected was 10%[3] and the lowest enrollment ratio was 0.94 for prospective cohort studies, where patients choose their route of DMPA administration[1].

Initial surveys will be completed on an iPad or on paper and will be stored in a locked location accessible only to study staff. Follow up surveys will be primarily collected via secure text-messaging app with password-protected access only for study staff. For patients who prefer to follow up by phone, survey responses will be directly entered in a password-protected database. All study data will be stored in a password-protected database, which will be accessible only to study team members. Patients will be identified by ID numbers and links between any personal health information, with the exception of email or phone number used for secure email or text message follow up, will be stored separately from the primary data file. Data cleaning will be done using standard statistical software, to ensure quality control of data. Appropriate inferential statistics will be used to compare continuation rates and level of satisfaction between patients using self-administered DMPA-SC and provider-administered DMPA, as well as determine associations between patients' demographic and clinical characteristics and continuation of DMPA. Data will be stored for 3 years after publication of study results.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

Follow up surveys will assess whether study participants have experienced adverse events related to DMPA use. Study participants will be able to indicate in the survey whether they desire additional follow up with the study team if they have experienced adverse events. Participants will also be able to report adverse events to the study team at any time, independent of survey completion. Serious adverse events will be evaluated by the study team at the time that they are reported. We do not anticipate any conditions that would trigger immediate suspension of the research study, as both formulations of DMPA to be used in the study are FDA-approved for use in humans and are considered safe.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

The only source of information about study participants will be information that is self-reported by participants in study surveys. The study surveys will include questions about participants' obstetrical and contraceptive history which they may find intrusive. Study participants may decline to answer any survey question which they do not wish to answer and will be free to withdraw from further participation in the study at any time.

ECONOMIC BURDEN TO PARTICIPANTS

The initial dose of either DMPA-IM or DMPA-SC will be provided to study participants at the study location at the time of enrollment free of charge. Study participants will be responsible for the cost of DMPA for subsequent doses at 3 and 6 months follow up. Both DMPA-IM and DMPA-SC are preferred, covered drugs under Illinois Medicaid insurance plans, thus we anticipate patients to incur minimal costs when obtaining these medications. Patients will not incur any additional costs by virtue of participating in the research study compared to the costs they would have incurred when obtaining DMPA for contraception outside of the research study.

CONSENT PROCESS

We will obtain written consent from potential study participants prior to enrollment in the study. The consent process will take place at the study location, will take approximately 10 minutes to complete, and will be conducted in English. There will be no waiting period between informing a potential study participant about the research study and obtaining consent. In order to avoid undue influence or coercion, consent will be obtained by study team members who are not staff at the study location. Participants' understanding will be ensured by conducting the

consent process both verbally and with the aid of written materials which will be written at no higher than an 8th grade reading level (see consent document). Ongoing consent will be ensured by including language in follow up surveys reminding participants that they are free to withdraw from the study at any time and request no further contact from the study team.

NON-ENGLISH SPEAKING PARTICIPANTS

One of the exclusion criteria for the study is patients who do not read and speak English. The consent process will be conducted in English.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

The study will involve collection of the following PHI: name, age, telephone number, address, and ZIP code. HIPAA authorization does not apply to the study as all PHI collected will be self-reported by study participants, will not be obtained from the medical record, and will not be placed in the medical record after collection.

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

Approximately 13,000 patients present to the study location annually for abortion services and of those, 15% request DMPA for post-abortion contraception, giving us a population of approximately 1,950 from which to recruit annually. We plan to enroll 653 study participants and would need to recruit and enroll 50% of potential participants in order to complete enrollment in the 8-month time frame outlined above. We estimate that for each study participant we will devote 10 minutes to the consent process. For study participants who choose DMPA-SC we estimate devoting an additional 10 minutes to patient education on self-injection of DMPA. Recruitment, the consent process, study enrollment, initial survey completion, patient education on self-injection of DMPA, and administration of initial doses of DMPA will take place at Family Planning Associates, a free-standing abortion clinic. For study participants who experience an adverse event related to the study, which requires medical intervention, the study team will facilitate referral to appropriate medical care at Northwestern Memorial Hospital (NMH) or to a different facility if a study participant is unable to follow up at NMH. The principal investigator will be responsible for ensuring that all people assisting with the research are informed about research protocols and procedures as well as study team member duties and functions. The principal investigator has conducted multiple research studies in the past including randomized controlled trials.

REFERENCES

1. Cover J, Namagembe A, Tumusiime J, Nsangi D, Lim J, Nakiganda-Busiku D. Continuation of injectable contraception when self-injected vs. administered by a facility-based health worker: a nonrandomized, prospective cohort study in Uganda. *Contraception*. 2018;98(5):383-388. doi:10.1016/j.contraception.2018.03.032

2. Burke HM, Chen M, Buluzi M, et al. Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomised controlled trial. *Lancet Glob Health*. 2018;6(5):e568-e578. doi:10.1016/S2214-109X(18)30061-5

3. Cover J, Ba M, Drake JK, NDiaye MD. Continuation of self-injected versus provider-administered contraception in Senegal: a nonrandomized, prospective cohort study. *Contraception*. 2019;99(2):137-141. doi:10.1016/j.contraception.2018.11.001

4. Kohn JE, Simons HR, Della Badia L, et al. Increased 1-year continuation of DMPA among women randomized to self-administration: results from a randomized controlled trial at Planned Parenthood. *Contraception*. 2018;97(3):198-204. doi:10.1016/j.contraception.2017.11.009

5. Hatcher RA. *Contraceptive Technology*.; 2018.

6. Jan 29 P, 2020. DMPA Contraceptive Injection: Use and Coverage. KFF. Published January 29, 2020. Accessed November 13, 2021. https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/

7. NSFG - Listing C - Key Statistics from the National Survey of Family Growth. Published November 8, 2021. Accessed November 13, 2021. https://www.cdc.gov/nchs/nsfg/key_statistics/c-keystat.htm

8. Shoupe D, Mishell J, eds. *The Handbook of Contraception: A Guide for Practical Management*. 2nd ed. 2016. Springer International Publishing : Imprint: Humana; 2016. doi:10.1007/978-3-319-20185-6

9. Curtis KM. Update to U.S. Selected Practice Recommendations for Contraceptive Use: Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate. *MMWR Morb Mortal Wkly Rep*. 2021;70. doi:10.15585/mmwr.mm7020a2

10. Burke HM, Chen M, Buluzi M, et al. Women's satisfaction, use, storage and disposal of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) during a randomized trial. *Contraception*. 2018;98(5):418-422. doi:10.1016/j.contraception.2018.04.018

11. Burke HM, Packer C, Buluzi M, Healy E, Ngwira B. Client and provider experiences with self-administration of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) in Malawi. *Contraception*. 2018;98(5):405-410. doi:10.1016/j.contraception.2018.02.011

12. Cameron ST, Glasier A, Johnstone A. Pilot study of home self-administration of subcutaneous depo-medroxyprogesterone acetate for contraception. *Contraception*. 2012;85(5):458-464. doi:10.1016/j.contraception.2011.10.002

13. Mvundura M, Di Giorgio L, Morozoff C, Cover J, Ndour M, Drake JK. Cost-effectiveness of self-injected DMPA-SC compared with health-worker-injected DMPA-IM in Senegal. *Contracept X*. 2019;1:100012. doi:10.1016/j.conx.2019.100012

14. Di Giorgio L, Mvundura M, Tumusiime J, Morozoff C, Cover J, Drake JK. Is contraceptive self-injection cost-effective compared to contraceptive injections from facility-based health workers? Evidence from Uganda. *Contraception*. 2018;98(5):396-404. doi:10.1016/j.contraception.2018.07.137

15. Beasley A, White KO, Cremers S, Westhoff C. Randomized clinical trial of self versus clinical administration of subcutaneous depot medroxyprogesterone acetate. *Contraception*. 2014;89(5):352-356. doi:10.1016/j.contraception.2014.01.026

16. Burke HM, Chen M, Packer C, Fuchs R, Ngwira B. Young Women's Experiences With Subcutaneous Depot Medroxyprogesterone Acetate: A Secondary Analysis of a One-Year Randomized Trial in Malawi. *J Adolesc Health*. 2020;67(5):700-707. doi:10.1016/j.jadohealth.2020.03.038

17. Goldberg AB, Cardenas LH, Hubbard AE, Darney PD. Post-abortion depot medroxyprogesterone acetate continuation rates: a randomized trial of cyclic estradiol. *Contraception*. 2002;66(4):215-220. doi:10.1016/s0010-7824(02)00391-8