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Society of Family Planning committee consensus on self-administration of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) ☆

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ABSTRACT

Depot medroxyprogesterone acetate (DMPA) is a highly-effective, injectable contraceptive method that requires injections every 12 to 15 weeks. The need for return visits to a healthcare provider may present barriers to access, use, and continuation of DMPA. Studies demonstrate that self-administration of subcutaneous DMPA (DMPA-SC) outside clinical settings is safe, effective, feasible, acceptable, and can improve continuation. Based on existing evidence and potential to improve contraceptive access and autonomy, the Society of Family Planning recommends that DMPA-SC self-administration be made widely available as an additional option for patients. Provider-administered DMPA must also remain available to meet patients' individual needs and preferences.

1. Background

Depot medroxyprogesterone acetate (DMPA) is a highly-effective, progestin-only injectable contraceptive used by approximately two percent of females ages 15 to 49 in the U.S. and is used widely internationally [1]. It is also used for non-contraceptive indications, including menstrual suppression, treatment of dysmenorrhea and endometriosis, and management of heavy menstrual bleeding. Available in both intramuscular (IM) and subcutaneous (SC) formulations, DMPA requires injections approximately every 13 weeks and may be given up to 15 weeks without requiring additional contraceptive protection [1]. The intramuscular and subcutaneous formulations are dosed differently at 150 mg and 104 mg, respectively, but are therapeutically equivalent with similar safety profiles [2].

The need to return to a healthcare provider every 12 to 15 weeks can be a barrier to access and may hinder use and continuation of this highly-effective method. The need for repeat visits and associated costs may be especially burdensome for people in rural areas and those who are uninsured, lack reliable transportation, or have difficulty getting to appointments, such as adolescents and those who must take time off from work or school. The COVID-19 pandemic has further highlighted the need to maintain timely and flexible access to contraception; DMPA self-administration provides an additional option to maintain or improve access to this method [3].

Self-injection of medications is common for many other indications, including diabetes and infertility. Sayana® Press (DMPA 104 mg) was designed for self-administration and is labeled as such in other countries, but is not approved for use in the U.S. Currently, only one DMPA-SC product is available in the U.S. (Depo-subQ provera 104®), which was approved by the Food and Drug Administration (FDA) in 2004. This DMPA-SC product is a single-use, prefilled syringe and is labeled for administration by a healthcare professional, such that self-administration is currently "off-label."

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Nevertheless, studies show that self-administration of this product is feasible, acceptable, safe, effective, and can improve continuation [4]. Though we use the term "self-administration" for brevity, this term may also include injection by someone else, such as a family member, outside of a clinical setting.

2. Clinical questions

2.1. Is self-administration of DMPA feasible and acceptable to patients?

Numerous studies show that patients can successfully initiate and continue self-administration of DMPA-SC on schedule after brief in-person, video-based, or telehealth education [1]. One randomized controlled trial confirmed similar therapeutic MPA levels in both provider- and self-administration study groups, indicating that patients outside of the clinical setting were able to appropriately administer DMPA-SC and do so within the indicated intervals [5]. Patients who self-administered were also able to restart effectively without additional instruction if they delayed a dose beyond the grace period or temporarily discontinued use. Studies also show high patient-reported acceptability and satisfaction among those who self-administered DMPA-SC; many wished to continue self-administration and would recommend it to a friend [1].

2.2. Is self-administration of DMPA safe and effective?

A 2019 systematic review and meta-analysis found no significant differences in pregnancies, side effects, or adverse events between self-administered DMPA-SC and provider-administered DMPA-SC or DMPA-IM study groups in randomized controlled trials [4]. Two controlled cohort studies reported increased injection site reactions such as pain, swelling, redness, indentation, and dimpling with self-administered DMPA-SC. It is possible that this finding is due to the type of injection itself (subcutaneous) rather than the self-administration: both studies compared self-administration of DMPA-SC with provider administration of DMPA-IM. A 2016 systematic review of the safety of DMPA-SC reported that users may experience injection site reactions more frequently, but these generally resolve without further intervention [2].

2.3. Does self-administration of DMPA improve method continuation?

A 2019 systematic review and meta-analysis concluded that self-administration of DMPA-SC can improve continuation rates compared to provider administration without increasing pregnancies or serious adverse events [4]. Among three randomized controlled trials, two conducted in the U.S. (New York; Texas and New Jersey) and one in Malawi, self-administration was associated with greater continuation at 12 months compared with provider administration [5–7]. Meta-analysis of three observational studies [8–10] found similar results. The systematic review concluded that DMPA self-administration can equal or improve contraceptive continuation rates compared with provider administration without notable increases in pregnancy or safety concerns [4].

2.4. What is the existing clinical guidance?

Based on existing evidence, both the U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR) and the World Health Organization updated guidance to include DMPA-SC self-administration as a safe and effective contraceptive option [1,11]. Both recommend that self-administered DMPA-SC should be made available as an additional approach to deliver injectable contraception. The U.S. SPR further specifies that this option be offered in a noncoercive manner through shared decision-making, with a focus on patient preferences and equitable access to the full range of contraceptive methods, including provider-administered DMPA [1].

2.5. Who is eligible for self-administration?

DMPA-SC self-administration is an option for anyone eligible to use provider-administered DMPA, including adolescents; the U.S. Medical Eligibility Criteria (MEC) should be used to assess medical eligibility for DMPA-SC use [1]. Providers should use clinical judgment to determine whether self-administration is appropriate for any specific patient while centering their individual preferences and circumstances.

2.6. What patient education/training and materials/supplies are needed?

Several organizations have developed resources for implementing DMPA-SC self-administration [12]. Important elements to include in patient education and training—whether in-person or via telehealth—as well as materials and supplies, are outlined in the box below.

Patient education/training and materials for implementing DMPA-SC self-administration

Implementation Question	Implementation Suggestion
What education/ training should I provide to patients choosing DMPA-SC self-administration?	Patient education and training, whether in-person or via telehealth, should include instruction on: • proper medication preparation, injection, and storage; • re-injection windows and guidance for missed doses; • safe sharps disposal; • access to follow-up care, including options for switching to provider-administered DMPA or other contraceptive methods if desired; and • administrative issues such as costs and billing (and pharmacy information, if applicable). Providers may also use videos (new or existing) for patient education at initiation and/or subsequent injections (i.e., for patients to watch later).
What materials/ supplies should I give to patients choosing DMPA-SC self-administration?	Aside from the medication, materials and supplies for patients to take home should include, at minimum: • step-by-step instructions for self-injection with pictures (in English, Spanish, or other common languages as needed); • calendar and/or reminder card highlighting re-injection dates/windows or use of birth control reminder apps; • instructions on safe sharps disposal; and • instructions for follow-up, including contact information for questions or concerns. Providers may also offer patients additional supplies like small sharps disposal containers, surgical gloves, alcohol pads, cotton pads, or band-aids.

Additionally, research studies provided up to three medication doses for patients to take home. Some also gave small sharps disposal containers, surgical gloves, alcohol pads, cotton pads, or band-aids. No studies to date have compared educational methods or materials for DMPA-SC self-administration.

2.7. What patient follow-up is needed?

Guidance for patient follow-up is the same for provider-administered DMPA. Providers might also consider implement-

ing reminder systems for all DMPA patients (self- and provider-administered), whether through portals, text messages, apps, or other methods [13]. Similarly, all patients should have information on who to contact for questions or concerns, or if they wish to return to the clinic.

3. Recommendations

Based on current evidence and potential to improve contraceptive access, continuation, and reproductive autonomy, we recommend the following:

1. Self-administered DMPA-SC should be made widely available as an additional approach to deliver injectable contraception. This includes "self" administration as well as administration by other capable individuals, such as trained family or community members.
2. Healthcare providers should follow the existing MEC for provider-administered DMPA-SC when offering self-administration.
3. Provider-administered DMPA should also remain widely available to best meet individual patients' needs and preferences.

4. Future considerations and research

There is sufficient evidence to support broad implementation of DMPA-SC self-administration. What is most needed is implementation research on this practice so that we may learn about facilitators and barriers to uptake of DMPA-SC self-administration outside of research settings. Future studies might explore optimal methods of provider and/or patient education, training, and support. While numerous resources have been developed in the context of research studies—some outside of research contexts—no published studies have compared different educational methods. Implementation and/or communication research may further help to refine available tools, perhaps drawing on the longstanding history of self-administration of other injectable medications for other indications. Any such research should be informed by patients themselves.

Perhaps the greatest unknown is how the U.S. healthcare payer system will accommodate this service delivery innovation. This may present a barrier for providers to offer self-administration, as they may be uncertain how to charge and/or bill and how such services will be covered by insurance plans. Yet this must not be a roadblock to offering this promising, evidence-based, patient-centered contraceptive option. It is through real-world practice and research that we will best learn how to navigate this uncertain terrain. Further, as DMPA-SC self-administration is currently "off-label" in the U.S. despite evidence of its safety and effectiveness, product labeling may affect providers' willingness to prescribe off-label and insurers' willingness to cover the medication. Existing evidence warrants consideration of a label change.

Finally, given the proliferation of telehealth, DMPA-SC self-administration is a prime candidate for remote provision. Given the ability to educate patients remotely via videoconference, and to reinforce education with electronic reminders and/or video refreshers, there is great potential for both clinical practice and research in this area.

Authorship

This Committee Consensus was prepared by Julia Kohn, Elise Berlan, Jennifer Tang, and Anitra Beasley and was reviewed and approved by the Clinical Affairs Committee on behalf of the Board of Directors of the Society of Family Planning.

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