Clinical Training Center for Sexual + Reproductive Health

Training the Nation's Title X Workforce

A Toolkit for Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate

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Overview

This toolkit is a collection of evidence-based resources related to self-administered subcutaneous depot medroxyprogesterone acetate (DMPA-SC), an FDA-approved, progestin-only injectable contraceptive method. This toolkit is intended for Title X staff but includes resources that can be shared with DMPA-SC users as well. The goal of the DMPA-SC toolkit is to assist clinics in adopting best practices and provide clinical recommendations for DMPA-SC. The toolkit does not have to be used sequentially and any topic can be accessed according to your needs and interests.

Each section provides details on DMPA-SC and is followed by resources relevant to that section. Resources are hyperlinked to external websites and PDF files. Except where noted, the tools in this collection have not been created by the Clinical Training Center for Sexual and Reproductive Health (CTCSRH) but have been vetted by CTCSRH subject matter experts for relevance and accuracy.

DMPA-SC

Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) is a highly effective, FDA-approved, progestin-only injectable contraceptive method which can be administered by a health care professional or self-administered. This toolkit focuses on self-administration of DMPA-SC.

Terminology Used in This Toolkit

In this toolkit, we refer to *subcutaneous depot medroxyprogesterone acetate* as DMPA-SC, but it is also sometimes referred to as DMPA-SQ.

Similarly, we use the term “self-administered” but acknowledge that some patients may have a friend or family member administer the injection.

Lastly, we use the term “individuals” rather than “women” to be inclusive of all people eligible to use DMPA-SC, regardless of gender identity. However, when describing specific resources and studies, we have used the terms employed by the authors.

Toolkit Sections

What Is DMPA-SC?

Depot medroxyprogesterone acetate is an FDA-approved, progestin-only injectable contraceptive method (also known as depo-provera, or "depo" or "the shot" for short). It comes in both the subcutaneous (SC) and intramuscular (IM) formulations. DMPS-SC is like DMPA-IM but delivered subcutaneously (under the skin) in the anterior thigh or abdomen every 12 to 14 weeks, using a smaller needle, less liquid, and lower overall dose of *medroxyprogesterone acetate.*[1] DMPA-SC contains 104 mg of *medroxyprogesterone acetate* in a depot formulation, whereas IM contains 150 mg. In the U.S., DMPA-SC is supplied as a prefilled syringe and is manufactured by Pfizer as depo-subQ provera 104®; there are no generic products available at this time.

Recommendation

The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommend that self-administered injectable contraception be made available as an additional approach to deliver injectable contraception to persons of reproductive age.

DMPA was first used in the United States (U.S.) in 1959 for menstruation management and was approved by the FDA for use as a contraceptive in 1992, although it is also used for non-contraceptive indications like menstrual suppression, management of dysmenorrhea and abnormal uterine bleeding, and to decrease pain from endometriosis.[2] In the U.S., DMPA-SC was approved in 2004 by the Food and Drug Administration (FDA) for administration only by a healthcare professional[3] although it is used "off-label" for self-administration due to the ample evidence showing similar effectiveness and side effects/adverse events compared to health care professional-administered DMPA (SC and IM).[4] Self-administration of DMPA-SC has been used internationally for decades and is an important option in international family planning programs, particularly in Sub-Saharan Africa, where it is available under the brand name Sayana® Press using the needleless Uniject system.[4,5] Because it is "user-controlled," self-administered DMPA-SC offers the potential to improve contraceptive access, increase reproductive autonomy, and has been shown to increase continuation rates.[1,6]

Given the evidence that DMPA-SC is safe and effective for both provider- and self-administration, the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and the Society for Family Planning recommend that self- administered injectable contraception be made available as an additional approach to deliver injectable contraception to persons of reproductive age.[6,7,8,9,10,11]

Relevant Resources

Depo-SubQ Provera 104 for Patients and Providers

Pfizer

Find clinical and pharmacological information on DMPA-SC for pharmacists, providers, and patients, including what it is and how it works, effectiveness, prescribing information, contraindications, and ingredients.

Link type Website

DMPA Contraceptive Injection: Use and Coverage

Kaiser Family Foundation

This factsheet provides an overview of the types of contraceptive injection, use, awareness, availability, and insurance coverage of the injection in the U.S.

Link type Website

How Does DMPA-SC Work?

As with other progestin-only contraceptive methods, DMPA-SC works by preventing follicles from maturing and stopping ovulation, thickening and decreasing the amount of cervical mucus, and thinning the lining of the uterus.[12] It has a typical use failure rate of 4%.[13,14] Other benefits beyond pregnancy prevention include reduction of endometriosis pain and a lower risk of uterine cancer (when used long-term).[15] It does not protect against sexually transmitted infections (STIs).

Common side effects of DMPA-SC include amenorrhea, weight gain, delay in return of fertility, and irregular bleeding. These bleeding irregularities are not harmful and often decrease with continued use. The FDA includes a boxed warning (commonly referred to as a "black box warning") on DMPA due to bone mineral density loss, indicating it should only be used for more than 2 years if other birth control methods are "inadequate;" however, the American College of Obstetrics and Gynecology (ACOG), the CDC, and the WHO disagree with this characterization, noting that the resulting bone loss is not associated with fractures and is reversible with discontinuation, thus suggesting that DMPA can safely be used by adolescents and adults for extended time periods.[7,16]

Relevant Resources

DMPA and Bone Effects

American College of Obstetrics and Gynecology

This is a direct link to ACOG's statement regarding the use of DMPA and bone loss.

Link type Website

Progestin-Only Hormonal Birth Control: Pill and Injection

American College of Obstetrics and Gynecology

Answers to frequently asked questions regarding progestin-only pills and injections, including information on what it is, how it works, benefits, and risks.

Link type Website

Who Can Use DMPA-SC?

DMPA-SC may be offered as an option to individuals seeking birth control. DMPA may be of particular interest for those who do not wish to use a daily method, need to avoid estrogen, or have other conditions that might benefit from treatment from hormonal therapy including, but not limited to, sickle cell disease, pelvic inflammatory disease (PID), uterine fibroids, endometriosis, and seizure disorders.

Contraindications for use of DMPA are the same in both formulations. The only U.S. Medical Eligibility Criteria (MEC) category 4 condition (a condition which represents an unacceptable health risk if the contraceptive method is used) is if the patient has had breast cancer within the last 5 years.

Good for Those Who

Need birth control, but don't want to use a daily method

Should avoid estrogen

Have conditions that benefit from hormonal therapy

Other U.S. MEC category 3 conditions for which the theoretical or proven risks usually outweigh the advantages of using the method include:

- Multiple risk factors for atherosclerotic cardiovascular disease
  (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)
- Systolic ≥160 mm Hg or diastolic ≥100 mm Hg
- Hypertension with vascular disease
- Current and history of ischemic heart disease
- Breast cancer in the past — no evidence of recurrent disease for 5 years
- Diabetes with nephropathy, retinopathy, or neuropathy, or other vascular disease
- Diabetes of more than 20 years' duration
- Cirrhosis — severe, decompensated
- History of benign or malignant liver tumor
- History of stroke
- Unexplained vaginal bleeding (suspicious for serious condition before evaluation)
- Systemic lupus erythematosus:
  - Positive (or unknown) antiphospholipid antibodies (initiation and continuation of the method)
  - Severe thrombocytopenia (initiation of the method only — continuation of DMPA is category 2)

Relevant Resources

U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention

The U.S. MEC, developed by the CDC after review of the scientific evidence and in consultation with national experts, can be referenced to determine medical eligibility for DMPA-SC. The U.S. MEC is comprised of recommendations for the use of specific contraceptive methods by patients who have certain characteristics or medical conditions. The CDC notes that although these recommendations are meant to serve as a source of clinical guidance, health care providers should always consider the individual clinical circumstances of each person seeking family planning services.

Link type Website

U.S. Selected Practice Recommendations for Contraceptive Use

Centers for Disease Control and Prevention

The U.S. Selected Practice Recommendations (U.S. SPR), developed by the CDC after review of the scientific evidence and consultation with national experts, "addresses a select group of common, yet sometimes controversial or complex, issues regarding initiation and use of specific contraceptive methods." It includes a section on injectables and DMPA-SC specifically.

Link type Website

CDC Contraception App

Centers for Disease Control and Prevention

Developed by the Division of Reproductive Health, this downloadable app covers more than 60 characteristics or medical conditions (U.S. MEC) and numerous clinical situations (U.S. SPR). These recommendations are intended to assist healthcare providers when they counsel women, men, and couples about contraceptive method choice and use.

Link type Website

Identification of Candidates for DMPA-SC

Candidates for DMPA-SC include individuals who are interested in an autonomous form of contraception, and those who may have difficulty returning to a clinic for health care professional-administered contraception.

Data suggest that self-administered DMPA-SC may have better continuation rates than health care professional-administered DMPA (SC and IM), with comparable low pregnancy rates and no additional safety concerns.[3,4] Self-administered DMPA-SC also offers client privacy, convenience, and autonomy. No previous experience with self-injection is necessary for successful initiation of DMPA-SC. Further, patients who have switched from clinic-administered DMPA-IM to self-administered DMPA-SC suggest that this option should be made available to all people interested in contraceptives without stereotyping the typical user.[17] DMPA-SC may also improve access to care by removing the need to return to a clinical office every 3 months.[17] One injection is effective for 3 months which can be an advantage over daily pills.

Candidates for Self- Injected DMPA-SC Include

Those who want the freedom to control their own contraception

Those who want an injectable contraceptive who may not be able to easily return to a clinic every 3 months

Some of the disadvantages or adverse reactions of self-administered DMPA-SC may include time to learn how to self-inject the medication. Some users experienced local site irritation and soreness on the first and second injection. This irritation and soreness may improve over time.[3] According to the label, 1 in 100 clients experienced dimpling at the injection site.

Relevant Resource

Sample Script for Staff to Assess DMPA-SC Self-Administration Interest

Clinical Training Center for Sexual and Reproductive Health

Health center staff may find the following script useful when providing outreach to patients, if applicable. Staff familiar with providing counseling and education about contraception can utilize this sample script to initiate calls or conversations with patients who are candidates for DMPA SC.

Link type Website

Prescribing DMPA-SC

DMPA-SC is available in the U.S. as depo-subQ provera 104®. It is available in prefilled, single-dose syringes and should be stored at room temperature. Recommendations for initiation, follow-up, and reinjection of DMPA-SC are the same as the IM formulation.[6] Among healthy individuals, no examinations or tests are needed before initiating DMPA. However, baseline weight and BMI may be useful to monitor over time since some studies have shown weight gain with DMPA use.[18]

Initiation

No exams or tests are needed before prescribing

Patients can record weight and BMI at time of prescription

Initiate anytime it is reasonably certain patient is not pregnant

DMPA can be initiated anytime it is reasonably certain the individual is not pregnant.[19] If there is concern that the patient could be pregnant, providers may recommend the patient take a pregnancy test before initiating DMPA-SC. However, as suggested in the CDC's U.S. SPR, "the benefits of starting to use a contraceptive method likely exceed any risk," even in situations in which the health care provider is uncertain whether the individual is pregnant. As such, the risks of not starting contraception should be weighed against the risks of initiating contraception in an individual who might already be pregnant. Studies also have shown no increased risk for neonatal or infant death or developmental abnormalities among infants exposed *in utero* to DMPA.[19,20,21,22] Therefore, the health care provider can consider having patients start using DMPA at any time, with a follow-up pregnancy test in 2 to 4 weeks.

Prescriptions for depo-subQ provera 104® should include a quantity of 4 syringes to allow for a 1-year supply. Reinjection should be administered every 13 weeks (about 3 months). Repeat DMPA injections can be given up to 2 weeks late (up to 15 weeks from the last injection) without needing additional contraceptive protection.[6]

Relevant Resources

Clinical Protocol Template – DMPA-SC Self-Administration

Clinical Training Center for Sexual and Reproductive Health

This template protocol is intended to as-sist clinical providers in developing local protocols for implementing self-administration of depot medroxyprogesterone acetate subcutaneously (DMPA SC) in family planning settings. If your organization decides to use this template protocol, the author will tailor the contents to their own organization and create a local protocol.

Link type Website

DMPA-SQ: A Provider's Guide

Bedsider Providers

A quick reference guide and resources for providers on prescribing and managing subcutaneous (SQ) administration of the birth control shot at home.

Link type Website

Quick Reference Guide for Prescribing and Dispensing User-Administered DMPA SC

Clinical Training Center for Sexual and Reproductive Health

This guide provides a quick reference for why to offer DMPA-SC to patients, who is eligible, what to say, contraindications, and additional resource links.

Link type Website

Patient Counseling and Communication

The quality of interpersonal communication affects health care outcomes including patient satisfaction, use of preventive care, and adherence to medication.[23] Patient-centered care is one of the six domains of healthcare quality and is defined by the National Academy of Medicine as care that is "respectful of, and responsive to, individual patient preferences, needs, and values."[24] In alignment with these goals of care, U.S. providers should aim to provide contraceptive counseling through equitable, client-centered, shared decision-making that is non-coercive and offers the full range of options to everyone without stereotypes, including self-administration of DMPA-SC.[25]

Providers Should Understand

Patient-centered care

The history of race and racism in reproductive medicine

Shared decision-making

How to offer contraceptive counseling through a variety of modalities

This kind of care is perhaps even more important when it comes to reproductive and sexual health as there is a long-documented history of the U.S. government and health care institutions controlling the means of reproduction. For example, before emancipation, enslaved African women were considered property and had no control over their own bodies or reproduction—they were forced to have children who were often taken away from them as they

were considered property of slaveowners.[26,27] Inequities and assertation of control over the bodies of people of color continued long after emancipation. Some examples include the non-consensual sterilization of poor people and people of color in the 1960s and 1970s, the targeted marketing of DMPA injection to people of color, immigrants, and people of lower economic status, and the unethical testing of the oral contraceptive pill in Puerto Rico.[28] These injustices have resulted in many having reasonable skepticism about the government's involvement in reproductive health.

Given that the clinical relationship is a hierarchical one with health care professionals traditionally having more power than patients, we recommend that those offering contraceptive counseling acknowledge these power dynamics and recognize how this history of racism, with its intersecting oppressions, such as sexism and classism, have affected the ability of people to obtain contraceptive care that they want.[29] U.S. health care professionals should consider how this history affects the individuals that interact with the health care system, including members of the LGBTQIA+ community, and they should orient their approach to care alongside the leaders in our communities of color who have long led us through their activism to address these injustices.[30,31]

Additionally, these injustices have led to current-day disparities in use of certain contraceptives.[32] Specifically, in terms of DMPA, the CDC reports that while only 2% of U.S. individuals aged 15–49 years used DMPA (IM or SC) for contraception during 2017–2019, the majority of those are younger (aged 15–24 years), non-Hispanic Black, and people with lower income.[33] Additionally, when looking at interest for self-administration of DMPA, those reporting difficulty obtaining or refilling a prescription are twice as likely to have interest than those reporting no difficulty.[34] As DMPA-SC can make contraception more accessible given that it can be administered outside the clinic setting, ensuring that self-administration to DMPA-SC is available, especially to those who lack access to clinical settings, is an issue of equity and quality of care.[35]

Communication Best Practices

- Given that there are no requirements for in-person examination or laboratory evaluation for the use of DMPA-SC, **patients should be offered contraceptive care that is in-person, over the phone, or over video—whichever modality works best for the patient,** as long as all options remain available. While some clinics do not have the ability to offer video, telephone visits are also appropriate for counseling and prescribing DMPA-SC.
- No matter how patients would like to access services, it is important to **assure confidentiality and privacy as well as identity confirmation** with name, date of birth (DOB), medical record number (MRN), and location.
- Please remember that individuals learn differently—some learn from visual aids, some learn from verbal descriptions, and some learn from physical interaction. Whether in-person or via telehealth, make sure to **provide visual aids, videos, and real-time instruction to teach about injections.**
- Also remember to **practice "teach-back" methods** that allow patients to explain to you their understanding of the material if new instruction is provided.

- Additionally, **ensure that patients have an easy way to contact the clinic** if they are experiencing side effects or have any other questions about contraceptive options and use.

Relevant Resources

Contraception: Counseling and Selection

UpToDate

This online, expert-written and reviewed article presents the goals of quality contraceptive counseling, reviews different approaches to counseling and its relationship to health equity, and provides a step-by-step guide to providing high-quality, patient-centered counseling. Information specific to each contraceptive method is presented in detail separately.

Link type Website

Teaching How to Inject

When counseling about DMPA-SC, providers should:

1. Screen patients for contraindications to DMPA
2. Counsel patients about side effects
3. Teach patients how to inject
4. Educate patients about interval of injection and how to set reminders for continued injections
5. Remind patients how to store medications
6. Review information about safe needle disposal with patients

Teach Injection Via

Telehealth

In-person

Patient experience with injection is not required.

Individuals can be prescribed and taught to administer DMPA-SC via a telehealth visit (ideally synchronous audio/video) or during an in-person visit. DMPA-SC is a good choice for those who are comfortable with self-injection whether they are new to DMPA or want to switch to this delivery method. However, previous experience with self-injection is not necessary for successful use of self-administered DMPA-SC.

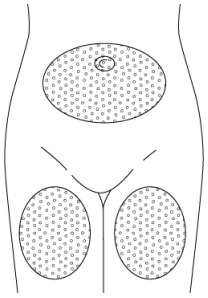
Step 1: Prepare the Injection Area

Choose injection site: abdomen or anterior thigh

Consider icing for 5 minutes prior to injection to decrease sensation at site

Wash hands

Wipe chosen injection site with alcohol pad



Step 2: Prepare the Syringe

Hold syringe by the barrel, pointing upward

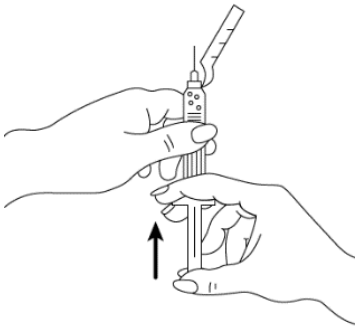
Shake for 1 minute

Unscrew and remove the protective cap

Attach needle to barrel, and move safety shield away from needle

Remove plastic needle cover

Gently push syringe plunger until liquid is at the top and air bubbles are removed



Step 3: Inject the DMPA-SC

Grasp skin with thumb and forefingers and insert needle at 45-degree angle

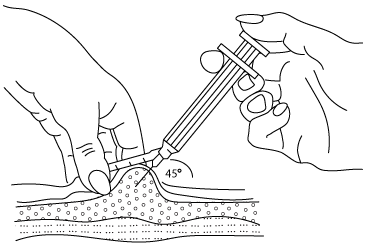
Press syringe slowly while counting to 5

Make sure to give the entire dose

Remove needle from skin

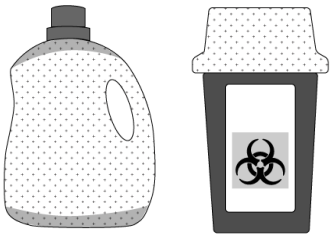
Cap safety shield

Apply pressure, but don't rub



Step 4: Dispose of the Needle

Different states have different requirements for safe needle disposal. Some require a sharps container, which some states offer for free at a pharmacy. Ideally this is what you would use. Otherwise, you can use a hard plastic container as an alternative. Provide this resource to patients to find a location to dispose of their needles in their container: Safe Needle Disposal



Provider Resources

This Is How I Teach: Self-Injection DMPA-SC

Innovating Education in Reproductive Health

This video shows providers how they can teach their patients to do self-injection of DMPA-SC.

Link type Website

Patient Resources

Subcutaneous DP Instructions

Harbor-UCLA OBGYN

This video provides visual step-by-step instructions on how patients can give themselves a DMPA-SC shot at home. The video also provides information on the DMPA-SC shot including is effectiveness rate, benefits, and side effects. There are 2 videos, one in English and one in Spanish.

Link type Website

Depo-Provera Sub-Q User Guide

Reproductive Health Access Project

This factsheet explains the basics of how to use DMPA-SC. It also answers common questions such as: How does depo work? How do I use depo? What if I am late for the next shot? Does depo have risks? This is a printable resource available in English, Spanish, Chinese, Hindi, and Vietnamese.

Link type Website

Depo Dosing Calendar

Clinical Training Center for Sexual and Reproductive Health

A calendar for patients to record their injection history. Based on 3-month/15-week dosing intervals between weeks 13-15 to be used with intramuscular injection (IM) and subcutaneous injections (SC).

Link type Website

Safe Needle Disposal

SafeNeedleDisposal.org

An interactive map allows users to select the state they reside in for specific guidance and regulation of sharps. The website also has various downloadable materials on safe needle disposal.

Link type Website

Billing and Advocacy for DMPA-SC Coverage

While self-administered DMPA-SC has been in use around the world for over a decade, DMPA-SC is currently approved by the FDA only for administration by a health care professional in the U.S. In May 2021, the CDC updated recommendations in the U.S. SPR for Contraceptive Use to state that, "self-administered DMPA-SC should be made available as an additional approach to deliver injectable contraception."[6]

Coverage Varies

Though some states and insurance plans provide coverage for self-administered DMPA-SC, billing still varies state by state and by private insurance.

According to the CDC, "although the FDA label states that DMPA-SC is only to be administered by a health care professional, health care providers might prescribe an FDA-approved drug for off-label use (including administering a drug in a different way, such as self-administration) when medically indicated, as determined by the health care provider, for their patient." [6,17]

Though some states and insurance plans provide coverage, billing still varies state by state and by private insurance. It is important to check the formulary for your patients' plans to determine co-pay and burden of cost. Additionally, insurers may place utilization requirements such as prior approval upon its use, so provide an explanation if a prior approval (TAR) is issued by the insurer. Finally, as many insurers do not routinely cover DMPA as a pharmacy benefit, some patients may only access it at provider offices. In cases like this, clinics can offer to mail it to patients directly.[36] To bill and be paid optimally for their services, clinicians should document contraceptive counseling services provided including the time spent with the patient. DMPA-SC may be dispensed in person, including curbside, or delivered/mailed by the clinic or clinic's pharmacy. If DMPA-SC is a pharmacy benefit, DMPA-SC can be ordered to the pharmacy of choice for the patient.

The Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) code for DMPA (J1050) is per 1 mg, so it is necessary to report total units based on the dosage

(i.e., report 104 units for DMPA-SC or 150 units for DMPA-IM). The billed charge should also be reported per 1 mg. It is a billing best practice to check individual payer guidance for expected codes and reporting units and review DMPA payments for accuracy. Claims with low payments for the drug should be corrected to avoid revenue loss.

There may be some extra steps in advocating for coverage on behalf of our patients, but it is worth it for them to get to choose a safe and reliable method of contraception that works for them!

Billing Aids

Coding and Billing Recommendations for Counseling, Education and Ongoing Monitoring of Patients Electing to use DMPA Subcutaneously via Self-administration (PDF)

Clinical Training Center for Sexual and Reproductive Health

This resource includes CPT, ICD-10, and common procedure codes to capture the counseling, instruction, and prescribing for DMPA-SC for medical providers and pharmacists.

Link type PDF

P

Tools for Advocacy

Sample Letter for Advocacy for DMPA-SC (MS Word)

Clinical Training Center for Sexual and Reproductive Health

This letter provides a sample argument to advocate for coverage of DMPA-SC as a pharmacy benefit. You can use this letter as a request to State Medicaid programs and Family Planning Waiver programs as well as to private insurers. While written generically, the language in this letter can also be applied to TAR if requested by the insurer for an individual patient. If using it for that purpose, please describe why it is important for the client to autonomously provide the medication and the additional risk or burden of coming to the clinic to receive the IM formulation.

Link type Word document

W

Podcast Discussion between Two Providers Who Expanded DMPA-SC in California

Contraception Podcast

This 17-minute interview with Dr. Jennifer Karlin by Dr. Jennifer Russo from the October 2020 *Contraception Podcast* discusses barriers and successes to implementing the expansion of DMPA-SC in California during

COVID-19 pandemic. It discusses some of the background for the implementation project published in the journal *Contraception* and is helpful for developing strategies for advocating for coverage of DMPA-SC.

Link type Website

Self-Injectable Contraception: What Is the Evidence?

Clinical Training Center for Sexual and Reproductive Health

This 1-hour video presentation from the 2021 Virtual National Reproductive Health Conference reviews not only the evidence behind the use of self-administered DMPA-SC but also discusses the implementation strategies employed by two providers in California and Louisiana to expand the option of self-administered DMPA-SC to their patients during the COVID-19 pandemic. Both providers successfully employed creative solutions to respond to barriers unique to their local settings. This presentation can offer providers an approach to implementing the expansion of DMPA-SC in their own settings.

Link type Website

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