

DEPO-MEDROXYPROGESTERONE ACETATE (DMPA)
INJECTION
(SUB-Q AND IM)

I. INTRODUCTION

DMPA is a progestin-only, injectable method of birth control available in two formulations:

- A. A 1 cc crystalline suspension of 150 mg depo medroxyprogesterone acetate that is injected intramuscularly (IM) every three months (11-13 weeks)
- B. A low dose 104 mg of medroxyprogesterone acetate in a 0.65 ml solution that is injected subcutaneously (subQ) every three months. (12-14 weeks)

Perfect use failure rate in the first year of use: 0.3%

Typical use failure rate in the first year of use: 3%

When administered at the recommended dose to women every 3 months, DMPA works as a contraceptive by inhibiting the secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation and results in endometrial thinning.

II. CLIENT SELECTION

A. Indications:

- 1. DMPA may be provided when contraindications do not exist.
- 2. May be a good choice for clients that cannot use/have medical contraindications to estrogen-containing method.
- 3. May be a good choice for clients that desire a long-term, highly efficacious, non-coitus dependent, private contraceptive method.

B. Contraindications (USMEC 3-- Risks outweigh advantages for method use; USMEC 4- - Unacceptable risk for method use):

- 1. Unexplained vaginal bleeding (USMEC 3 before evaluation)
- 2. Breast cancer (current USMEC 4) (past USMEC 3)
- 3. History of myocardial infarction, ischemic heart disease or stroke (USMEC 3)
- 4. Cirrhosis (severe-decompensated) (USMEC 3)
- 5. Liver tumors – adenoma or hepatoma (USMEC 3)
- 6. Hypertension (≥ 160 systolic or ≥ 100 diastolic) (USMEC 3)
- 7. Diabetes with nephropathy/retinopathy/neuropathy (USMEC 3)
- 8. Other vascular disease or diabetes of >20 years duration (USMEC 3)
- 9. Systemic Lupus Erythematosus –positive (or unknown) antiphospholipid antibodies, and severe thrombocytopenia (USMEC 3)
- 10. Rheumatoid Arthritis-Immunosuppressive therapy – (USMEC 3 for continuation)
- 11. Migraine with aura at any age (USMEC 3 for continuation)

FDA Labeling Changes

The following black box warning has been added to the package labeling:

- Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.
- It is unknown if use of the Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture later in life.
- Depo-Provera Contraceptive Injection should be used as long-term birth control methods (e.g. longer than two years) only if other birth control methods are inadequate.

Reference:

FDA Package Labeling, November 2004

Risk Benefit Analysis

- Available studies have not demonstrated an increase in the rate of bone fractures in women who have used DMPA.
- However, other birth control methods should be considered in the risk/benefit analysis for the use of DMPA in women with osteoporosis risk factors – alcoholism, strong family history of osteoporosis, metabolic bone disease, anorexia nervosa, chronic use of drugs that can reduce bone mass (such as anticonvulsants or corticosteroids) and tobacco use. Osteoporosis information sheet should be provided if requested.

III. MEDICAL SCREENING AND EVALUATION

- A. Comprehensive medical evaluation (history, physical examination and laboratory testing, as indicated) should be completed prior to the provision of DMPA.
- B. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment). The reason for the deferral must be documented in the client's medical record. A complete history, height, weight and blood pressure measurement is required in the medical record and cannot be deferred/delayed.
- C. Written results of a physical exam done elsewhere within the last 12 months are acceptable (with the exception of history, height, weight and blood pressure - which must be taken and documented prior to providing DMPA).
- D. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- E. There is no time at which a pelvic exam is required for continued provision of the method as long as all eligibility requirements are met
- F. Pap test screening according to current screening recommendations and site-approved protocols must be followed.

IV. WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site Medical Director. In addition, there should be consultation with the site Medical Director if needed.
- B. A request for hormonal contraceptives by women with special conditions/risk factors must be signed and this must be documented in the medical record for any client with the following medical conditions:
- C. Multiple risk factors for arterial cardiovascular disease (USMEC 3)
 - 1. Older age
 - 2. Smoking
 - 3. Diabetes
 - 4. Hypertension

V. DMPA METHOD INITIATION

- A. QuickStart: **QuickStart protocols are highly encouraged** when a patient is starting (or restarting) DMPA. Quickstart improves compliance with starting the second month of contraceptive ring use, and may decrease risk of unintended pregnancy
 - 1. Administer the first injection on the day of the clinic visit and use a backup method (condoms, etc.) for 7 days.
 - 2. If there is concern about undetectable early pregnancy, the client should have a repeat pregnancy test prior to the next depo injection.
 - 3. If the repeat pregnancy test is negative and the client has no sign of pregnancy (i.e. nausea, breast tenderness), continue the method.
- B. Timing of Initiation: The table below should be followed when initiating DMPA. Alternative timings must be individualized to ensure contraceptive protection.

Current Method	First DMPA Injection	Back-Up
No hormonal method or no IUD in current cycle	<p>Anytime in cycle if it is reasonably certain client is not pregnant.</p> <p>If possibility of pregnancy is suspected, a highly sensitive urine pregnancy test must be completed prior to initiation. If pregnancy test is negative, give DMPA and advise client to repeat pregnancy test in two weeks.</p> <p>For any woman who receives DMPA beyond first 5 days of menstrual bleeding, urine pregnancy test must be performed before the subsequent DMPA injection may be given.</p> <p>For post-ECP DMPA administration the following are options for the initiation of DMPA after ECP:</p> <ul style="list-style-type: none"> A. Initiate during 1st 5 days of next menses B. Initiate within 24 hours post ECP use and: <ul style="list-style-type: none"> 1. Perform a highly sensitive urine 	If more than 5 days since menstrual bleeding started, back-up for 7 days.

	<p>pregnancy test prior to initiation unless 1st day LNMP within past 5 days.</p> <ol style="list-style-type: none"> 2. Advise client to repeat pregnancy test in 3-4 weeks 3. Advise back-up method for 7 days unless first day LNMP within past 5 days 4. For these women, a urine pregnancy test must be performed before the next DMPA injection may be given 	
Correct use of COCs, patch or ring in current cycle	Any time in cycle	None
IUD	<p>Any time in cycle</p> <ol style="list-style-type: none"> A. Within five days of onset of menses B. Beyond first five days and has had sexual intercourse this cycle C. Beyond first five days and has not had sexual intercourse this cycle <p>If initiated beyond first five days of menstrual bleeding and IUD is removed prior to next menses (or >3 weeks since LMP), urine pregnancy test must be performed before the subsequent DMPA injection may be given.</p>	<p>None, may remove IUD at time of injection</p> <p>Delay removal of IUD until next menses or x3 wks if no menses</p> <p>Back-up for seven days, if IUD is used as back-up. Delay removal of IUD until next menses or x3 wks if no menses.</p>
Post partum or post-surgical abortion or post spontaneous abortion	Any time before onset of intercourse	Back-up for seven days
Post medical abortion	<p>No sooner than the day after Misoprostol and up to seven days after Mifepristone</p> <p>Beyond seven days after Mifepristone and before onset of intercourse</p>	<p>None</p> <p>Back-up for seven days</p>

VI. DISPENSING, ADMINISTRATING AND PRESCRIBING DMPA

A. Up to five injections of DMPA may be prescribed for initial and annual clients.

- B. Trained clinic personnel may administer injections. Providers must be familiar with proper injection procedures, timing of injections, and infection control guidelines.
- C. Selection of DMPA formulation:
 - 1. It is NOT acceptable to use the 400 mg/ml concentration for contraceptive purposes.
 - 2. SubQ injections: 0.65 ml of a 104 mg/0.65 ml solution of DMPA must be used.
 - 3. For IM injections: 1.0 ml of a 150 mg/ml solution of DMPA must be used.
- D. Giving the injection
 - 1. Shake vial vigorously for at least one minute just prior to use
 - 2. Give SubQ injection in the upper thigh or abdomen (do not use the arm), using the safety needle provided (may follow the directions for injection from package insert).
 - 3. Give deep IM injection in gluteus or deltoid, using 1 ½ inch 21-23 gauge needle.
 - 4. Do not massage injection site whether IM or SubQ
 - 5. Document the procedure in the clients medical record
 - 6. Protocols must be in place for the management of vaso-vagal fainting episodes and possible anaphylactic reactions.

VII. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a DMPA should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. DMPA users must be advised on the importance of regular weight bearing exercise, not smoking and taking extra calcium, either through diet or by added Calcium and Vitamin D supplements. Recommended daily amounts of Calcium (1300-1500 mg) and Vitamin D (400 – 800 mg) should be encouraged.
- D. Information that DMPA does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- E. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- F. If DMPA is being provided/prescribed to a client with risk factors, then a Request for Contraception in Women with Risk Factors form should be reviewed and signed.
- G. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- H. Emergency, 24-hour telephone number and location where emergency services can be obtained
- I. Clinic access information

VIII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

- A. Irregular Bleeding Patterns:
 - 1. Bleeding patterns tend to regularize after the first year of use.
 - 2. Obtain/perform the following:
 - a. Interval history with focus on the possibility of pregnancy or genital tract infection
 - b. Pelvic examination, as indicated, to exclude pregnancy, infection, or an anatomic lesion

- c. Return for a repeat pregnancy test in 2 weeks. If the repeat pregnancy test is negative and the client has no signs of pregnancy (i.e. nausea, breast tenderness), continue the method
- d. Laboratory tests:
 - i. Highly sensitive pregnancy test, if indicated.
 - ii. Hemoglobin, if history suggests prolonged or heavy bleeding. If **<10**, refer for medical evaluation.
 - iii. Gonorrhea and Chlamydia tests, if a cervical or upper tract infection is suspected.
- 3. If no obvious cause of bleeding is found, reassure the client that bleeding patterns are not dangerous and may resolve with time.
- 4. If inter-menstrual bleeding becomes problematic, the client may try over the counter (OTC) medication such as Ibuprofen 800 mg PO TID for 5 days.
- 5. Instruct the client that treatment may temporarily improve bleeding pattern, but there is substantial possibility that the irregular pattern will return after discontinuation of treatment.
- 6. Discontinuation may be required if the client continues to find the bleeding bothersome.
- B. Possible Pregnancy:
 - 1. There is an increased risk of ectopic for DMPA failures
 - 2. Obtain/perform the following:
 - a. Interim history update, focusing on pregnancy signs and symptoms
 - b. Pelvic examination, as indicated, to evaluate uterine softening or enlargement, adnexal tenderness or mass
 - c. Highly sensitive urine pregnancy test.
 - i. If positive, evaluate for symptoms and signs of ectopic pregnancy; begin workup or refer immediately if suspected.
 - ii. If negative, counsel and reassure the client that amenorrhea while using DMPA is an expected side effect and not dangerous.
- C. Headache: (NOTE: migraine with aura any age is a "USMEC 3" for continuation on DMPA)
 - 1. Obtain a headache history in an attempt to differentiate tension headache from migraine.
 - 2. If the headaches seem to be of the tension variety, explain that discontinuation of DMPA is unlikely to change the pattern.
 - 3. For mild headaches without neurological symptoms, attempt treatment with ibuprofen or other analgesic.
 - 4. If analgesics fail or signs of migraine aura are present, weigh the risks and benefits of continuing DMPA.
- D. Weight Change:
 - 1. Instruct regarding control of weight gain with adequate exercise and moderate dietary restriction.
 - 2. If these measures fail and weight gain becomes problematic, discontinuing DMPA may become necessary.
- E. Pain or inflammation at injection site:
 - 1. Examine site for signs/symptoms of infection (redness, swelling, pain, tenderness, warmth).
 - a. Measure affected area
 - b. Document findings
 - 2. Mild inflammation:

- a. Advise warm compresses, elevation, and rest the area as appropriate.
- b. Communicate with client in 24-48 hours to evaluate and assess for improvement and/or need for antibiotics.
- c. Refer as indicated.
- 3. Significant inflammation:
 - a. Advise warm compresses, elevation, and rest the area as appropriate.
 - b. If minimal or no improvement in 24 hours, refer to private physician or refer immediately to emergency room.
 - c. Ensure that client has written agency contact information to use in case of emergency.
- F. Injection site reactions (refer to above as well): 5% report injection site reactions with 1% having persistent changes, typically described as small areas of indurations or atrophy.

IX. FOLLOW-UP

DMPA Re-injection Visit:

- A. Every 12-14 weeks for Sub-Q and 11-13 weeks for IM.
- B. While the repeat DMPA injection can be given up to 4 weeks late without requiring additional contraceptive protection, this **does not** mean that goal should be to extend the regular DMPA injection interval by 4 weeks. (Note: The WHO expert working group considers the risk of ovulation to be minimal within 4 weeks following the time for a repeat injection of DMPA, i.e. 3 months).
- C. Client should be queried about changes in personal history, possible side effects, and menstrual cycle/bleeding pattern over the previous 3 months.
- D. Re-educate on side effects:
 - a. Severe headaches
 - b. Depression
 - c. Pain, pus, allergic reaction at the injection site

X. DOCUMENTATION

- A. Order for DMPA must be written in the medical record initially, annually and upon method change.
- B. All DMPA administered must be documented in the medical record and family planning data system.
- C. All education/counseling must be documented.

REFERENCES

1. CDC. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
2. Ziemann, M., et al. Managing Contraception for Your Pocket. 2010-2012

CLIENT EDUCATION FOR DEPO-PROVERA

PLEASE READ CAREFULLY

- Depo-Provera is a progestin only contraceptive method. Depo-Provera is 99.7% effective if given on schedule:
- Every 11 to 13 weeks as a deep intramuscular injection of 150 milligrams (mg) or
- Every 12 to 14 weeks as a subcutaneous injection of 104 milligrams (mg).

BENEFITS: In addition to prevention of pregnancy, some women experience the following benefits from using Depo-Provera:

- Scanty or no menstrual bleeding
 - Less anemia
 - It can be used by breast feeding mothers as it does not contain estrogen
 - Decreased menstrual cramps and pain
 - Suppression of pain associated with ovulation
 - Decreased risk of endometrial cancer, ovarian cancer
 - Decreased risk of PID (Pelvic Inflammatory Disease)
 - Management of pain associated with endometriosis
 - Long-term effective contraception
 - Low risk of ectopic (tubal) pregnancy
 - Decreased incidence of seizures in women with seizure disorders

You should not use the shot if you:

- Are or think you are pregnant
- Have abnormal bleeding from the vagina that has not been evaluated
- Have a known or suspected cancer of the breast
- Liver tumors (hepatocellular adenoma or malignant (hepatoma)
- Have multiple cardiovascular risk factors (45 years of age or older, heavy cigarette smoking, high blood pressure, high levels of cholesterol, diabetes)
- Have history of heart attack or stroke

While using Depo-Provera you may experience the following side effects:

- Menstrual cycle disturbances
- Weight gain
- Breast tenderness
- Depression
- Increased or decreased sex drive
- Allergic reactions (rare)
- Skin rash or spotty darkening of the skin
- Headaches
- Nausea, abdominal discomfort
- Nervousness, dizziness
- Hair (loss/increased) on face or body
- Decrease in bone density
- Decrease in HDL lipid values

Depo-Provera use may decrease the amount of calcium in your bones. The longer you are on Depo-Provera the more calcium you may lose. This increases the risk of your bones weakening if you use Depo-Provera continuously for a long time (for more than 2

years). Calcium levels may not return completely once you stop using Depo-Provera. The loss of calcium may increase your risk of osteoporosis and broken bones, particularly after your menopause. Calcium is generally added to bones during teenage years. The decrease of calcium in your bones is of most concern if you are a teenager or having the following risk factors:

- * Bone disease
- * A strong family history of osteoporosis
- * An eating disorder
- * Drug use that can lower the amount of calcium in bones (drugs for epilepsy or steroids)
- * Smoking cigarettes
- * Drinking a lot of alcohol

Women who use Depo-Provera contraceptive injection may lose significant bone mineral density. Depo-Provera should be used as a long-term birth control method (that is, longer than 2 years) only if other birth control methods are inadequate.

To lessen the chances of serious problems, you should seek medical care if experiencing any of the following symptoms:

- Repeated, very painful headaches - Yellowing of the skin or eyes
- Unusually heavy bleeding from the vagina - New lump in your breast
- Severe depression
- Severe lower abdominal pain (may be a sign of pregnancy)
- Pus, prolonged pain or bleeding at the injection site

Use of Depo-Provera requires a clinic visit every 12 weeks for a reinjection.

Depo-Provera does not provide protection from sexually transmitted infections.

Stopping Depo-Provera and Future Fertility: Depo-Provera may prevent a woman from getting pregnant for more than 12 weeks after her last injection. The average delay in return of fertility is 10 months following the last injection. Depo-Provera does not decrease a woman's fertility in the long run.

Bone Mineral Testing: This testing provides information of your current bone density status. You may desire to discuss this with your primary care physician if you are at high risk (smoker, high alcohol use, teenager, strong family history of bone density disease, eating disorder or you are on medications that lower calcium in your bones).

CONSENT FOR DEPOT MEDROXYPROGESTERONE ACETATE (DMPA)

I, (print or type name) _____,
request the contraceptive injection of depot medroxyprogesterone acetate (also known as DMPA, Depo-Provera®, depo-subQ provera 104, Depo, or “the Shot”), as my family planning method.

I have received a educational information packages with the DMPA that has information about the benefits and risks of DMPA and how to use DMPA.

I understand that no birth control method is perfect and that some women have gotten pregnant while on DMPA (3 out of every 1000 women during the first year of use).

I understand DMPA will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with DMPA to decrease the effectiveness of DMPA. I know it is important to tell all my health care providers that I am on DMPA.

I understand that when using DMPA, the chances of developing health problems increase with certain conditions such as:

- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using DMPA:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with DMPA include:

- Weight gain
- Irregular bleeding or spotting
- Breast tenderness
- Hair loss
- Acne
- Depression

I know to watch for “A.C.H.E.S.” as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I understand that there may be a risk of osteoporosis (thinning of the bones) with use of DMPA and that after stopping DMPA the bone structure might not return to normal. Current evidence does not show an increased risk of bone fractures in later years. Other types of contraception are not associated with changes in bone density (thinning).

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

- An interpreter was offered to the client. Yes No
- This form has been read to the client in the client’s spoken language. Yes No
- Patient’s Language (specify): _____
- Interpreter Name: _____
(print or type name of interpreter)
- Interpreter Services provided by (agency): _____
- Date: _____ Interpreter Signature: _____

Staff Use only

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____