

# CHAPTER V: PROGESTIN-ONLY INJECTABLES

## WHAT ARE PROGESTIN-ONLY INJECTABLES (POIs)?

- POI contraceptives contain the synthetic hormone progestin and are administered via deep intramuscular (IM) injection.
- These contraceptives are available in the Philippines in the following preparations:
  - 1 mL of 150 mg depot medroxyprogesterone acetate (DMPA; Depo-Provera)
  - 3 mL of 150 mg DMPA (Depo-Trust)
  - 1 mL ampoule of 200 mg norethisterone enanthate (NET-EN; Noristerat)
- DMPA is given every three months, whereas NET-EN is given every two months.



*Another preparation is DMPA SQ (Uniject), which contains only 104 mg of progestin (30% less than that in the regular DMPA). It is available only in the US and the UK. This preparation is given subcutaneously every three months and has similar contraceptive effectiveness but with fewer side effects, such as weight gain.*



## HOW EFFECTIVE ARE POIs?

- POIs are 99.7% effective with perfect use and 97.0% effective with typical use, which means about three pregnancies for every 100 women who use the method during the first year. This number is reduced to less than one pregnancy per 100 users with continued use.
- The effectiveness of injectables depends on whether the client returns on time for the re-injection. The risk of pregnancy increases when the interval between injections increases or when an injection is actually missed.

## HOW DO POIs WORK?

- POIs suppress ovulation. After a 150 mg injection of DMPA, ovulation does not occur for at least 14 weeks. Levels of the follicle stimulating hormone (FSH) and luteinizing hormone (LH) are reduced, and an LH surge does not occur.

- POIs thicken the cervical mucus and impair the entry of sperm into the uterus.

### WHAT ARE THE ADVANTAGES OF USING POIs?

- Long-acting and reversible
- No need for daily intake
- Does not interfere with sexual intercourse
- Perceived as culturally acceptable by some women
- May be self-administered and may not always be facility/clinic-based
- Involves neither estrogen-related side effects, such as nausea and dizziness, nor serious complications, such as thrombophlebitis or pulmonary embolism
- Does not affect quantity and quality of breast milk
- Provides beneficial non-contraceptive effects:
  - Helps prevent iron-deficiency anemia because of scanty menses and the consequent amenorrhea
  - Does not affect anti-epileptic drug levels, particularly lamotrigine
  - Reduces the risk of ectopic pregnancies
  - Prevents endometrial cancer, uterine fibroids, and symptomatic pelvic inflammatory disease
  - Reduces sickle cell crises among women with sickle cell anemia
  - Reduces symptoms of endometriosis (pelvic pain and irregular bleeding)

### WHAT ARE THE DISADVANTAGES OF USING POIs?

- Delays return to fertility by an average of 10 months from the last injection.
- Requires an injection every two or three months
- Does not protect against STIs such as HIV/AIDS
- Results in menstrual irregularity during the first few months of use
- Amenorrhea, which causes some women to become anxious about not having menses
- Impossible to discontinue immediately (only until DMPA is cleared from the body)
- Possible bone loss for long-term users, although a study has shown potential reversibility

WHO CAN USE POIs?

Most women of any reproductive age or parity can generally use POIs safely and effectively.

Table 10. MEC categories for POIs

Category 1: Use the method without restriction.

<ul style="list-style-type: none"><li>Women aged 18 to 45 years old</li></ul>	<ul style="list-style-type: none"><li>Diagnosed with benign ovarian tumor, endometriosis, severe dysmenorrhea</li></ul>
<ul style="list-style-type: none"><li>Women who may or may not have given birth</li></ul>	<ul style="list-style-type: none"><li>Women with gestational trophoblastic disease, endometrial cancer, or ovarian cancer</li></ul>
<ul style="list-style-type: none"><li>Breastfeeding women, more than six weeks after childbirth</li></ul>	<ul style="list-style-type: none"><li>Among women with uterine anatomical abnormalities (e.g., fibroids)</li></ul>
<ul style="list-style-type: none"><li>Any time for non-breastfeeding postpartum women</li></ul>	<ul style="list-style-type: none"><li>Benign breast disease, or family history of cancer</li></ul>
<ul style="list-style-type: none"><li>Any time post-abortion</li></ul>	<ul style="list-style-type: none"><li>Cervical ectropion</li></ul>
<ul style="list-style-type: none"><li>Past ectopic pregnancy</li></ul>	<ul style="list-style-type: none"><li>Current or history of PID or STIs such as HIV/AIDS</li></ul>
<ul style="list-style-type: none"><li>History of pelvic surgery</li></ul>	<ul style="list-style-type: none"><li>Schistosomiasis</li></ul>
<ul style="list-style-type: none"><li>Women who smoke at any age</li></ul>	<ul style="list-style-type: none"><li>Tuberculosis</li></ul>
<ul style="list-style-type: none"><li>Body mass index of more than or equal to 30 kg/m</li></ul>	<ul style="list-style-type: none"><li>Women with body mass index of more than or equal to 30 kg/m</li></ul>
<ul style="list-style-type: none"><li>2 and more than 18 years old</li></ul>	<ul style="list-style-type: none"><li>2 and who are less than 18 years old (for NET-EN only)</li></ul>
<ul style="list-style-type: none"><li>Body mass index of more than or equal to 30 kg/m</li></ul>	<ul style="list-style-type: none"><li>Women with body mass index of more than or equal to 30 kg/m</li></ul>
<ul style="list-style-type: none"><li>2</li></ul>	<ul style="list-style-type: none"><li>2 and who are less than 18 years old (for NET-EN only)</li></ul>
<ul style="list-style-type: none"><li>and more than 18 years old</li></ul>	<ul style="list-style-type: none"><li>History of gestational diabetes</li></ul>
<ul style="list-style-type: none"><li>Malaria</li></ul>	<ul style="list-style-type: none"><li>Any thyroid disorder</li></ul>
<ul style="list-style-type: none"><li>History of high blood pressure during pregnancy</li></ul>	
<ul style="list-style-type: none"><li>Family history of DVT/PE</li></ul>	<ul style="list-style-type: none"><li>Family history of DVT/PE</li></ul>
<ul style="list-style-type: none"><li>Surgery WITHOUT immobilization</li></ul>	<ul style="list-style-type: none"><li>Any classification of viral hepatitis</li></ul>
<ul style="list-style-type: none"><li>Superficial venous thrombosis</li></ul>	<ul style="list-style-type: none"><li>Mild liver cirrhosis</li></ul>
<ul style="list-style-type: none"><li>Any type of valvular heart disease</li></ul>	<ul style="list-style-type: none"><li>Anemias such as thalassemia, sickle cell disease, or iron-deficiency anemia</li></ul>
<ul style="list-style-type: none"><li>Epilepsy</li></ul>	<ul style="list-style-type: none"><li>Current use of lamotrigine, broad-spectrum antibiotics, antifungal, or antiparasitics</li></ul>
<ul style="list-style-type: none"><li>Depressive disorders</li></ul>	<ul style="list-style-type: none"><li>Current use of lamotrigine, broad-spectrum antibiotics, antifungal, or antiparasitics</li></ul>

Category 2: Generally use the method but with more than the usual follow-up.

- Menarche to 18 years old
- Women more than 45 years old
- Women with body mass index of more than or equal to 30 kg/m<sup>2</sup>, and less than 18 years old (for DMPA only)
- History of hypertension, in which blood pressure CANNOT be evaluated
- Adequately controlled hypertension, in which blood pressure CAN be evaluated
- Have increased blood pressure (systolic of 140 mm Hg to 159 mm Hg or diastolic of 90 mm Hg to 99 mm Hg)
- History or currently diagnosed with DVT/PE on anticoagulant therapy
- Major surgery with prolonged immobilization
- Known thrombogenic mutations
- Known hyperlipidemia
- Systemic lupus erythematosus on immunosuppressive treatment
- Migraine with or without aura
- Women with irregular vaginal bleeding patterns
- Diagnosed with cervical intraepithelial neoplasia or cervical cancer prior to treatment
- Undiagnosed breast mass
- Diabetes with non-vascular disease
- Any gallbladder disease
- History of COC-related cholestasis
- Benign liver tumors such as focal nodular hyperplasia
- Current use of non-nucleoside reverse transcriptase inhibitors and ritonavir-boosted protease inhibitors, certain anticonvulsants, rifampicin or rifabutin therapy (for NET-EN only)

WHO CANNOT USE POIs?

According to the WHO MEC, clients with the following characteristics and conditions cannot use the method:

Category 3: Do not use the method unless no other appropriate method is available and with close supervision.

- Breastfeeding women, less than six weeks after childbirth
- Multiple risk factors for arterial cardiovascular disease such as old age, smoking, diabetes, and hypertension
- Have high blood pressure (systolic of more than or equal to 160 mm Hg or diastolic of more than or equal to 100 mm Hg)
- Hypertension with vascular disease
- Acute DVT/PE
- Current or history of ischemic heart disease or stroke
- History of breast cancer with no evidence of disease in the last five years
- Unexplained vaginal bleeding prior to evaluation
- Initiation of method in women with systemic lupus erythematosus (with positive antiphospholipid antibodies and severe thrombocytopenia)
- Diabetes with nephropathy, retinopathy, neuropathy, or other vascular diseases
- Severe liver cirrhosis
- Liver tumors such as hepatocellular adenoma or malignant hepatoma

Category 4: Do NOT use the method.

- Diagnosed with breast cancer

## ARE POIs SAFE TO USE?

- POIs are very safe. Similar to other progestin-only contraceptives, POIs can be used by women who want a highly effective contraceptive, including those who are breastfeeding or who are not eligible to use estrogen-containing low-dose combined oral contraceptives (COCs).
- There is no known harm to the fetus if DMPA is given during pregnancy.
- Extensive studies by the WHO emphasize that DMPA presents no overall risks for cancer, congenital malformations, or infertility. Research has revealed the following:
  - Similar to COCs, DMPA exerts a strong protective effect against endometrial cancer.
  - The use of DMPA does not increase the risk of breast cancer.
  - No relationships exist between ovarian cancer and the use of DMPA.
  - DMPA does not increase the risk of liver cancer in areas where hepatitis is endemic.

## WHAT ARE THE POSSIBLE SIDE EFFECTS OF POIs?

- The following changes in menstrual bleeding patterns are possible:
  - Amenorrhea
  - Menstrual irregularity: breakthrough bleeding and spotting, which are common
- On very rare occasions, allergic reactions occur immediately following an injection.

## WHAT ARE THE MODES OF ADMINISTRATION OF POIs?

POIs are best administered using autodisable (AD) syringes or disposable syringes and needles when available using the following dosing schemes:

- One dose of DMPA (150 mg) by deep IM injection given every 12 weeks
- One dose of NET-EN (200 mg) by deep IM injection given every eight weeks



Disposable syringes and needles should not be reused. Sharps disposal containers improve injection safety for clients, healthcare workers, and communities by reducing the reuse of needles and by preventing needle stick injuries. Place AD and disposable syringes and needles in puncture-proof containers.



## HOW IS DMPA ADMINISTERED?

1. Wash hands thoroughly with soap and water and then dry.
2. Check vial for contents/dosage and the expiration date. If contents are less than the indicated volume, do not use the vial.
3. Gently shake the vial (vigorous shaking will make the solution foamy). Remove the metal cover from the vial without touching the rubber stopper. Failure to mix the solution will cause some of the drug to remain as sediment in the vial, resulting in an inadequate dose and, possibly, lower contraceptive effectiveness.
4. Swab the skin at the injection site with alcohol or other antiseptics to remove any visible dirt. Allow the antiseptic to dry before the injection.
5. Put the vial in a flat surface and slightly tilt the vial, or hold the vial upside down at eye level while aspirating the solution. Doing so ensures that the solution is completely aspirated from the vial.
6. Slowly aspirate the contents of the vial. Make sure that none is spilled as air is expelled from the syringe. Use a 2 mL to 5 mL disposable syringe with a 21–23 gauge needle, 1–1.5 inches in length.
7. Inject the contents of the syringe deep into the upper outer arm (deltoid muscle) or into the upper outer quadrant of the buttocks (gluteal muscle) to prevent hitting the sciatic nerve.

8. Do not massage the injection site. Instruct the client not to massage or rub the site, as this can cause the DMPA to be absorbed fast.
9. Dispose used assembled needle and syringe in puncture-proof sharps containers.
10. Wash and dry hands thoroughly.

## WHEN SHOULD POI USE BEGIN?

### For interval clients

- Any time that the client is reasonably certain that she is not pregnant.
- Within the first seven days of the menstrual cycle, the client needs no backup method.
- After seven days of the menstrual cycle, advise the client to use a backup method or to exercise abstinence for the next seven days.

### For breastfeeding clients

- As early as six weeks after delivery.
- If the client's menses have resumed, she can start injectables at any time as long as she is reasonably certain that she is not pregnant.
- ***Fully or nearly fully breastfeeding***
  - Less than six months after giving birth
    - Delay her first injection until six weeks after giving birth.
    - If the client's monthly bleeding has not returned, she can start POIs at any time between six weeks and six months. A backup method is not necessary.
    - If the client's monthly bleeding has returned, she can start POIs as advised for women having menstrual cycles.
  - More than six months after giving birth
    - If the client's monthly bleeding has not returned, she can start POIs at any time as long as she is reasonably certain she is not pregnant. Instruct the client to use a backup method for the next seven days after the injection.
    - If the client's monthly bleeding has returned, she can start POIs as advised for women having menstrual cycles.



- ***Partially breastfeeding***

- Less than six weeks after giving birth
- Delay the client's first injection until at least six weeks after giving birth. However, if chances are strong that she cannot come back for the method at six weeks and she asks for an injectable, she may be given the first shot.
- More than six weeks after giving birth
- If the client's monthly bleeding has not returned, she can start POIs at any time as long as she is reasonably certain that she is not pregnant. Instruct the client to use a backup method for the next seven days after the injection.
- If the client's monthly bleeding has returned, she can start POIs as advised for women having menstrual cycles.

#### For postpartum women who are NOT breastfeeding

- Less than four weeks after giving birth
  - She can start injectables any time after giving birth. A backup method is not necessary.
- More than four weeks after giving birth
  - If the client's menses have not returned, she can start the injectable at any time as long as she is certain that she is not pregnant. Instruct the client to use a backup method for the first seven days after injection.
  - If the client's menses have returned, she can start the injectable within seven days of her menses without the need for a backup method. If more than seven days have passed since her menses, she can have the injection but will need to use a backup method for the first seven days after the injection.

#### For post-abortion clients

- May use immediately or within seven days after an abortion.
- If later than seven days, any time that she is reasonably certain that she is not pregnant. She should avoid sex or use condoms for the next seven days.

#### Clients switching from non-hormonal methods such as IUD

- The client can start POIs immediately.

## Clients switching from a hormonal method

- The client can start POIs immediately if she has been using the hormonal method consistently and correctly or if she is reasonably certain that she is not pregnant. No need to wait for her next monthly bleeding. No need for a backup method.
- If the client is switching from another injectable, she can have POIs when the next injection would have been given. A backup method is not necessary.

## IS FOLLOW-UP NEEDED? HOW AND WHEN?

The client is instructed to return to the clinic for re- injection every three months (12 weeks) for DMPA and every two months (8 weeks) for NET-EN.

Encourage the client to come back on time for her injections.

- DMPA can be administered four weeks early or late; NET-EN can be administered two weeks early or late.
- If the client is less than four weeks late for the next DMPA or less than two weeks late for the next NET-EN injection, she can receive the reinjection.

No need for a backup method, and no need to assess for pregnancy, as the client is not likely to be pregnant.

- However, if she is more than four weeks late for the next DMPA injection or more than two weeks late for the next NET-EN injection, she has to be assessed for probability of pregnancy. If she is not likely to be pregnant, she can have her reinjection but should abstain from sex or use a backup method for seven days. She should be instructed to come on time for her scheduled injections; otherwise, her risk of pregnancy increases. If she is unable to adhere to the schedule, ask the client to consider shifting to another method.
- If pregnancy cannot be ascertained, perform a pregnancy test, or ask the client to abstain from sexual activity or use a backup method in the meantime and to return in one month. Pregnancy may be determined then. If the client is not pregnant, she may be given the next injection, and discuss the possibility of shifting to a convenient method for her.
- For any questions or problems, the client should be encouraged to visit the clinic.



## WHAT ARE THE IMMEDIATE AND LASTING EFFECTS OF POI USE?

Aside from the long-term effective contraception provided by POIs, these contraceptives commonly cause breakthrough bleeding or spotting during the first months of use. These effects lessen or disappear with time.

Very heavy (twice as much as the usual menses) or prolonged (more than eight days) bleeding is rare but requires attention.

- When bleeding occurs, counsel the client that menstrual irregularities are common.
- Rule out other possible problems/causes.
- To control heavy or prolonged bleeding, COC pills may be given for one to three cycles until bleeding decreases.
  - Non-steroidal anti-inflammatory drugs, such as mefenamic acid (500 mg) or ibuprofen (800 mg), may also be prescribed; the client must be instructed to take one tablet two to three times daily for five days.
  - Tranexamic acid (1 g) may also be given, along with instructions to take one capsule every six hours for five days.
- Another option is to administer the next injection early (four weeks after the first injection).
- Advise the client to take iron supplements or iron-rich food.
- If the problem persists, refer the client for gynecologic examination.
- Help the client choose another method if the problem is intolerable.

Another 50% of women using DMPA develop amenorrhea after a year of use.

This condition is not harmful but occurs because of the effect of the drug on the endometrium.

- Counsel the client that amenorrhea is normal and does not indicate a problem. Assure her that this condition does not indicate pregnancy and that menstrual blood is not building up inside her.
- Explain that this situation can improve her health by preventing anemia.

Weight gain (average of 1 to 2 kg each year) may be experienced because of an increase in appetite. This is a common side effect and can be controlled by shifting to a low-calorie diet.

## WHAT ARE THE POTENTIAL COMPLICATIONS OF USING POIs?

- A theoretical concern is that DMPA might affect bone development in women under 18 years. Whether DMPA prevents adolescents from reaching their potential peak bone mass remains unclear. Although DMPA decreases bone mass, reversal has been observed after discontinuation. The WHO concludes that the advantages of the method generally outweigh this theoretical disadvantage.
- A nine-year study by the WHO revealed that DMPA does not increase women's overall risk of breast cancer, invasive cervical cancer, liver cancer, or ovarian cancer. In their study, DMPA decreased the risk of endometrial cancer. Studies are still ongoing on whether DMPA might accelerate the development of pre-existing breast cancer. The WHO Collaborative Study did not find a significantly increased risk of breast or cervical cancer among DMPA users.
- There is no known harm to the fetus if DMPA is given during pregnancy.



## WHAT HAPPENS WHEN CLIENTS STOP USING THE POI?

The average delay in return of fertility is 9 to 10 months for DMPA and 6 months for NET-EN from the last injection. This method does not affect fertility in the long term.

## IS A REFERRAL NEEDED? HOW AND WHEN?

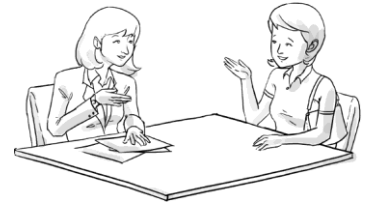
Clients should be instructed to report back to the clinic for any of the following warning signs:

- Recurring unbearable headaches
- Heavy bleeding
- Depression
- Severe lower abdominal pain, which may be a sign of pregnancy
- Pus, prolonged pain, or bleeding at injection site

## COUNSELING TIPS

Counsel the client on the possibility of changes in menstrual bleeding patterns, which may include the following:

- Amenorrhea: Reassure the client that amenorrhea is an expected side effect and that she can expect menstrual cycles to return to normal within six months of discontinuing the POIs.
- Menstrual irregularity: Reassure the client that breakthrough bleeding and spotting are common.



Emphasize to the client the proper timing of the injection, that is, the time when the client receives the first injection and when the next injection is due, as well as how often she will receive the injections. Returning for injections regularly (every three months for DMPA) is imperative.

## WHAT ARE FACTS ABOUT POIs?

Contrary to popular beliefs,

- POIs do not cause birth defects and will not harm the fetus if a woman becomes pregnant while using them or accidentally starts POIs when she is already pregnant. POIs neither disrupt an existing pregnancy nor cause an abortion.
- bleeding episodes should not be used as a guide for the injection schedule; rather, the injection should be given every three months for DMPA regardless of whether a woman has bleeding or not.
- POIs are not used to regulate monthly periods, especially for those with irregular cycles.
- women younger than 35 who smoke any number of cigarettes and women aged 35 years and older who smoke less than 15 cigarettes a day can safely use POIs.
- POIs generally do not cause changes in a woman's mood or sexual drive. POIs are safe for women with varicose veins. Women with DVT/PE should not use POIs.
- POIs do not cause a woman to be infertile, but regaining fertility may be delayed after stopping the use of POIs; pregnancy usually becomes possible after around eight months.