

Care and Treatment Plan: Progestin-Only Hormonal Contraceptives

This Decision Support Tool (DST) provides clinical guidance for the provision of progestin-only hormonal contraception. It is meant to be used in concert with DST 800: Assessment and Diagnostic Guideline: Contraceptive Management.

Definition

Progestin-only hormonal contraception (POHC) is a hormonal contraceptive method that contains only progestin. There are four types of POHCs available in Canada:

- Progestin-only oral contraceptive pills
- Progestin-only injectable (Depot-Medroxyprogesterone Acetate) (Injectable)
- Progestin-only implant device
- Levonorgestrel-releasing intrauterine system

For the purposes of this DST, Certified Practice Registered Nurses, or RN(C)s, may only autonomously prescribe and dispense oral, injectable, and implant types of POHC (BCCNM, 2021). Therefore, POHC in this DST refers only to the first three progestin-only methods of contraception: oral, injectable, and implant.

Indications

For the purposes of Contraceptive Management RN(C)s, POHCs are indicated for any client who is seeking a reliable, reversible method of contraception. POHCs are a reliable and effective contraceptive option for clients unable to use estrogen-containing contraception (Hatcher et al., 2018). Hormonal contraception is further indicated for a number of menstrual/monthly bleeding-related conditions or symptoms and the non-contraceptive benefits they confer (Hatcher et al., 2018). However, clients seeking or using hormonal contraception solely for purposes other than contraception must be referred for a client specific order or transfer of care (BCCNM, 2021). Please see *DST 800: Assessment and Diagnostic Guideline: Contraceptive Management* for examples.

Pharmacokinetics

Oral

Oral POHCs are supplied in packages of 28 tablets, each containing 35mcg of norethindrone (Hatcher et al., 2018).

Injectable

Injectable POHCs are supplied in vials of 150mg to be injected intramuscularly every 12-13 weeks, with a range of 10 to less than 15 weeks being acceptable (Hatcher et al., 2018).

Implant

Implant POHC is supplied as a 68mg etonogestrel, radiopaque implant device to be inserted subdermally in the upper arm once every three years (Hatcher et al., 2018).

Action

The primary method of action of POHCs is inhibition of the secretion of pituitary gonadotropins, which then suppresses ovulation (Hatcher et al., 2018). POHCs also make cervical mucus more viscous, which impedes sperm transport and induces endometrial atrophy, making the endometrium unreceptive to implantation (Hatcher et al., 2018).

Onset

Contraceptive benefits of POHCs are realized within seven days of consistent and correct POHC use.

If the implant is inserted less than five days since menstrual/monthly bleeding pattern started, no backup is needed. Otherwise, contraceptive benefits are realized within seven days (Merck, 2020).

Consultation and/or Referral

RN(C)s are restricted to prescribing, dispensing or administering POHCs to clients who classify as category 1 or 2 as defined by the *U.S. Medical Eligibility Criteria for Contraceptive Use* (Curtis et al., 2016).

RN(C)s cannot independently prescribe, dispense, or administer POHCs without an order to clients who classify as category 3 or 4 (BCCNM, 2021; Curtis et al., 2016).

Relative Contraindications

As per *U.S. Medical Eligibility Criteria for Contraceptive Use*, Category 3 (Curtis et al., 2016).

Absolute Contraindications

As per *U.S. Medical Eligibility Criteria for Contraceptive Use*, Category 4 (Curtis et al., 2016).

RN(C)s must refer or consult with a physician or nurse practitioner for the following clients:

- Clients wanting to use a POHC in the presence of relative or absolute contraindications (*U.S. Medical Eligibility Criteria for Contraceptive Use* categories 3 and 4) (Curtis et al., 2016).
- Clients whose medical condition has changed so that they might be using a POHC in the presence of relative or absolute contraindications (*U.S. Medical Eligibility Criteria for Contraceptive Use* Categories 3 and 4) (Curtis et al., 2016).
- Clients who are currently taking POHCs and demonstrate any of the following symptoms:
 - ACHES (abdominal pain, chest pain, headache, eye problems and severe leg pain)
 - Jaundice
 - Syncope
 - Severe depression
 - Unexplained vaginal/genital bleeding
 - Severe or worsening migraine headaches, with or without aura
 - Severe allergic reaction
- Clients taking medications that might be affected by hormonal contraception.

Drug Interactions

The following drugs and drug classes are considered a *U.S. Medical Eligibility Criteria* category 3 or 4 and could have some effect on POHC absorption and metabolism (WHO, 2015). Clinicians should always refer to the most current *U.S. Medical Eligibility Criteria* for up-to-date drug interactions. RN(C)s must refer or consult with a physician or nurse practitioner for clients taking any of the following medications:

Oral

- Certain anticonvulsants: phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine (WHO, 2015).
- Certain antimicrobials: Rifampicin or Rifabutin therapy (Centers for Disease Control and Prevention, 2020).

Note: With the exception of Rifampicin or Rifabutin therapy, antibiotic use does not affect POHC efficacy. Barrier methods should be used while on Rifampicin or Rifabutin therapy. Hormonal contraceptives should not be stopped. Antibiotics need to be taken for their full course. (Simons et al., 2017).

Injectable

- Aminoglutethimide used to treat Cushing disease.

Note: This interaction is not found in the U.S. Medical Eligibility Criteria but aminoglutethimide may decrease effectiveness of injectable POHC (Pfizer, 2021).

Implant

There are no drug interactions noted in the *U.S. Medical Eligibility Criteria* (Centers for Disease Control and Prevention, 2020).

Pregnancy and Breastfeeding/Chestfeeding

Pregnancy

There is no known harm to the person, the course of the pregnancy, or the fetus if POHCs are inadvertently used during pregnancy (Black et al., 2016).

The relationship between injectable POHC use during pregnancy and its effects on the fetus remain unclear (Black et al., 2016).

If a POHC is inadvertently initiated with a pregnant client or the client becomes pregnant during POHC use, the POHC should be discontinued immediately (Black et al., 2016).

Postpartum

Initiation of POHCs can occur directly post-partum regardless of breastfeeding/chestfeeding status (Black et al., 2016).

Breastfeeding/Chestfeeding

Progestin is excreted in human milk in small quantities, but is unlikely to have an effect on the infant (Black et al., 2016).

Breastfeeding/chestfeeding is not a contraindication for POHC use (Black et al., 2016).

Precautions and Considerations

Precautions and Considerations Specific to ORAL Progestin-Only Hormonal Contraceptives

- Clients who have undergone malabsorptive procedures, such as gastric bypass or biliopancreatic diversion, are categorized as *U.S. Medical Eligibility Criteria* category 3 (Centers for Disease Control and Prevention, 2020).
- Malabsorption related to chronic gastrointestinal inflammation and active diarrhea might cause ineffectiveness of any oral contraception (WHO, 2015).
- Repeated vomiting (e.g., bulimia, severe GI illness) and/or severe, persistent diarrhea can decrease the absorption of the pill and might decrease its effectiveness. Vomiting within two hours of pill ingestion might require repeated doses (WHO, 2015).

Precautions and Considerations Specific to INJECTABLE Progestin-Only Hormonal Contraceptives

- Injectable POHCs are associated with decreased bone mineral density that is generally temporary and reversible (Pfizer, 2021). The advantages of injectable use generally outweigh theoretical concerns regarding fracture risk. The available evidence does not justify limiting duration of injectable use due to bone density concerns. Use of injectable POHCs in the absence of symptoms or other risk factors (e.g.: strong family history of osteoporosis) is not an indication for bone mineral density testing (Pfizer, 2021).
- Clients should be informed about the potential effects of injectable POHCs on bone mineral density and counselled about bone health, including calcium and vitamin D supplements, smoking cessation, weight-bearing exercise, and decreased alcohol and caffeine consumption (Pfizer, 2021).
- To rule out a rare but possible severe allergic reaction to injectable POHCs, clinicians should recommend that clients wait in the care setting for 15 minutes following injection (BCCNM, 2021).
- Injectable POHCs may lead to a slower return to fertility than other hormonal contraceptives. The average return to fertility is 15-49 weeks from the last injection (Hatcher et al., 2018).

Precautions and Considerations Specific to IMPLANTED Progestin-Only Hormonal Contraceptives

- The implant can be felt under the skin and is approximately the size of a matchstick (Merck, 2020).
- Clients with known clotting disorders or those on anticoagulant therapy may not be suitable candidates and should be assessed by a nurse practitioner or physician prior to receiving the implant (Merck, 2020).
- Clients may return to the provider at 4-6 weeks for follow-up for any side effects, menstrual changes/monthly bleeding pattern changes, difficulty palpating the implant, or if a local reaction occurs (Merck, 2020).

Adverse Effects

Side effects from POHCs are often mild and transient and respond to a change in formulation (Black et al., 2016). Acknowledgment and management of side effects are crucial to successful continuation of POHCs.

Common Possible Side Effects

Common side effects of POHCs include, but are not limited to:

- Appetite changes (can result in weight gain)
- Breast/chest tenderness
- Menstrual/monthly bleeding pattern disturbance including breakthrough bleeding, irregular bleeding, and amenorrhea
- Headaches (mild, without aura)
- Decreased libido
- Mood changes
- Delayed return to fertility (injectable POHC only)
- Weight gain (injectable and implanted POHC only)
- Pain/bruising at site of insertion (implanted POHC only).

Warning and Precautions

Serious complications from POHCs are rare (Black et al., 2016).

The following symptoms should be investigated immediately, and client should be referred to a physician or nurse practitioner. These symptoms might also warrant discontinuation of POHCs (Black et al., 2016; Centers for Disease Control and Prevention, 2020):

- ACHES (abdominal pain, chest pain, headache, eye problems and severe leg pain)
- Moderate to severe depression
- Blood pressure >160/100
- Under the *U.S. Medical Eligibility Criteria for Contraceptive Use*, RN(C) may prescribe, dispense, and administer oral and implant POHC as Category 2; however, RN(C)s should refer client for hypertension assessment
- Under the *U.S. Medical Eligibility Criteria for Contraceptive Use*, injectable POHC is Category 3; RN(C) must refer client for contraception and a hypertension assessment
- Jaundice
- Severe or worsening migraine headaches with or without aura
- Severe allergic reaction
- Unexplained vaginal/genital bleeding
- In rare circumstances, the implant may migrate. If client cannot feel the implant, they should visit their health care provider.

Client Education Specific to CHC Use

Irregular menses is common within the first several months of POHC use and after 6-12 months, amenorrhea is more likely (Black et al., 2016).

Oral

A missed oral POHC pill by more than three hours from the regular time requires use of back-up contraception (e.g.: condom) for 48 hours after the missed dose (Hatcher et al., 2018). Clients can consider use of emergency contraception if intercourse occurred within the past 5-7 days with no other form of contraception such as a condom.

Note: If available, advise the client to follow the product monograph, or advise the client to contact a health care provider or clinic. Some clinics choose to develop client hand-outs or resources specific to missed or late POHC doses. The Society of Obstetricians and Gynecologists of Canada (SOGC) or the US Medical Eligibility Criteria Selected Practice Recommendations for

Hormonal Contraceptive Use (2016) have guidelines for missed hormonal contraceptives that can be used as a resource for health care providers.

Injectable

- Weight gain is possible with the injectable contraceptive (Hatcher et al., 2018).
- In regard to bone health, clients using injectable POHCs should be counselled regarding calcium intake and or supplementation, supported with smoking cessation and perform weight-bearing exercises at least three times a week (Black et al., 2016).
- If it has been 14 weeks or more since the last injection, a urine pregnancy test should be performed (Hatcher et al., 2018). Use of emergency contraception can be considered if intercourse has occurred within the last 5-7 days (Hatcher et al., 2018). A back-up contraceptive method should be recommended for the subsequent seven days. Depending on the client's risk of pregnancy, a repeat urine pregnancy test may be indicated at two weeks or prior to the next injection (Hatcher et al., 2018).
- Counsel client that once the injectable POHC is administered, there is no way to reverse it (Hatcher et al., 2018).
- Clients should be counselled about the longer return to fertility with injectable POHCs (see Precautions Specific to INJECTABLE Progestin-Only Hormonal Contraceptives above).

Implant

- Counsel clients to contact their health care provider if they are unable to palpate the implant at any time (Merck, 2020).
- Counsel client that once implant is administered, it must be removed by a health care provider in order to have it reversed.

Prescribing, Dispensing, and Administering POHC

For prescribing and dispensing POHCs, refer to DST 800: Assessment and Diagnostic Guideline: Contraceptive Management.

Administering Injectable POHC

- Mix the suspension well by shaking the vial before drawing up the medication.
- Using a 21-23-gauge needle appropriate for muscle mass, administer 1cc of 150mg/mL injectable POHC via intramuscular injection into the deltoid or ventrogluteal muscle depending on the client's preference (Hatcher et al., 2018). The ventrogluteal muscle might be less painful for the client.
- Do not massage the injection site.

Administering and Removing Implanted POHC

RN(C)s MUST complete an implant-specific, hands-on recommended training or equivalent (e.g.: UBC CPD) program *prior to* autonomous insertion or removal of a contraceptive implant.

Documentation

For documentation specific to POHCs, refer to DST 800: Assessment and Diagnostic Guideline: Contraceptive Management.

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Appendix 1: POHC Screening Tool

This does not replace the most current practice recommendations. RN(C) should always check medical eligibility against the most current *US Medical Eligibility Criteria*.

Are there any relative or absolute contraindications for Progestin-Only Hormonal Contraceptive Use?		
Questions to assist in determining Medical Eligibility for POHC use:		
Have you ever been told you have breast/chest cancer?	NO	YES
Have you ever been told you have ophthalmic vascular disease?	NO	YES
Have you ever had a stroke or problems with your heart?	NO	YES
Have you ever been told you have liver disease or jaundice?	NO	YES
Have you ever been told you have diabetes?	NO	YES
Have you ever been told you have lupus or rheumatoid arthritis?	NO	YES
Have you ever been told you have high blood pressure?	NO	YES
Do you have problems with severe diarrhea, poor absorption or other bowel disorders?	NO	YES
Do you get migraine headaches?	NO	YES
Do you have any unexplained vaginal/genital bleeding?	NO	YES
Do you take any medications including natural remedies?	NO	YES
Do you take anti-retroviral medications?	NO	YES
Do you take medications for seizures?	NO	YES
Do you take medications for Cushing disease?	NO	YES
Do you take medications for tuberculosis?	NO	YES

**IF YES to any:
STOP - EXPLORE OR REFER**
Client may not be a good candidate for POHC. Counsel about other contraceptive methods or consult/refer to MD/NP if client is a MEC category 3 or 4.

**IF YES to any:
STOP – EXPLORE**
Client may not be a good candidate for POHC. Counsel about other contraceptive methods or consult/refer to Dr/NP if client is a MEC category 3 or 4.

