Care and Treatment Plan: Combined Hormonal Contraceptives (CHCs)

This Decision Support Tool (DST) provides clinical guidance for Registered Nurses certified in Contraceptive Management (referred to as RN(c)s in this document) for the provision of Combined Hormonal Contraceptives (CHCs). It is meant to be used in concert with DST 800: Assessment and Diagnostic Guideline: Contraceptive Management.

Definition

Combined Hormonal Contraceptives (CHCs) are contraceptives containing both estrogen and progestin. There are three types of CHCs available in Canada:

- Oral contraceptive pills
- Transdermal contraceptive patch
- Intravaginal/intragenital contraceptive ring

Indications

For the purpose of RN(C)s certified in Contraceptive Management, CHCs are indicated for any client who is seeking a reliable, reversible method of contraception (Cason et al., 2023). RN(C)s may independently prescribe, dispense, and/or administer CHCs of a dosage less than or equal to 50 mcg of ethinyl estradiol per day, if they meet BCCNM's limits and conditions for certified practice registered nurses: Section 8: Restricted activities for certified practice.

Action

The primary method of action of CHCs is through the suppression of gonadotropins induced by the estrogen and progestin effects on the hypothalamic/pituitary axis, thereby inhibiting ovulation (Cason et al., 2023. Progestin suppresses luteinizing hormone (LH) secretions, thereby eliminating the LH surge, while estrogen suppresses follicle-stimulating hormone (FSH) secretion, thereby decreasing follicular maturation (Cason et al., 2023). Other mechanisms of action may include the development of endometrial atrophy, making the endometrium unreceptive to implantation, and cervical mucus changes that impede sperm transport (Cason et al., 2023).

Pharmacokinetics

Dose

The majority of CHCs contain ethinyl estradiol (EE) and progestin in various doses and combinations (Cason et al., 2023). The amount of estrogen in CHCs varies, and the amount and type of progestin vary and differ in potency and metabolic effect. A low-dose CHC preparation is preferred to provide effective contraception, acceptable cycle control, and the least amount of side effects for the individual (Hatcher et al., 2018). CHCs that provide a daily dose of 50 mcg or less of ethinyl estradiol are considered to be 'low dose' (Black et al., 2017).

In 2021, a new plant-based estrogen called estetrol (also known as 'E4') (trade name: Nextstellis®) was added to the Canadian market (Fruzzetti et al., 2021).

Oral CHC Formulations

Oral CHCs are taken daily, at the same time each day. There is a range of different formulations of oral CHCs available, for example, 21/7, 24/4, or extended use.

- Monophasic: Each tablet contains a fixed amount of estrogen and progestin
- Biphasic: Each tablet contains a fixed amount of estrogen, and the amount of progestin increases in the second half of the cycle
- Triphasic: The amount of estrogen can be fixed or variable, and the amount of progestin increases in three equal phases

Transdermal CHC Formulations

The transdermal patch is changed once a week for three weeks, followed by one week patch-free.

Each transdermal patch contains ethinyl estradiol 0.6mg and norelgestromin 6mg. The transdermal patch releases approximately ethinyl estradiol 35 mcg and norelgestromin 150 mcg per 24 hours (Cason et al., 2023).

Intravaginal/Intragenital CHC Formulations

The intravaginal/intragenital ring is worn inside the vagina/internal genitalia for three weeks followed by one week ring-free.

Each intravaginal/intragenital ring delivers ethinyl estradiol 15 mcg/day and etonogestrel 120 mcg/day (Cason et al., 2023).

Onset

Peak serum concentrations of combined estrogen and progestin vary between products. Contraceptive benefits are realized within seven days of consistent and correct CHC use (Hatcher et al., 2018).

Counsel clients on the timing of contraceptive initiation based on current best practice guidelines and individual circumstances. The *Quick Start Method* is considered the best practice recommendation for initiation (Cason et al., 2023).

Consultation and/or Referral

RN(C)s are restricted to prescribing, dispensing, and/or administering CHCs to clients who classify as category 1 or 2 as defined by the *U.S. Medical Eligibility Criteria for Contraceptive Use* (Nguyen et al., 2024). RN(C)s cannot independently prescribe, dispense, or administer CHCs to clients who are classified as category 3 or 4 without an order (Nguyen et al., 2024).

RN(C)s consult with, refer to, or transfer care to other health professionals about the treatment plan or as needed to meet the client's needs as per Section 8: Restricted activities for certified practice.

Relative Contraindications

As per *U.S. Medical Eligibility Criteria for Contraceptive Use*, Category 3 (Nguyen et al., 2024).

Absolute Contraindications

As per *U.S. Medical Eligibility Criteria for Contraceptive Use*, Category 4 (Nguyen et al., 2024)

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

- Clients wanting to use CHCs in the presence of relative or absolute contraindications as defined by the *U.S. Medical Eligibility Criteria for Contraceptive Use*, Categories 3 and 4 (Nguyen et al. 2024).
- On follow-up, clients whose medical condition has changed so that they might be using CHCs in the presence of relative or absolute contraindications as defined by the *U.S. Medical Eligibility Criteria for Contraceptive Use*, Categories 3 and 4 (Nguyen et al. 2024).

  For Example:
  - ACHES (abdominal pain, chest pain, headache, eye problems and severe leg pain)
- Clients with chronic health conditions that increase serum potassium or clients taking medications that increase serum potassium, if considering the use of a CHC containing drospirenone.
- Intravaginal/intragenital ring users with a history of Toxic Shock Syndrome (TSS). Rare cases of TSS have been reported by ring users, though causation has not been determined.
- Clients reporting headaches that are new and/or worsening with the use of hormonal contraception (Nguyen et al., 2024).
- Clients taking medications that might be affected by hormonal contraception.

Drug Interactions

The *U.S. Medical Eligibility Criteria for Contraceptive Use* identifies the following drugs and drug classes as Category 3 or 4 and could have some effect on CHC absorption (Nguyen et al., 2024). RN(C)s must refer or consult with a physician or nurse practitioner for clients taking any of the following:

- Anticonvulsants: phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, lamotrigine alone
  Note: Lamotrigine/valproate combo does not interact with hormones (Nguyen et al., 2024).

- Antimicrobials: Rifampicin or Rifabutin therapy

  Note: With the exception of Rifampicin or Rifabutin therapy, antibiotic use does not affect hormonal contraceptive 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).

- Fosamprenavir (antiretroviral) (Nguyen et al., 2024)

The following drugs may be impacted by CHC use. RN(C)s must refer or consult with a physician or nurse practitioner for clients taking any of the following (WHO, 2015):

- Clients taking theophylline, tricyclic antidepressants, diazepam, or lithium, who may require dosage adjustments.
- Clients taking CHCs containing drospirenone. Drospirenone may increase potassium. Clients should be advised to inform their healthcare provider if they have kidney, liver, or adrenal disease, as the use of drospirenone-containing CHCs in the presence of these conditions could cause serious heart and/or health problems. Clients should also inform their healthcare provider if they are currently on daily, long-term medications for chronic conditions such as NSAIDs, potassium-sparing diuretics, potassium supplementation, ACE inhibitors, or angiotensin-II receptor antagonists, heparin, aldosterone antagonists, or strong CYP3A4 inhibitors (Bayer Pharmaceuticals, 2022).

Pregnancy and Breastfeeding/Chestfeeding

There is no known harm to the person, the course of the pregnancy, or the fetus if CHCs are inadvertently used during pregnancy (Curtis et al. 2024). However, if a CHC is inadvertently initiated with a pregnant client or the client becomes pregnant during CHC use, the CHC should be discontinued immediately (Curtis et al. 2024).

Postpartum

Initiation of CHC in the post-partum period is dependent on the level of risk (Curtis et al. 2024). A summary is provided, but a detailed breakdown can be reviewed in the most up-to-date *U.S. Selected Practice Recommendations (SPR) for Contraceptive Use* (Curtis et al. 2024).

U.S. Medical Eligibility Criteria Category 4

(Curtis et al. 2024)

- Less than 21 days post-partum

U.S. Medical Eligibility Criteria Category 3

(Curtis et al. 2024*)*

- Breastfeeding/chestfeeding: 21 to < 30 Days
- Breastfeeding/chestfeeding: 30–42 days postpartum with other risk factors for VTE, such as:
  - Age ≥35 years
  - Previous VTE
  - Thrombophilia
  - Immobility
  - Transfusion at delivery
  - Peripartum cardiomyopathy
  - BMI ≥30 kg/m2
  - Postpartum haemorrhage
  - Postcesarean delivery
  - Preeclampsia
  - Tobacco use (smoking)
- Non-breastfeeding/chestfeeding: 21–42 days postpartum with other risk factors for VTE, such as:
  - Age ≥35 years

- Previous VTE
- Thrombophilia
- Immobility
- Transfusion at delivery
- Peripartum cardiomyopathy
- BMI ≥30 kg/m2
- Postpartum hemorrhage
- Postcesarean delivery
- Preeclampsia
- Tobacco use (smoking)

Breastfeeding/Chestfeeding

Conflicting studies suggest theoretical concerns about the effects of CHCs on breast milk/human milk volume. Estrogen and progestin are both excreted in breast milk/human milk in small quantities but are unlikely to have an effect on the baby (Cason et al., 2023; WHO, 2015).

Precautions and Considerations

In general, for all CHCs, the risk of VTE is highest in the first year of use and among first-time users (Black et al., 2017; Cason et al., 2023). The risk of VTE in CHC users remains significantly less than the risk of VTE in pregnancy and the postpartum period.

CHCs should not be withheld from clients with a family history of venous thromboembolism (VTE) unless they demonstrate symptoms of VTE. Family history of VTE in a first-degree relative is a category 2. Some thrombophilia conditions that increase the risk for deep vein thrombosis (DVP) or pulmonary embolism are heritable. Testing for underlying thrombophilia might be indicated for clients with a personal family history of VTE in a first-degree relative with a history of spontaneous VTE (i.e., not associated with pregnancy, cancer, airline travel, surgery, obesity, immobilization, etc.). In the absence of symptoms, routine laboratory screening for thrombophilia or other bleeding disorders is not recommended (Black et al., 2017; Curtis et al., 2024). Additionally, screening of asymptomatic clients is not recommended.

Precautions and Considerations Specific to Oral CHCs

(Black et al. 2017; Curtis et al. 2024)

- Malabsorption related to chronic gastrointestinal inflammation and active diarrhea theoretically may cause ineffectiveness of any oral contraception, and steps can be followed as outlined in U.S. *SPR for Contraceptive Use* (Curtis et al. 2024).
- Repeated vomiting (e.g., bulimia) and/or severe diarrhea can decrease the absorption of the pill and might decrease its effectiveness. Vomiting within two hours of pill ingestion might require repeated doses.
- The effectiveness of oral CHCs might be slightly decreased among clients who are obese (BMI >30). However, no association has been found between pregnancy risk and body mass index (BMI). It is likely that even a small decrease in effectiveness in clients who are obese still confers high overall effectiveness.

Precautions and Considerations Specific to Transdermal CHCs

(Black et al., 2017; Cason et al. 2023)

The effectiveness of the patch might be slightly decreased among clients weighing greater than 90kg or who are obese (BMI >30). However, no association has been found between pregnancy risk and body mass index (BMI). It is likely that even a small decrease in effectiveness in clients who are obese still confers overall effectiveness to be high and therefore should not be a reason to avoid this method.

- Clients with conditions that affect the skin, such as eczema, psoriasis, cuts, rash or sunburn, should not apply the patch to these areas.

Precautions and Considerations Specific to Intravaginal/Intragenital CHCs

(Black et al., 2017)

- Clients who have significant medical constraints, such as those listed below, are not good candidates for the intravaginal/intragenital ring:
  - Pelvic relaxation
  - Vaginal/genital stenosis
  - Utero-vaginal/utero-genital prolapse
  - Physical constraints such as vaginal/genital obstruction
  - Inability to reach their own genitalia
  - Desire not to touch their genitalia due to previous trauma or gender dysphoria
- Intravaginal/intragenital CHCs might not be suitable for clients who have conditions that make the vagina/genital area more susceptible to irritation or ulceration.
- Clients who have genital outbreaks of herpes simplex virus are able to use the intravaginal/intragenital contraceptive ring.
- Intravaginal/intragenital CHCs should not be used in conjunction with the diaphragm/cervical cap, as it could dislodge this barrier.

Adverse Effects

Side effects from CHCs are often mild and transient and can respond to a change in formulation (Black et al., 2017; Cason et al., 2023). Acknowledgment and management of side effects are crucial to the successful continuation of CHCs.

A theoretical understanding of the different side effects implicated by hormones is helpful. The Society of Obstetricians and Gynecologists of Canada (SOGC) or the *U.S. Medical Eligibility Criteria Selected Practice Recommendations for Contraceptive Use* (Curtis et al., 2024) *and U.S. Medical Eligibility Criteria for Contraceptive Use* (Nguyen et al., 2024) have resources for understanding side effects related to contraceptives that can be used as a resource for health care providers.

Common Possible Side Effects

Common side effects of CHCs include, but are not limited to (Cason et al., 2023):

- Absence of withdrawal bleed
- Appetite changes (can result in weight gain)
- Breast/chest tenderness
- Breakthrough bleeding/spotting
- Mild headaches without aura
- Nausea
- Mood changes
- Libido changes
- Skin changes

Warning and Precautions

Serious side effects from CHCs are rare (Cason et al., 2023). The following symptoms should be investigated immediately, referred to a physician or nurse practitioner, and might warrant discontinuation of CHCs:

- ACHES (abdominal pain, chest pain, headache, eye problems and severe leg pain)
- Moderate to severe depression
- Jaundice
- Unexplained vaginal/genital bleeding

- Syncope
- Blood pressure >140/>90
- Severe or worsening migraine headaches with or without aura
- Severe allergic reaction

Client Education Specific to CHC Use

Missed or Late CHC Doses

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 handouts or resources specific to missed or late CHC doses. The Society of Obstetricians and Gynecologists of Canada (SOGC) or the *U.S. SPR for Contraceptive Use* (Curtis et al., 2024) have guidelines for missed hormonal contraceptives that can be used as a resource for health care providers.

Continuous Use, Extended Use, and Shortened Hormone-Free Intervals

(Black et al., 2017; Cason et. Al., 2023)

- When determining the CHC method of use, the RN(C) should discuss continuous use, extended use, and shortened hormone-free intervals with the client.
- All oral, transdermal and vaginally/genitally administered CHCs can be used as continuous, extended use and/or with shortened hormone free intervals.
- Continuous use, extended use, and shortened hormone-free intervals increase contraceptive efficacy and are associated with some benefits, such as fewer overall missed pills.
- The rate of side effects and adverse events with continuous use regimes is similar to conventional CHC use.
- The length of the continuous use or extended use of CHC regimens should be administered according to the preference of the client.

Common Side Effects of Continuous and Extended Use

(Hatcher et al., 2018)

The most common side effect of continuous and extended use of CHCs is irregular bleeding or spotting. This might result in higher discontinuation rates than 28-day CHC regimes or shortened hormone-free interval regimes. It is important to counsel clients on how to manage these side effects and inform them that the unscheduled bleeding will decrease over time.

Prescribing and/or Dispensing

For prescribing and/or dispensing of CHCs, refer to the DST 800: Assessment and Diagnostic Guideline: Contraceptive Management.

Some intravaginal/intragenital contraceptive rings require cold chain medication. Once the cold chain has been broken, it is stable at room temperature for up to four months (Hatcher et al., 2018). For products that require a cold chain, an "insert by" expiry date, 4 months from time of cold chain breakage, should be clearly labelled on the outside of the ring package.

References

More recent editions of any of the items in the References List may have been published since this DST was published. If you have a newer version, please use it.

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