This decision support tool is effective as of February 2014. For more information or to provide feedback on this or any other decision support tool, email certifiedpractice@crnbc.ca

COMBINED HORMONAL CONTRACEPTIVES (CHCs)

This decision support tool (DST) provides clinical guidance for the provision of combined hormonal contraception. It is meant to be used in concert with the *Contraceptive Management: Assessment DST*.

DEFINITION

Contraception that contains both estrogen and progestin. Three types of combined hormonal contraception are available in Canada: oral contraceptive pills, the transdermal contraceptive patch and the intravaginal contraceptive ring.

INDICATIONS

For the purpose of contraceptive management certified practice, CHCs are indicated for any woman seeking a reliable, reversible, coitally-independent method of contraception. RN(C)s * independently dispense or administer only CHCs that provide a daily dose of less than 50mcg ethinyl estradiol.

RN(C)s only dispense CHCs for the purpose of contraception. Clients seeking or using CHCs for a sole purpose other than contraception must be referred to a physician or nurse practitioner (NP) for an order or transfer of care.

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. Progestin suppresses luteinizing hormone (LH) secretions thereby eliminating the LH surge while estrogen suppresses follicle stimulating hormone (FSH) secretion, thereby decreasing follicular maturation. 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.

* Note: RN(C) is an authorized title recommended by CRNBC that refers to CRNBC-certified RNs, and is used throughout this Decision Support Tool (DST).

PHARMACOKINETICS

Dose

Combined hormonal contraception contains ethinyl estradiol (EE) and a progestin in various doses and combinations. The amount of EE in CHCs ranges from 15mcg – 50mcg. 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 that individual. All CHCs providing a daily dose of less than 50mcg ethinyl estradiol are considered low-dose.

Oral CHC Formulations

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

- Monophasic (each tablet contains a fixed amount of estrogen and progestin)
- Biphasic (each tablet contains a fixed amount of estrogen; the amount of progestin increases in the second half of the cycle)
- Triphasic (the amount of estrogen can be fixed or variable; the amount of progestin increases in three equal phases)

Transdermal CHC Formulations

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

- Each transdermal contraceptive patch contains 150mcg norelgestromin and 60mcg ethinyl estradiol (EE), which is approximately 20-35mcg EE per day.

Intravaginal CHC Formulations

The intravaginal contraceptive ring is worn inside the vagina for three weeks followed by one week ring free.

- Each intravaginal ring delivers 120mcg etonogestrel and 260mcg ethinyl estradiol, which is approximately 15mcg EE per day.

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.

CONSULT OR REFER

RN(C)s are restricted to dispensing or administering CHCs to women who classify as category 1 or 2 as defined by the *U.S. Medical Eligibility Criteria for Contraceptive Use*. RN(C)s cannot independently dispense or administer CHCs without an order to women who classify as a category 3 or 4 as defined by the *U.S. Medical Eligibility Criteria for Contraceptive Use*.

Relative Contraindications

As per *U.S. Medical Eligibility Criteria for Contraceptive Use*, category 3 (see *Contraceptive Management: Assessment DST* Appendix 2: Medical Eligibility for Initiating Contraception).

Absolute Contraindications

As per *U.S. Medical Eligibility Criteria for Contraceptive Use*, category 4 (see *Contraceptive Management: Assessment DST* Appendix 2: Medical Eligibility for Initiating Contraception).

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

- Women wanting to use CHCs in the presence of relative or absolute contraindications (*U.S. Medical Eligibility Criteria for Contraceptive Use*, categories 3 and 4).
- Women whose medical condition has changed so that they might be using combined hormonal contraception in the presence of relative or absolute contraindications (*U.S. Medical Eligibility Criteria for Contraceptive Use*, categories 3 and 4).
- Women with chronic health conditions that increase serum potassium or women taking medications that increase serum potassium if considering use of a drosperinone containing CHC.
- Women who are currently taking CHCs and demonstrate any of the following symptoms: ACHES (abdominal pain, chest pain, headache, eye problems and severe leg pain); unexplained vaginal bleeding; jaundice; syncope; blood pressure >140/>90; severe migraine headaches (with aura); severe depression; and/or severe allergic skin rash.
- Transvaginal ring users with a history of toxic shock syndrome (TSS). Rare cases of TSS have been reported by ring users. Causation has not been determined.
- Clients with a strong family history consistent with inherited thrombophilia, such as unprovoked venous thromboembolism (VTE) in a first or second degree relative under the age of 50 [†]. Routine screening for inherited thrombophilias is not recommended, however, the physician/NP may elect to screen the above clients.
- Clients reporting headaches that are new and or worsening with the use of hormonal contraception.
- Clients taking medications that might be affected by hormonal contraception

Drug Interactions

The following drugs and drug classes are considered an US MEC category 3 or 4 and could have some effect on CHC absorption. RN(C)s must refer or consult with a physician or nurse practitioner for clients taking any of the following:

[†] Unprovoked VTE includes VTE not associated with pregnancy, cancer, airline travel, surgery, obesity or immobilization.

- St. John's Wort (not in US MEC but may decrease efficacy of hormonal contraception)
- Anticonvulsants: phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine
- Lamotrigine alone (lamotrigine/valproate combo does not interact with hormones)
- Protease inhibitors (e.g., nelfinavir, ritonavir)
- Rifampicin or Rifabutin therapy
- Some antiretroviral therapies (See US MEC June 22, 2012 – Update to CDC MEC Revised recommendations for HIV for a special note and specific breakdown about hormonal contraceptives and antiretroviral therapies. RN(C)s who work closely with clients who take antiretroviral therapies should become familiar with this annex.)

Note: Except for rifampicin, antibiotic use does not affect CHC efficacy.

Drugs that may be affected by CHC use (consult or refer to physician or NP for appropriate management of these clients):

- Clients taking theophylline, tricyclic antidepressants, diazepam or lithium may need dosage adjustments.
- Drospirenone containing oral CHCs can interact with other potassium-sparing drugs such as ACE inhibitors, angiotensin-II antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists and long term NSAID use. These clients should have their serum potassium checked about 14 days following initiation of a drospirenone-containing CHC.

PREGNANCY AND BREASTFEEDING

Pregnancy

There is no known harm to the woman, the course of her pregnancy or the fetus if CHCs are inadvertently used during pregnancy. 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.

Postpartum

Initiation of CHCs prior to 21 days post-partum is not recommended due to an increased risk of venous thromboembolism (VTE) (category 4).

There are different recommendations for women during the postpartum period depending on whether they are breastfeeding or not. Here is a summary of the recommendations:

Non-Breastfeeding Women

- less than 21 days postpartum: category 4
- 21 - <42 days postpartum without additional VTE risk factors:[†] category 2
- 21 - <42 days postpartum and have additional VTE risk factors:[†] category 3
- more than 42 days postpartum: category 1

Breastfeeding Women

- less than 21 days postpartum: category 4
- 21 - <30 days postpartum: category 3
- 30-42 days postpartum without additional VTE risk factors:[†] category 2
- 30-42 days postpartum and have additional VTE risk factors:[†] category 3
- more than 42 days postpartum: category 2

Breastfeeding

Conflicting studies suggest theoretical concerns about the effects of CHCs on breastmilk volume. Estrogen and progestin are both excreted in breastmilk in small quantities, but are unlikely to have an effect on the baby. Progestin-only hormonal contraception is preferred for women who are breastfeeding. Refer to the US MEC in Appendix 2 of the Contraception Management Assessment DST to determine appropriate times to initiate CHC use dependent on breastfeeding status.

PRECAUTIONS AND CONSIDERATIONS

The risk of VTE is highest in the first year of CHC use and in first-time users. The risk of VTE in CHC users remains significantly less than the risk of VTE in pregnancy and the post-partum period. In the absence of symptoms, routine laboratory screening for thrombophilia or other bleeding disorders is not recommended.[*]

Precautions and Considerations Specific to the Oral Contraceptive Pill

- There may be a slight increased risk of VTE from drospirenone-containing CHCs in comparison to other non-drosperinone-containing CHCs, however, this risk remains low, especially in comparison to the risk of VTE during pregnancy and the post-partum period.

[†] Examples of VTE Risk Factors: smoking, age ≥35 years, previous VTE, deep venous thrombosis/pulmonary embolism, known thrombogenic mutations, peripartum cardiomyopathy, immobility, transfusion at delivery, BMI ≥30 kg/m2, postpartum hemorrhage, postcesarean delivery, preeclampsia.

[*] CHCs should not be withheld from women 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 a deep vein thrombosis (DVP) or pulmonary embolism are heritable. Testing for underlying thrombophilias might be indicated for women 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). Screening of asymptomatic women is not recommended.

- Malabsorption related to chronic gastrointestinal inflammation and active diarrhea might cause ineffectiveness of any oral contraception.
- 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 overall effectiveness to be high.

Precautions and Considerations Specific to the Transdermal Contraceptive Patch

- The effectiveness of the patch might be somewhat decreased among women weighing >90kg or who are obese (BMI >30). However, no association was 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
- Women 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 the Intravaginal Contraceptive Ring

- Women who have significant pelvic relaxation, vaginal stenosis or utero-vaginal prolapse and are unable to touch their genitalia or who have vaginal obstruction are not good candidates for the intravaginal ring.
- Might not be suitable for women who have conditions that make the vagina more susceptible to irritation or ulceration. Women who have genital outbreaks of herpes simplex virus are able to use the intravaginal contraceptive ring.
- Should not be used in conjunction with the diaphragm 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. Acknowledgment and management of side effects are crucial to successful continuation of CHCs. A theoretical understanding of the different side effects implicated by hormones might be helpful.

Common Possible Side Effects

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

- Absence of withdrawal bleed
- Appetite changes (can result in weight gain)
- Breast tenderness
- Breakthrough bleeding
- Headaches (mild, without aura)
- Nausea
- Mood changes

- Libido changes
- Skin changes
- Spotting

Serious Possible Side Effects

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

- ACHES
- Severe depression
- Jaundice
- Unexplained vaginal 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 hand-outs or resources specific to missed or late CHC doses. The Society of Obstetricians and Gynecologists of Canada (SOGC) or the US MEC Selected Practice Recommendations for Hormonal Contraceptive Use (2013) 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

Refer to the *Contraceptive Management Certified Practice* introduction for definitions of continuous use, extended use and shortened hormone free intervals.

- When determining CHC method of use, the RN(C)s can discuss continuous use, extended use and shortened hormone free intervals with the client.
- All oral, transdermal and vaginally 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.
- 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 combined hormonal contraceptive CHC regimens should be administered according to the preference of the woman or the provider.

Common Side Effects of Continuous and Extended Use

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. Counseling clients on managing these side effects and informing them that the unscheduled bleeding will decrease over time is important.

DISPENSING

For dispensing CHCs, refer to the see *Contraceptive Management: Assessment DST*

The intravaginal contraceptive ring is a cold chain medication. Once the cold chain has been broken, it is stable at room temperature for up to four months. The "insert by" expiry date should be indicated on the package as soon as cold-chain storage is broken.

MANAGEMENT AND FOLLOW UP

- After initiation or change of a CHC, recommend follow-up visits between 3-6 months and annually thereafter. Blood pressure should be evaluated at these visits.
- For the purpose of this DST, initiation of hormonal contraception is when no hormonal contraception has been used within the last three months or the client is switching from a CHC to a POHC or vice versa.

DOCUMENTATION

- Refer to *Contraceptive Management: Assessment DST*

Appendix 1: CHC Screening Tool

Are there any relative or absolute contraindications for Combined Hormonal Contraceptive Use?

Questions to assist in determining Medical Eligibility for CHC use:

Have you ever been told you have breast cancer?	NO	YES
Have you ever had a stroke or problems with your heart?	NO	YES
Have you ever had a blood clot in your leg or lungs?	NO	YES
Have you ever been told you have a bleeding disorder?	NO	YES
Have you ever been told you have gall bladder disease, liver disease or jaundice?	NO	YES
Have you ever been told you have diabetes?	NO	YES
Have you ever been told you have lupus?	NO	YES
Have you ever been told you have high blood pressure or high cholesterol?	NO	YES
Have you ever had an organ transplant?	NO	YES
Do you have problems with severe diarrhea, poor absorption or other bowel disorders?	NO	YES
Do you get migraine headaches?	NO	YES
Are you planning any major surgery in the next 6 months?	NO	YES
Do you smoke cigarettes?	NO	YES
Have you been pregnant in the past 42 days?	NO	YES
Are you currently breastfeeding?	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 tuberculosis?	NO	YES

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

IF YES to any:
CAUTION - EXPLORE
Further assessment required. Evaluate client condition. If client is MEC category 3 or 4 consult/refer to Dr/NP.

If client answers "NO" to all questions.

PROCEED
Client falls into MEC category 1 or 2

Is client's blood pressure more than 140/90? — Yes → **Consult or refer to MD/NP**

No

Is there a possibility of pregnancy? — Yes → **Pregnancy Test** – urine βHCG

No

Provide CHC based on client desires, availability, side effects, non-contraceptive benefits, costs and prior client experience

Negative
- Consider Emergency Contraception if indicated

Positive
- Client does not require CHC at this time.
- Counsel appropriately

REFERENCES

For help obtaining any of the references on this list, please contact the CRNBC Helen Randal Library at circdesk@crnbc.ca

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

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