

## COMBINED HORMONAL CONTRACEPTIVES (CHCS)

### I. INTRODUCTION

Combined Hormonal Contraceptives contain both estrogen and progestin. The types of CHCs that are available include:

- A. **Combined oral contraceptives (COCs)** are the most widely used reversible method of contraception in the United States. Low dose COCs offer high efficacy, safety, and convenience and provides a number of significant non-contraceptive health benefits. COCs consisting of monophasic or multiphasic products (35 ug or less ethinyl estradiol and a low dose progestin) should be used.
- B. **Vaginal contraceptive ring (NuvaRing®)** is a non-biodegradable, flexible and transparent vaginal ring used for monthly combination hormonal contraception. It contains two active components - ethinyl estradiol (an estrogen) and etonogestrel (the biologically active metabolite of desogestrel, a third generation progestin). Etonogestrel is also known as 3-keto-desogestrel. When placed in the vagina each ring releases on average 120ug/day of etonogestrel and 15 ug/day of ethinyl estradiol over a three week period of use. The ring is made of ethylene vinyl acetate copolymers and magnesium stearate. It has an outer diameter of 54 mm (2 inches) and a cross sectional diameter of 4mm (1/8 inch).
- C. **Transdermal contraceptive patch (OrthoEvra®)** is a combination transdermal contraceptive patch containing 6.0 mg norelgestromin (NGMN) and 0.75mg of ethinyl estradiol (EE). The patch has a contact surface area of 20cm<sup>2</sup>. It releases 150 micrograms of norelgestromin and 20 micrograms of ethinyl estradiol into the bloodstream per 24 hours. In 2008 the manufacturer changed the package insert to address the slight increase in the risk of adverse events including venous thromboembolism.\*\*\*

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\*\*\*In 2005, the package labeling for OrthoEvra® was changed to include recent findings that 60% more estrogen is absorbed from the patch than from some low dose pills and the ring. Increased levels of estrogen may raise the risk of side effects, including VTE.

There are conflicting findings regarding increased risk of DVT. Two recent studies (one comparing the patch to a pill with levonorgestrel and the other to a pill with norgestimate) found a two-fold increased risk of blood clots among women using the patch, although in absolute numbers, the risk remains very low. Even a two-fold increase risk is dwarfed by the risk of VTE associated with pregnancy. A third study, recently updated with an additional 17 months of data, found no increase in risk for DVT in patch users compared to a norgestimate-containing pill. Clients need to be aware of this issue since there are ongoing lawsuits.

The FDA considers OrthoEvra® safe and effective when it is used according to the labeling. (Sources: FDA, Ortho, January 18, 2008)

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## II. CLIENT SELECTION

- A. Indications - CHCs may be provided when contraindications do not exist for contraception.
- B. Contraindications – (USMEC 3-- Risks outweigh advantages for method use; USMEC 4-- Unacceptable risk for method use): “Request for Hormonal Contraceptives by Women with Risk Factors Consent Form” must be signed and this must be documented in the medical record if medical conditions exist.
  1. History of or current deep vein thrombosis (DVT)/pulmonary embolism (PE) (USMEC 3, 4)
  2. Major surgery with prolonged immobilization (USMEC 4)
  3. Stroke (history of cerebrovascular accident) (USMEC 4)
  4. Known thrombogenic mutations (e.g. Factor V Leiden, Prothrombin mutation, Lupus Anticoagulant, Protein C, Protein S and Antithrombin deficiencies) (USMEC 4)
  5. Smoking  $\geq$  35 years of age
    - a. < 15 cigarettes/day (USMEC 3)
    - b. 15 cigarettes/day (USMEC 4)
  6. History of or current ischemic heart disease (USMEC 4)
  7. Multiple cardiovascular risk factors (older age, smoking, diabetes, hypertension) (USMEC 3,4)
  8. Hypertension
    - a. Adequately controlled (USMEC 3)
    - b. Systolic  $\geq$ 160 or diastolic  $\geq$  100 (USMEC 4);
    - c. Systolic  $\geq$ 140-159 or diastolic of 90-99 (USMEC 3)
  9. Known hyperlipidemia (USMEC 2,3) (consult with medical director)
  10. Diabetes mellitus with nephropathy, retinopathy, neuropathy (USMEC 3,4)
  11. Vascular disease or diabetes of > 20 years duration (USMEC 3,4)
  12. Medically Diagnosed Migraine
    - a. Without aura  $\geq$  35 years of age (USMEC 4 for initiation; USMEC 3 for continuation)
    - b. With aura “any age” (USMEC 4)
  13. Viral hepatitis (acute or flare) (USMEC 3,4)
  14. Cirrhosis-severe (decompensated) (USMEC 4)
  15. Solid organ transplant (complicated) (USMEC 4)
  16. Liver tumor (adenoma or hepatoma) (USMEC 4)
  17. Breast cancer (current--USMEC 4); or (past--USMEC 3)
  18. Valvular heart disease -complicated (pulmonary hypertension, history of sub-acute bacterial endocarditis, risk for atrial fibrillation) (USMEC 4)
  19. Peripartum cardiomyopathy (USMEC 3,4)
  20. Post-partum (non-breastfeeding or breastfeeding) < 21 days (USMEC 4)
  21. Post-partum (non-breastfeeding or breastfeeding) 21- 42 days with other risk factors for VTE (age  $\geq$  35 years previous VTE, thrombophilia, immobility, transfusion at delivery, BMI 30 or >, post-partum hemorrhage, post cesarean delivery, preeclampsia, or smoker) (USMEC 3)
  22. Post-partum (breastfeeding) 21 - 30 days without VTE risk factors (USMEC 3)
  23. Gallbladder disease– symptomatic (current or medically treated) (USMEC 3)
  24. History of cholestasis- (past COC related) (USMEC 3)
  25. Systemic Lupus Erythematosus – With positive (or unknown) antiphospholipid antibodies (USMEC 4)

- 26. Inflammatory bowel (ulcerative colitis, Crohns) (USMEC 2,3)
- 27. Bariatric surgery (history of)—malabsorption procedures (USMEC 3 for COC only)

The CDC 2010 Medical Eligibility Criteria for Contraceptive Use address headaches as follows: Among women with migraine, women who also had aura had a higher risk for stroke than did those without aura. Women with a history of migraine who use COCs are about 2-4 times as likely to have an ischemic stroke as nonusers with a history of migraine (USMEC 4).

See Clinician Information Sheet on Migraine Headaches attached the end of this guideline

### III. Management of 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. “Request for Hormonal Contraceptives by Women with Risk Factors Consent Form” must be signed and this must be documented in the medical record if medical conditions exist.
- C. Management of Medication Issues with Combined Hormonal Contraceptives

<b>Drugs Known To Increase Liver Enzyme Metabolism/Decrease Contraceptive Effectiveness</b>	
<b>Anti Epilepsy Drugs (AEDs)</b> – may also be used to treat certain psychiatric illnesses, headaches, chronic pain and other conditions (USMEC 3)	Carbamazepine (Tegretol) Oxcarbazepine (Trileptal) Phenobarbital, Phenytoin (Dilantin), Primidone (Mysoline), Topiramate (Topamax - mild decrease), Lamitrigene
<b>Antiretroviral (ARV) therapy</b>	Ritonavir-boosted protease inhibitors (USMEC 3)
<b>Anti-Mycobacterials</b> (Drugs used to treat tuberculosis) (USMEC 3)	Rifampin, Rifampicin – or rifabutin therapy, Rifamate

1. ARVs - HIV positive women who choose to use hormonal contraception should be encouraged to use condoms with each act of intercourse. Choice of hormonal contraceptive should be based on the woman's ARV regimen and in consultation with the provider delivering HIV care.
2. Anti-Epileptic Drugs (AEDS) and others listed above –use of monophasic is preferred. Use of back-up barrier methods and the benefits and risks of using DMPA, IUD, or sterilization as alternatives should be discussed with women who need a high degree of protection.
3. Most broad-spectrum antibiotics do not affect the contraceptive effectiveness of CHCs (CDC 1).

### 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 combined hormonal contraceptives.
- B. Delayed Exam
  - 1. 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).
  - 2. The reason for the deferral of pelvic exam must be documented in the client's medical record.
  - 3. A complete history, height, weight and BP is required in the medical record.
  - 4. Written results of a physical exam done by another provider within the last 12 months are acceptable.
  - 5. Clients transferring from another provider must have a blood pressure measurement prior to providing CHCs.
  - 6. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- C. Agency site Medical Director approved Pap test screening protocols that are current must be in place and followed. .

### IV. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a diaphragm should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to diaphragms, including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues
- C. Instruction on care of diaphragm (cleaning and inspection)
- D. Information that that CHCs provides no protection against STIs/HIV
- E. Method specific informed consent
- F. "Request for Hormonal Contraceptives by Women with Risk Factors Consent Form" must be signed by clients with special conditions/risk factors (such as diabetes, chronic hypertension, or multiple cardiovascular risk factors), as indicated.
- G. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- H. Written and verbal instruction on method use (may use Package Insert)
- I. Upon request, a copy of the method specific consent form
- J. Emergency, 24-hour telephone number and location where emergency services can be obtained
- K. Clinic access information

### V. PRESCRIBING COMBINED HORMONAL CONTRACEPTIVES

- A. Up to 14 cycles of CHCs may be prescribed for initial and annual clients
- B. Quick Start (same day start method) can be initiated if it is reasonably certain client is not pregnant and the client is not in need of emergency contraception.
  - 1. Instruct the client on the day of the clinic visit to:
    - a. Take the first pill in the pill pack, or
    - b. Insert the vaginal ring, or
    - c. Apply the first patch

2. Instruct client to use a backup method (condoms, etc.) for 7 days.
  3. If there is concern about undetectable early pregnancy, the client should 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.
- C. Prescribing vaginal contraceptive ring:
1. Follow the Package Insert Dispensing Information
  2. Only four rings may be dispensed to the client at any one time due to the expiration and storage condition requirements.
  3. An expiration date must be placed on the label of each ring package. This date should not exceed either four months from the date of dispensing or the product expiration date, whichever comes first.
  4. Prior to dispensing, ring must be stored in the refrigerator.
  5. After dispensing to the client, contraceptive ring can be stored for up to 4 months at 25°C (77°F). If vaginal ring becomes frozen, they are considered unusable.
  6. Vaginal ring should never be stored in direct sunlight or at temperatures above 30°C (86°F).
- D. Prescribing COC with Drospirenone (progesterone used in some combined hormonal contraceptives): If this progesterone is provided to a woman taking any of the medications (listed below) that predispose to hyperkalemia on a daily, long-term basis, the package insert states the client should have their potassium level checked during the first month of COC use.

#### **Medications to Check Prior to Prescribing Drospirenone**

- Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Motrin, Advil) and Naprosyn (Aleve), when taken long-term and daily for treatment of arthritis or other problems;
- Potassium-sparing diuretics such as spironolactone;
- Potassium supplementation;
- ACE (angiotensin converting enzyme) inhibitors such as Capoten (captopril), Vasotec (enalapril) and Zestril (lisinopril).
- Angiotensin - II receptor antagonists such as Cozaar (losartan potassium,) Diovan (valsartan) and Avapro (irbesartan);
- Heparin

Source : Contraceptive Technology, 19th Edition

- E. Prescribing Transdermal Patch: the effectiveness of the patch may be decreased among women who weigh >90 kg (198 lbs.) (USMEC 2).
- F. Timing of Initiation — The table below should be followed when initiating CHC. Alternative timings must be individualized to ensure contraceptive protection.

<b>Current Method</b>	<b>CHC Initiation</b>	<b>Back-Up</b>
No effective contraception	Anytime in cycle if it is reasonably certain client is not pregnant. If possibility of pregnancy is suspected, a highly sensitive urine test must be completed. If pregnancy test is negative, initiate COC and advise client to repeat urine test in 2 weeks.	If more than 5 days since menstrual bleeding started, back-up for 7 days
Correct use of vaginal contraceptive ring or transdermal contraceptive patch (changing to COC)	Within 24 hours of the removal of ring or patch	None
	At end of cycle, anytime within 7 days of last patch or ring removed.	None
Correct use of COC or patch (Changing to vaginal contraceptive ring)	Within 24 hours of the last COC tablet taken or patch removed	None
	At end of cycle, anytime within 7 days of last COC tablet or patch removed.	None
Correct use of COC or vaginal contraceptive ring (Changing to patch)	Anytime within 5 days of the last active COC tablet	None
	Within 24 hours of ring removal	None
Progestin-Only Pills	Any day of the month. There should be no skipped days between last pill and first day of COC use.	None
Implant	On same day implant is removed	Back-up method for 7 days
DMPA	On day when next injection is due	None
Intrauterine contraception in place	On same day IUD is removed	Back-up method for 7 days
Post-surgical abortion	Within five days of a completed procedure	None
Post-medical abortion (Can initiate prior to ultrasound confirmation of termination of pregnancy)	Day of Misoprostol up to seven days after Mifepristone	None
	Beyond seven days after Mifepristone if intercourse not already resumed	Back-up method for 7 days

- A. Clients should be provided an instruction sheet regarding management of deviations (e.g. missed pills, ring left in vagina >3 weeks) from the recommended CHC regimen

## VI. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

- A. Warning Signs (ACHES) – May or may not be related to CHC use and further clinical evaluation is necessary to determine whether continuation of CHC is appropriate
  - A—Abdominal pain
  - C—Chest pain
  - H—Headaches
  - E—Eye Problems
  - S—Severe Leg Pain
- B. Vaginal Bleeding - Irregular menstrual patterns (spotting to menstrual flow) are common in the first 2-3 cycles of use. If these patterns continue past the first three cycles or if heavy bleeding continues, the client needs to be assessed.
  - 1. Irregular Bleeding – After determining consistent usage; no underlying pathology; R/O pregnancy; and if not at risk of STI's, reassure patient. Use of a three-day course of NSAID's may help.
  - 2. Amenorrhea – R/O pregnancy
- C. Other side effects such as nausea, vomiting, breast tenderness, and headache should be further assessed to determine possible etiology and whether change in contraceptive method is needed.

## VII. FOLLOW-UP

- A. A blood pressure check should be conducted within 3 weeks of initiation when patient is on active part of CHC (not when she is on placebo week or week off ring, patch, etc.). At this visit response to and satisfaction with method can be assessed.
- B. CHC user must be advised to return to the clinic for additional follow-up if:
  - 1. A significant CHC related problem is suspected
  - 2. She is at increased risk for complications resulting from CHC use
  - 3. Pre-hypertensive (SBP is 120-139 or DBP is 80-89) on two consecutive visits):
    - a. The client may continue CHCs but should be counseled regarding lifestyle modifications.
    - b. Referral to a primary care provider is also recommended.
- C. At each CHC related medical visit, the client should be queried about changes in personal history, headaches, blurred or double vision, pain or swelling in arms or legs, chest pain or shortness of breath, abdominal pain, jaundice, or severe depression.
- D. When starting a new method, especially with teens, can consider follow-up visit to check for adherence to method and to assess for method satisfaction.

## VIII. DOCUMENTATION

- A. Orders must be written in medical record initially, annually and upon method change.
- B. All CHCs distributed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented

## REFERENCES

1. CDC Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 57, No.RR-4, June 18, 2010
2. Manufacturer's FDA Product Patient Insert (Ring Dispensing)

## Management of Clients Using CHC Who Develop High Blood Pressure Algorithm A

### Systolic (SBP) 140-159 or Diastolic (DBP) 90-99 (USMEC 3)

Instruct client to return two or more times within a four week period for BP checks. At each visit, take two readings, five minutes apart, sitting in a chair. Confirm elevated readings in contralateral arm. Base decision on the average of these readings.

- A. If the average of at least two properly measured BPs at any visit is SBP  $\geq 160$  or DBP  $\geq 100$ :
  1. **Discontinue CHC.** (USMEC 4)
  2. Recommend or refer for medical evaluation
  
- B. If the average of at least two properly measured BPs is SBP  $\geq 140-159$  or DBP  $\geq 90-99$  on at least two different visits:
  1. **Discontinue CHC** (USMEC 3)
  2. Educate client on alternative methods of birth control.
  3. With client's consent, initiate a non-estrogen containing method. (Please note if prescribing DMPA, BP  $\geq 160/100$  is a special condition requiring further evaluation)
  4. Re-check BP within three months
  5. If BP returns to normal ( $<120/80$ ) or prehypertensive range (SBP 120-139 or DBP 80-89), may consider initiating lower dose CHC, if available.
  
- C. If the average of two properly obtained readings each visit is SBP 120-139 or DBP 80-89 (prehypertension)
  1. May continue CHC
  2. Provide education on lifestyle modifications (dietary and exercise)
  3. Consider BP re-check in three to six months
  
- D. If  $<120/80$  on all readings:
  1. May continue CHC.

(Source: NIH Publication No. 03-5231, 2003)

## CLIENT EDUCATION FOR COMBINED HORMONAL CONTRACEPTIVES (CHCs)

Before you start taking CHCs, be sure you understand both the benefits and the possible problems of using them. This information sheet also lists the danger signs you should watch for. If you have any questions as you read, we will be happy to talk about them with you.

You will begin written information explaining the use, effectiveness, and medically recognized benefits and risks of the available birth control methods and devices. You should read the package insert or the CHC fact sheet and ask questions about anything you do not understand.

Combined Hormonal Contraceptives contain the hormones estrogen and progesterone, similar to hormones produced by a woman's body. They primarily work to prevent pregnancy by keeping eggs from being released by the ovaries. You should not take CHC's if you have reason to think you might be pregnant.

In addition to its value as a method of birth control, most women will have the following benefits from using a CHC:

- Predictable, regular menstrual cycles;
- Decreased menstrual cramps and blood loss;
- Less iron deficiency anemia;
- Less acne;
- Some protection from non-cancerous breast tumors and ovarian cysts;
- Some protection from ovarian and uterine lining cancer;
- Decreased risk of infection of the pelvis (PID);
- Fewer ectopic pregnancies.

There may be less protection from pregnancy when CHCs are taken with certain drugs, especially those used to control seizures. You should talk to your clinician about what to do if you take any other medicine with CHCs. If you see a health care provider for any reason, you should tell them you are taking a CHC.

CHC users have a slightly greater chance than non-users of developing certain serious problems that may cause death in rare cases including:

- Blood clots in the legs that can travel to the lungs
- Stroke
- Heart attack
- Liver tumors

You should **NOT** use any CHC if you have had, now have, or develop in the future any of the following:

- Blood clots in the veins or arteries
- Serious liver disease
- A heart attack or stroke
- Cancer of the breast
- Headaches with numbness or weakness in the arms or legs
- Headaches with vision problems or feeling as if the room is spinning

- Multiple cardiovascular risk factors (tobacco use, diabetes, high blood pressure, high cholesterol)
- Valvular heart disease with complications
- Known blood clotting conditions
- Jaundice with prior hormonal contraceptive use or with pregnancy
- Prolonged immobilization due to recent/anticipated surgery or illness
- Known or suspected pregnancy
- Gallbladder disease (currently symptomatic or medically treated)
- Systemic lupus
- History of bariatric surgery-malabsorptive procedure (pill only)
- Less than 21 days post-partum delivery (breastfeeding or not breastfeeding)
- Less than 21-42 days (breastfeeding or not breastfeeding) with risk factors for blood clots (age  $\geq$  35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI 30 or >, post-partum hemorrhage, post cesarean delivery, preeclampsia, or smoker)
- Smoking and age 35 and over
- Cardiac disease related to pregnancy (before or after)
- Organ transplant

Minor reactions to CHCs may include:

- Nausea, vomiting, headache
- Breast tenderness
- Weight gain or loss
- Spotting between periods
- Skin irritation (Patch only)
- Increased vaginal discharge (Ring only)

You should watch for the following danger signals and report any to a clinician **immediately**:

- Sharp or crushing chest pain or coughing blood
- Shortness of breath
- Unusual swelling or pain in the legs or arms
- Sudden severe headaches
- Changes in the frequency, severity, or associated symptoms of your headache
- Eye problems such as loss of vision
- Severe pain in the stomach or abdomen
- Yellowing of the skin or eyes
- Severe depression
- Unusually heavy bleeding from the vagina
- New lump in your breast
- No period after having a period every month

Some other things to be aware of:

- The patch may be less effective for women who weigh more than 198# (90 kg); (Patch only).
- If you are using oil-based vaginal medications on a regular basis or for more than several days in a row, you should discuss this with your clinician. (vaginal contraceptive ring only).
- Using a CHC does not protect against sexually transmitted infections/HIV and a serious infection could cause sterility. If you or your partner has other sexual partners, you should use latex condoms to prevent infections.

## CONSENT FOR COMBINED HORMONAL CONTRACEPTION

I, (print or type name) \_\_\_\_\_,  
request Combined Hormonal Contraceptives as my family planning method.

- I have received educational materials as well as the patient package insert that explains the, benefits and risks of using \_\_\_\_\_ which is the type of combined hormonal contraception I have selected.
- I understand that no birth control method is perfect and that some women have gotten pregnant while on the CHC (3 out of every 1000 women during the first year of perfect use).
- I understand CHCs 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 the CHC to decrease the effectiveness of the CHC. I know it is important to tell all my health care providers that I am on the CHC.
- I understand that while using the CHC the chances of developing health problems increase with certain conditions such as:
  - Cigarette smoking
  - 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 taking the CHC
  - Blood clots in the lungs, legs, or brain
  - Unexplained bleeding from the vagina
  - Inflammation of the veins
  - Cancer of the breast or uterus
  - Liver disease
  - Heart disease or stroke
- I understand that side effects sometimes associated with the CHC include:
  - Nausea and vomiting
  - Weight gain or loss
  - Breast tenderness
  - Spotting between periods

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 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's 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: \_\_\_\_\_  
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