# ORAL CONTRACEPTION

## I. INTRODUCTION

Oral contraceptives (OCs), also known as "the pill", are the most popular method of contraception among female adolescents. The primary mechanism of action is inhibition of ovulation. In addition, oral contraceptives produce an endometrium that is not receptive to ovum implantation and cervical mucus that becomes thick and hostile to sperm transport. Tubal and endometrial motility are slowed.

Perfect use failure rate in the first year: 0.3%
Typical use failure rate in the first year: 8%

Typical use failure is directly related to patient compliance with use. Studies show that teens have a difficult time complying with daily use of OCs, therefore, alternative methods of contraception should be encouraged.

The progestin-only pill (the minipill) is less effective than combined oral contraceptives in preventing pregnancy.

Patients using oral contraceptives (COC or POP) should receive counseling about and, as needed, prescriptions for emergency contraception (EC).

## II. ORAL CONTRACEPTIVE PILL TYPES, FORMULATIONS, AND PILL-USE PATTERNS

A. There are two types of oral contraceptives:
   1. Combined oral contraceptives (COCs), which contain an estrogen and a progestin
   2. Progestin-only contraceptives (POPs), which contain a progestin but no estrogen. This pill is often referred to as "the minipill"

B. Combined oral contraceptives are available in 2 basic formulations:
   1. The monophasic formulation, in which each active pill contains the same doses of estrogen and progestin.
   2. The multiphasic formulations can have varying amounts of estrogen and/or progestin in the active pills.

C. There are multiple different patterns of combined oral contraceptive pill use that are options
   1. **28-Day Cycling** – Most pill packs have 21 active hormone pills and 7 inactive (placebo) pills.
   2. **Shortened pill-free interval** – Starting the new pack of pills on the first day of menstruation usually decreases the pill-free interval thus allowing less time for a new follicle to develop. Pill-free interval should not be more than 7 days.
   3. **Extended regimens** – There is no biological reason to have monthly withdrawal bleeding on oral contraception. There are multiple extended regimens, and there are some pills that are formulated and packaged specifically for this type of extended regimen. If a client chooses an extended regimen, a monophasic, combined oral contraceptives must be used.

Extended regimens in one form or another provide options for women who need to control the timing of their bleeding or have severe symptoms when bleeding. All clients using extended regimens have the potential for breakthrough bleeding and must be counseled as such.

a. Bi-Cycling – Skipping the placebo pills at the end of every other pack of pills yields one period after 6 weeks of active pills.
b. Tri-Cycling – Skipping the placebo pills at the end of 2 out of every 3 packs of pills yields one period after 9 weeks of active pills.
c. Other Extended Regimens (e.g. Seasonale®) - COCs may be packaged by manufacturers as extended regimens. Seasonale®, for example, has 84 active pills followed by 7 inactive pills. The progestin and estrogen are the same as Nordette®.
d. Continuous – The client takes only active pills daily continuously. Breakthrough bleeding will occur.

D. The progestin-only contraceptive pill is taken every day without interruption.

## III. BENEFITS AND DISADVANTEGES OF COCs and POCs

A. Combined oral contraceptives (COCs) benefits:
   1. Effectiveness
   2. Safety in years of consecutive use without risk of complications
   3. Ease of reversibility
   4. Positive menstrual effects such as
      a. Decreased cramps
      b. Decreased blood loss
      c. Reduction of premenstrual symptoms
   5. Health benefits are listed in Appendix A.

B. Combined oral contraceptives (COCs) disadvantages:
   1. Must be taken daily
   2. Expensive
   3. Provide no protection against sexually transmitted infections including HIV.
   4. Have Possible side effects including
      a. Missed periods
      b. Breakthrough bleeding
      c. Nausea
      d. Vomiting
      e. Headaches
      f. Depression
      g. Decreased libido
   5. Have potential health risks (listed in Appendix B)

C. Progestin-only contraceptive pill (POCs) benefits:
   1. Estrogen-free, and therefore, useful for clients unable to tolerate the estrogen effects of combined oral contraceptives or who have contraindications against taking an estrogen-containing contraceptive
   2. Can be taken during lactation
   3. Appears to have no harmful effect on blood pressure or on coagulation

D. Progestin-only contraceptive pills (POCs) disadvantages:
   1. Irregular menstruation

2. Requirement for more exact timing of daily dosage than with the combined pills. If the minipill is taken 3 or more hours later than the usual time, a back-up method should be used for at least 48 hours.

## IV. CLIENT SELECTION

**Refer to section on Combined Hormonal Contraception for a review of indications and contraindications for OCP use.**

A. Consider the precautions prior to prescribing combined oral contraceptives (Appendix C). Refrain from providing combined oral contraceptives to those with major risk factors and use caution in prescribing for those with relative risk factors.
B. In healthy clients over age 35 or those with a family history or premature death from cardiovascular disease, it is desirable to obtain a lipid profile and fasting blood sugar prior to prescribing combined oral contraceptives. If that is not feasible, those tests can be obtained at the time the next pill supply is given.
C. Be cautious in prescribing combined oral contraceptives for clients with oligomenorrhea or amenorrhea. They may be infertile. Unless such a client's diagnosis is already known, she should be advised that an endocrine evaluation might be appropriate.
D. The ADA recommends that health care providers consider screening patients at 3-year intervals beginning at age 45, particularly in those with BMI ≥25 kg/m. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors such as a first-degree relatives (parent, sibling, or child) who have diabetes mellitus, history of gestational diabetes, history of PCOS, or hyperlipedemia.
E. Postpartum clients with a history of gestational diabetes should have a fasting 75-g oral glucose tolerance test 6 weeks postpartum to assess for ongoing diabetes.
F. The vaginal contraceptive ring may interfere with lactation. Once lactation is well established, progestin-only contraceptives are preferable for those clients requesting to use a hormone contraceptive while breastfeeding. For non-breastfeeding clients the vaginal contraceptive ring may be initiated at 4 weeks postpartum. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period. See section below on method initiation for specific postpartum initiation instructions and precautions.
G. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D)

## V. INITIATION OF ORAL CONTRACEPTIVE PILLS

A. Patients starting on OCP are not required to have a pelvic examination, and access to contraception should not be delayed while waiting for cervical cancer screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
B. Pill choice principles:
    1. Use the lowest dose of oral contraceptives that will provide pregnancy protection, provide non-contraceptive benefits, and minimize side effects.

2. Monophasic formulations should be ordered if cycle lengths are to be extended with elimination of some pill-free intervals.
3. Triphasic formulations may be preferable to reduce certain pill side effects when it is not desirable to increase hormone levels throughout the entire cycle or when it is desirable to reduce total cycle progestin levels.

C. QuickStart: **QuickStart protocols are highly encouraged** when a patient is starting (or restarting) oral contraceptive pills (COC or POP). Quickstart improves compliance with starting the second month of OCP, and may decrease risk of unintended pregnancy.
   1. Take the first pill of the pack on the day of the visit.
   2. A back-up method of contraception is recommended for 7 days.
   3. If the client is in need of emergency contraception, she should take both tablets of Plan B® at once on the visit day and start her pills no later than the next day.
   4. Her next menses may be delayed until she completes her first cycle of pills.
   5. Quick start does not increase irregular spotting or bleeding.
   6. The client should check a pregnancy test if she has not seen a normal menses within 4 weeks of starting OCP.

D. First-Day Start:
   1. Take the first pill of the pack on the first day of the menses.
   2. No back-up contraception is needed.

E. Sunday Start:
   1. Take the first pill of the pack on the Sunday after the first day of the menses.
   2. A back-up method of contraception is recommended for 7 days.
   3. Sunday starts usually result in no periods on the weekends.

F. COC Start in post partum, non-breastfeeding women:
   1. In women who are <21 days postpartum, combined hormonal contraceptives should not be used (USMEC category 4).
   2. In women who are 21--42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (USMEC Category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (USMEC Category 2).
   3. In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives related to postpartum status.
   4. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period.

G. For new COC starts, dispense a 3-month supply. Also provide the client with a prescription for a year-supply of the OCP, so access to contraception is not limited by requiring the client to return to clinic. Clients may return for additional pills to be dispensed as needed.

H. New users should return in 1-3 months for a blood pressure check, and to assess compliance.

## VI. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided an oral contraceptive should receive the following:

A. Information/counseling regarding all contraceptive options available
B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
E. Instruction on missed pills - American manufacturers of combined oral contraceptives now have standardized instructions to users on what to do when one or more contraceptive pills are missed (Appendix E). Instruct the client to follow these recommendations. Additionally, for some situations the use of emergency contraceptive pills may be considered.
F. Information that oral contraceptives do not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
G. Informed consent (form attached to this guideline) and a copy of the same upon request
H. If COC is being provided/prescribed, then CHC consent form should be reviewed and signed.
I. If COC is being provided/prescribed to client with risk factors then Request for CHC for Women with Risk Factors form should be reviewed and signed.
J. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
K. Written and verbal instruction on method use (may use Package Insert)
L. Emergency, 24-hour telephone number and location where emergency services can be obtained
M. Clinic access information

## VII. FOLLOW-UP

A. The client should return in 1-3 months for evaluation for oral contraception continuation. The client should have a blood pressure check and be evaluated for side effects.
B. Serious side effects that may warrant immediate consultation and discontinuation of combined oral contraceptives include:
    1. Sharp chest pain, coughing up blood, or sudden shortness of breath
    2. Pain in calf or leg
    3. Crushing chest pain or tightness in the chest
    4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
    5. Sudden partial or complete loss of vision
    6. Breast masses suspicious for potential malignancy
    7. Severe abdominal pain or tenderness.
    8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
    9. Jaundice
    10. Swelling of the fingers or ankles

## VIII. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

**Refer to section on Combined Hormonal Contraception for more detailed information regarding side effects and complications related to CHC use.**

A. Symptoms such as headache, nausea, vomiting, mastalgia, weight gain, irritability, fatigue, and mood changes are usually transient and often respond to changes in pill formulation.
B. Breakthrough bleeding in the first few months should be managed by encouragement and reassurance. If it occurs after many months of use, a short course of exogenous estrogen or changing to another oral contraceptive may be offered after appropriate evaluation.
C. With 28-day cycling one missed period with a negative pregnancy test may be managed by reassurance or a change to another oral contraceptive. After 2 or more missed periods the client should be examined. Consideration may be given to additional evaluation and/or a change in contraception.
D. Weight gain on combined oral contraceptives, although not typical, can occur in certain individuals. A change in oral contraceptive formulation with less estrogen and progestin may be helpful.
E. If a woman experiences signs or symptoms of serious side effects related to CHC use reviewed above, discontinuation of oral contraceptive and immediate evaluation is warranted.
F. In addition to signs or symptoms of DVT or other clotting disorders or liver dysfunction, sometimes discontinuation of oral contraception may be necessary for other reasons. Reasons for stopping combined oral contraceptives:
    1. If major surgery or immobilization for an extended period of time is contemplated, the client should discuss the elimination of oral contraception with her surgeon.
    2. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on 3 separate visits or any BP ☐160/100 are reasons to discontinue oral contraception and refer the client for medical evaluation. Begin the client on a progestin-only or non-hormonal method of contraception immediately.
    3. With evidence of severe clinical depression, refer the client for psychiatric evaluation. If depression is felt to be worsened by the oral contraceptives, you may consider stopping the method and initiating a non-hormonal method immediately. For mild mood changes a different formulation may be offered.
    4. Any client desiring to become pregnant may be advised to continue use of OCP until pregnancy is desired. Most women can become pregnant within a year of stopping OCP, similar to women who are not using hormonal contraception. The client should receive preconception counseling and be instructed in the importance of taking a daily multivitamin preparation containing 0.4 mg of folic acid.
    5. Any client with post-pill amenorrhea of more than 6 months should be referred for evaluation.

## IX. DOCUMENTATION

A. Order must be written in medical record initially, annually, and upon method change.

B. Oral contraceptives dispensed must be documented in the medical record and/or computer system.
C. All education/counseling must be documented.

REFERENCES


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APPENDIX A

## POSSIBLE HEALTH BENEFITS OF COMBINED ORAL CONTRACEPTIVES

1. Decreased menstrual bleeding
2. Less dysmenorrhea
3. Less pelvic inflammatory disease
4. Less risk for functional ovarian cyst
5. Less risk of ovarian and endometrial cancer
6. Less risk for benign breast disease
7. Decrease in frequency of ectopic pregnancy
8. Possible improvement of acne and hirsutism
9. Decrease in endometriosis
10. A protective effect against osteoporosis
11. Decreased number of sickle cell crises

APPENDIX B

## POSSIBLE HEALTH RISKS OF COMBINED ORAL CONTRACEPTIVES

1. Blood pressure elevation
2. Thrombophlebitis and venous thrombosis with or without embolism
3. Arterial thromboembolism
4. Pulmonary embolism
5. Myocardial infarction
6. Cerebral hemorrhage
7. Cerebral thrombosis
8. Gall bladder disease
9. Hepatic adenoma

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use combined oral contraceptives should be strongly advised not to smoke.

APPENDIX C

## PRECAUTIONS IN PROVIDING COMBINED ORAL CONTRACEPTIVES

Refrain from providing combined oral contraceptives for women with:

1. Thrombophlebitis, thromboembolic disorders
2. A past history of deep vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Valvular heart disease with complications
5. Severe hypertension (>160/100 mm Hg)
6. Diabetes mellitus complicated by vascular disease or of more than 20 years' duration
7. Headaches with focal neurological symptoms and/or aura
8. Major surgery with prolonged immobilization
9. Known or suspected carcinoma of the breast or personal history or breast cancer
10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
11. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use
12. Acute hepatocellular disease with abnormal liver function. Women who are hepatitis carriers, or who have had a history of hepatitis, but now have normal liver function may use estrogen-containing birth control.
13. Hepatic adenomas or carcinomas
14. Known or suspected pregnancy
15. Hypersensitivity to any component of combined oral contraceptives
16. Smoking and over age 35
17. Migraine headaches (without aura) and age > 35
18. Migraine headaches (without aura) and other risk factors for cardiovascular events, such as smoking or hypertension.

Exercise caution in providing combined oral contraceptives for women with:

1. Severe migraine
2. Hypertension (<160/100 mm Hg)
3. Active gall bladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Hyperlipidemia or history thereof
7. Lactation
8. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
9. Amenorrhea or oligomenorrhea
10. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
11. Undiagnosed vaginal/uterine bleeding
12. Cardiac or renal disease or history thereof
13. Over 50 years of age
14. Family history of the death of a parent or sibling due to myocardial infarction before age 50

APPENDIX D

## DRUG INTERACTIONS

Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples include:

1. Barbiturates (Phenobarbital)
2. Griseofulvin
3. Rifampin
4. Phenylbutazone (Butazolidin®)
5. Primidone (Mysoline®)
6. Phenytoin (Dilantin®)
7. Carbamazepine (Tegretol®)
8. Felbamate (Felbatol®)
9. Oxcarbazepine (Trileptal®)
10. Topiramate (Topamax®)
11. St. John's Wort
12. Anti-HIV protease inhibitors

APPENDIX E

## WHAT TO DO IF YOU MISS PILLS

If you miss 1 “active” pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.

2. You do not need to use a back-up birth control method if you have sex.

3. The clinician should offer emergency contraception if the missed pill is at the beginning of the pack.

If you miss 2 “active “ pills in a row in week 1 or week 2 of your pack:

1. Take 2 pills on the day you remember and 2 pills the next day.

2. Then take 1 pill a day until you finish the pack.

3. You could become pregnant if you have sex in the 7 days after you miss pills. You must use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you miss 2 “active” pills in a row in week 3:

1. If you are a Sunday starter:
   Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.

   If you are a Day 1 starter:
   Throw out the rest of the pill pack and start a new pack that same day.

2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your health care professional because you might be pregnant.

3. You could become pregnant if you have sex in the 7 days after you miss pills. You must use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you miss 3 or more “active” pills in a row (during the first 3 weeks):

1. If you are a Sunday starter:
   Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.

   If you are a Day 1 starter:
   Throw out the rest of the pill pack and start a new pack that same day.

2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your health care professional because you might be pregnant.

3. You could become pregnant if you have sex in the 7 days after you miss pills. You must use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you forget any of the 7 “reminder” pills in week 4:

1. Throw away the pills you missed.

2. Keep taking one pill each day until the pack is empty.

3. You do not need a back-up method.

If you are still not sure what to do about the pills you have missed:

1. Use a back-up method anytime you have sex.

2. Keep taking 1 “active” pill each day until you can reach your health care provider.

You should still have a “period” each month. If this is delayed, or if you have a lighter-than-normal period, you should check a pregnancy test immediately. If this test is positive, please call your clinician.

# CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS)

I, (print or type name) _____,
request birth control pills ("the Pill") as my family planning method.

I have received a pamphlet (included with each pack of pills) that has information about the benefits and risks of birth control pills and how to properly take birth control pills.

I understand that no birth control method is perfect and that some women have gotten pregnant while on the Pill (8 out of every 100 women during the first year of typical use).

I understand the Pill 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 Pill to decrease the effectiveness of the Pill. I know it is important to tell all my health care providers that I am on the Pill.

I understand that when taking the Pill, 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 Pill:

- 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 Pill 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: _____

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If translation of CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS) was required:

- A translator was offered to the client. ☐ yes ☐ no
- The client chose to use her own translator. ☐ yes ☐ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____

Date: _____ Translator Signature: _____

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- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____