

## Combined Oral Contraceptives\*

### Q.1. When is the best time to start COCs?

Recommendations	Rationales
<p>a) COCs may be started any time you can be reasonably sure that the woman is not pregnant, for example, during the 7 days which begin with the onset of menses (days 1 through 7 of the menstrual cycle).</p> <p>(See Q.2. for postpartum initiation and Q.3. for post-abortion initiation.)</p>	<p>a) Starting within the first 7 days lowers the possibility of beginning the pill while she is already pregnant (although there is the possibility that the client is pregnant and implantation bleeding has been mistaken for menses).</p> <ol style="list-style-type: none"><li>1) Dixon GW, Schlesselman JJ, Ory HW, Blye RP. Ethinyl estradiol and conjugated estrogens as postcoital contraceptives. <i>Journal of the American Medical Association</i> 1980;244:1336-1339.</li><li>2) Gray RH, Pardthaisong T, McDaniel EB, Doyle P. The timing of the first injection of Depo Provera. <i>IPPF Medical Bulletin</i> 1975;9(3):3-4.</li><li>3) Schiphorst LE, Collins WP, Roystar JP. An estrogen test to determine the times of potential fertility in women. <i>Fertility and Sterility</i> 1985;44:328-334.</li></ol>

---

\* These recommendations presume the COCs used will contain no more than 35 micrograms of ethinyl estradiol (or similar estrogen).

Recommendations	Rationales
<p>b) For a woman having menstrual cycles, no back-up method is needed if she is in the first 7 days of her menstrual cycle and is still menstruating. If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week.</p> <p>COCs may be started anytime you can be reasonably sure the woman is not pregnant. However, if COCs are started after day 7 of a regular cycle, the woman should also be counseled that:</p> <ul style="list-style-type: none"><li>● her regular bleeding pattern may be altered, and</li><li>● a back-up method (or abstinence) should be used for 7 days.</li></ul> <p>(For information concerning need for back-up method see COCs Q.7.)</p>	<p>b) A back-up method is NOT needed if the first package of pills is started while the woman is menstruating because the risk of conception is virtually nil.</p> <ul style="list-style-type: none"><li>● After day 5 of the cycle, the risk of pregnancy begins to rise.</li></ul> <p>1) Smith SK, Kirkman RJE, Arce BB, McNeilly AS, Loudon NB, Baird DT.</p> <p>The effect of deliberate omission of Trinordiol® or Microgynon® on the hypothalamo-pituitary-ovarian axis. <i>Contraception</i> 1986;34(5):513-522.</p> <p>Some programs might recommend a back-up method for women who are not menstruating at the time of COC initiation because there is a very slight risk of conception from unprotected intercourse on day 7 of the cycle.</p> <p>When back-up (or abstinence) is needed, it must be used for 7 days because 7 days of exposure to COCs are required to suppress follicular development.</p> <p>1) Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? <i>British Medical Journal</i> 1985;290:1474-1475.</p>
<p>c) If the client is using the 28-day pill packet, she should start a new packet the day after she finishes the previous packet (without a break). If the client is using the 21-day pill packet, she should skip 7 days before starting a new packet. If the pills are taken correctly, the client will always begin a new packet on the same day of the week.</p>	<p>c) The longer the pill-free interval, the higher the risk of ovulation (e.g., a 10-day pill free interval confers a 10% risk of ovulation).</p> <p>1) Landgren BM, Emiczky CS. The effect on follicular growth and luteal function of "missing the pill." <i>Contraception</i> 1991; 43(2):149-159.</p> <p>2) Killick SR, Bancroft K, Oelbaums MJ, Elstein M. Extending the duration of the pill-free interval during combined oral contraception. <i>Advances in Contraception</i> 1990;6:33-40.</p>

## Q.2. When can COCs be started postpartum?

Recommendations	Rationales
<p><b>For Breastfeeding Women:</b> (These restrictions do not apply to women who are only doing token, i.e., minimal, breastfeeding.)</p> <p>a) COCs should not be used in the first 6 weeks postpartum. COCs are considered by many experts to be the method of LAST choice during any state of lactation, especially in the first 6 weeks to 6 months.</p> <p>b) After 6 to 8 weeks postpartum, breastfeeding women desiring hormonal contraception should be encouraged to use progestin-only pills (POPs) or injectables or NORPLANT® Implants. (Before 6 to 8 weeks postpartum, there is no risk of conception for a fully or nearly fully breastfeeding woman - see How to Be Reasonably Sure the Woman Is Not Pregnant.)</p> <p>c) If COCs remain the method of choice, but the woman chooses to rely on the Lactational Amenorrhea Method (LAM) initially, start COCs when her menses return,** or when the woman is no longer fully or nearly fully breastfeeding or at 6 months postpartum, whichever comes first. COC packets may be given to the woman before this time to ensure that she is able to start the method when she needs to.</p> <p>** In breastfeeding women, bleeding in the first 56 days (8 weeks) postpartum is NOT considered "menstrual" bleeding, because it is not preceded by ovulation.</p>	<p>a-b) Even low dose (30 to 35 mcg) COCs decrease breastmilk production.</p> <p>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30(6):505-521.</p> <p>c) For fully breastfeeding women, there is no known advantage to initiating COCs during LAM or while the LAM criteria apply.</p> <p>1) Kennedy KI. Breastfeeding and the double protection dilemma. <i>Family Health International</i>, September 1991.</p> <p>2) Labbok M, Cooney K, Coly S. Guidelines: Breastfeeding, Family Planning, and the Lactational Amenorrhea Method - LAM. Washington, DC: Institute for Reproductive Health, 1994.</p> <p>In fact, initiating COCs before they are necessary may be a disadvantage because COCs have a detrimental effect on breastmilk volume and composition, which may affect the infant's health and growth.</p> <p>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984; 30(6):505-521.</p> <p>2) WHO Task Force on Oral Contraceptives. Special Programme of Research, Development, and Research Training in Human Reproduction. Effects of hormonal contraceptives on breast milk composition and infant growth. <i>Studies in Family Planning</i> 1988; 19(6):361-369.</p>

<b>Recommendations</b>	<b>Rationales</b>
<p>d) If she does <b>not</b> want to rely on LAM but is breastfeeding, she should be advised to choose a non-estrogenic method. If she still makes an informed choice to use COCs, they can be started anytime after the first 8 to 12 weeks postpartum if she is still amenorrheic, or whenever the service provider can be reasonably sure that the woman is not pregnant.</p> <p><b>For Non-Breastfeeding Women:</b></p> <p>a) If not breastfeeding, a woman can begin COCs after the second to third postpartum week.</p>	<p>d) Even low dose (30 to 35 mcg) COCs decrease breastmilk production. Waiting at least 8 to 12 weeks postpartum permits breastfeeding to be better established. Whether exposure of the neonate (in the first 8 weeks) to exogenous estrogens and progestins may, in theory, affect neonatal growth and development is a question under study.</p> <p>a) Blood coagulation and fibrinolysis are essentially normalized by 3 weeks postpartum (and are close to normal at 2 weeks postpartum).</p> <p>1) Dahlman T, Hellgren M, Blombäck M. Changes in blood coagulation and fibrinolysis in the normal puerperium. <i>Gynecologic and Obstetric Investigation</i> 1985;20(1):37-44.</p>

### Q.3. May COCs be started immediately post-abortion?

Recommendations	Rationales
<p>a) Yes, COCs are appropriate for use immediately post-abortion (spontaneous or induced), in either the first or second trimester, and should be initiated within the first seven days post-abortion (or anytime you can be reasonably sure the woman is not pregnant).</p>	<p>a) Ovulation returns almost immediately post-abortion (spontaneous or induced): within 2 weeks for first trimester abortion and within 4 weeks for second trimester abortion. Within 6 weeks of abortion, 75% of women have ovulated.</p> <p>1) Lähteenmaki P, Ylöstalo P, Sipinen S, Toivonen J, Ruusuvaara L, Pikkola P, Nilsson CG, Luukkainen T. Return of ovulation after abortion and after discontinuation of oral contraceptives. <i>Fertility and Sterility</i> 1980;34(3): 246-249.</p> <p>Immediate use of COCs post-abortion (spontaneous or induced) does <b>not</b> affect return to fertility following discontinuation of COCs.</p> <p>1) Lähteenmaki P. Oral contraception and immediate post-abortion pituitary-ovarian function. <i>Acta Obstetrica et Gynecologica</i> 1978;76(Suppl):9-43.</p>

Recommendations	Rationales
b) If a client has a history or current indication of excessive clotting (coagulopathy), COCs should <b>not</b> be recommended.	<p>b) COCs may be safely started within the first week post-abortion (spontaneous or induced). Hypercoagulability of pregnancy probably does not become clinically significant until the third trimester. However, some experts recommend starting COCs exactly one week post-abortion, as there is a suggestion of a slight increase in coagulation factors measurable in the first few days after first trimester abortion in women initiating COCs immediately post-abortion. If started later than one week, COCs may not be immediately effective because the ovary resumes follicular development as soon as one week after first trimester (spontaneous or induced) abortion.</p> <ol style="list-style-type: none"><li>1) Lähteenmaki P. Postabortal contraception. <i>Annals of Medicine</i> 1993;25: 185-189.</li><li>2) Lähteenmaki P, Toivoneh J, Rasi V, Luukkainen T, Myllyä G. Coagulation factors in women using oral contraceptives or intrauterine contraceptive devices immediately after abortion. <i>American Journal of Obstetrics and Gynecology</i> 1981;141:175-179.</li></ol> <p>Incomplete abortion may also result in a condition of excessive blood clotting (disseminated intravascular coagulation), in which estrogens should be avoided.</p>

## Q.4. How many COC cycles should be given at the first visit for a new user? At subsequent visits?

Recommendations	Rationales
<p>a) At first visit and each follow-up visit, give as many as 13 cycles, although only 3 or 4 may be programmatically reasonable. The greatest need is to guarantee continuous, ready access.</p> <p>b) Encourage a 3-month follow-up visit for counseling with initial acceptors to assess whether the client is satisfied with the method and is correctly using the method, to reinforce instructions, and to help clients with the management of side effects.</p> <p>c) The number of cycles dispensed may be limited for programmatic, logistic or financial reasons, including client's ability to pay in a cost recovery system.</p> <p>d) The re-supply system should be flexible, so that the client can obtain pills easily <b>in the amount and at the time she requires.</b></p> <p>e) There is no compelling medical reason for a routine return visit before one year, but clients should be encouraged to return at any time with concerns, problems and questions.</p>	<p>a-e) While some providers suspect that clients who receive multiple pill cycles may "share" these with friends, this is likely to be as safe as over-the-counter distribution methods.</p> <p>Some women (and/or some programs) may be able to afford to buy (dispense) many pill cycles at one visit.</p>

## Q.5. Is a "rest period" advisable for women on COCs after some period of use?

Recommendations	Rationales
a) No, a "rest period" is not necessary. A woman may use COCs for as long as she is at risk of pregnancy.  b) Stopping COCs 2 weeks before major elective surgery or after serious accidents that necessitate immobilization of the legs and resuming COCs once the woman is mobile is <i>optimal</i> , if she has a reliable alternative method.	a) A rest period would disrupt the woman's preferred and successful method of contraception.  b) Due to the fact that estrogen may slightly increase the risk of post-operative thrombosis, it may be reasonable to stop COCs for 2 weeks before major elective surgery and resume COCs once the woman is mobile, before she resumes sexual activity. However, this small risk must be weighed against the risk of pregnancy and whether the client has a reliable alternative method.  1) Quinn DA, Thompson BR, Terrin ML, Thrall JH, Athanasoulis CA, McKusick KA, Stein PF, Hates CA. A prospective investigation of pulmonary embolism in women and men. <i>Journal of the American Medical Association</i> 1992;268(13):1689-1696.

## Q.6. Is there a minimum age to receive COCs? A maximum?

Recommendations	Rationales
<p>COCs may be used at any age at which the woman is at risk of pregnancy (e.g., past menarche and through menopause).</p> <p>a) Women over age 40 can take COCs, provided other risk factors have been considered (e.g., smoking, high blood pressure, diabetes).</p> <p>b) Use of COCs does not compromise future fertility.</p>	<p>a) Cardiovascular risks from COC use are minimal in healthy, non-smoking, older women.</p> <ol style="list-style-type: none"> <li>1) Speroff L, Glass RH, Kase NG. <i>Clinical Gynecologic Endocrinology and Infertility</i>, 4th edition. Baltimore, Williams &amp; Wilkins, 1989, p 487.</li> <li>2) Guillebaud J. Contraception for women over 35 years of age. <i>British Journal of Family Planning</i> 1992;17:115-118.</li> </ol> <p>b) On average, the return to fertility after discontinuing COCs is about 2 months longer than for non-hormonal methods. The risk of amenorrhea after discontinuing COCs is small and more common in women who had irregular menses prior to COC use. Rather than causing "post-pill amenorrhea," COCs mask the irregular pattern by inducing cyclic withdrawal bleeding. Women who have irregular menses are more likely to develop secondary amenorrhea whether they take COCs or not.</p> <ol style="list-style-type: none"> <li>1) Bracken MB, Hellenbrand KG, Holford TR. Conception delay after oral contraceptive use: The effect of estrogen dose. <i>Fertility and Sterility</i> 1990; 58:21-7.</li> <li>2) Speroff L, Glass RH, Kase NG. <i>Clinical Gynecologic Endocrinology and Infertility</i>, 4th edition. Baltimore, Williams &amp; Wilkins, 1989, p 481.</li> <li>3) American College of Obstetricians and Gynecologists. Safety of oral contraceptives for teenagers. <i>International Journal of Gynaecology and Obstetrics</i> 1992;37:309-312.</li> <li>4) Jacobs HS, Knuth UA, Hull MGR, Franks S. Post-"pill" amenorrhea – Cause or coincidence? <i>British Medical Journal</i> 1977;2:940-942.</li> </ol>

## Q.7. Are back-up methods advisable in the following situations:

Recommendations	Rationales
<p>a) If the client is taking <b>antibiotics</b>?</p> <p>No — except rifampin or griseofulvin (an antifungal medication).</p>	<p>a) Rifampin, rifampicin, and griseofulvin require use of a back-up method (or increased COC dose if back-up is not possible) to compensate for hepatic micro-enzyme induction. Hepatic micro-enzyme induction by rifampin lasts for 4 weeks for short-term use and for 8 weeks for long-term use. Although anecdotal reports of failure to prevent pregnancy exist for other antibiotics, epidemiologic evidence suggests that antibiotics (except rifampin and griseofulvin) do not require a back-up method.</p> <p>1) Orme M, Back DJ. Oral contraceptive steroids – Pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7: 325-331.</p>
<p>b) If the client is taking <b>anticonvulsants</b> (except valproic acid)?</p> <p>Use of one of the following may be necessary:</p> <ul style="list-style-type: none"> <li>● switch to Depo Provera<sup>®</sup> or an effective non-hormonal method;</li> <li>● a back-up method (for short-term anti-convulsant use);</li> <li>● higher dose COCs (i.e., 50 mcg ethinyl estradiol (EE), or two 30 to 35 mcg EE COCs per day for more efficient contraception and/or to produce regular menses without breakthrough bleeding).</li> </ul>	<p>b) Anticonvulsants include phenobarbitol/phenobarbitone, primidone, carbamazepine, and ethosuximide. Anticonvulsants, except valproic acid, significantly increase liver metabolism of estrogen and progestins, which decreases the effectiveness of COCs.</p> <p>Taking two 30 to 35 mcg COCs per day will provide adequate estrogen to compensate for increased metabolism. Levonorgestrel levels are also reduced by phenytoin (and presumably other anti-epileptics). Therefore, doubling up on COCs which contain Levonorgestrel is particularly important.</p> <p>1) Orme M, Back DJ. Oral contraceptive steroids – Pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-331.</p>

Recommendations	Rationales
<p>c) If it is the client's <b>first cycle</b> of COCs? If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week. COCs may be started anytime you can be reasonably sure the woman is not pregnant (see definition). However, if COCs are started after day 7 of a regular cycle, the woman should also be counseled that her regular bleeding pattern may be altered and that additional contraceptive protection (or abstinence) is needed for the first 7 days. Dispensing a back-up method, however, especially condoms, is a good idea in case of failures of correct use, as well as for sexually transmitted disease protection when needed.</p>	<p>c) The COC effect on cervical mucus is not as strong as the effect of progestin-only methods. COCs require 7 days to suppress follicular development.</p> <p>1) Sparrow MJ. Pregnancies in reliable pill takers. <i>New Zealand Medical Journal</i> 1989;102(879):575-577.</p>
<p>d) If the client has <b>missed pills</b>?  Back-up is needed only if 2 or more pills are missed, and back-up must be used until the client has taken 7 active pills (one active pill per day for 7 days).</p>	<p>d) If two or more pills are missed, a back-up must be used until the client has taken 7 active pills. Missed pills may occur at the beginning of the cycle (extending the pill-free interval from 7 to 9 days and perhaps allowing escape ovulation to occur).</p> <p>1) Killick SR, Bancroft K, Oelbaums MJ, Elstein M. Extending the duration of the pill-free interval during combined oral contraception. <i>Advances in Contraception</i> 1990;6:33-40. 2) Family Health International. <i>New simplified OC instructions</i>. April 1992.</p> <p>Seven days of exposure to COCs are required to suppress follicular development.</p> <p>1) Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? <i>British Medical Journal</i> 1985;290:1474-1475. 2) Guillebaud J. The forgotten pill – and the paramount importance of the pill free week. <i>British Journal of Family Planning</i> 1987;12:35-43.</p>

Recommendations	Rationales
<p>e) If the client has <b>diarrhea and/or vomiting</b>?</p> <p>Back-up may be advisable whenever vomiting or severe diarrhea occurs within one hour after taking the tablet. If vomiting or severe diarrhea persists for more than 24 hours (then two pills will have been missed), a back-up method will be needed (until client has taken one active pill per day for 7 days).</p> <p>f) If the client is taking <b>anti-malarial medication</b>?</p> <p>No back-up is needed.</p>	<p>e) Acute vomiting and severe diarrhea may interfere with the effectiveness of the pill. In these cases, a back-up method is reasonable.</p> <ol style="list-style-type: none"> <li>1) Orme M, Back DJ. Oral contraceptive steroids – Pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-331.</li> <li>2) Orme M, Back D, Breckenridge A. Clinical pharmacokinetics of oral contraceptive steroids. <i>Clinical Pharmacokinetics</i> 1983;8:95-136.</li> </ol> <p>f) Anti-malarials studied to date have not been found to decrease the efficacy of COCs. Chloroquine and primaquine have not demonstrated an effect on plasma COC hormonal levels or on ovulation inhibition. Tetracycline (which is used at low dosage in combination with quinine) has not been found to compromise the effect of COCs.</p> <ol style="list-style-type: none"> <li>1) Back DJ, Breckenridge AM, Grimer S, Orme M, Purba H. Pharmacokinetics of oral contraceptive steroids following the administration of anti-malarial drugs primaquine and chloroquine. <i>Contraception</i> 1984;30(3):289-295.</li> <li>2) Gupta KC, Joshi JV, Desai NK, Sankolli GM, Chowdhary VN, Joshi UM, Chitalange S, Satoskar RS. Kinetics of chloroquine and contraceptive steroids in oral contraceptive users during concurrent chloroquine prophylaxis. <i>Indian Journal of Medical Research</i> 1984;80:658-662.</li> <li>3) Murphy A, Zacur H, Charache P, Burkman R. The effect of tetracycline on levels of oral contraceptives. <i>American Journal of Obstetrics and Gynecology</i> 1991;164:28-32.</li> <li>4) D'Arcy PF. Drug interaction and reaction: Update: Drug interactions with oral contraceptives. <i>Drug Intelligence and Clinical Pharmacy</i> 1986;20: 353-362.</li> </ol>

**Q.8. Does a client need to visit a clinic or see a doctor to receive COCs?**

Recommendations	Rationales
<p>a) No.</p> <p>Trained providers other than doctors, including community-based distribution (CBD) workers, can initiate and resupply COCs both in clinical and non-clinical situations. Additionally, COCs may be provided "over-the-counter" if adequate information is given to clients (see "Specific counseling points for COC use," on last page of the Classification of Selected Procedures for Low Estrogen Combined Oral Contraceptives section).</p> <p>Community-based distributors (CBD) and other non-clinical FP providers should use screening checklists to identify conditions for which the woman can receive a limited supply of COCs and also be referred to a clinic. These screening checklists should, ideally, contain only 5 to 10 items.</p> <p>b) If complaints or symptoms arise which are of concern to the provider or to the woman (and which may or may not be due to COCs), the woman should be referred to an appropriate facility. If the woman wants to continue COCs, they should be continued unless a serious problem with estrogen (such as excess blood clotting) is suspected.</p>	<p>a) Studies show that COCs may be safely and effectively administered through non-clinical distribution.</p> <ol style="list-style-type: none"> <li>1) Contraceptive social marketing: Lessons from experience. <i>Population Reports Series J</i>, no. 30, July-August 1985.</li> <li>2) Pharmacists and family planning. <i>Population Reports Series J</i>, no. 37, November 1989.</li> <li>3) Rosenfield A, Maine D, Gorosh ME. Nonclinical distribution of the pill in the developing world. <i>International Family Planning Perspectives</i> 1980;6(4):130-135.</li> <li>4) Zavala AS, Perez-Gonzales M, Miller P, Welsh M, Wilkens LR, Potts M. Reproductive risks in a community-based distribution program of oral contraceptives, Matamoros, Mexico. <i>Studies in Family Planning</i> 1987;18(5):284-90.</li> </ol> <p>b) Much harm can be done by stopping COCs unnecessarily (e.g., risks of pregnancy and risks of abortion).</p>

## Q.9. When during the cycle can one switch from COCs to other methods?

Recommendations	Rationale
<p>A client can switch methods at any time. If she has been taking the pills correctly and consistently, you can be reasonably sure she is not pregnant.</p> <p>A back-up method is not required. However, the provider may want to recommend that she continue to take her COC the day she gets her first injection or the implants.</p> <p>Some clinicians recommend that the woman finish her pack of pills to delay the onset of her next bleed.</p>	<p>Injectables and NORPLANT® Implants are usually effective within 24 hours, unless the woman already has fertile cervical mucus. The woman should take her pill as a back-up, if she is not menstruating, because there is a slight risk of conception from unprotected intercourse during those 24 hours until the injectable or implants become effective.</p> <ol style="list-style-type: none"><li>1) Technical Guidance Working Group. Recommendations for updating selected practices in contraceptive use: results of a technical meeting. Volume I. Chapel Hill, NC: INTRAH, 1994.</li><li>2) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990, p 2.</li></ol>

## Q.10. How should amenorrhea in COC users be addressed?

Recommendations	Rationale
<p>Although amenorrhea is not unusual among COC users, the possibility of pregnancy should be considered. If the woman is correctly and consistently taking COCs and has no other symptoms of pregnancy, only reassurance is needed because the probability of pregnancy is extremely low. Even if the woman is pregnant and the embryo is exposed to COCs, the best evidence is that there is no harm to the embryo.</p> <p>If symptoms or other reasons to suspect pregnancy exist, such as missed pills, evaluate accordingly. If pregnancy evaluation cannot be performed immediately, the client can be advised to continue taking the pills until this evaluation is completed or referred to a health unit where she can be evaluated.</p>	<p>Amenorrhea may be a side effect of COCs. Amenorrhea is not uncommon in women using the low dose pills, 35 mcg or less of estrogen, due to a lack of buildup of the uterine lining.</p> <p>While pregnancy is a possibility, COCs are over 99% effective when used correctly.</p> <p>It is always recommended that a pregnant woman avoid unnecessary medication. However, if the woman is pregnant and is using COCs, there does not seem to be an increased risk of birth defects for the embryo.</p> <ol style="list-style-type: none"><li>1) Hatcher R, Trussell J, Stewart F, Stewart G, Kowal D, Guest F, et al. The pill: combined oral contraceptives. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:223-84.</li><li>2) Bracken M. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-7.</li><li>3) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li></ol>

## Classification of Selected Procedures for Low Estrogen Combined Oral Contraceptives (COCs)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>• Conditions which would restrict use of COCs should be identified by history before method initiation.</li> <li>• A pelvic exam may reveal reproductive tract infections or reproductive tract malignancies which should be treated for optimal preventive care. Routine pelvic exam screening for asymptomatic women, in the absence of tests for cervical cancer, however, is a low yield procedure<sup>1</sup>.</li> <li>• A pelvic exam may help evaluate the question of pregnancy: in this case it is Class A.</li> <li>• A pelvic exam is not necessary to ensure safe use of COCs as a contraceptive method.</li> </ul>
Blood pressure	B	<ul style="list-style-type: none"> <li>• Due to their estrogen component, COCs have subtle (and usually insignificant) effects on blood pressure<sup>2</sup>. Where possible, for clients at risk of high blood pressure, blood pressure screening would ideally accompany initiation of COCs.</li> <li>• Women with a long history of severe hypertension are at high risk of vascular disease, and thus arterial thrombosis (clotting), which estrogens may worsen.</li> </ul>
Breast examination	B	Lumps that are suspicious for cancer should be evaluated. While any hormonal treatment may in theory cause such lumps to grow <sup>3</sup> , pregnancy causes much higher hormonal levels; therefore, a potential malignancy of the breast should not be a reason to delay a woman's access to the use of this contraceptive method.
STD screening by lab tests (for asymptomatic persons)	C	For optimal health care, clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible. However, presence of an STD will not affect the safe use of COCs.

Procedure	Class	Rationale
Cervical cancer screening	C	<p>Cervical cancer screening is indicated for women at risk of cervical carcinoma, and is recommended (where possible) for optimal preventive health care for women of reproductive age or beyond (particularly women at risk of STDs).</p> <p><b>NOTE:</b> Though causality has not been established, long-term (more than 5 years) COC use may be associated with a slight increased risk of cervical cancer<sup>4,5</sup>. Cervical cancer screening is advised for optimal preventive care for all women at risk of cervical cancer (e.g., smokers, women with partners having multiple partners, women with young age at first intercourse, etc.<sup>4,5</sup>). All women at risk should ideally have access to a practical method of cervical cancer screening, treatment and follow-up.</p>
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effects of COCs on cholesterol, blood glucose and normal liver function are slight, and of <b>no</b> demonstrated clinical significance <sup>6</sup> .
<p>Specific counseling points for COC use:</p> <ul style="list-style-type: none"> <li>● efficacy</li> <li>● common side effects</li> <li>● correct use of method (including instructions for missed pills)</li> <li>● signs and symptoms for which to see a health provider</li> <li>● STD protection (when/as appropriate)</li> </ul>	A	<ul style="list-style-type: none"> <li>● Accurate client education is essential for maximum quality of family planning services.</li> <li>● Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation<sup>7</sup>.</li> </ul>
Counseling concerning change in menses, including irregular or absent menstrual bleeding	A	Low dose COCs commonly cause "breakthrough bleeding" (spotting or bleeding during the three weeks of active pills), especially in the first three months of COC use. Low dose COCs also commonly cause very light menses, and amenorrhea (absence of withdrawal bleeding) may occur.

**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

**Citations:**

- 1) Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. *Studies in Family Planning* 1975;6(2):49-51.
- 2) Task Force on Oral Contraceptives, WHO Special Programme of Research, Development and Research Training in Human Reproduction. The WHO Multicentre trial of the vasopressor effects of combined oral contraceptives: Comparisons with IUD. *Contraception* 1989;40:129-145.
- 3) Droegemueller W. Breast Diseases, in Herbst AL, Mishell DR, Stenchever MA, Droegemueller W (eds). *Comprehensive Gynecology*, 2nd edition. St. Louis, Mosby Year Book, 1992, pp 377-408.
- 4) Brinton LA. Oral contraceptives and cervical neoplasia. *Contraception* 1991;43(6):581-595.
- 5) Schlesselman JJ. Oral contraceptives in relation to cancer of the breast and reproductive tract - an epidemiological review. *British Journal of Family Planning* 1989;15:23-33.
- 6) Speroff L, Glass RH and Kase NG. *Clinical Gynecologic Endocrinology and Infertility*, 5th edition. Baltimore, Williams and Wilkins, 1994, pp 726-727.
- 7) Cotten N, Standback J, Maidouka H, Taylor-Thomas JT, Turk T. Early discontinuation of contraceptive use in Niger and The Gambia. *International Family Planning Perspectives* 1992;18(4):145-149.