

Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives

Research findings have established that combined oral contraceptives (COCs) are safe and effective for use by most women, including those who are at risk of sexually transmitted infections (STIs) and those living with or at risk of HIV infection. For some women, COCs are not recommended because of the presence of certain medical conditions, such as ischemic heart disease, stroke, and breast cancer. For these reasons, women who desire to use COCs must be screened for certain medical conditions to determine if they are appropriate candidates for COCs.



The Ministry of Public Health and Sanitation, Division of Reproductive Health (DRH), in collaboration with Family Health International (FHI), has developed this simple checklist (see center spread) to help health care providers screen clients who were counseled about contraceptive options and made an informed decision to use COCs. This checklist is a revised version of the *Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives* produced in 2007. Changes reflected in this version are based on the recently revised recommendations of the *Medical Eligibility Criteria for Contraceptive Use, 4th edition* (WHO, 2009) as advised by research over the past several years, and the *National Family Planning Guidelines for Service Providers* (DRH, 2010).

The checklist is designed for use by both clinical and nonclinical health care providers, including community health workers. It consists of 17 questions and provides guidance based on clients' responses. The first 11 questions are designed to identify medical conditions that would prevent safe COC use or require further evaluation. Clients who are ruled out because of their response to some of the medical eligibility questions may still be good candidates for COCs if the suspected condition can be excluded through appropriate evaluation. The last six questions enable providers to determine with reasonable certainty that a woman is not pregnant before initiating the method. Women who are already pregnant do not require contraception. However, if COCs are accidentally taken during pregnancy, the World Health Organization states that there is no known harm to the woman, the course of her pregnancy, or fetus.

This checklist is part of a series of provider checklists developed for family planning providers in Kenya. The other checklists include the *Checklist for Screening Clients Who Want to Initiate DMPA (or NET-EN)*, the *Checklist for Screening Clients Who Want to Initiate Use of the Copper IUCD*, the *Checklist for Screening Clients Who Want to Initiate Contraceptive Implants*, and the *Checklist on How to be Reasonably Sure a Client is Not Pregnant*. For more information about the provider checklists, please visit Kenya Ministry of Health and Sanitation, DRH Web site at www.drh.go.ke.

Assessing Medical Eligibility for COCs

1. Are you currently breastfeeding a baby less than six months of age?

Because COC use during breastfeeding diminishes the quantity of breast milk and can decrease the duration of lactation, a breastfeeding woman should delay COC use until her baby is at least six months old. However, if a client does not plan to continue breastfeeding, she may be a good candidate for COCs even before the baby reaches six months of age.

2. Have you given birth in the last 3 weeks?

Women who are within three weeks of giving birth may be at a higher risk of thrombosis if they take COCs. However she may start taking COCs at three weeks postpartum (if she is not planning to breastfeed).

3. Do you smoke cigarettes *and* are you more than 35 years of age?

Women who are over 35 years of age and smoke cigarettes may be at increased risk of cardiovascular disease (e.g., heart attack). This is a two-part question

— both parts need to be asked together, and the answer “yes” must apply to both parts of the question for the woman to be ineligible. This is because a woman less than 35 years of age who smokes, as well as a woman over the age of 35 years who is a nonsmoker, are not at increased risk for cardiovascular disease. The answer “no” to one or both parts of this question means a client may be eligible for COC use.

4. Do you have repeated severe headaches, often on one side, and/or pulsating, causing nausea, and which are made worse by light, noise, or movement?

This question is intended to identify women with migraines, a particular type of headache that may increase the risk of stroke in women using COCs. The use of the



words, “repeated severe headache, often on one side,” and the occurrence of other problems during the headache are essential parts of this question. These words help the client distinguish between the types of headaches that make her ineligible for COC use (such as migraines) and the less severe (more common) mild headaches, which do not rule out COC use.

5. Have you ever been told you have breast cancer or do you have an undiagnosed breast lump?

This question is intended to identify women who know they have had or currently have breast cancer. These women are not good candidates for COCs, because breast cancer is a hormone-sensitive tumor, and COC use may adversely affect the course of the disease. Women with an undiagnosed breast lump can initiate COCs while having the lump evaluated. If diagnosed with benign breast disease, COC use may be continued. If diagnosed with breast cancer, COC use should be discontinued. Non-clinical COC providers should refer any woman with an undiagnosed breast lump for evaluation and offer the woman an alternative method to use in the meantime.

6. Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?

This question is intended to identify women with already known serious vascular disease, not to determine whether women might have an undiagnosed condition. Women with these conditions may be at increased risk of blood clots if they take COCs. Women who have had any of these conditions will often have been told about it and will answer “yes” if appropriate.

7. Do you regularly take any pills for tuberculosis (TB), seizures (fits), or ritonavir for ARV therapy?

This question is intended to identify women who take drugs that are known to affect the efficacy of COCs. The following medications make COCs less effective; hence, women taking these medications should generally not use COCs: rifampicin or rifabutin (for tuberculosis), certain anticonvulsants including phenytoin, carbamazepine, primidone, topiramate, oxcarbazepine, lamotrigine, and barbiturates (for epilepsy/seizures), or ritonavir (as part of an antiretroviral regimen).

8. Do you have gall bladder disease or serious liver disease or jaundice (yellow skin or eyes)?

This question is intended to identify women who know that they currently have gall bladder disease (because COC use may aggravate symptoms); or a serious liver disease such as severe cirrhosis; acute hepatitis; malignant liver tumors; or benign liver tumors, with the exception of focal nodular hyperplasia (a tumor that consists of scar tissue and normal liver cells). Women with serious liver conditions should not use COCs because the hormones used in COCs are processed by the liver and may further compromise liver function. Women

with other liver problems, such as chronic hepatitis, can use COCs safely.

9. Have you ever been told you have high blood pressure?

This question is intended to identify women with high blood pressure. Women with elevated blood pressure should not use COCs because they may be at increased risk of stroke and heart attack. Women who have ever been told that they have high blood pressure should have their blood pressure evaluated by a trained provider before receiving COCs.

10. Have you ever been told you have diabetes (high sugar in your blood)?

This question is intended to identify women who know that they have diabetes, not to assess whether they may have an undiagnosed condition. Among women with diabetes, those who have had the disease for 20 years or longer, or those with vascular complications, should not be using COCs because of the increased risk of blood clots. Evaluate or refer for evaluation as appropriate and, if these complications are absent, the woman may still be a good candidate for COCs.

11. Have you ever been told that you have a rheumatic disease, such as lupus?

This question is intended to identify women who have been diagnosed with systemic lupus disease. Women who have systemic lupus disease and who are not on immunosuppressive treatment should not use COCs, due to concerns about a possible increased risk of thrombosis.

Determining Current Pregnancy

Questions 12–17 are intended to help a provider determine, with reasonable certainty, whether a client is not pregnant. If a client answers “yes” to any of these questions, and there are no signs or symptoms of pregnancy, it is highly likely that she is not pregnant. The client can start COCs now.

If the client is within 5 days of the start of her menstrual bleeding, she can start the method immediately. No back-up method is needed.

If it has been more than 5 days since her first day of bleeding, she can start taking COCs immediately but must use a back-up method (i.e., using a condom or abstaining from sex) for 7 days to ensure adequate time for the COCs to become effective.

If you cannot determine with reasonable certainty that your client is not pregnant (using the checklist), and if you do not have access to a pregnancy test, then she needs to wait until her next menstrual period begins before starting COCs. She should be given condoms to use in the meantime.

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To determine if the client is medically eligible to use COCs, ask questions 1–11. As soon as the client answers **YES** to **any question**, stop, and follow the instructions after question 11.

NO	1. Are you currently breastfeeding a baby less than six months of age?	YES	
NO	2. Have you given birth in the last 3 weeks?	YES	→
NO	3. Do you smoke cigarettes <i>and</i> are you more than 35 years of age?	YES	→
NO	4. Do you have repeated severe headaches, often on one side, and/or pulsating, causing nausea, and which are made worse by light, noise, or movement?	YES	→
NO	5. Have you ever been told you have breast cancer or do you have an undiagnosed breast lump?	YES	→
NO	6. Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?	YES	→
NO	7. Do you regularly take any pills for tuberculosis (TB), seizures (fits), or ritonavir for ARV therapy?	YES	→
NO	8. Do you have gall bladder disease or serious liver disease or jaundice (yellow skin or eyes)?	YES	→
NO	9. Have you ever been told you have high blood pressure?	YES	→
NO	10. Have you ever been told you have diabetes (high sugar in your blood)?	YES	→
NO	11. Have you ever been told that you have a rheumatic disease such as lupus?	YES	→

If the client answered **NO** to **all of questions 1–11**, the client can use COCs. Proceed to questions 12–17.

If the client answered **YES** to **any of questions 1–7**, she is not a good candidate for COCs. Counsel about other available methods or refer.

If the client answered **YES** to **any of questions 8–11**, COCs cannot be initiated without further evaluation. Evaluate or refer as appropriate, and give condoms to use in the meantime. See explanations for more instructions.

Ask questions 12–17 to be reasonably sure that the client is not pregnant. As soon as the client answers **YES** to **any question**, stop, and follow the instructions after question 17.

YES	12. Did your last menstrual period start within the past 7 days?	NO	
YES	13. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	NO	
YES	14. Have you abstained from sexual intercourse since your last menstrual period or delivery?	NO	
YES	15. Have you had a baby in the last 4 weeks?	NO	
YES	16. Have you had a miscarriage or abortion in the last 7 days?	NO	
YES	17. Have you been using a reliable contraceptive method consistently and correctly?	NO	

If the client answered **YES** to **at least one of questions 12–17** and she is free of signs or symptoms of pregnancy, you can be reasonably sure that she is not pregnant. The client can start COCs now.

If the client began her last menstrual period **within the past 5 days**, she can start COCs now. No additional contraceptive protection is needed.

If the client began her last menstrual period **more than 5 days ago**, tell her to **begin taking COCs now**, but instruct her that she must **use condoms or abstain from sex for the next 7 days**. Give her condoms to use for the next 7 days.

If the client answered **NO** to **all of questions 12–17**, pregnancy cannot be ruled out. The client should await menses or use a pregnancy test.

Give her the COCs but instruct her to start using them anytime during the first 5 days of her next menstrual period.

Give her condoms to use in the meantime.