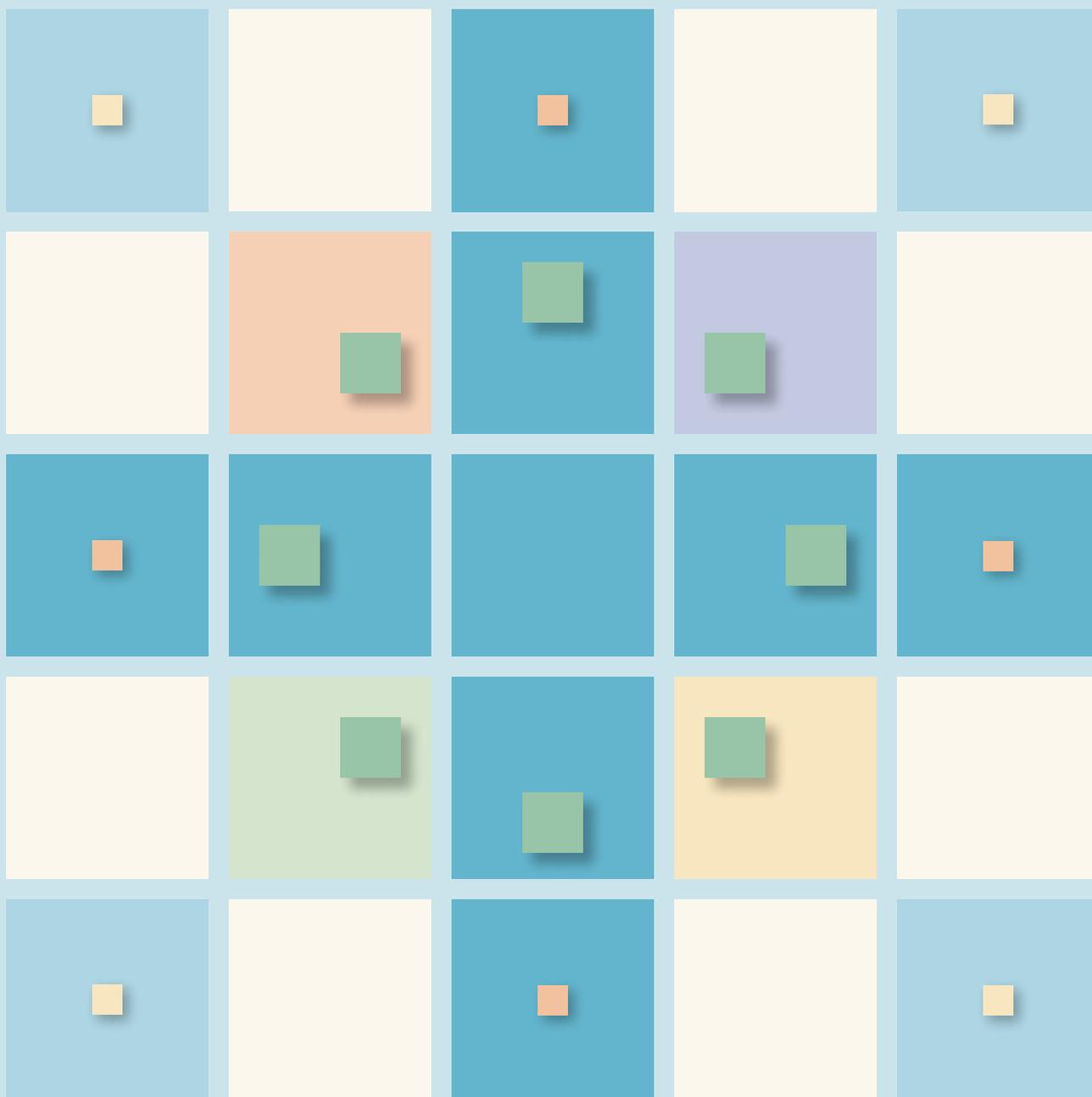


Training and Reference Guide for a Screening Checklist to Initiate COCs



This *Training and Reference Guide for a Screening Checklist to Initiate COCs* was developed by Family Health International (FHI), a nonprofit organization working to improve lives worldwide through research, education, and services in family health. Similar guides, providing training and reference materials on other FHI provider checklists, are also being published.

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This training and reference guide was developed for family planning service providers interested in using the *Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives*, commonly referred to as the “COC Checklist”. Designed to serve as both a training and reference tool, the guide is composed of two parts: a training module and a collection of essential, up-to-date reference materials on combined oral contraceptives. This guide is part of a series to train on other checklists, including 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 IUD*, and the checklist entitled *How to Be Reasonably Sure a Client is Not Pregnant*.

The COC Checklist was developed to assist service providers in screening clients who have already been counseled about contraceptive options and who have made an informed decision to use combined oral contraceptives (COCs). This simple job aid is based on guidance provided in the *Medical Eligibility Criteria for Contraceptive Use* (WHO 2004) and supports the application of these guidelines into actual service delivery practice.

Research findings have established that 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. However, for some women with certain medical conditions — such as breast cancer, ischemic heart disease, or stroke — COC use is not recommended. The COC Checklist provides a series of questions designed to screen for such medical conditions and thereby determine whether a woman is medically eligible to begin using COCs.

The COC Checklist also provides a series of questions to rule out pregnancy. Health care providers are generally required to rule out pregnancy before providing contraceptives, such as COCs, because women who are pregnant do not require contraception. Also, it is considered good practice to avoid all unnecessary drugs during pregnancy. There is, however, no evidence that COCs can harm pregnancy or a developing fetus. Pregnancy can be reliably determined with pregnancy tests, but in many areas of the world these tests often are either unavailable or unaffordable. In such cases, clients who are not menstruating at the time of their visit (occasionally referred to in this guide as “nonmenstruating women”, for the sake of simplicity) are often denied contraception by providers who rely on the presence of menses as an indicator that a woman is not pregnant. Usually, these women are required to wait for their menses to return before they can initiate a contraceptive method, thus putting them at risk of an unwanted pregnancy. The pregnancy-related questions on the COC Checklist are taken directly from the checklist entitled *How to Be Reasonably Sure a Client is Not Pregnant*. This checklist, referred to as the “Pregnancy Checklist”, has been shown to be 99 percent effective in ruling out pregnancy.

Purpose of the Training and Reference Guide

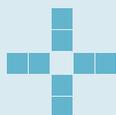
This publication is intended to provide program managers, administrators, trainers, and service providers with:

- a training module on how to use the COC Checklist;
- an overview of the COC Checklist and guidance for adapting it for local use;
- information on the most current research regarding the validity, effectiveness and use of the COC Checklist; and
- current, essential, evidence-based information on COCs.

Intended Users of this Guide

This guide can be used by:

- trainers, facilitators, program managers and administrators responsible for training service providers to use the COC Checklist;
- service providers who need to apply the COC Checklist in their practice and are responsible for teaching themselves how to use it;
- policy-makers and program managers interested in introducing the COC Checklist for use in their community.



Note: This guide focuses exclusively on how to use the COC Checklist. In order to provide quality services, providers who offer or plan to offer COCs to their clients may also need training or information on additional topics, such as various contraceptive methods and family planning counseling techniques.

Intended Participants of the Training

Training on the COC Checklist would benefit both clinical and non-clinical service providers who provide clients with COCs, including:

- facility-based family planning counselors and service providers;
- community-based health workers;
- pharmacists and others who sell drugs and are authorized to screen clients and provide COCs;
- health care providers who integrate family planning services into HIV/AIDS prevention and care services, such as voluntary counseling and testing (VCT) counselors and health staff at antiretroviral treatment sites;
- health care providers in resource-constrained settings, such as refugee camps.

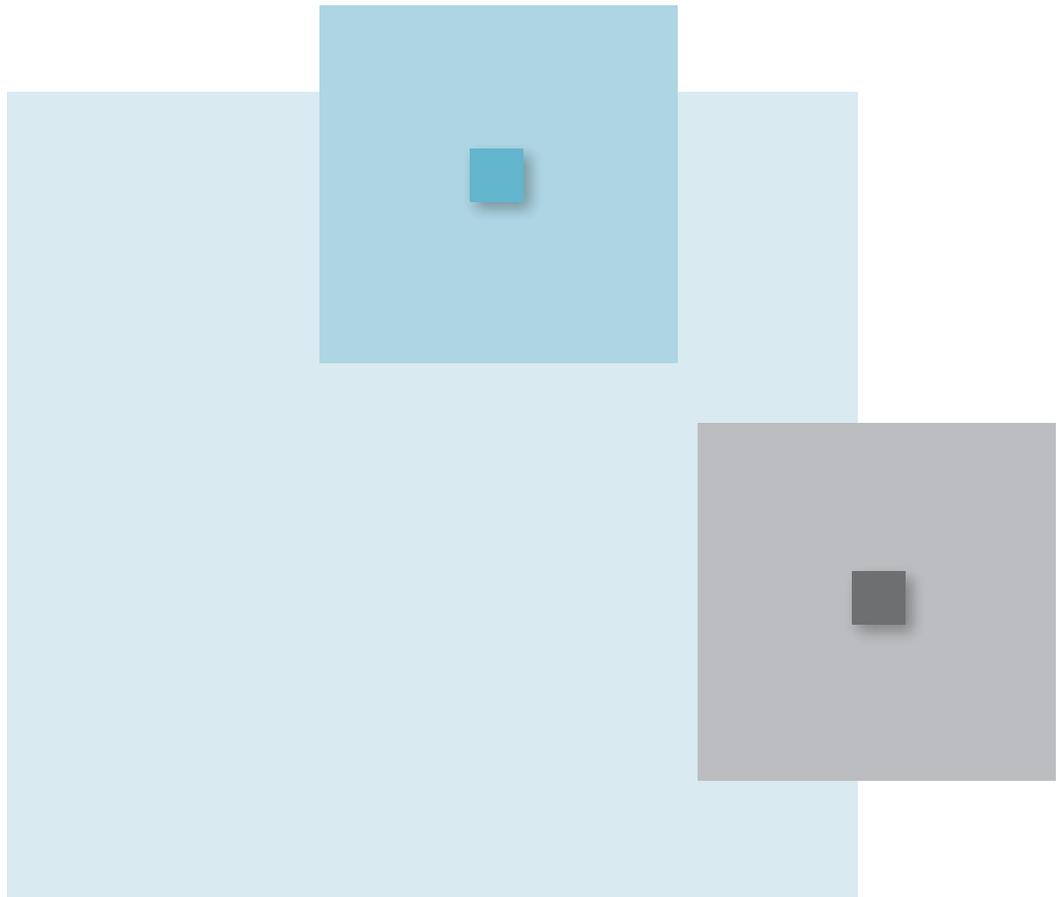
How to Use this Guide

Using the guide as a training tool

This guide provides a curriculum for training service providers to use the COC Checklist. Training on the COC Checklist can be completed in approximately five hours. Facilitators are free to adapt the training to better serve the needs of their particular audience and may add or delete activities or use the information provided to create their own training. Additional tools that may assist the facilitator in adapting the training include a CD-ROM and training schedules for different types of audiences. The CD-ROM is located in the pocket inside the back cover, and the training schedules may be found in the section entitled Supplementary Training Schedules, page 69.

Using the guide as a reference tool

This guide also provides reference information that supplements the training. This information includes recommendations on adapting the checklist to the local context, basic evidence-based information on COCs, and an annotated bibliography.



Learning Objectives

By the end of the training, participants will have learned or become familiar with:

- the rationale, purpose, and design of the COC Checklist;
- the medical eligibility criteria to screen clients for COC initiation; and
- proper use of the checklist.

Number of participants

No more than 30 people are recommended per training.

Time

A minimum of five hours is required to complete all four sessions. This includes the Optional Session but does not include breaks.

Structure of the Module

Session	Time	Topic	Training Method
1	30 minutes	Welcome and introductions Exercise A: Peel the Cabbage	Large group activity; group discussion
2	20 minutes	Rationale and purpose of the COC Checklist	Facilitator presentation
	30 minutes	Exercise B: Review of the WHO Medical Eligibility Criteria	Small group activity
	10 minutes	Exercise C: Demonstrating the Benefits of Using the Pregnancy Checklist	Large group activity
3	40 minutes	Design of and instructions for using the COC Checklist	Facilitator presentation
	140 minutes	Exercise D: Practice Using the COC Checklist	Small group activity
4	15 minutes	Wrap-up	Group discussion
Optional Session	15 minutes	Summary of Research Findings	Facilitator presentation

Each training session has four components:

- **Objective** — a short description of the purpose and learning objective(s) for the session
- **Time** — anticipated length of the session
- **Training Steps** — basic steps that guide the trainer through the activities
- **Facilitator's Resource** — detailed information to convey to participants, as indicated in the training steps

Training Materials

Facilitators will need the following materials:

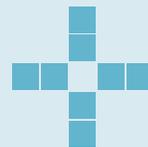
- flip chart paper
- tape
- markers
- colored pencils for all participants (red and green are recommended)
- training handouts, found on pages 35-48 and on the CD-ROM, including:
 - the *Checklist for Screening Clients Who Want to Initiate Use of COCs*
 - two versions of the Quick Reference Chart (one with the categories colored in and one with no color)
 - Scenario Exercises for Participants
 - Answer Guide to Scenarios

Advance Preparation for Trainers

In order to understand the purpose, content, and approach of the training, we recommend that facilitators master the information in this guide, as well as the materials on the CD-ROM. Facilitators should also be very familiar with the training handouts used in conjunction with the participant exercises. Some sessions require advance preparation, such as photocopying, preparing flip charts, or preparing components for exercises. Facilitators should know their audience and adapt the training accordingly.

Due to the technical nature of the subject matter, it is highly likely that questions on COCs will arise that are beyond the scope of the information provided in the training portion of this guide. The information provided in the reference guide or on the CD-ROM may help facilitators to address some of these questions. Because this guide is not intended to comprehensively answer all questions around COC provision, additional training may be required.

Key information for the facilitator is noted throughout the training module with the following symbol.

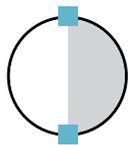


The CD-ROM



The CD-ROM accompanying this module provides information on all four screening checklists to enhance the training for a variety of participant groups. The CD-ROM contains the following materials.

1. Suggested schedule for a combined training on all four checklists
2. *PowerPoint* presentations for orienting different audiences on the checklists:
 - *PowerPoint* presentation A: How to Use Screening Checklists to Initiate Use of Contraceptives (for facilitators)
 - *PowerPoint* presentation B: Screening Checklists to Initiate Use of Contraceptives — Tools for Service Providers (for policy-makers and program managers)
3. Handouts for participants:
 - Scenario Exercises for Participants
 - Answer Guide to Scenarios
 - Quick Reference Charts
 - Four Screening Checklists
 - Certificate of Attendance (sample)
4. Electronic versions of all four Training and Reference Guides
5. Basic, essential, evidence-based information on COCs, DMPA, and IUDs:
 - *Medical Eligibility Criteria for Contraceptive Use*, WHO 2004
 - *Selected Practice Recommendations for Contraceptive Use*, WHO 2004
 - *PowerPoint* presentation C: Overview of COCs
 - *PowerPoint* presentation D: Overview of Injectables — DMPA and NET-EN
 - *PowerPoint* presentation E: Overview of the IUD
 - *PowerPoint* presentation F: Hormonal Contraceptives — Considerations for Women with HIV and AIDS



**30
minutes**

- Objectives:**
- To present the learning objectives of the training.
 - To facilitate introductions among participants and facilitator(s).
 - To develop a common understanding of training expectations and group norms.
 - To “break the ice” and help participants become engaged in the training.

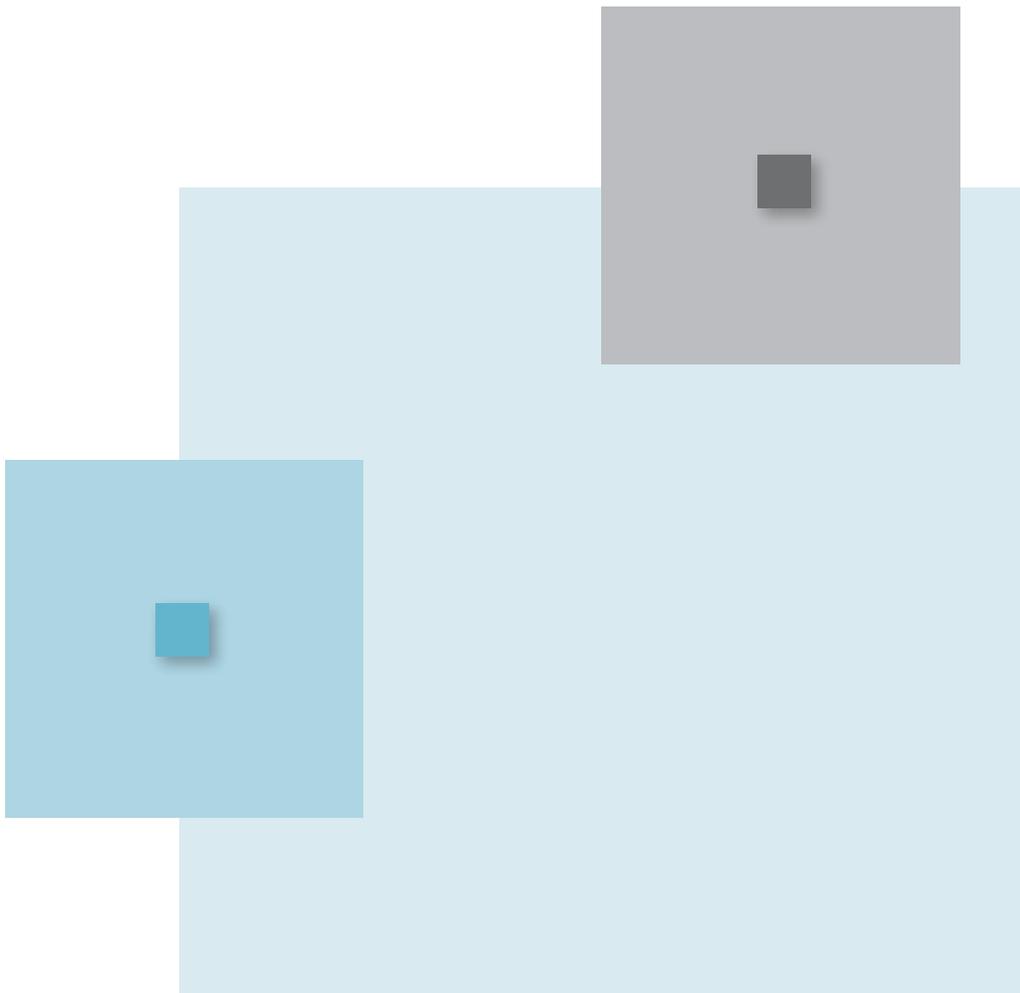
Training Steps:

1. Welcome the participants and introduce yourself and any other facilitators. Provide an opportunity for participants to also introduce themselves. You may choose to have participants do this by stating their name and area of expertise or by using the icebreaker activity in the shaded box below. The icebreaker activity will also help you to better understand your audience.
2. Ask participants to state what they expect to learn from the workshop. Write their expectations on flip chart paper and save them until the end of the workshop. These expectations will be valuable at the end of the workshop as an evaluation tool.
3. Ask participants to suggest guidelines, or norms, to be followed by the group during the training session. Group norms could include: switching off mobile phones, respecting others’ right to speak, etc.
4. Launch the training by discussing the title of the COC Checklist and the learning objectives of the training. Highlight any relevant expectations that were previously expressed by participants.
5. Conduct Exercise A (page 12) to engage participants in an introductory discussion of their current practices for screening women who wish to start using COCs.

Icebreaker Activity

Each participant talks to the person next to them for five minutes to find out: a) their name, b) the name of their organization and the nature of their work, and c) why they are attending the training today. Participants should then present this information back to the group.

6. Explain that the *Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives*, which we will often refer to as the “COC Checklist”, was developed to help providers correctly determine that a woman has no conditions which would prevent her from safely initiating COCs.
7. Explain that participants will review the COC Checklist and will practice using it later in the training. In so doing, they will discover the answers to the following questions.
 - Why was the COC Checklist developed?
 - How should service providers use the COC Checklist?
 - What is the basis for the COC Checklist?
 - How does the COC Checklist work?



Exercise A: Peel the Cabbage

Advance Preparation

Prior to the training, write the following three questions at least four times, each on a different piece of paper. You should have at least 12 pieces of paper. Mix the pages up and then layer and crumple them so that they resemble a cabbage. Include additional questions on additional pieces of paper, as appropriate. Also write these three questions on the flip chart, each on a different page, and tape them up for all to see.

Name one practice that you follow to determine if a woman can safely initiate COCs.

Name one approach to ruling out pregnancy prior to COC initiation.

Name one health condition that prevents women from using COCs.

Objective: Participants will discuss their current practices for screening women who wish to start using COC's.

1. Toss "the cabbage" to one of the participants. The person holding the cabbage must peel off the top layer and answer the question. After answering the question, the participant "tosses the cabbage" to another participant to answer the next question. If this question has already been asked, the participant cannot repeat the same answer. Continue tossing the cabbage until all the questions are answered. Possible answers are given below.

Name one practice that you follow to determine if a woman can safely initiate COCs.

Answers could include: medical histories, questions about the presence of certain symptoms, laboratory tests, the COC Checklist, etc.

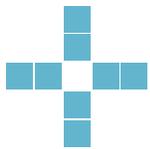
Name one approach to ruling out pregnancy prior to COC initiation.

Answers could include: a pregnancy test, presence of menses, pelvic exam, Pregnancy Checklist, etc.

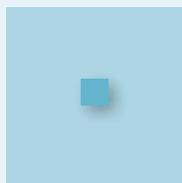
Name one health condition that prevents women from using COCs.

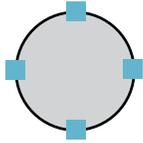
Answers could include: heart disease, high blood pressure, migraine headaches, etc.

2. If appropriate for your audience, you may chose to make the exercise fun by having the group give some form of mild “penalty” to participants who cannot answer their question. This might include such things as raising one hand, bending their head to one side or standing on one foot until the cabbage is completely peeled. Let the participants be creative.
3. Conclude the exercise by telling participants that they will have the opportunity to see whether their answers were correct or not at the end of Exercises B and C in Session Two.

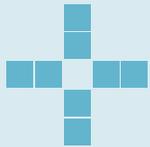


Remember that participants may already have extensive knowledge and practical experience in family planning. Make an effort to incorporate participants’ questions, knowledge, and experiences into your training session, as appropriate.





60
minutes



If there are national guidelines or protocols for family planning provision, it is important to link the checklists to these documents to promote utilization of the checklist.

Objective: To learn why and how the checklist was developed.

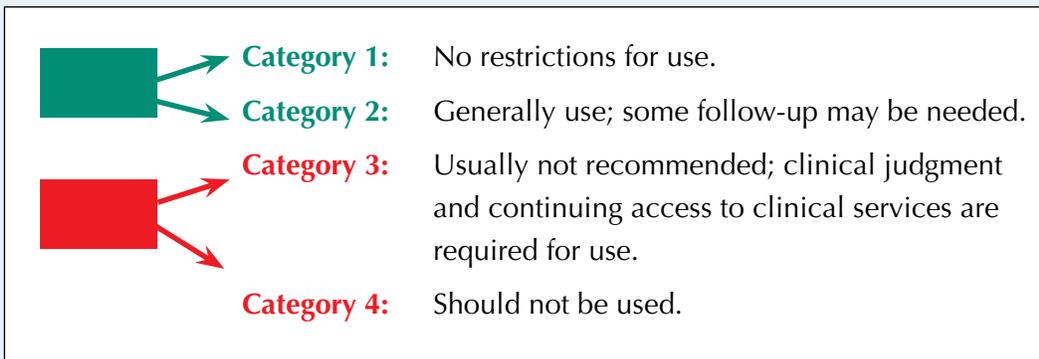
Training Steps:

1. Hold up a copy of the COC Checklist to show participants, **but do not distribute it until later in the session, at the end of Exercise B.** Check to see if they are already familiar with the checklist, by asking the following questions.
 - How many of you currently use this checklist to decide if a woman can safely use COCs?
 - For those who use the checklist, do you find it useful in your work? How?
2. Explain what the COC Checklist is and why it was developed. If appropriate for your audience and if needed, you may also choose to discuss the research on the rationale for the Pregnancy Checklist, located in the Optional Session, page 32.
3. Engage participants in a discussion on how service providers should use the COC Checklist. Ask participants the following question to emphasize the use of this job aid to improve efficiency in their daily work.
 - In your daily work, how easy is it to use your national guidelines/protocols to determine if a woman can safely use COCs?
4. Discuss the basis for the two sets of questions on the COC Checklist.
 - First, introduce the WHO Medical Eligibility Criteria and explain its purpose.
 - Then perform Exercise B (page 15) to help participants better understand how the categories work in relation to the use of COCs.
 - Next, introduce the concept of Pregnancy Checklist questions, what they are, and why they were developed.
 - Perform Exercise C (page 17) to help participants understand the usefulness of the Pregnancy Checklist questions for ruling out pregnancy among women who are not menstruating at the time of their visit.

Exercise B: Review of the WHO Medical Eligibility Criteria

Advance Preparation

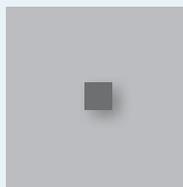
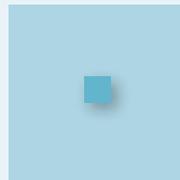
- Prior to the training, make sufficient photocopies of both Quick Reference Charts (pages 43-44) and the COC Checklist (pages 45-48) to distribute to each participant.
- You will also need green and red pens or markers for each participant.
- In addition, you may want to prepare a flip chart page containing the information in the box below.



Objective: Participants will review the Quick Reference Chart to become familiar with relevant conditions that have been studied and determined to either be safe or not safe for COC initiation and use.

1. Give each participant a blank copy of the Quick Reference Chart, along with a green and a red pen/marker.
2. Present the information in the box above and explain how the categories are grouped into two colors: GREEN — representing categories 1 and 2, and RED — representing categories 3 and 4.
3. Ask participants to use the green or red pens/markers to color in the rectangles to the right of the conditions listed on the chart. Choose a maximum of four conditions, such as diabetes, high blood pressure, HIV/AIDS, and endometrial cancer. Have them use GREEN if they think the condition falls under category 1 or 2 and RED if they believe the condition falls under category 3 or 4. They should choose the color based on their knowledge, assumptions or best guess. At your discretion, participants can work individually, in pairs, or as a group. Allow them 10 minutes to complete this task. (If no colored pencils or markers are available, have participants write a “G” for green or an “R” for red in the rectangles.)

4. Now, give each participant a copy of the color version of the Quick Reference Chart and ask them to compare their own answers to it. Allow about 10 minutes for them to assess whether their answers were correct or incorrect. **Note that the color version has four colors, one for each category. To make this activity simpler, only two colors are being used instead of four. Clarify to participants that light red/pink is red and light green is green.**
5. Ask volunteers to share which color or category they assigned to each condition. Correct any misinformation as you go along.
6. Distribute a copy of the COC Checklist. Ask participants to compare the first nine questions of the COC Checklist with the conditions colored in red on the Quick Reference Chart. Participants will quickly see that the checklist questions only ask about category 3 and 4 conditions (red categories). Explain that these questions were written to identify women who should not use COCs or who will require additional evaluation by a higher level provider before initiating COCs. Category 1 and 2 conditions (green categories) are not addressed on the checklist because research shows that women with these conditions can use COCs safely.



Exercise C: Demonstrating the Benefits of Using the Pregnancy Checklist

Advance Preparation

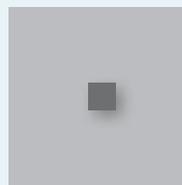
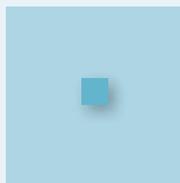
In advance of the training, write each of the following statements on a separate piece of paper. The statements represent six circumstances that prevent a woman from becoming pregnant and one that does not.

- **Client 1:** “I’ve not had sexual intercourse since my last menstrual period.”
- **Client 2:** “I always use condoms during intercourse, but I want to start using something else.”
- **Client 3:** “I just started my menses six days ago.”
- **Client 4:** “I have a 3-week-old baby.”
- **Client 5:** “Five days ago, I had a miscarriage.”
- **Client 6:** “I am fully breastfeeding my 5-month-old baby. Since having my baby, I have not had my menstrual period.”
- **Client 7:** “It has been two weeks since I had my last menstrual period.”

Objective: Participants will gain a better understanding of the benefits of using the Pregnancy Checklist by visually comparing the number of women who would potentially receive contraception at the time of their visit when providers do and do not use the checklist. This exercise is based on studies of the Pregnancy Checklist done in Kenya, Guatemala, Mali, Senegal, and Egypt.

1. Ask 7 participants to come to the front of the room. They will represent 7 female clients seeking COCs who are not menstruating at the time of their visit.
2. Tell the rest of the participants they will act as providers and will be asked to determine as they would usually do (i.e., based on their current practices) if these women are not pregnant. For example, participants might suggest that the client would be:
 - sent home with condoms and asked to return when they are menstruating, or to return four weeks later for an exam if they are not menstruating, whichever comes first;
 - given a pregnancy test;
 - given a pelvic or abdominal exam;
 - asked more questions; or
 - provided COCs with instructions to start taking them on the first day of their next menses.

3. Distribute the above statements, one to each client. Have the first volunteer “client” read their statement out loud, then ask the group acting as providers if pregnancy can be ruled out for this client — Yes or No, and why. Require participants to explain their answers and correct any mistakes as you go along.
4. Repeat the exercise for all seven clients.
5. Conclude the exercise by stating that clients 1-6 represent the six questions on the Pregnancy Checklist that allow pregnancy to be ruled out. Emphasize that if these questions were not asked, these clients would not be able to receive COCs right away. Point out that the Pregnancy Checklist prompts providers to inquire about all six of these conditions when facing a client. Explain that for client 7 pregnancy has not been ruled out. Since it has been two weeks since her last menstrual period, there is a possibility she might be pregnant. However, the Pregnancy Checklist cannot determine that this woman is, in fact, pregnant.



Facilitator's Resource:

Why was the COC Checklist developed?

- The COC Checklist was developed to help family planning providers determine quickly and with confidence whether a client may safely use COCs as their contraceptive method of choice by screening women for certain medical conditions.
- Screening is necessary because some medical conditions can prevent safe and effective COC use. **Most** women who want to initiate use of COCs can safely and effectively do so. **Some** women need further evaluation and/or treatment before starting to use COCs. For example, a woman who has diabetes should not be given COCs unless further evaluation shows that she has no vascular complications. A **few** women should not use COCs under any circumstances, such as those who have breast cancer or serious liver disease.
- Screening for COC initiation should also include ruling out pregnancy, because women who are already pregnant do not require contraception.
- The COC Checklist can be used in many settings by both clinical and non-clinical family planning service providers, including:
 - facility-based family planning counselors and service providers;
 - community-based health workers trained to safely provide oral contraceptives;
 - pharmacists and others who sell drugs and are authorized to screen clients and provide COCs;
 - health care providers who integrate family planning services into HIV/AIDS prevention and care services, such as voluntary counseling and testing (VCT) counselors and health care staff at antiretroviral treatment sites;
 - health care providers in resource-constrained settings, such as refugee camps.

How should service providers use the COC Checklist?

- As a screening/decision-making tool
 - The COC Checklist can be used as a screening tool to help a provider determine whether a woman (1) is a good candidate for COC use, (2) will need further evaluation, or (3) should choose another family planning method. It is **not** a diagnostic tool, such as a blood test, which can determine whether a woman has a particular disease or condition.

- The COC Checklist should only be used with women who have made an informed decision to use COCs. In order to make an informed decision, all women should be counseled about their contraceptive options by providers who are properly trained in counseling techniques and in providing information on various contraceptive methods. The checklist itself is not a counseling tool, but may be used after counseling has been completed.
- As a job aid for using resources more efficiently
 - The COC Checklist can save time for both providers and clients by asking simple questions to rule out pregnancy and eliminating the need for most nonmenstruating clients to make another appointment.
 - Evidence-based practice guidelines can be lengthy and sometimes complicated. Use of the COC Checklist provides a way to apply these same guidelines in a simple, efficient, and timely manner.

What is the basis for the COC Checklist?

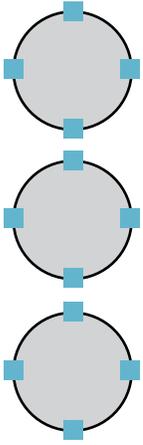
- The COC Checklist is composed of two sets of questions: questions 1-9 for determining if the client is medically eligible to use COCs and questions 10-15 to be reasonably sure that the client is not pregnant. First we will discuss the questions related to medical eligibility, and then we will discuss the questions designed to rule out pregnancy.
- **Medical Eligibility Questions (Questions 1-9)**
 - The first set of questions on the COC Checklist is based on the WHO *Medical Eligibility Criteria for Contraceptive Use* (MEC). The WHO MEC is a set of recommendations to support the development of guidelines for providing contraceptives. It is updated by a WHO expert working group every three to four years (or as needed), in order to reflect the latest clinical and epidemiological data. The Quick Reference Chart on page 44 is a condensed version of the information contained in the WHO MEC (2004).
 - The WHO MEC takes various individual characteristics (e.g., age, breastfeeding status) or health conditions (e.g., diabetes, hypertension) that may or may not affect eligibility for the use of each contraceptive method and classifies them into four categories.

Category	Recommendation
1	No restriction for use of method
2	Advantage of using method outweighs theoretical or proven risk: method generally can be used, but follow-up may be required
3	Theoretical or proven risk outweighs the advantages of using method: method not recommended except if other more appropriate methods are not available/acceptable
4	Method should not be used

- The COC checklist includes questions related to categories 3 and 4 only. These two categories include conditions for which the method is either not recommended or should not be used. Category 1 and 2 conditions are not addressed on the checklist because research shows that women with these conditions can use COCs safely.

■ Pregnancy-Related Questions (Questions 10-15)

- The second set of questions on the COC Checklist is taken directly from another checklist entitled *How to Be Reasonably Sure a Client is Not Pregnant* (Pregnancy Checklist). The pregnancy-related questions were added to the COC Checklist in order to address a medical barrier that women often encounter when seeking COCs at a time when they are not menstruating. In countries where resources are limited and pregnancy tests are often unavailable or unaffordable, many providers worry that these women may be pregnant (unless they are within four weeks postpartum). Many of these clients are sent home, often without contraception, to await menses. Those who are unable to return — often because of time and money constraints — risk unintended pregnancy.
- The questions from the Pregnancy Checklist help providers to be reasonably sure a woman is not pregnant or to decide that another approach is required to rule out pregnancy. Each question describes a situation that effectively **prevents** a woman from getting pregnant. **The checklist is not a diagnostic tool for determining if a woman is pregnant.** (Note that women in whom pregnancy was not ruled out by questions 10-15 are not necessarily pregnant.)



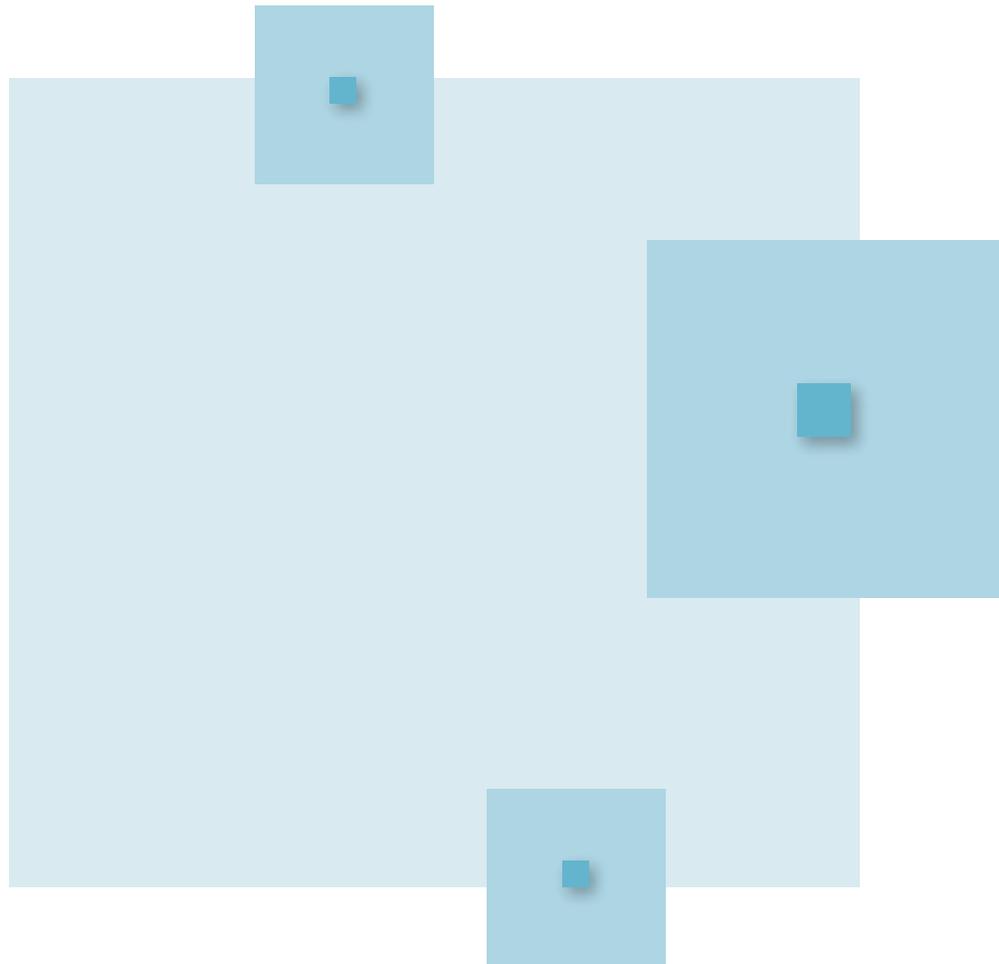
3 hours

Objectives: To understand the design of the COC Checklist.

To practice using the COC Checklist in different scenarios to ensure that participants are comfortable using it.

Training Steps:

1. Discuss the checklist’s design and explain how to use the checklist. Then ask participants if they have any questions, and clarify anything they did not understand.
2. Conduct Exercise D to allow everyone in the group to practice administering the checklist.



Exercise D: Practice Using the COC Checklist

Advance Preparation

Prior to the training:

- photocopy the Scenario Exercises for Participants (pages 35-36);
- make sure you are familiar with the information provided in the Answer Guide to Scenarios (pages 37-42);
- make photocopies, if desired, of the Answer Guide to distribute at the end of the session;
- prepare a flip chart page containing the following questions:
 - Is this client a good candidate for receiving COCs during today's visit?
 - Why or why not?
 - What course of action would you take next? (For example: counsel, refer, provide COCs, send a client home with condoms to await menses, administer a pregnancy test, etc.)
 - Did you experience any problems applying the checklist to your scenarios?

Objective: To help participants become comfortable using the COC checklist.

1. Introduce the scenario exercises and explain that participants will be grouped into pairs. Each pair will receive two scenarios. Within each pair, one participant will play the role of the client and the other will play the provider administering the checklist. Participants will then switch roles for the second scenario and repeat the process. This way, everyone will have a chance to practice using the checklist and to experience both roles.
2. Explain that after they role-play their scenarios, each pair should discuss and be able to answer the questions on the flip chart.
3. Divide the participants into pairs and distribute two scenarios to each pair. Participants will have 10 minutes to role-play each scenario and 10 minutes to answer the questions on the flip chart (40 minutes total). Give the following instructions, according to the role the participants will play:

For participants acting as providers

- Make sure you have read and understood the checklist questions and explanations before administering the checklist to the client.
- Ask the client the checklist questions and follow instructions to determine if the client can initiate COCs.
- Trust the client's response.

- Base your decisions on the COC Checklist questions only, and not on any assumptions about the client. Doing so could lead you to the wrong conclusion and cause you to unnecessarily deny your client access to contraception.
- You may answer questions or define terms, if necessary. However, do not make substantive changes to the checklist questions; for example, do not separate one question into two questions or combine two questions into one.

For participants acting as clients

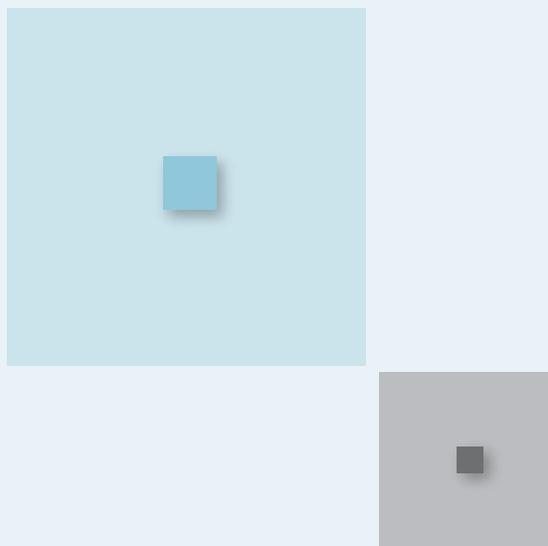
- Read the scenario carefully and answer the checklist questions based on the situations outlined in scenario.
- If a situation is not specifically described in the scenario, you should answer “NO”. For example, if the scenario does not specify that the woman’s last menstrual period started within the past seven days, you, as a client, should answer NO to that question.

4. Reconvene the group and discuss each scenario with the whole group. Depending on the number of participant pairs, this part of the exercise may take between one and a half to two hours. For each scenario, ask a participant pair to share their answers to the questions on the flip chart. If they do not answer questions 1 or 2 correctly, or if additional possibilities exist in answer to question 3, solicit responses from the other participants, or provide it from the answer guide.
5. For each checklist question, discuss any concerns participants have about its phrasing or clarity. Help the group find ways to explain or rephrase the question without changing its meaning. **Be familiar with the information in the Adapting the Checklist to the Local Context section of this guide, page 51.**
6. When discussing a scenario in which pregnancy cannot be ruled out, emphasize that the client should be told she is not **necessarily** pregnant, but that, due to her responses, another approach will be needed to rule out pregnancy (either a pregnancy test, a pelvic exam, or awaiting her next menses). If she has to wait to rule out pregnancy, always provide her with some form of protection against pregnancy, such as condoms. Also, if possible, provide her with an advance supply of COCs and instruct her to start using them on the first day of her menses, or to come back if her menses are late.
7. After all the scenarios have been discussed, the Answer Guide to Scenarios (page 37) may be distributed to the participants for their future reference.

8. A course of action has been outlined for each scenario. However, if any adaptations are made to the scenarios and/or checklist, it should be recognized that the course of action may change somewhat as well.
9. The scenarios have been designed to work with any provider training group. To further adapt the training to meet the needs of a specific audience, scenarios may be modified by the facilitator or by another qualified person. Additional scenarios may also be created.

Optional approaches for conducting scenarios

- Ask one or more of the participant pairs to role-play in front of the larger group. Have the whole group discuss each scenario before going on to the next one.
- Instead of role-playing in pairs, ask participants to work individually, each one developing a response to their scenario(s). Then have some participants present their response to the larger group.
- Ask participants to work individually and then find two or three people who had the same scenario. They should discuss their responses and see how they differ. These small groups could then share with the larger group.

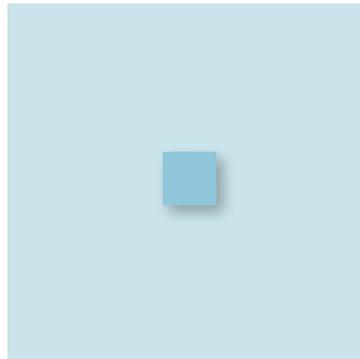


Facilitator's Resource:

How does the COC Checklist work?

- The COC checklist is designed to use the provider's time as efficiently as possible. **Notice that instructions for both sets of questions on the checklist state: "As soon as the client answers YES to any question, stop, and follow the instructions below."** This means that if the client answers "YES" to any question, the provider is finished with that set of questions. Therefore, depending on the client's responses, the questioning may proceed question by question, OR the provider may discover the woman is not a good candidate early in the questioning.
- The COC Checklist consists of 15 questions, as well as instructions for providers based on a woman's responses. The first set of questions is meant to determine if the woman can use COCs (questions 1-9, related to medical eligibility). The second set of questions is meant to identify women who are not pregnant and to determine if they can start using COCs right away (questions 10-15, related to pregnancy). Each of the checklist questions is explained in more detail on the reverse side of the checklist. Providers should refer to these explanations to understand the intent of the questions.
- **Medical Eligibility Questions**
 - **"Yes" response** — If a woman answers "YES" to any **one** of these questions, she is not medically eligible for COCs; however, some of these women may become medically eligible after further evaluation. See the instruction box at the bottom of this set of questions and follow the guidance provided there.
 - **"No" response** — If a woman answers "NO" to **all** questions, the client is medically eligible to receive COCs. However, pregnancy must be ruled out first. Proceed to the pregnancy-related questions.
- **Pregnancy-Related Questions**
 - **"Yes" response** — If a woman answers "YES" to any **one** question and is free from signs and symptoms of pregnancy, providers can be 99 percent sure she is not pregnant. Provide COCs according to the instructions.
 - **"No" response** — If a woman answers "NO" to **all** questions, she has not been protected from pregnancy. To rule out pregnancy in these women, the provider will need to do a pregnancy test, conduct a pelvic exam, or have the woman return when she is menstruating. If the client is sent home to await her menses, always provide her with condoms to use in the meantime. (Note for facilitator: Where possible, also consider giving such a woman an advance supply of pills with instructions to start using them on the first day of her menses. Advise her to come back if her menses are late.)

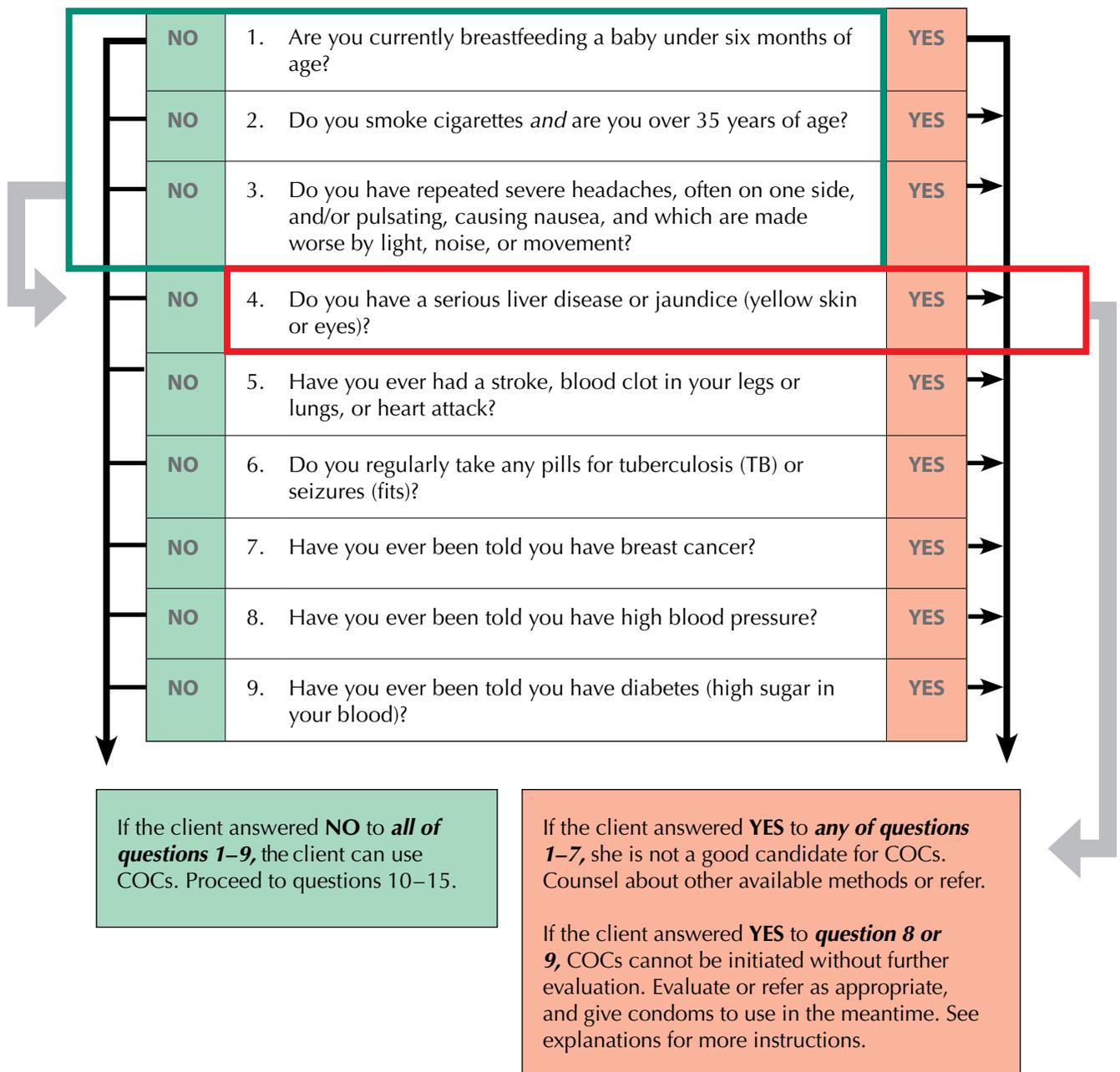
- When asking women questions from the checklist, providers should not confuse or replace diseases and conditions with signs and symptoms.
 - One symptom can indicate several possible conditions. Also, many symptoms are not accurate indicators, so their presence could unnecessarily prevent a woman from using COCs. For example, if the original question asks a woman if she has ever had a heart attack, it should not be changed to instead ask if she has ever had chest pain or shortness of breath. These symptoms may have many causes and do not necessarily indicate a history of heart attack. (Shortness in breath may indicate poor physical condition, asthma, common cold, bronchitis, heart disease, heart attack, etc.)
- Generally, the conditions asked about on the checklist are serious enough that a woman would know if she has them because she would have had to seek medical attention for them. This is why several of the questions begin with “Have you ever been told ...”, “Do you have...”, and “Have you ever had...”. If a woman has not been told she has a condition, providers should assume she does not have it.
- Providers should make an effort to build trusting relationships with clients before administering the COC Checklist. For example, the provider might wish to convey to the client the necessity of answering as accurately and as honestly as possible, in order to avoid possible complications of COCs. The majority of women will answer honestly to the best of their ability.



Example for medical eligibility questions

A woman answers “NO” to questions 1, 2, and 3, but then she answers “YES” to question 4 because she has been told she has jaundice. The provider should stop asking questions and read the instructions in the red box under the set of questions. The instruction is that this woman is not a good candidate for COCs. She should be counseled about other available methods and, if needed, be referred for evaluation or treatment of her medical condition.

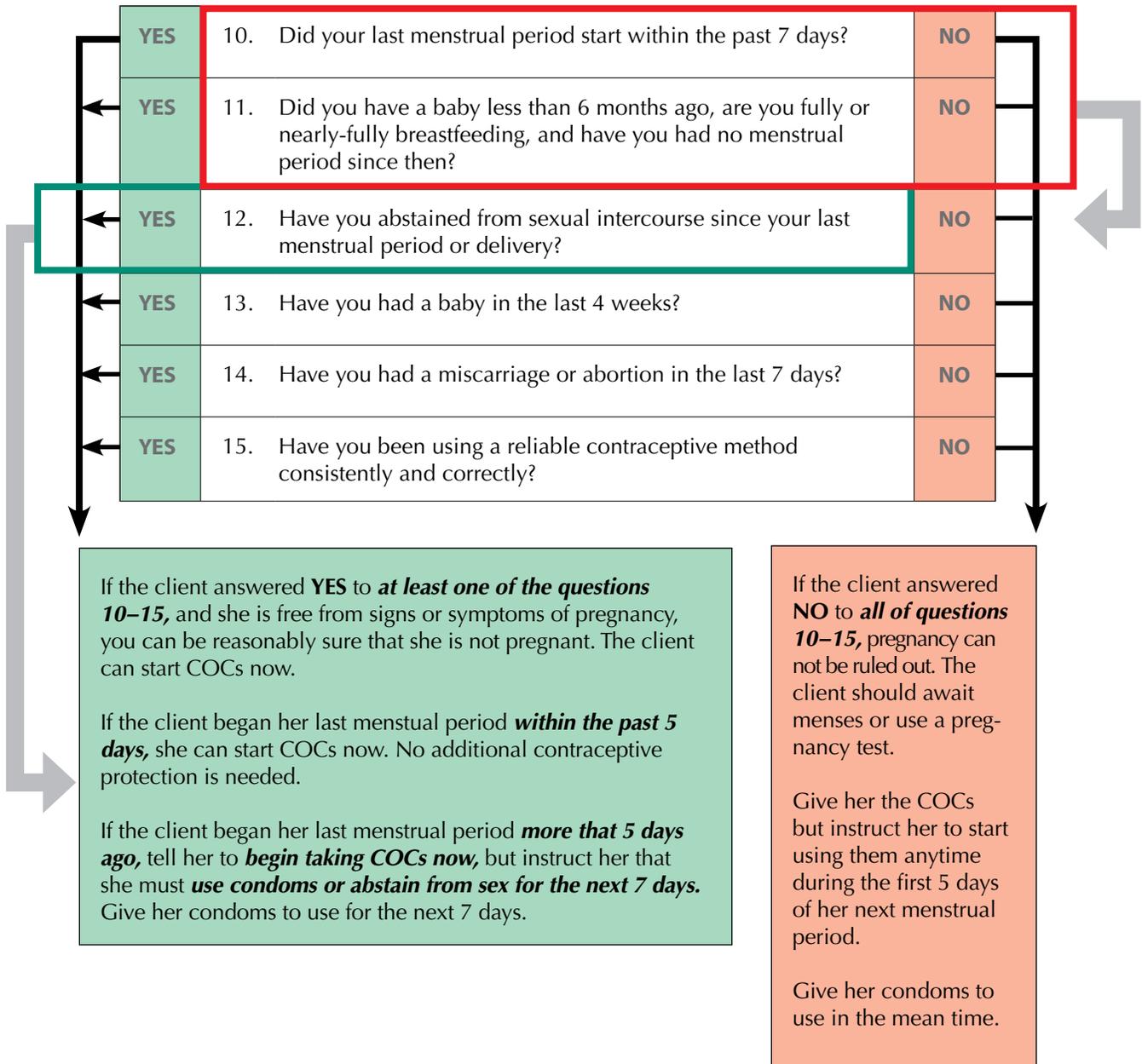
To determine if the client is medically eligible to use COCs, ask questions 1-9. As soon as the client answers YES to any question, stop and follow the instructions below.



Example for pregnancy-related questions

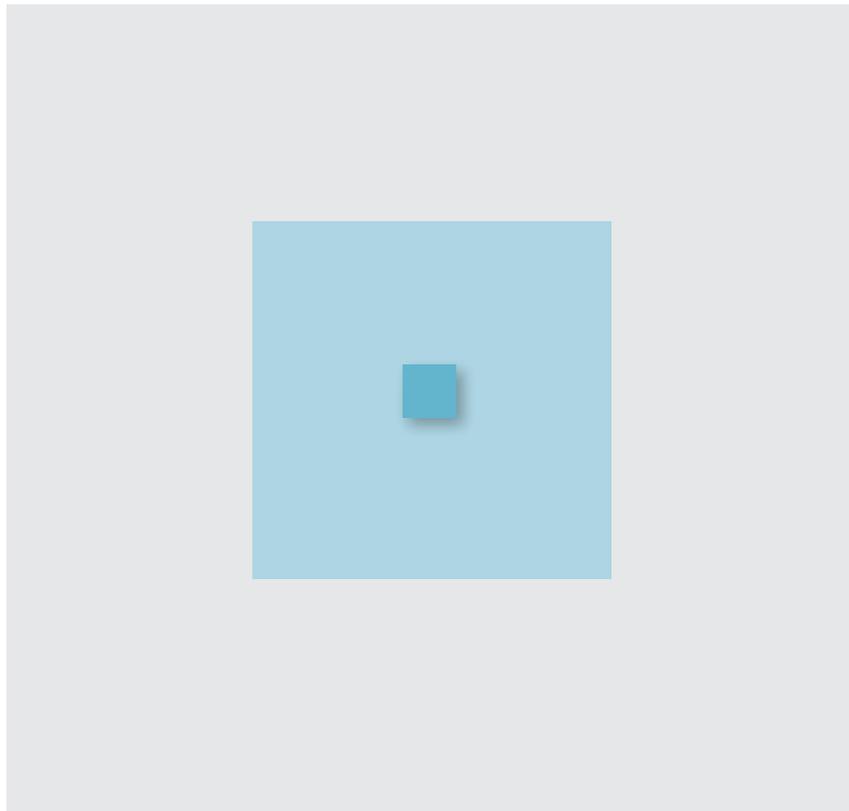
A woman answers “NO” to questions 10 and 11, but then answers “YES” to question 12 because she has abstained from sexual intercourse since her last menstrual period. The provider should now stop asking questions because a “YES” response to any of the questions indicates a circumstance under which it is highly unlikely that a woman could be pregnant.

Ask questions 10-15 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 below.

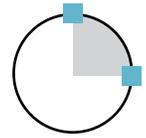


Optional information: If participants are curious and asking questions about the design elements of the checklist, such as arrows and colors, an explanation is provided below for your use in addressing these questions. It is important to note that while these design elements provide visual cues, they are secondary to the main instructions on the checklist, which participants must follow.

- The arrows next to the “YES” responses and the straight lines next to the “NO” responses offer cues as to how to proceed through the questions. The arrows indicate the provider should end the questioning and jump directly to the instruction box below that set of questions. The straight lines indicate the provider must proceed to the next question.
- Generally, if the client’s response falls in the GREEN boxes, she is a good candidate, and if her response falls in the RED box, she is probably not a good candidate. However, for the eligibility questions, ALL of the client’s answers must fall in the green boxes for the woman to be a good candidate, whereas for the pregnancy questions ONE answer in the green boxes is sufficient for her to be a good candidate.



- Objectives:**
- To summarize what was accomplished during the training session.
 - To address any remaining issues.
 - To thank participants for their attention and participation.



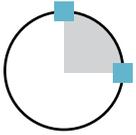
15 minutes

Training Steps:

1. Briefly summarize the objectives and accomplishments of the training.
2. Show participants the flip chart page containing the expectations they expressed at the beginning of the training. Ask participants if these expectations have been met.
3. Engage participants in a wrap-up discussion, by asking the following questions:
 - Was the COC Checklist easy to use?
 - Was it easy to explain questions to the client?
 - What problems did you encounter while using the checklist?
 - Do you foresee any barriers to using the checklist in your work? How could these barriers be overcome?
 - What would help you to use the checklist in your work?
 - Do you have any suggestions for improving the checklist or for getting more providers to use it?
 - What did you find helpful about the training?
 - Could the training be improved in any way? If so, how?

This is a good way to end the training, because it allows you to address any issues or concerns that participants may have. Also, FHI requests that you compile these responses and forward them to our staff at publications@fhi.org for future improvements to this guide.

4. Thank the participants for their time and energy. Tell them whom they should contact for more information or materials.
5. Distribute certificates of attendance to each participant.



15 minutes

Objective: To understand the research surrounding the need for and the effectiveness of the Pregnancy Checklist.

Training Steps:

1. Summarize the research on the rationale for the Pregnancy Checklist.
2. Summarize the research validating the Pregnancy Checklist.

Facilitator's Resource:

Research on the rationale for the Pregnancy Checklist

- The checklist was developed to reduce barriers to contraception for women who are not menstruating at the time of their visit. Research on menstruation requirements has been done in several countries.
 - Kenya — an estimated one-third of all new clients were sent home without a contraceptive method because of a menstruation requirement (Stanback et al. 1999).
 - Ghana — 76 percent of health care providers said they would send a client home if she was not menstruating at the time of her visit (Twum-Baah and Stanback 1995).
 - Cameroon — only one-third of nonmenstruating clients received hormonal contraceptive methods because providers were unsure of clients' pregnancy status (Nkwi et al. 1995).
 - Jamaica — 92 percent of clients were required to be menstruating or to have a negative pregnancy test at the time contraceptives were provided (McFarlane et al. 1996).
- Additional research evaluated whether using the checklist reduced the number of women denied contraceptives because they were not menstruating at the time of their visits.
 - In Guatemala, 16 percent of nonmenstruating women were denied their contraceptive method of choice when no checklist was used. After providers began using the checklist, only 2 percent of women were denied (Stanback et al. 2005).
 - In Senegal, the situation was similar; fewer women were denied their contraceptive method of choice after providers were introduced to the checklist — 11 percent were denied without the checklist versus 6 percent when the checklist was available (Stanback et al. 2005).

Research on the validity of the Pregnancy Checklist

- The Pregnancy Checklist has been extensively tested to ensure that it is valid and that women identified by the checklist as not pregnant truly are not pregnant. Research has been done in Kenya, Guatemala, Mali, Senegal, and Egypt. Those studies posed several questions to determine the checklist's validity.

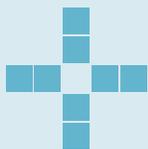
Does the checklist accurately predict that a woman is not pregnant?

Yes — Researchers compared the checklist results with a pregnancy test and found that more than 99 percent of the time the checklist was correct in ruling out pregnancy. In the very rare cases where the checklist ruled out pregnancy but the client was actually pregnant, the reasons included contraceptive failure or inaccurate answers given by the client.

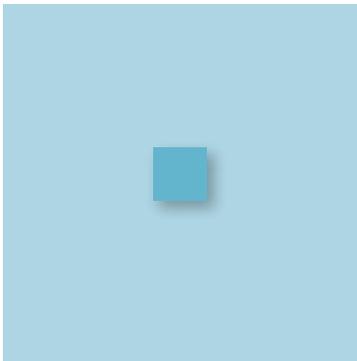
Does the checklist accurately predict that a woman is pregnant?

No — Most women who are identified as possibly pregnant are, in fact, not pregnant. Researchers gave pregnancy tests to women who answered no to all questions and found that less than 15 percent were actually pregnant. If pregnancy is not ruled out by the checklist, the woman should be referred for additional evaluation or a pregnancy test, or should await menses.

Optional information: At the end of the Pregnancy Checklist, it states that “If the client answered **YES to at least one of the questions** and she is free of signs or symptoms of pregnancy, provide client with desired method.” Research shows that the six questions are much more reliable in determining whether a woman is not pregnant than are signs and symptoms. If a provider is trained to do so, signs and symptoms should be assessed in addition to, but not instead of, administering the checklist. If a provider is not trained to assess signs and symptoms of pregnancy, the provider should feel confident that pregnancy has been ruled out based on the questions alone. (Symptoms may include nausea, mood changes, and missed menstrual period(s), and signs may be uterine softness and breast tenderness.)



Emphasize that the checklist was developed to RULE OUT pregnancy and to minimize barriers women face in seeking contraception. The checklist CANNOT be used to diagnose pregnancy.



1

COC Scenario

You are a 42-year-old woman with two children who is requesting COCs. You have a history of diabetes that was first diagnosed when you were 18 years old.

2

COC Scenario

You are a 24-year-old woman who gave birth to your first child five months ago. You are fully breastfeeding and have not had a menstrual period since childbirth, but you need to return to work full-time in two weeks. Because this will make it impossible to keep up your breastfeeding schedule, you are plan to switch to formula and other supplementary foods as soon as you return to work.

3

COC Scenario

You are a 30-year-old woman who has three children. You complain about repeated headaches, but when asked about the nature of your headaches, you say that that they are mild, have no distinctive pattern, and are not accompanied by other symptoms. Your last menstrual period started six days ago.

4

COC Scenario

You are a 34-year-old woman who was diagnosed with tuberculosis two months ago and is taking rifampicin.

5

COC Scenario

You are a healthy woman who answers “NO” to all the checklist questions.

6

COC Scenario

You are a 41-year-old woman who smokes two cigarettes a day.

7 **COC Scenario**

You have severe headaches on the left side of your head that make you sick to your stomach. Any type of light, even candlelight, makes your headache worse.

8 **COC Scenario**

You are currently being treated for viral hepatitis.

9 **COC Scenario**

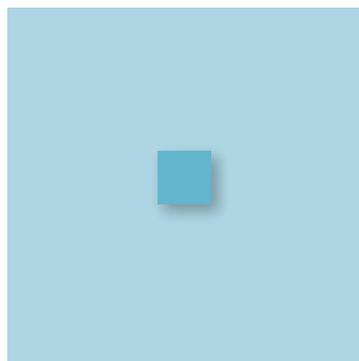
You had a heart attack five years ago, saw a doctor, and were hospitalized for one week.

10 **COC Scenario**

You had surgery two years ago to remove a breast cancer tumor.

11 **COC Scenario**

You were told you had high blood pressure when you went to the clinic two years ago.



COC Scenario 1

You are a 42-year-old woman with two children who is requesting COCs. You have a history of diabetes that was first diagnosed when you were 18 years old.

1. *Is this client a good candidate for receiving COCs during today's visit?*

No.

2. *Why or why not?*

She is not medically eligible because she answers "YES" to question 9 — *Have you ever been told you have diabetes (high sugar in your blood)?* Diabetic women who have had the disease for at least 20 years, or who have vascular complications, should not use COCs because of the increased risk of blood clots.

3. *What course of action would you take next?*

Counsel the client on other available contraceptive options, such as IUDs, implants, condoms or sterilization. For these contraceptive methods, a long history of diabetes is not a contraindication to use.

COC Scenario 2

You are a 24-year-old woman who gave birth to your first child five months ago. You are fully breastfeeding and have not had a menstrual period since childbirth, but you need to return to work full-time in two weeks. Because this will make it impossible to keep up your breastfeeding schedule, you plan to switch to formula and other supplementary foods as soon as you return to work.

1. *Is this client a good candidate for receiving COCs during today's visit?*

Yes.

2. *Why or why not?*

The explanation for question 1 on the COC checklist states that whereas breastfeeding women should not use COCs, since they may decrease the duration of lactation, a woman who plans to discontinue breastfeeding may be a good candidate for the method.

3. *What course of action would you take next?*

Proceed with initiation of COCs.

COC Scenario 3

You are a 30-year-old woman who has three children. You complain about repeated headaches, but when asked about the nature of your headaches, you say that they are mild, have no distinctive pattern, and are not accompanied by other symptoms. Your last menstrual period started six days ago.

1. Is this client a good candidate for receiving COCs during today's visit?

Yes.

2. Why or why not?

According to the explanation for question 3, only migraines with focal symptoms (*severe headaches, often on one side, and/or pulsating, causing nausea*) may preclude use of COCs. Because the woman's headaches are mild and are not accompanied by other symptoms, she may be a good candidate for COCs. Also, pregnancy is ruled out because she confirmed that her last menstrual period started within the past seven days (question 10).

3. What course of action would you take next?

Proceed with initiation of COCs. Because the woman's menses started more than five days ago, she must use condoms or abstain from sex for the next seven days while using COCs.

COC Scenario 4

You are a 34-year-old woman who was diagnosed with tuberculosis two months ago and is taking rifampicin.

1. Is this client a good candidate for receiving COCs during today's visit?

No.

2. Why or why not?

She is not medically eligible because she answered "YES" to question 6 — *Do you regularly take any pills for tuberculosis (TB) or seizures (fits)?* According to the explanation for question 6, women who take rifampicin should generally not use COCs. This is because rifampicin has been shown to adversely affect the efficacy of COCs.

3. What course of action would you take next?

Counsel the woman about other contraceptive options, such as condoms, DMPA, IUDs and sterilization. Help her to choose an appropriate method. Also inform her that when she has completed her tuberculosis treatment, she can be re-evaluated for COC use, if she is still interested.

COC Scenario 5

You are a healthy woman who answers “NO” to all the checklist questions.

1. Is this client a good candidate for receiving COCs during today’s visit?

No.

2. Why or why not?

She is not eligible because pregnancy has not been ruled out. (She answered “NO” to questions 10-15.) Although she is medically eligible to use COCs, she does not need a contraceptive if she is pregnant.

3. What course of action would you take next?

Let the client know that she is not *necessarily* pregnant, but that in her case, another approach will be needed to rule out pregnancy (either a pregnancy test, a pelvic exam, or awaiting her next menses). Be sure not to lead the client to believe she is pregnant. Always provide her with some form of protection against pregnancy, such as condoms, while waiting to rule out pregnancy. If possible, also provide her with COCs and instructions to start using them on the first day of her next menses.

COC Scenario 6

You are a 41-year-old woman who smokes two cigarettes a day.

1. Is this client a good candidate for receiving COCs during today’s visit?

No.

2. Why or why not?

She is not eligible because she answered “YES” to question 2 — *Do you smoke cigarettes and are you over 35 years of age?* Women who are over 35 years of age and who smoke cigarettes may be at increased risk of cardiovascular

disease. This is a two-part question. Both parts need to be asked and the answer “YES” must apply to both parts of the question for the woman to be ineligible. This is because a woman younger than 35 years who smokes, or a woman older than 35 years who does not smoke, is not at increased risk of cardiovascular disease. If a client answers “NO” to one or both parts of this question, she may be eligible for COC use.

3. *What course of action would you take next?*

Counsel the woman on other available contraceptive options, such as DMPA, IUDs, implants, condoms or sterilization. For these methods, smoking is not a contraindication to use at any age.

COC Scenario 7

You have severe headaches on the left side of your head that make you sick to your stomach. Any type of light, even candlelight, makes your headache worse.

1. *Is this client a good candidate for receiving COCs during today’s visit?*

No.

2. *Why or why not?*

She is not eligible because she answered “YES” to question 3 — *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 who have migraines with aura, 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 with aura) and the less severe or mild headaches, which do not rule out COC use.

3. *What course of action would you take next?*

Counsel the woman on other available contraceptive options, such as DMPA, IUDs, implants, condoms or sterilization. For these methods, a history of migraines is not a contraindication to use.

COC Scenario 8

You are currently being treated for viral hepatitis.

1. Is this client a good candidate for receiving COCs during today's visit?

No.

2. Why or why not?

She is not medically eligible because she answered "YES" to question 4 — *Do you have a serious liver disease or jaundice (yellow skin or eyes)?* This question is intended to identify women who have serious liver disease. It can also be used to distinguish current serious liver disease (such as severe cirrhosis, liver tumors or active hepatitis) from past liver problems (such as a history of hepatitis/hepatitis carrier). Women with serious liver disease should not use COCs, because COCs are processed by the liver and their use may worsen liver function that is already weakened by the disease.

3. What course of action would you take next?

Counsel the woman on other available contraceptive options, such as IUDs or condoms, for which active viral hepatitis is not a contraindication to use. Also encourage her to talk with your about her liver condition and the possibility of beginning COCs after treatment is completed.

COC Scenario 9

You had a heart attack five years ago for which you were hospitalized for one week.

1. Is this client a good candidate for receiving COCs during today's visit?

No.

2. Why or why not?

She is not medically eligible because she answered "YES" to question 5 — *Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?* 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 would likely answer yes.

3. What course of action would you take next?

Counsel the woman on other available contraceptive options, such as IUDs, implants, condoms and sterilization. For these methods, a history of heart attack is not a contraindication to use.

COC Scenario 10

You had surgery two years ago to remove a breast cancer tumor.

1. *Is this client a good candidate for receiving COCs during today's visit?*

No.

2. *Why or why not?*

She is not medically eligible because she answered “YES” to question 7 — *Have you ever been told you have breast cancer?* Women who have a history of breast cancer or current breast cancer 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.

3. *What course of action would you take next?*

Counsel the woman on other available contraceptive options, such as IUDs, condoms and sterilization. For these methods, breast cancer is not a contraindication to use.

COC Scenario 11

You were told you had high blood pressure when you went to the clinic two years ago.

1. *Is this client a good candidate for receiving COCs during today's visit?*

No.

2. *Why or why not?*

She is not medically eligible because she answered “yes” to question 8 — *Have you ever been told you have high blood pressure?* Women with elevated blood pressure should not use COCs because they may be at increased risk of stroke or heart attack.

3. *What course of action would you take next?*

Refer the client to a higher-level provider to have her blood pressure evaluated. She may still be eligible to receive COCs, depending on the outcome of the evaluation. In the meantime help her to choose another method of contraception.

Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use – to initiate use of combined oral contraceptives (COCs), depot-medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), copper intrauterine device (Cu-IUD)

CONDITION	COC	DMPA/NET-EN	Cu-IUD
Age	Menarche to 39 years		
	40 years or more		
	Menarche to 17 years		
	18 years to 45 years		
Nulliparous	More than 45 years		
	Menarche to 19 years		
	20 years or more		
Breastfeeding	Less than 6 weeks postpartum		*
	6 weeks to 6 months postpartum		
Smoking	6 months postpartum or more		
	Age < 35 years		
	Age ≥ 35 years, < 15 cigarettes/day		
Hypertension	Age ≥ 35 years, ≥ 15 cigarettes/day		
	History of hypertension where blood pressure: CANNOT be evaluated		
	Is controlled and CAN be evaluated		
Headaches	Systolic 140 - 159 or diastolic 90 - 99		
	Systolic ≥ 160 or diastolic ≥ 100		
	Non-migrainous (mild or severe)		
	Migraine without aura (age < 35 years)		
History of deep venous thrombosis	Migraine without aura (age ≥ 35 years)		
	Migraines with aura		
Superficial thrombophlebitis			
Complicated valvular heart disease			
Ischemic heart disease/stroke			
Diabetes	Non-vascular disease		
	Vascular disease or diabetes of > 20 years		
Malaria			
Non-pelvic tuberculosis			
Thyroid disease			
Iron deficiency anemia			
Sickle cell anemia			

CONDITION	COC	DMPA/NET-EN	Cu-IUD
Known hyperlipidemias			
	Cervical		
	Endometrial		
Cancers	Ovarian		
Cervical ectropion			
Breast disease	Undiagnosed mass	**	**
	Family history of cancer		
	Current cancer		
Uterine fibroids without cavity distortion			
Endometriosis			
Trophoblast disease (malignant gestational)			
Vaginal bleeding patterns	Irregular without heavy bleeding		
	Heavy or prolonged, regular and irregular		
	Unexplained bleeding		
Cirrhosis	Mild		
	Severe		
Current symptomatic gall bladder disease			
Cholestasis	Related to the pregnancy		
	Related to oral contraceptives		
Hepatitis	Active		
	Client is a carrier		
Liver tumors			
STIs/PID	Current purulent cervicitis, chlamydia, gonorrhea		
	Vaginitis		
	Current pelvic inflammatory disease (PID)		
HIV	Other STIs (excluding HIV/hepatitis)		
	Increased risk of STIs		
	Very high individual risk of exposure to STIs		
AIDS	High risk of HIV or HIV-infected		
	No antiretroviral therapy (ARV)		
Use of:	Not clinically well on ARV therapy		
	Clinically well on ARV therapy		
	Griseofulvin		
	Rifampicin		
	Other antibiotics		

Category 1 There are no restrictions for use.
 Category 2 Generally use; some follow-up may be needed.
 Category 3 Usually not recommended; clinical judgment and continuing access to clinical services are required for use.
 Category 4 The method should not be used.

* Breastfeeding does not affect initiation and use of the IUD. Regardless of breastfeeding status, postpartum insertion of the IUD is Category 2 up to 48 hours postpartum, Category 3 from 48 hours to four weeks, and Category 1 four weeks and after.
 ** Evaluation should be pursued as soon as possible.



Source: Adapted from Medical Eligibility Criteria for Contraceptive Use, Geneva: World Health Organization, Third edition, 2004. Available: <http://www.who.int/reproductive-health/publications/MEC/>

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 ischaemic 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.



Family Health International (FHI), with support from the U.S. Agency for International Development (USAID), has developed a simple checklist (see next page) 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 COCs* produced by FHI in 2002. Changes reflected in this version are based on the recently revised recommendations of the *Medical Eligibility Criteria for Contraceptive Use* (WHO, 2004) as advised by research over the past five years. The main changes in this checklist include removal of fungal infection as a condition that would prohibit the use of COCs and the inclusion of a series of questions to determine with reasonable certainty whether a woman is not pregnant before initiating the method.

The checklist is designed for use by both clinical and nonclinical health care providers, including community health workers. It consists of 15 questions designed to identify medical conditions that would prevent safe COC use or require further screening, as well as provide further guidance and directions based on clients' responses. Clients who are ruled out because of their response to some of the medical eligibility questions may still be good candidates for COCs after the suspected condition is excluded through appropriate evaluation.

This checklist is part of a series of provider checklists for reproductive health services. 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 IUD*, and the *Checklist on How to be Reasonably Sure a Client is Not Pregnant*. For more information about the provider checklists, please visit www.fhi.org.

Assessing Medical Eligibility for COCs

1. Are you currently breastfeeding a baby under 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. Do you smoke cigarettes and are you over 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 — and 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.

3. 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

Continued on page 48

Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives

To determine if the client is medically eligible to use COCs, ask questions 1–9. As soon as the client answers **YES** to **any** question, stop, and follow the instructions below.

NO	1. Are you currently breastfeeding a baby under six months of age?	YES
NO	2. Do you smoke cigarettes and are you over 35 years of age?	YES
NO	3. 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	4. Do you have a serious liver disease or jaundice (yellow skin or eyes)?	YES
NO	5. Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?	YES
NO	6. Do you regularly take any pills for tuberculosis (TB) or seizures (fits)?	YES
NO	7. Have you ever been told you have breast cancer?	YES
NO	8. Have you ever been told you have high blood pressure?	YES
NO	9. Have you ever been told you have diabetes (high sugar in your blood)?	YES

If the client answered **NO** to **all of questions 1–9**, the client can use COCs. Proceed to questions 10–15.

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 **question 8 or 9**, 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 10–15 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 below.

YES	10. Did your last menstrual period start within the past 7 days?	NO
YES	11. 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	12. Have you abstained from sexual intercourse since your last menstrual period or delivery?	NO
YES	13. Have you had a baby in the last 4 weeks?	NO
YES	14. Have you had a miscarriage or abortion in the last 7 days?	NO
YES	15. Have you been using a reliable contraceptive method consistently and correctly?	NO

If the client answered **YES** to **at least one of questions 10–15** 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 10–15**, 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.

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.

4. Do you have a serious liver disease or jaundice (yellow skin or eyes)?

This question is intended to identify women who know that they currently have a serious liver disease and to distinguish between current severe liver disease (such as severe cirrhosis or liver tumors) and past liver problems (such as treated hepatitis). Women with serious liver disease should not use COCs, because COCs are processed by the liver and their use may adversely affect women whose liver function is already weakened by the disease.

5. 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.

6. Do you regularly take any pills for tuberculosis (TB) or seizures (fits)?

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 (for tuberculosis), and phenytoin, carbamazepine, and barbiturates (for epilepsy/seizures).

7. Have you ever been told you have breast cancer?

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.

8. 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.

9. 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.

Determining Current Pregnancy

Questions 10–15 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.

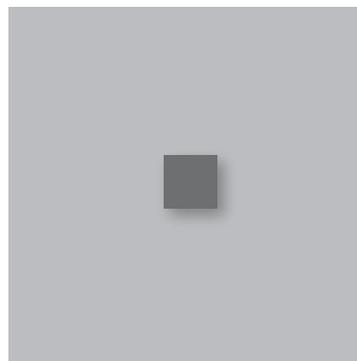
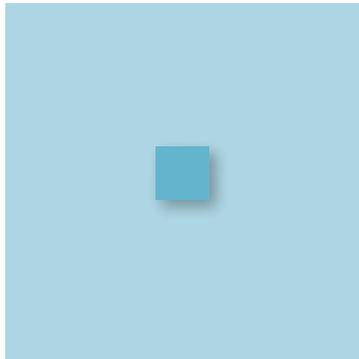
If it has been more than 5 days since her first day of bleeding, she can start taking COCs immediately but must use a back-up method (i.e., using a condom or abstaining from sex) for 7 days to ensure adequate time for the COCs to become effective.

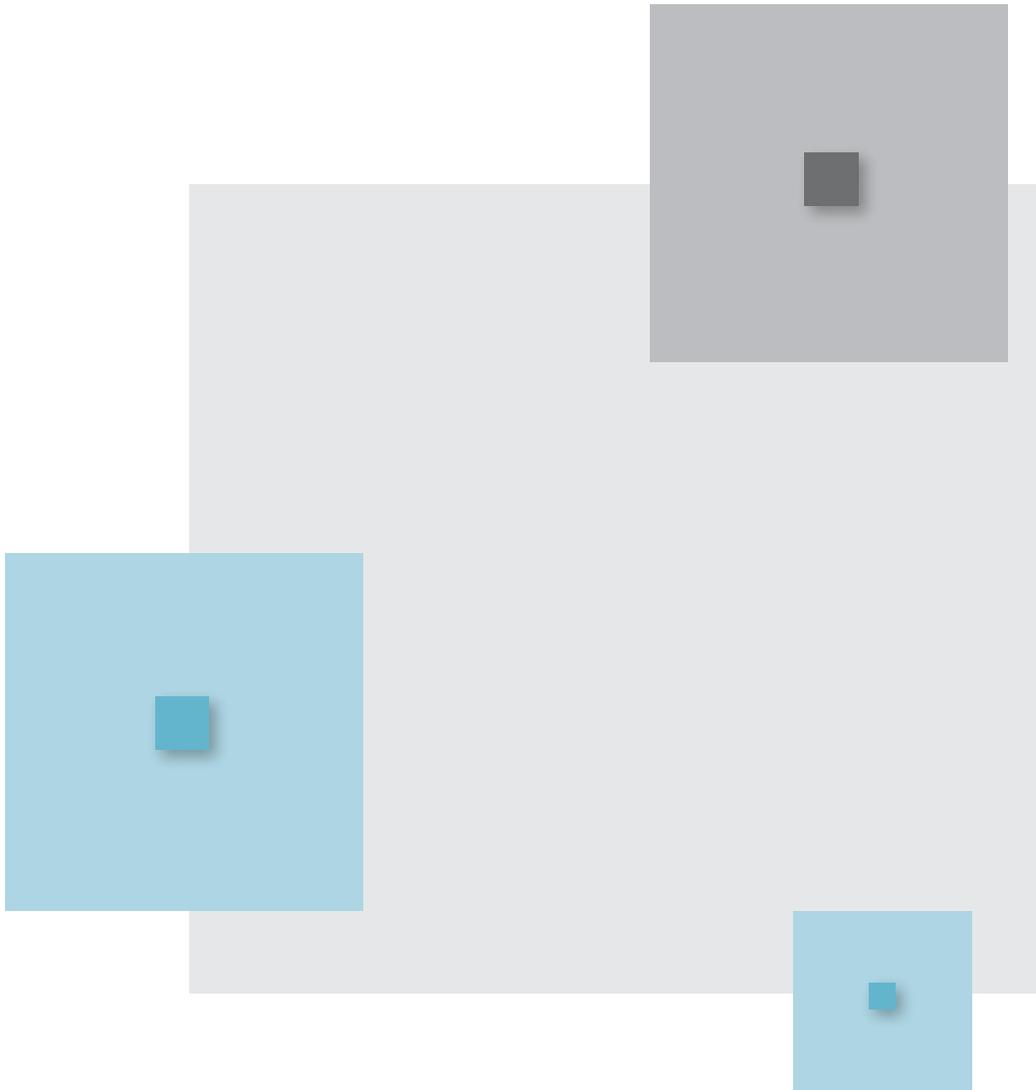
If you cannot determine with reasonable certainty that your client is not pregnant (using the checklist) and if you do not have access to a pregnancy test, then she needs to wait until her next menstrual period begins before starting COCs. She should be given condoms to use in the meantime.

The purpose of this reference guide is to provide essential information that supplements the training module. This information includes:

- recommendations on adapting the checklist to the local context;
- basic evidence-based information on COCs; and
- an annotated bibliography.

The facilitator should anticipate — and be well prepared to answer — questions that are likely to arise and that are beyond the scope of the COC Checklist. The checklist is intended solely to help providers decide if clients may or may not safely initiate COCs. However, participants may well inquire about such issues as COC side effects or COC use by specific client populations, such as women who are at risk of HIV or who are living with AIDS, etc. This guide does not attempt to provide comprehensive information about COCs, and trainers should consult other resources as needed.





The COC Checklist can be adapted to meet the specific needs of a local area or program, or to align with national guidelines that may apply. However, before the adapted version is finalized and put into use, we strongly recommend that any changes be reviewed by an expert who understands the medical basis for the checklist. Likewise, the corresponding training module should be adjusted to reflect any changes. The intent of each question is explained on the reverse side of the checklist to help with these adaptations. The following are examples of situations in which adaptation may be needed.

- **Adapting the checklist to the local language and style**

Whenever necessary, the checklist should be translated and the style adapted to meet the cultural and linguistic needs of the intended users of the checklists and their clients. In addition to English, the checklist has been produced in French, Spanish, Kiswahili and several other languages. These checklists are available on FHI's web site, www.fhi.org.

- **Adapting for local culture**

Some of the questions on the checklist deal with personal issues and may need to be asked in a sensitive manner. For example, question 14 asks about miscarriage and abortion. To help ensure that the client feels safe and comfortable answering honestly, it may be useful to rephrase the question to "Have you lost a pregnancy in the last seven days?".

- **Adapting the checklist for comprehension**

Adaptations may also be made if the questions are too technical to be understood. Be careful, however, not to inadvertently change the intent of the question, because even small changes in wording can cause significant changes in meaning. For audiences with low literacy levels, it may be helpful to develop materials that convey key messages through illustrations with simple captions. Illustrations also should be appropriate for the local target audience.

The purpose of the COC Checklist is to safely allow more women to receive these contraceptives. Poor adaptations could prevent eligible women from receiving COCs. The following are examples of **poorly adapted** checklist questions.

Original Question	Poorly Adapted Question	Reason
Describing diseases or conditions using symptoms		
Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?	Do you suffer from severe chest pain or unusual shortness of breath?	The original question intends to identify women who <i>know</i> they have a history of cardiovascular disease. It is not intended to identify or diagnose new conditions that may be contraindications for COC use. By listing symptoms, the adaptation turns the question into a diagnostic one and therefore changes its intention.
Have you ever been told you have breast cancer?	Do you have or have you ever had a breast lump?	The original question intends to identify women with a history of breast cancer. It does not intend to diagnose breast cancer. COC use is contraindicated for women with a history of breast cancer, but not for women who have an undiagnosed mass or benign breast disease (although evaluation is recommended after these women initiate COCs).
Original Question	Poorly Adapted Question	Reason
Changes to the approach/structure of the question		
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?	Are you fully or nearly fully breastfeeding and have you had no menstrual period since you gave birth?	The structure of the question is changed in this example. The original question identifies women who are experiencing lactational amenorrhea, which is defined by the three criteria in the question, and can be used to effectively prevent unintended pregnancy. Removing “Did you have a baby less than 6 months ago?” removes one of the criteria, so this question can no longer be used to identify women with lactational amenorrhea.
Do you smoke cigarettes <i>and</i> are you over 35 years of age?	Do you smoke 15 or more cigarettes per day and are you over 35 years of age?	Adding the number of cigarettes smoked to this question suggests that women 35 years of age or older who smoke fewer than 15 cigarettes per day are good candidates for COCs, which is not true. Research has shown that women 35 years of age or older who smoke — regardless of the number of cigarettes smoked per day — are at increased risk of cardiovascular disease, especially heart attack.
Do you smoke cigarettes <i>and</i> are you over 35 years of age?	Do you smoke cigarettes? Are you over 35 years of age?	This adaptation has separated the original question into two parts. By doing so, the most important point of the original question — to identify women who both smoke and are over 35 years old, and thus have an increased risk of cardiovascular disease — could be lost. This poor adaptation could prevent eligible women from receiving COCs. Women who smoke but are younger than 35 are eligible to receive COCs. Women over 35 who do not smoke may also receive COCs.

FACT SHEET: Combined Oral Contraceptives (COCs)

Combined oral contraceptives (COCs) are pills that are taken once per day to prevent pregnancy. They contain the hormones estrogen and progestin.

Primary mechanisms of action

- Prevent ovulation (release of eggs from the ovaries)
- Thicken cervical mucus (make it difficult for sperm to penetrate)

Characteristics of COCs

- Safe and very effective if used consistently and correctly
- Reversible, rapid return to fertility
- Do not interfere with intercourse
- Easy to discontinue use
- Have beneficial non-contraceptive effects (regular menstrual cycles; lighter menses; fewer menstrual cramps; protection from ectopic pregnancy, ovarian and endometrial cancer, and symptomatic pelvic inflammatory disease; may help protect against ovarian cysts and anemia; reduce symptoms of endometriosis)
- Require daily use
- Incorrect use is common (easy to miss taking a pill)
- Require resupply
- No protection against sexually transmitted infections, including HIV
- Have common side effects
- Serious complications very rare

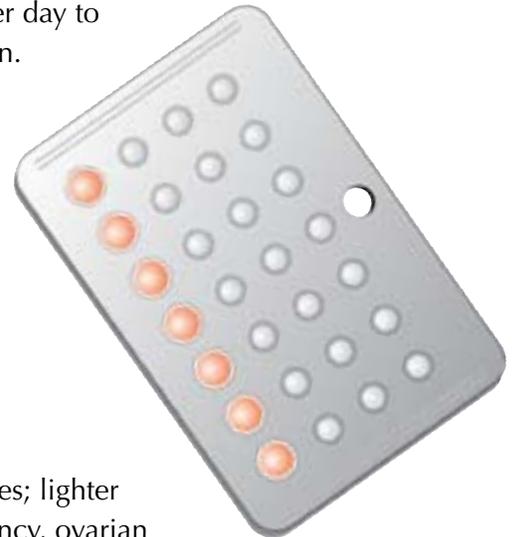
Possible side effects of COCs (generally not signs of a health problem)

- Headaches, dizziness
- Nausea
- Breakthrough bleeding or spotting
- Breast tenderness
- Mood changes
- Weight change
- Amenorrhea

Who can use COCs

Women of any parity or reproductive age who:

- want to use this method of contraception
- have no health conditions that preclude the use of COCs



Who should not use COCs (for a complete list, see WHO eligibility criteria)

Women who have the following conditions (contraindications):

- breastfeeding, during the first six weeks postpartum (also not a good method for women who want to continue breastfeeding up to six months)
- first three weeks postpartum if not breastfeeding
- age 35 or older, who smoke heavily (15 cigarettes/day or more)
- current breast cancer
- liver tumors, active hepatitis or severe cirrhosis
- cardiovascular conditions (i.e., high blood pressure; diabetes with vascular complications; history of or current deep venous thrombosis, stroke, or ischemic heart disease)
- migraine with aura or any migraine in women older than age 35
- taking drugs that affect liver enzymes: rifampicin (for tuberculosis) or anticonvulsants (for epilepsy)

COC use by women with HIV and AIDS

- Women with HIV and AIDS can use COCs without restrictions.
- Women with AIDS who take antiretroviral drugs (ARVs) can generally use COCs, but follow-up may be required (the effectiveness of COCs may be compromised by ARVs, particularly if a woman cannot take COCs on schedule).
- Women with HIV who choose to use COCs should be counseled about dual method use and consider using condoms in addition to COCs.

Provide follow-up and counseling for

- Any client concerns or questions
- Common side effects
- Correct COC use (ability to take pills on schedule, what to do when pills are missed)
- Any signs of complications (thrombosis or thromboembolism); counsel the woman to come back immediately if any of the following symptoms develop:
 - severe chest pain or shortness of breath
 - severe headache with vision problems
 - sharp pain in leg or abdomen

Dispelling myths regarding COCs

Contraceptive pills **do not**:

- cause birth defects
- cause infertility
- require a “rest” period
- decrease sex drive
- build up in a woman’s body

No More Waiting!

Using a Checklist to Rule out Pregnancy is an Effective Way to Increase Access to Contraceptives

Summary

Nonmenstruating women need not wait for the onset of their menses to initiate their contraceptive method of choice. Several research studies conducted in various countries show that a simple checklist developed to help providers rule out pregnancy among such clients is correct 99 percent of the time and is effective in reducing the proportion of clients denied contraceptive services. Using this checklist offers an effective and inexpensive alternative to laboratory tests and increases women's access to essential family planning services.

Family planning providers are required to determine whether a woman might already be pregnant before initiating use of her contraceptive method of choice. When pregnancy tests are unavailable or unaffordable, health providers often rely on the presence of menstruation as an indicator to rule out pregnancy. When women do not present with menses at the time of their visit, they are sent home — often without any contraception — to await the onset of menses. This is because providers fear that contraception can harm an unrecognized pregnancy. Data analyzed from family planning programs in Cameroon, Ghana, Jamaica, Kenya and Senegal have found that a significant proportion of new, nonmenstruating clients (25% to 50%) are denied their desired method as a result of their menstrual status.¹ Clients sent home because of such menstruation requirements risk unplanned pregnancies, if they are unable to return due to time and financial constraints.

How to be Reasonably Sure a Client is Not Pregnant

Ask the client questions 1-6. As soon as the client answers **YES** to **any question**, stop, and follow the instructions.

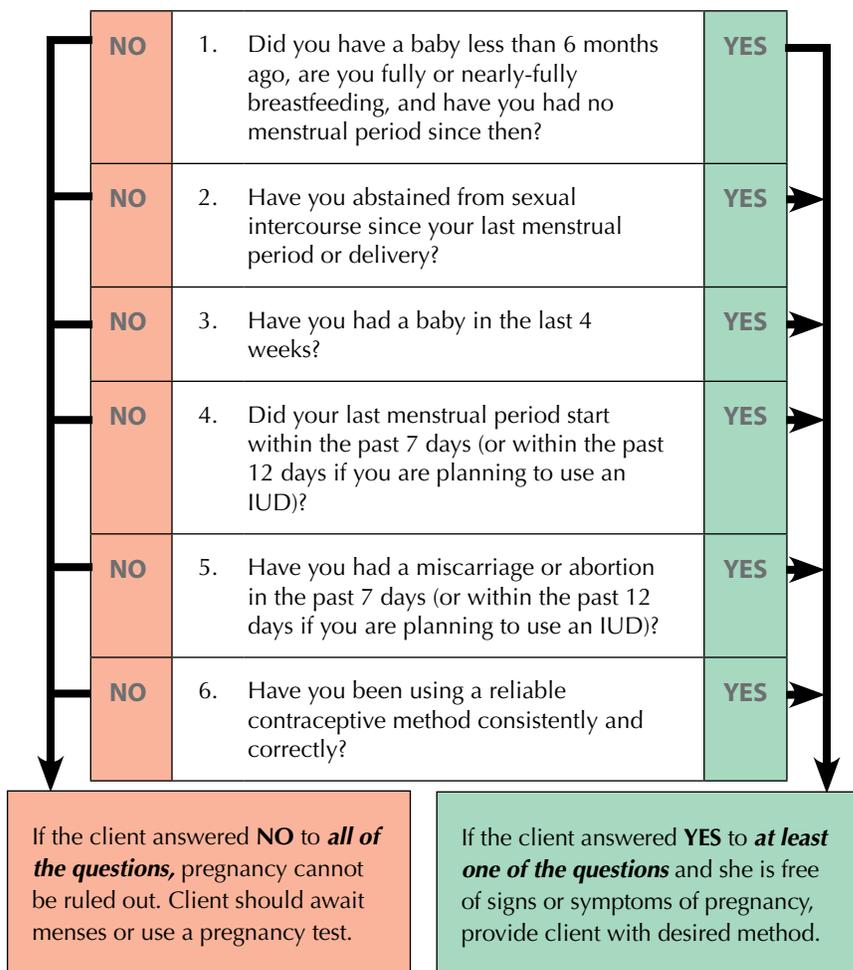


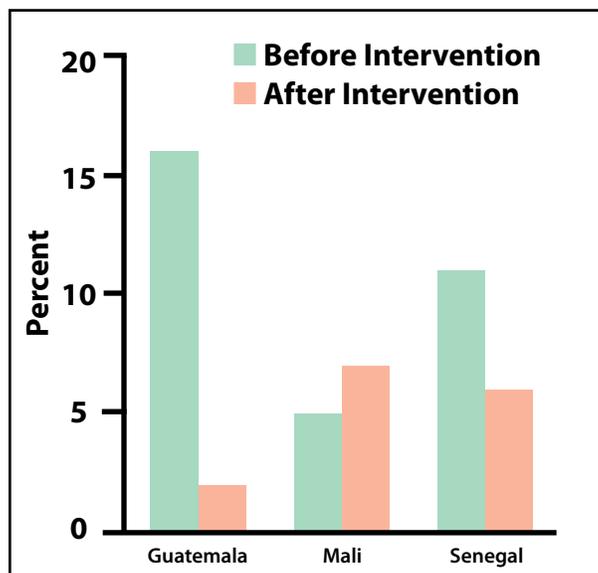
Figure 1

Family Health International (FHI) developed a simple checklist to rule out pregnancy among such clients with a reasonable degree of certainty. The checklist consists of six questions that providers ask clients while taking their medical history. If the client answers “yes” to any of these questions, and there are no signs or symptoms of pregnancy, then a provider can be reasonably sure that the woman is not pregnant. (See Figure 1.) The six questions are based on criteria established by the World Health Organization (WHO) that indicate conditions that effectively prevent a woman from getting pregnant.

Checklist Correctly Rules Out Pregnancy

A study to test the validity of the checklist against a standard pregnancy test was first conducted in Kenya² in 1999 and later repeated in Egypt in 2005. In both studies, the checklist correctly ruled out pregnancy 99% of the time. In addition, each of the six individual questions indicated a high predictive value in ruling out pregnancy. As a result, both studies concluded that in low resource settings, where pregnancy tests are not available, nonmenstruating women should not leave a family planning clinic without an effective method, given that providers can be reasonably sure a woman is not pregnant as determined by a “yes” response to any of the six questions on the checklist.

Figure 2
Percentage of all new family planning clients denied their desired method as a result of their menstrual status, before and after the checklist intervention, in Guatemala, Mali, and Senegal, 2001-03



Checklist Allows Significantly More Women Access to Contraceptives

An operations research study was conducted in Guatemala, Mali, and Senegal from 2001 to 2003 to determine the impact of the checklist on family planning services.³ The study results showed that where denial of services to nonmenstruating family planning clients was a problem, introduction of the pregnancy checklist significantly reduced denial rates and improved access to contraceptive services.

Among new family planning clients, denial of the desired method due to menstrual status decreased significantly — from 16 percent to 2 percent in Guatemala and from 11 percent to 6 percent in Senegal. In Mali, denial rates were essentially unchanged, but were low from the start. (See Figure 2.)

1. Stanback J, Thompson A, Hardee K, Janowitz B. Menstruation requirements: a significant barrier to contraceptive access in developing countries. *Stud Fam Plann* 1997;28(3):245-50.

2. Stanback J, Qureshi Z, Sekadde-Kigonde C, Gonzalez B, Nutley T. Checklist for ruling out pregnancy among family planning clients in primary care. *Lancet* 1999;354(9178):566.

3 Stanback J, Diabate F, Dieng T, Duarte de Moraes T, Cummings S, Traoré M. Ruling out pregnancy among family planning clients: the impact of a checklist in three countries. *Stud Fam Plann* 2005;36(4):311-15.

This brief was produced by Family Health International’s CRTU (Contraceptive and Reproductive Health Technologies Research and Utilization) program. Financial assistance for this work was provided by the US Agency for International Development (USAID). The contents do not necessarily reflect USAID views and policy.

Read more about the Pregnancy Checklist and download electronic copies at www.fhi.org. For more information or to order hard copies, please e-mail publications@fhi.org.

Uses of the Pregnancy Checklist Beyond Family Planning

Although originally developed as a tool for family planning providers, the pregnancy checklist may prove useful to other health providers in low-resource settings who also need to rule out pregnancy. For example, providers who prescribe and pharmacists who dispense medications that should be avoided during pregnancy, including certain antibiotics or anti-seizure drugs, can adapt the pregnancy checklist for use in their settings.

No Evidence that Contraceptive Pills and Patches Lead to Weight Gain

- The belief that contraceptive pills and patches cause women to gain significant weight is not supported by the evidence.
- Counseling could reduce misperceptions about weight gain and decrease the number of women who discontinue the use of these effective contraceptives.

Background

Many women and clinicians believe that the use of combination contraceptives — typically pills or patches that contain an estrogen and a progestin — may cause weight gain. Such concerns may prevent some women from starting combination contraceptives or perhaps lead to early discontinuation. These women may turn to less effective methods or use none at all.

Until 2003, no one had reviewed the scientific literature on the relation between combination contraceptives and weight gain. A Cochrane review remedied the situation with an exhaustive analysis of English-language publications on the subject. That 2003 review has now been updated by the authors¹. One strength of the review is that it is limited to randomized controlled trials — the “gold standard” of trial designs for reducing the potential for bias.

The Weight of Evidence

The Cochrane review, published in the *Cochrane Database of Systematic Reviews* 2006, Issue 1, includes two additional studies beyond those originally published in 2003 by scientists at Family Health International (FHI). The updated review examines 44 hormonal-contraceptive trials that contain information about weight changes experienced by participants in the studies. Most participants were users of oral contraceptives.

Three of the trials compared weight changes in women using either oral contraceptives or a skin patch versus weight changes in women taking placebos. None of the three placebo-controlled trials showed an association between these contraceptives and weight gain.

The remaining trials compared weight changes between women taking different regimens of combination contraceptives. Although some women gained weight and some lost weight, the overall differences between the groups were minimal — the largest difference in weight change between the groups was less than five pounds.

If estrogen causes weight gain, as some have suggested, then women who take a contraceptive with more estrogen should gain more weight. The review found no evidence that this occurs. However, the studies may not have been designed to detect subtle weight changes in response to different doses.

1 Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight. *Cochrane Database of Systematic Reviews* 2006, Issue 1. Art. No.: CD003987. DOI: 10.1002/14651858.CD003987.pub2.

Most trials did not use careful methods to measure a woman's weight; indeed, only one trial identified "weight gain" as a primary outcome. Weight measurements can be affected by poorly calibrated scales, the amount of clothing a woman wears, and the time of day the woman is weighed. These factors could dilute differences between groups, and so mask minor changes caused by the treatments.

Also, some trials included in the Cochrane review did not provide information about weight changes for women who did not complete the study. These studies would have been more informative if weight changes were reported for all of the participants, regardless of whether they finished the trial.

The Cochrane review does not eliminate the possibility that the use of combination contraceptives is associated with minor changes in weight. Unraveling a potential association is complicated by several factors. For one thing, it is difficult to compare the results from many oral contraceptive regimens. In addition, many people gain weight over time, regardless of whether they use contraception. A well designed study would need to include a nonhormonal placebo group to control for other factors like an increase in weight over time.

Programmatic Implications

Providers should be informed that the evidence does not support a causal association between the use of combination contraceptives and weight gain. Providers should discuss the effect that eating habits and a sedentary lifestyle can have on weight. Adolescents should also be counseled about the natural increases in weight associated with growth and development. Appropriate counseling may help to reduce misperceptions about weight gain and decrease the number of women who discontinue the use of these effective contraceptives.

The review was first published in 2003. An update in 2005 was published in 2006. The Cochrane Collaboration is an international organization that promotes and provides up-to-date information about the effects of healthcare practices. Systematic reviews of clinical trials are published electronically in the Cochrane Library. For more information about the Cochrane Collaboration and Library, see <http://www.cochrane.org/index.htm>.

Source: The preceding Global Health Technical Brief is reprinted from the MAQ Website (Maximizing Access and Quality), a USAID initiative.

Hormonal Contraception and HIV: More Research Needed; No Changes in Family Planning Practices Currently Warranted

- No conclusive evidence exists that hormonal contraceptive use increases the risk of HIV acquisition, transmission, or disease progression.
- Current knowledge does not indicate a need to change existing recommendations that women at risk of HIV infection or those who are HIV-infected may safely use hormonal contraception.
- Hormonal contraceptive users at elevated risk of HIV infection should also use condoms consistently and correctly.

Background on Topic

Scientists seeking to identify factors that could contribute to the spread of HIV have raised the possibility of an association between hormonal contraceptive use and HIV acquisition. Research on the topic has been conflicting and inconclusive. Recently, however, data from the largest prospective study ever conducted specifically on hormonal contraceptive use and HIV acquisition has helped clarify this issue. These findings, as well as the current knowledge concerning a potential relationship between hormonal contraception and HIV transmission or HIV disease progression, do not warrant changing current family planning recommendations stating that women at risk of HIV infection or those who are HIV-infected may safely use hormonal contraception.¹

Hormonal Contraception Use and HIV Acquisition

Numerous studies have investigated a possible relationship between hormonal contraceptive use and HIV acquisition, but understanding of this matter has remained poor. Study results have been inconsistent, in part because nearly all these studies have been designed to investigate other research questions and have had important methodological shortcomings.

A study, published in the January 2, 2007 issue of the journal *AIDS*, clarifies this issue. It found no overall statistically significant association between the use of either combined oral contraceptive (COC) pills or depot medroxyprogesterone acetate (DMPA) and HIV acquisition. This four-year, prospective study, funded by National Institute of Child Health and Human Development, was conducted among some 6,100 HIV-negative women in Uganda, Zimbabwe, and Thailand. The primary finding of this study provides the best reassurance to date for women in need of highly effective contraception in settings of high HIV risk. The results from the study do not indicate that any changes should be made in the provision or use of DMPA or COCs. Neither the World Health Organization (WHO) nor the International Planned Parenthood Federation, which have reviewed the study results, plans at this time to change its guidelines for hormonal contraceptive use.

Notably, this study was conducted among family planning clients, who are considered to be at low risk of HIV infection and are similar to most women worldwide who use hormonal contraception. In contrast, while results of other studies have

been conflicting, those that have indicated an increased HIV risk associated with hormonal contraception were generally conducted among high-risk populations of women, such as sex workers.

Hormonal Contraceptive Use and HIV Transmission

Whether hormonal contraceptive use by HIV-infected women increases their risk of infecting sexual partners remains unknown. Only two studies of this issue have been prospective, and the results of four cross-sectional studies of HIV shedding from the genital tract (thought to be a marker of increased infectiousness) are conflicting, perhaps due to relatively small study samples.

Hormonal Contraceptive Use and HIV Disease Progression

The association between hormonal contraceptive use and clinical progression of HIV has not been studied directly. The only evidence so far that hormonal contraceptive use might affect HIV disease progression comes from a prospective study conducted among sex workers in Mombasa, Kenya.² In a subset of 156 HIV-infected sex workers, use of either oral contraceptives or DMPA at the time of HIV infection was associated with acquiring genetically diverse virus populations from a single partner. The women who acquired these genetically diverse virus populations also had significantly higher viral set points and significantly lower CD4 cell counts four to 24 months after infection than did those with only one strain of the virus. Both low CD4 cell counts and high viral set points are predictors of HIV disease progression. More research is needed to confirm this finding.

Interactions between Hormonal Contraceptives and Antiretroviral (ARV) Drugs

Limited evidence suggests that certain antiretroviral (ARV) drugs can either raise or lower concentrations of contraceptive hormones in the blood of HIV-infected women using combined oral contraceptives (COCs). Theoretically, lower contraceptive hormone levels could reduce contraceptive efficacy and increase pregnancy risk, while higher levels could increase hormone-related side effects. One of the concerns is a relatively modest reduction in blood hormone levels of 20 percent to 30 percent among women on COCs taking the commonly used ARV nevirapine. However, no studies have looked at actual clinical outcomes of these interactions, such as occurrence of ovulation and actual pregnancies. Few studies have looked at the question of how hormonal contraceptive use affects response to ARV therapy. But in the largest prospective study of the impact of HIV infection on U.S. women, hormonal contraceptive use did not reduce the effectiveness of the combinations of three or more different ARV drugs known as highly active antiretroviral therapy (HAART).³

Programmatic Considerations

No conclusive evidence exists that hormonal contraceptive use increases risk of either HIV acquisition or transmission. However, because hormonal contraception does not protect against HIV, uninfected hormonal contraceptive users at elevated risk of acquiring HIV should also use condoms consistently and correctly with each sexual act if they are not in a mutually monogamous relationship with an uninfected partner. HIV-infected women (regardless of contraceptive method they use)

should also use condoms consistently and correctly to reduce any possible risk of HIV transmission to their partners.

Hormonal contraceptive users who are HIV-infected and who — in the absence of definitive data about disease progression and hormonal contraceptive/ARV drug interactions — wish to continue hormonal contraceptive use can be counseled to do so. However, unanswered questions about the effects of ARVs on oral contraceptive effectiveness have led the WHO to caution that, although women on ARV therapy generally may use oral contraceptives, medical follow-up may be appropriate.⁴

HIV-positive hormonal contraceptive users who wish to switch methods should be counseled about other available contraceptive methods. Some of these women may prefer using a contraceptive method that is highly effective since the prevention of pregnancy by HIV-positive women plays a critical role in the prevention of mother-to-child transmission of the virus. In such cases, the intrauterine device and sterilization may be important contraceptive options from which to choose. Finally, the use of HIV voluntary counseling and testing (VCT) services should be encouraged so more individuals can determine their HIV status.

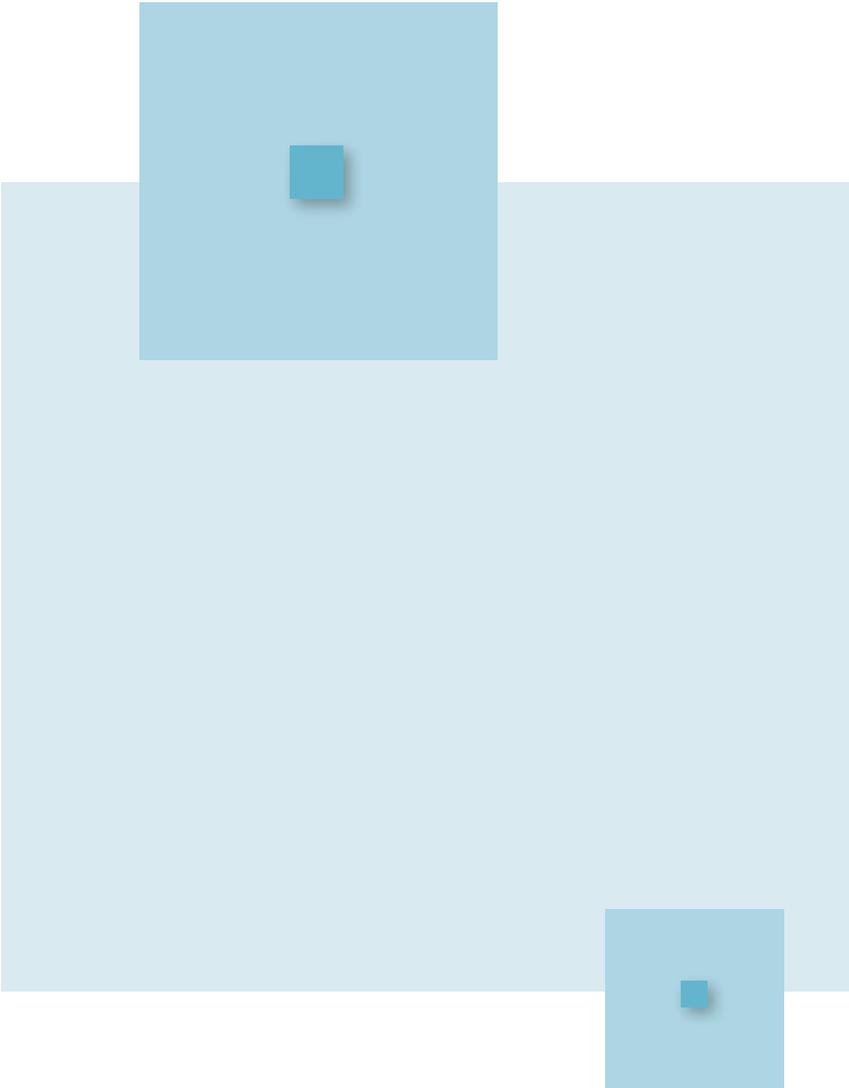
1 World Health Organization (WHO). *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use. Third Edition*. Geneva, Switzerland: WHO, 2004. Available: <http://www.who.int/reproductive-health/publications/mec/>.

2 Baeten J, Lavreys L, Sagar M, et al. Effect of contraceptive methods on natural history of HIV: studies from the Mombasa cohort. *J Acquir Immune Defic Syndr* 2005;38(Suppl 1):18-20.

3 Chu J, Gange SJ, Anastos K, et al. Hormonal contraceptive use and the effectiveness of highly active antiretroviral therapy. *Am J Epidemiol* 2005;161(9):881-90.

4 WHO.

Source: The preceding Global Health Technical Brief is reprinted from the MAQ Website (Maximizing Access and Quality), a USAID initiative.



Shelton J, Angle M, Jacobstein R. Medical barriers to access to family planning. *Lancet* 1992;340:1334-1335.

While well-intentioned and based partly on medical rationale, some service delivery practices are unnecessary and can prevent access to family planning services for women and men who could safely use methods. There are six types of medical barriers: inappropriate or out-of-date contraindications; too-stringent eligibility criteria; unnecessary physical exams and laboratory tests; provider biases; limiting contraception provision to physicians only; and government regulations that limit the types of contraceptives available. To reduce medical barriers, providers must work as a group to assess all service delivery practices, to determine whether they are essential to provision of contraception. The medical community should develop standard guidelines on contraceptive use. Family planning should be viewed as less medical: Women and men should be seen as clients, not patients, and increased emphasis should be placed on delivery of methods through community-based, over-the-counter and social marketing outlets. Additional research should be conducted to assess contraceptive risks and benefits, to evaluate ways to reduce unnecessary restrictions and to understand clients' perceptions of family planning methods and services.

Stanback J, Janowitz B. Provider resistance to advance provision of oral contraceptives in Africa. *J Fam Plann Reprod Health Care* 2003;29(1):35-36.

In Africa, many new family planning clients are not menstruating at the time they present for services. Where pregnancy tests are unavailable, clients are often denied their method of choice and sent home to await menses. The 'advance provision' of pills, common in much of the world, can be a solution to this problem for clients who want to initiate COCs. Advance provision is safe and can reduce unwanted pregnancies while saving clients' time and money. However, this practice is rare in Africa. A study to assess the level of provider resistance to advance provision of oral contraceptives, by adding questions about advance provision of pills to five provider surveys in Kenya, Ghana, and Senegal, was conducted between 1996 and 2000. In Kenya, only 16% of providers thought it safe to give women oral contraceptives to be started at a later date. In Ghana and Senegal, fewer than 5% of providers mentioned advance provision as a way to manage nonmenstruating pill clients. The study concluded that training programs and service delivery guidelines in developing countries should provide for advance provision of pills to appropriate clients.

Stanback J, Diabate F, Dieng T, Duarte de Morales T, Cummings S, Traoré M. Ruling out pregnancy among family planning clients: the impact of a checklist in three countries. *Stud Fam Plann* 2005;36(4):311-315.

Women in many countries are often denied vital family planning services if they are not menstruating when they present at clinics, for fear that they might be pregnant. A simple checklist based on criteria approved by WHO has been developed to help providers rule out pregnancy among such clients, but its use is not yet widespread. Researchers in Guatemala, Mali, and Senegal conducted operations research to determine whether a simple, replicable introduction of this checklist improved access to contraceptive services by reducing the proportion of clients denied services. From 2001 to 2003, sociodemographic and service data were collected from 4,823 women from 16 clinics in the three countries. In each clinic, data were collected prior to introduction of the checklist and again three to six weeks after the intervention. Among new family planning clients, denial of the desired method due to menstrual status decreased significantly — from 16 percent to 2 percent in Guatemala and from 11 percent to 6 percent in Senegal. Multivariate analyses and bivariate analyses of changes within subgroups of nonmenstruating clients confirmed and reinforced these statistically significant findings. In Mali, denial rates were essentially unchanged, but they were low from the start. Where denial of services to nonmenstruating family planning clients was a problem, introduction of the pregnancy checklist significantly reduced denial rates. This simple, inexpensive job aid improves women's access to essential family planning services.

Stanback J, Nakintu N, Qureshi Z, Nasution M. Does assessment of signs and symptoms add to the predictive value of an algorithm to rule out pregnancy? *J Fam Plann Reprod Health Care* 2006;32(1):27-29.

A WHO-endorsed 'pregnancy checklist' has become a popular tool for ruling out pregnancy among family planning clients in developing countries. The checklist consists of six criteria excluding pregnancy, all conditional upon a seventh 'master criterion' relating to signs or symptoms of pregnancy. Few data exist on the specificity of long-accepted signs and symptoms of pregnancy among family planning clients. A study based on a previous observational study in Kenya (n=1,852) found that signs and symptoms of pregnancy were rare (1.5 percent), as was pregnancy (1 percent). Signs and symptoms were more common (18.2 percent) among the 22 clients who tested positive for pregnancy than among the 1,830 clients (1.3 percent) who tested negative, but did not add significantly to their

predictive value. Although the 'signs and symptoms' criterion did not substantially improve the ability of the checklist to exclude pregnant clients, several reasons (including use of the checklist for IUD clients) render it unlikely that the checklist will be changed.

Stanback J, Nutley T, Gitonga J, Qureshi Z. Menstruation requirements as a barrier to contraceptive access in Kenya. *East Afr Med J* 1999;76(3):124-126.

A study was conducted in Kenya in 1996 to determine whether menstruation requirements pose a barrier to new clients seeking family planning services. Data were collected from eight public-sector health centers and one hospital in two provinces. Health providers tracked the menstrual status of women using a simple tally sheet. Forty-five percent of the women seeking services were not menstruating. Among the 345 nonmenstruating women, 51 percent were breastfeeding and amenorrheic, while 49 percent were between menstrual periods. Providers considered nonmenstruating women pregnant unless they were within six weeks postpartum. Women were told to go home and await the onset of menses or to have a pregnancy test at another facility. Researchers estimated that 78 percent of nonmenstruating women were sent home without their chosen method, and that up to one-third of all women were turned away. In most cases, pregnancy could have been ruled out with a simple checklist. Policy-makers should consider adopting national guidelines that remove the unnecessary menstruation requirement.

Stanback J, Qureshi Z, Sekadde-Kigundu C, Gonzalez B, Nutley T. Checklist for ruling out pregnancy among family-planning clients in primary care. *Lancet* 1999;354(9178):566.

Where pregnancy tests are unavailable, health providers, fearing possible harm to fetuses, often deny contraception to nonmenstruating clients. In Kenya, a trial (n=1,852) of a simple checklist to exclude pregnancy showed a negative predictive value of more than 99 percent. Use of this simple tool could improve access to services and reduce unwanted pregnancies and their sequelae.

Stanback J, Thompson A, Hardee K, Janowitz B. Menstruation requirements: a significant barrier to contraceptive access in developing countries. *Stud Fam Plann* 1997;28(3):245-250.

Some family planning clinics require women seeking hormonal contraception or IUDs to be menstruating before they can receive their chosen method. Studies in Ghana, Kenya, Cameroon, Senegal, and Jamaica have found that menstruation requirements negatively affect access to services for clients who could safely use contraceptives. As many as one-fourth to one-half of new clients

seeking contraceptive services are sent home to await the onset of menses. These clients risk an unplanned pregnancy, and many are unable to return to the clinic because of time and money constraints. Because pregnancy is a contraindication to contraceptive use, health providers have used menstruation as a proxy for expensive pregnancy tests. Another rationale for menstruation requirements is timing — hormonal methods are usually initiated and IUDs typically inserted during menses. In addition, some providers believe pregnant women may use contraceptives to induce abortion. While many providers believe that women know about menstruation requirements, data from Kenya and Cameroon show that clients do not. Denial of contraceptive methods to nonmenstruating women is a serious obstacle to services that could be reduced by using a simple checklist to rule out pregnancy.

Stang A, Schwingle P, Rivera R. New contraceptive eligibility checklists for provision of combined oral contraceptives and depot-medroxyprogesterone acetate in community-based programmes. *Bull World Health Organ* 2000; 78(8):1015-1020.

Community-based services (CBS) have long used checklists to determine eligibility for contraceptive method use, in particular for combined oral contraceptives (COCs) and the three-month injectable contraceptive depot-medroxyprogesterone acetate (DMPA). As safety information changes, however, checklists can quickly become outdated. Inconsistent checklists and eligibility criteria often cause uneven access to contraceptives. In 1996, WHO produced updated eligibility criteria for the use of all contraceptive methods. Based on these criteria, new checklists for COCs and DMPA were developed. This article describes the new checklists and their development. Several rounds of expert review produced checklists that were correct, comprehensible and consistent with the eligibility requirements. Nevertheless, field-testing of the checklists revealed that approximately half (48 percent) of the respondents felt that one or more questions still needed greater comprehensibility. These findings indicated the need for a checklist guide. In March 2000, WHO convened a meeting of experts to review the medical eligibility criteria for contraceptive use. The article also reflects the development of the resulting updated checklists.

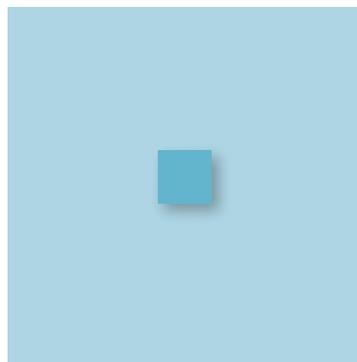
World Health Organization. *Medical Eligibility Criteria for Contraceptive Use. Third Edition.* Geneva, Switzerland: Reproductive Health and Research, 2004.

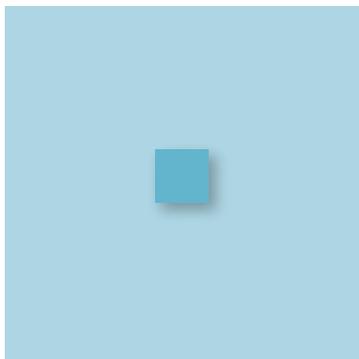
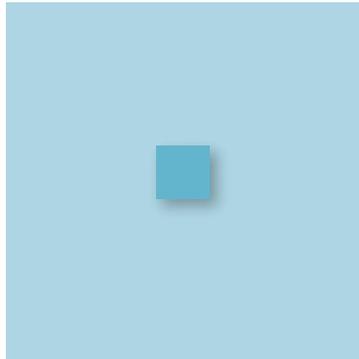
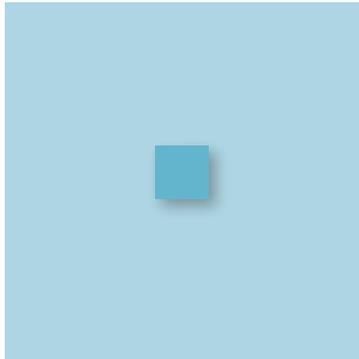
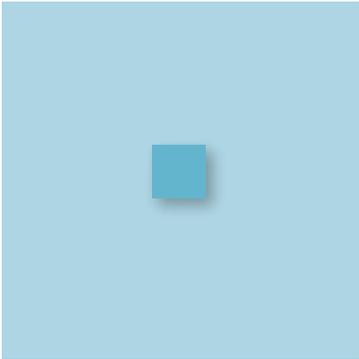
This document was developed by the WHO expert working group which brought together participants from 18 countries, including representatives of many agencies and organizations. The document is important for improving access to quality care in family planning, as it reviews the medical eligibility criteria used for selecting

appropriate methods of contraception for a variety of clients. The document provides recommendations for appropriate medical eligibility criteria based on the latest clinical and epidemiological data and is intended to be used by policy-makers, family planning program managers and the scientific community. It aims to provide guidance to national family planning and reproductive health programs in preparing guidelines for the service delivery of contraceptive methods.

World Health Organization. *Selected Practice Recommendations for Contraceptive Use. Second Edition.* Geneva, Switzerland: Reproductive Health and Research, Family and Community Health, 2004.

Selected Practice Recommendations for Contraceptive Use is one of two evidence-based guidelines on contraceptive use published by WHO. This document provides guidance for using contraceptive methods safely and effectively once they are deemed to be medically appropriate. It is the companion guideline to WHO's *Medical Eligibility Criteria for Contraceptive Use*. The document is intended to be used by policy-makers, program managers, and the scientific community. It aims to support national programs in preparing service delivery guidelines.



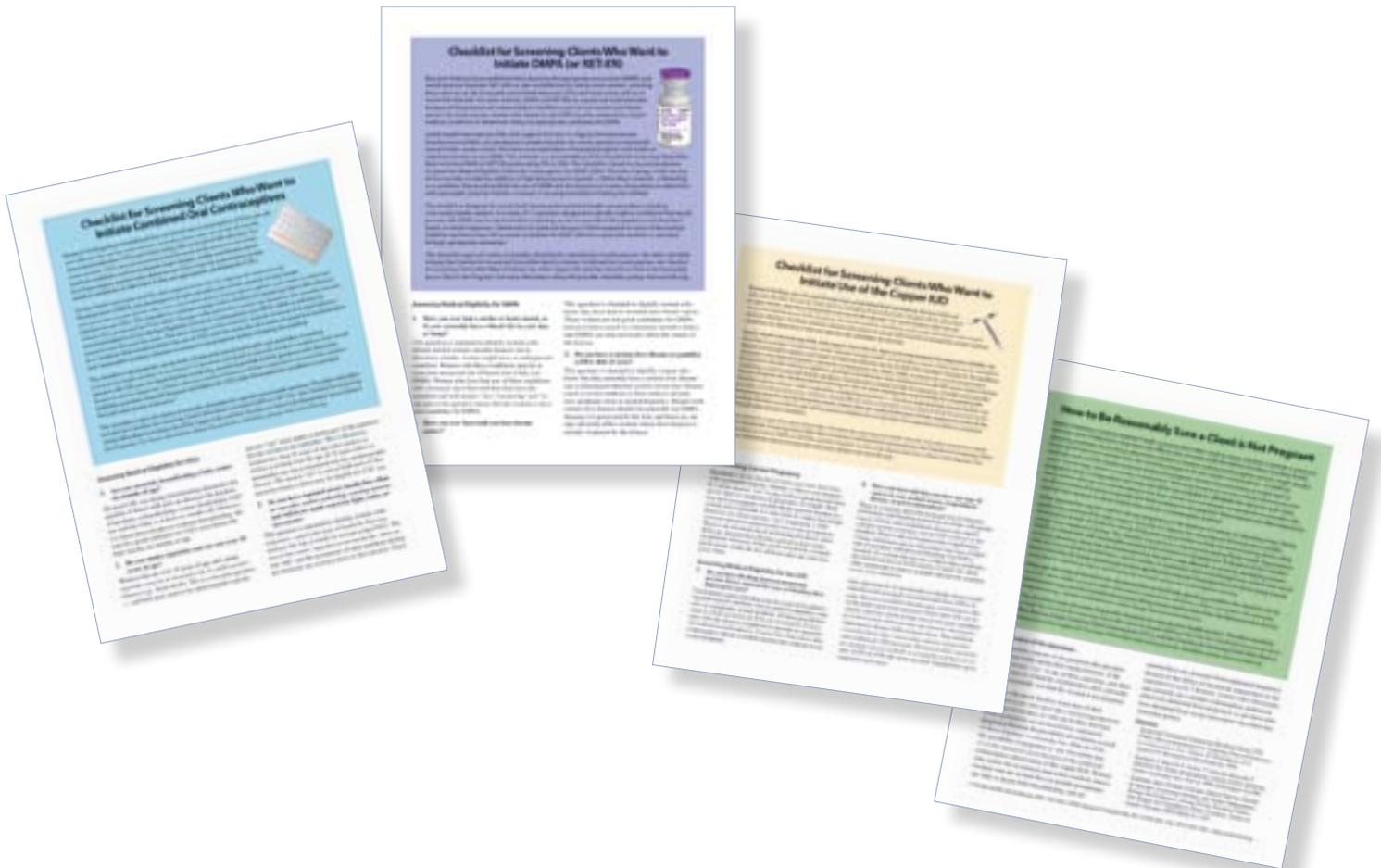


Supplementary Training Schedules

A. Combined Training Schedule for All Four Provider Checklists

FHI has produced a series of four easy-to-use checklists designed to assist clinical and non-clinical family planning service providers in screening women who want to initiate use of COCs, DMPA/NET-EN, or the IUD. The fourth checklist helps providers rule out pregnancy among nonmenstruating women seeking to initiate the contraceptive method of their choice. It is recommended that service providers be trained on how to use all four checklists, unless a particular checklist is not applicable to their scope of work.

A training and reference guide has also been produced for each checklist. Familiarity with all four guides is necessary for conducting a combined training. The following schedule is recommended for a combined training and follows the same structure used in the individual training guides. The Notes section of the outline will assist facilitators in determining what to include and how to adapt a section. Facilitators should carefully consider the training needs of participants when adapting the training.

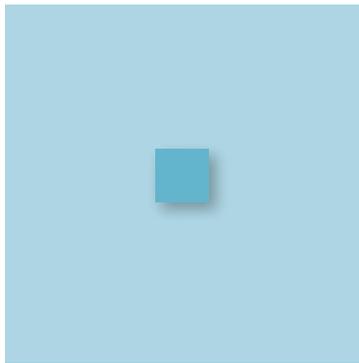


Session Overview and Schedule (Combined Training)

Time: 9 hours

Session	Time	Topic	Notes
1	40 minutes	Welcome and Introductions Exercise A: Peel the Cabbage	Adapt from any of the checklist trainings. Use the questions: <ul style="list-style-type: none"> • What practice is currently used to determine if a woman is medically eligible to receive contraception? (Consider COCs, DMPA and IUD.) • How is pregnancy ruled out? • Can you name some conditions that prevent women from using COCs, DMPA or an IUD? (Create a separate list of conditions for each contraceptive method.)
2	20 minutes	Rationale and Purpose	Adapt from the COC, DMPA or IUD Checklist trainings. <ul style="list-style-type: none"> • Show all four checklists, but do not distribute them to participants at this time. • Emphasize that all checklists were designed to assist providers in safely screening women for contraceptive eligibility and, therefore, to reduce barriers to contraceptive use. The Pregnancy Checklist may have other purposes as well. • Note that the checklists were designed for a variety of providers and can be used in a variety of settings. The IUD Checklist differs from the others in that it requires that some of the questions be administered by a provider trained to conduct a pelvic exam.
	60 minutes	Exercise B: Review of the WHO Medical Eligibility Criteria	<ul style="list-style-type: none"> • Follow steps 1-6 under Exercise B for COCs, DMPA and IUDs, with the following exceptions: <p>Step 3: Choose a maximum of four conditions for each of the three contraceptive methods and allow a total of 20 minutes to complete the task. The following conditions are suggested for the exercise.</p> <p><i>COCs and DMPA:</i> diabetes, high blood pressure, HIV/AIDS, and endometrial cancer.</p> <p><i>IUDs:</i> nulliparous, STI, PID, and HIV and AIDS.</p> <p>Step 4: Allow 20 minutes for participants to assess whether their answers were correct or incorrect.</p> <p>Step 6: Distribute a copy of the COC, DMPA, and IUD checklists and complete the step.</p> • Additional IUD discussion points should be brought up at this point (see Significant Issues Affecting Medical Eligibility in Facilitator's Resource for Session 2 of the IUD Guide).
	10 minutes	Exercise C: Demonstrating the Benefits of Using the Pregnancy Checklist	Additional detail on the research related to the Pregnancy Checklist can be found in the Optional Session.

Session	Time	Topic	Notes
3	30 minutes	Design of and Instructions for Using the Checklists	<p>All the checklists have the same basic design and instructions for use. Therefore, the training presented in this guide can be easily adapted to apply to all the checklists. Some notes:</p> <ul style="list-style-type: none"> • The Pregnancy Checklist contains one set of questions, the COC and DMPA Checklists contain two sets, and the IUD Checklist contains three sets. • The Pregnancy Checklist contains no questions related to medical eligibility.
	3-6 hours	Exercise D: Practice Using the four checklists	<p>Provide participants the opportunity to use the COC, DMPA and IUD Checklists. The time will vary depending on the number of scenarios selected. To save time, do not independently practice the Pregnancy Checklist, since it is incorporated into the other checklists. Review the optional approaches for conducting the scenarios as potential time-saving tools. The option chosen should be the most appropriate for the needs of the participants.</p>
4	20 minutes	Wrap-up	Modify as needed from this or any of the trainings.



B. Training Para-Professionals on the COC Checklist

The term “*para-professional*” is used here to designate service providers who have not received formal training in clinical health care delivery. Para-professionals could include auxiliary health care workers, community health workers, paramedics, pharmacists and others who sell drugs, and social workers. They may have limited training in screening clients and/or in providing COCs. Facilitators training para-professionals in the use of the COC Checklist should simplify the training content for this audience. Lecture sessions should generally be avoided, and the training should be practical in nature to ensure that para-professionals understand the checklist tool and are comfortable using it correctly. The outline below, which follows the same structure used in the individual training guides, is intended as a suggestion only. The Notes section of the outline will assist facilitators in determining what to include and how to adapt the different sections. Facilitators should carefully consider the training needs of participants when adapting the training.

Session Overview and Schedule (Para-professionals)

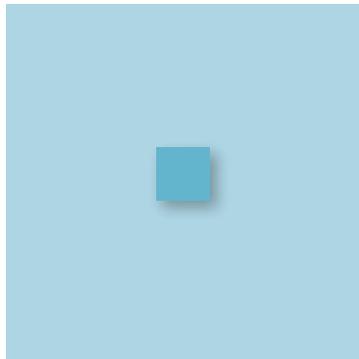
Time: 2 hours

Session	Time	Topic	Notes
1	15 minutes	Welcome and Introductions Icebreaker Activity	Use Session 1 from this guide. Do not perform Exercise A: Peel the Cabbage.
2	20 minutes	Rationale and Purpose Exercise C: Demonstrating the Benefits of Using the Pregnancy Checklist	Training Steps: <ul style="list-style-type: none"> • Distribute copies of the COC Checklist and the Quick Reference Chart to each participant. • Briefly and in simple language explain what the COC Checklist is and why it was developed. • Use the Quick Reference Chart to illustrate that many women, even those with certain medical conditions, can use COCs. Allow five minutes for participants to familiarize themselves with the Quick Reference Chart. Do not perform Exercise B: Review of the WHO Medical Eligibility Criteria. • Perform Exercise C: Demonstrating the Benefits of Using the Pregnancy Checklist to illustrate how the checklist can be effective in ruling out the possibility of pregnancy in women who are not menstruating at the time they are seen by the para-professional.
3	20 minutes	Design of and Instructions for Using the COC Checklist	Briefly and simply explain the design of the COC Checklist and go over instructions for using it. Then ask participants if they have any questions or need any items clarified.
	45 minutes	Exercise D: Practice Using the COC Checklist	Review the optional approaches for conducting the scenarios as potential time-saving tools. The option chosen should be the most appropriate for the needs of the participants.
4	15 minutes	Wrap-up	Modify as needed from this training.

C. Introducing Provider Checklists to Policy-makers and Program Managers

A slide presentation (*Powerpoint* presentation B) with expanded notes can be found on the CD-ROM that accompanies this training and reference guide. This presentation is targeted to policy-makers and program managers who may be interested in introducing the checklists in their service delivery settings.

The presentation focuses on introducing all four checklists and includes an explanation of their rationale and a discussion of general issues regarding their use. It does not go into details on how to use the checklists. Also included is a section that can be adapted to issues specific to local areas, such as checklist dissemination and resources.



Sample Energizers

Energizers are highly recommended during training sessions, in particular during trainings involving lectures. In this training, an energizer is recommended between sessions two and three.*

■ Coconut

The facilitator shows the group how to spell out C-O-C-O-N-U-T by using full movements of the arms and the body. All participants then try this together.

■ The sun shines on...

Participants sit or stand in a tight circle with one person in the middle. The person in the middle shouts out “the sun shines on...” and names a color or articles of clothing that some in the group are wearing. For example, “the sun shines on all those wearing blue” or “the sun shines on all those wearing socks” or “the sun shines on all those with brown eyes”. All the participants who have that attribute must change places with one another. The person in the middle tries to take one of their places as they move, so that there is another person left in the middle without a place. The new person in the middle shouts out “the sun shines on...” and names a different color or type of clothing.

■ Body writing

Ask participants to write their name in the air with a part of their body. They may choose to use an elbow, for example, or a leg. Continue in this way, until everyone has written his or her name with several body parts.

■ Football cheering

The group pretends that they are attending a football game. The facilitator assigns specific cheers to various sections of the circle, such as ‘Pass’, ‘Kick’, ‘Dribble’ or ‘Header’. When the facilitator points at a section, that section shouts their cheer. When the facilitator raises his/her hands in the air, everyone shouts “Goal!”

*Adapted from International HIV/AIDS Alliance. *100 ways to energise groups: games to use in workshops, meetings and the community*. Brighton, UK: International HIV/AIDS Alliance, 2002.

Sample Certificate of Attendance

Name of Sponsoring Organization	
<i>certifies that</i>	
Name of Participant	
<i>has successfully completed training on the</i>	
Checklist for Screening Clients Who Want to Use COCs	
_____	_____
(Date)	_____
_____	_____
(Place)	_____
Name of Person issuing certificate	Name of Person issuing certificate
_____	_____
Title	Title
_____	_____
Sponsoring Organization	Sponsoring Organization
_____	_____

