Unit 11

COMBINED ORAL CONTRACEPTIVES

Learning Objectives

By the end of this unit, learners will be able to:

- Define combined oral contraceptives (COCs)
- List the types and formulations of COCs available in Malawi and how they work
- State the effectiveness of COCs
- List the characteristics of COCs
- Correct misconceptions associated with COCs
- Determine a client's medical eligibility for COC use
- Explain when women in different situations can start COCs
- Describe the interactions that may occur between COCs and some drugs
- Provide client instructions for using COCs
- Describe the warning signs of COC health risks/complications
- Explain management of side effects and missed COCs
- Demonstrate knowledge and skills in counselling clients to make an informed choice about COCs.

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Unit 12: Combined Oral Contraceptives

Key Points

- COCs are safe and effective.
- ❖ One pill is taken each day. For greatest effectiveness, a woman must take pills daily and start each new pack of pills on time.
- ❖ Bleeding changes are common but not harmful. Typically, a woman experiences irregular bleeding for the first few months and then lighter and more regular bleeding.
- ❖ Take any missed pill as soon as possible. Missing pills risks pregnancy and makes some side effects worse.
- COCs can be given to women at any time to start taking later. If pregnancy cannot be ruled out, a provider can give a client pills to take later, when her monthly bleeding begins.

12.1 Defining Combined Oral Contraceptives

Combined oral contraceptives are pills containing low doses of two synthetic hormones, a progestin and an oestrogen. These hormones are very similar to the natural hormones progesterone and oestrogen naturally present in the woman's body. Combined oral contraceptives (COCs) are also called "the pill," or low-dose combined pills.

Types of COCs available in Malawi

- Microgynon: 30 μg ethinyl estradiol and 0.15 mg levonorgestrel per pill
- Lo-Feminal (to be phased out): 30 μg ethinyl estradiol and 0.30 mg norgestrel per pill

How COCs work

COCs work primarily by preventing the release of eggs from the ovaries (ovulation).

- Both oestrogen and progesterone prevent ovulation, which then prevents release of FSH and LH from the pituitary gland.
- The hormones also thicken the cervical mucus, which prevents passage of sperm.

TRIPHASIC COCS

Monophasic pills (such as Microgynon) provide the same amount of oestrogen and progestin in every hormonal pill. Biphasic and triphasic pills change the amount of oestrogen and progestin at different points of the pill-taking cycle. In *biphasic* COCs, the doses vary in two phases, and in *triphasic* COCs, the doses vary in three phases. Biphasic and triphasic pills are considerably more expensive than monophasic pills, though effectiveness and side effects are about the same. Triphasics are not currently available in Malawi.

12.2 Effectiveness of COCs

COCs are 92%-99.7% effective.

<u>Effectiveness depends on the user:</u> Risk of pregnancy is greatest when a woman starts a new pill pack 3 or more days late, or misses 3 or more pills near the beginning or end of a pill pack.

- As commonly used, about 8 pregnancies occur per year for every 100 women using COCs. (This means that 92 of every 100 women using COCs will not become pregnant.) This is known as "typical use."
- With no pill-taking mistakes, fewer than 1 pregnancy occurs per year for every 100 women using COCs. This is known as "perfect use."

12.3 Characteristics of COCs

Advantages

- Highly effective
- Effective immediately if initiated within the first 7 days of menstrual cycle
- Do not interfere with intercourse
- User can stop at any time she wishes to conceive.
- Fertility returns immediately after stopping.

Disadvantages

- Need to be taken daily; missed pills are common
- May cause some side effects
- Effectiveness can be reduced by interactions with certain drugs.
- Do not protect against STIs, including HIV
- Can have effects on metabolism (decreases HDL cholesterol, can increase blood pressure)

Side effects

Some users report the following:

- Changes in bleeding patterns including:
 - Lighter bleeding and fewer days of bleeding
 - Irregular bleeding
 - Infrequent bleeding
 - No monthly bleeding
- Dizziness
- Headaches
- Nausea
- Breast tenderness
- Weight change
- Mood change
- Acne (can improve or worsen, but usually improves)
- Other possible physical changes: Blood pressure increases a few points (mm Hg). When increase is due to COCs, blood pressure declines quickly after use of COCs stops.

Health benefits

- Help protect against cancer of the lining of the uterus (endometrial cancer), ovarian cancer, symptomatic pelvic inflammatory disease (PID)
- May help protect against ovarian cysts and irondeficiency anaemia
- Reduce menstrual cramps, menstrual bleeding problems, ovulation pain, excess hair on face or body, symptoms of polycystic ovarian syndrome (irregular bleeding, acne, excess hair on face or body), symptoms of endometriosis (pelvic pain, irregular bleeding)

Health risks/complications

Very rare:

 Blood clot in deep veins of legs or lungs [deep vein thrombosis (DVT) or pulmonary embolism]

Extremely rare:

- Stroke
- Heart attack

12.4 Correcting Misconceptions

Combined oral contraceptives:

- Do not build up in a woman's body (women do not need a "rest" from taking COCs)
- Must be taken every day, whether or not a woman has sex that day
- Do not make women infertile
- Do not cause birth defects or multiple births
- Do not change women's sexual behaviour
- Do not collect in the stomach; instead, the pill dissolves each day
- Do not disrupt an existing pregnancy.

12.5 Who Can Use COCs

Nearly all women can use COCs safely and effectively, including women who:

- Smoke cigarettes—if under 35 years old
- Have anaemia now or had in the past
- Have varicose veins
- Are infected with HIV.

12.6 Who Should Not Use COCs

Women with the following conditions should not use COCs:

WHO Category 3

- Not breastfeeding and less than 3 weeks since giving birth
- Primarily breastfeeding between 6 weeks and 6 months since giving birth
- Age 35 or older and smokes fewer than 15 cigarettes a day
- High blood pressure (systolic blood pressure between 140 and 159 mm Hg or diastolic blood pressure between 90 and 99 mm Hg)
- Controlled high blood pressure, where continuing evaluation is possible

- History of high blood pressure, where blood pressure cannot be taken (including pregnancy-related high blood pressure)
- History of jaundice while using COCs in the past
- Gall bladder disease (current or medically treated)
- Age 35 or older and has migraine headaches without aura
- Younger than age 35 and has migraine headaches without aura that have developed or have gotten worse while using COCs
- Had breast cancer more than 5 years ago, and it has not returned
- Taking barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate or rifampicin.

WHO Category 3/4

- Diabetes for more than 20 years or damage to arteries, vision, kidneys, or nervous system caused by diabetes (Assess according to severity of condition.)
- Multiple risk factors for arterial cardiovascular disease such as older age, smoking, diabetes, and high blood pressure (Category 4 if more than 1 risk factor)

WHO Category 4

- Breastfeeding and less than 6 weeks since giving birth
- Age 35 or older and smokes 15 or more cigarettes a day
- High blood pressure (systolic blood pressure 160 mm Hg and higher or diastolic blood pressure 100 mm Hg or higher)
- Vascular disease
- Current or history of deep venous thrombosis/pulmonary embolism

(For a more comprehensive list of conditions, see the MEC Summary Tables in Unit 4.)

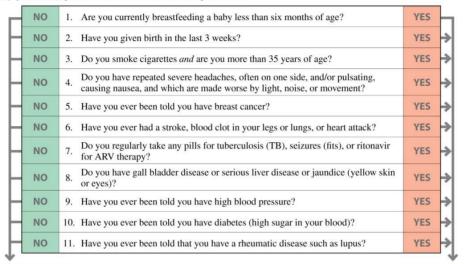
12.7 Combined Oral Contraceptives for Clients with HIV

Women with AIDS who are treated with ritonavir-boosted protease inhibitors, a class of antiretroviral (ARV) drugs, generally should not use COCs. (MEC 3). These ARV drugs may make the contraceptive method less effective. These women can use progestin-only injectables, implants, and other methods. Women taking other classes of ARVs can use any hormonal method.

12.8 Screening Checklist

Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives

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



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

Proceed to questions 12–17.

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

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

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

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

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

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

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

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

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

Give her condoms to use in the meantime.





12.9 Timing: When to Start COCs

Important: A woman can start using COCs any time she wants if it is reasonably certain she is not pregnant. To be reasonably certain she is not pregnant, use the Pregnancy Checklist (see previous page). Also, a woman can be given COCs at any time and told when to start taking them, if not immediately.

Woman's situation	When to start
Having menstrual cycles or switching from a nonhormonal method	Any time of the month If she is starting within 5 days after the start of her monthly bleeding, there is no need for a backup method. If it is more than 5 days after the start of her monthly bleeding, she can start COCs any time it is reasonably certain she is not pregnant. She will need a backup method* for the first 7 days of taking pills. (If you cannot be reasonably certain, give her COCs now and tell her to start taking them during her next monthly bleeding.) If she is switching from an IUCD, she can start COCs immediately.
Switching from a hormonal method	Immediately, if she has been using the hormonal method consistently and correctly or if it is otherwise reasonably certain she is not pregnant. No need to wait for her next monthly bleeding. No need for a backup method. If she is switching from injectables, she can begin taking COCs when the repeat injection would have been given. No need for a backup method.
Fully or nearly fully breastfeeding Less than 6 months after giving birth	Give her COCs and tell her to start taking them 6 months after giving birth or when breast milk is no longer the baby's main food—whichever comes first.
More than 6 months after giving birth	If her monthly bleeding has not returned, she can start COCs any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days of taking pills. (If you cannot be reasonably certain, give her COCs now and tell her to start taking them during her next monthly bleeding.) If her monthly bleeding has returned, she can start COCs as advised for women having menstrual cycles.
Partially breastfeeding Less than 6 weeks after giving birth	Give her COCs and tell her to start taking them 6 weeks after giving birth. Give her a backup method to use until 6 weeks after giving birth if her monthly bleeding returns before this time.
More than 6 weeks after giving birth	If her monthly bleeding has not returned, she can start COCs any time it is reasonably certain she is not pregnant.† She will need a backup method for the first 7 days of taking pills. (If you cannot be reasonably certain, give her COCs now and tell her to start taking them during her next monthly bleeding.)

Woman's situation	When to start
	If her monthly bleeding has returned, she can start COCs as advised for women having menstrual cycles.
Not breastfeeding Less than 4 weeks after giving birth	She can start COCs at any time on days 21–28 after giving birth. Give her pills any time to start during these 7 days. There is no need for a backup method.
More than 4 weeks after giving birth	If her monthly bleeding has not returned, she can start COCs any time it is reasonably certain she is not pregnant.† She will need a backup method for the first 7 days of taking pills. (If you cannot be reasonably certain, give her COCs now and tell her to start taking them during her next monthly bleeding.)
	If her monthly bleeding has returned, she can start COCs as advised for women having menstrual cycles.
No monthly bleeding (Not related to childbirth or breastfeeding)	She can start COCs any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days of taking pills.
After miscarriage or abortion	Immediately. If she is starting within 7 days after first- or second-trimester miscarriage or abortion, no need for a backup method.
	If it is more than 7 days after first- or second-trimester miscarriage or abortion, she can start COCs any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days of taking pills. (If you cannot be reasonably certain, give her COCs now and tell her to start taking them during her next monthly bleeding.)
After taking emergency contraceptive pills (ECPs)	She can start COCs the day after she finishes taking the ECPs. There is no need to wait for her next monthly bleeding to start her pills.
	A new COC user should begin a new pill pack.
	A continuing user who needed ECPs due to pill-taking errors can continue where she left off with her current pack.
	All women will need to use a backup method for the first 7 days of taking pills.

(WHO/RHR and CCP, Knowledge for Health Project 2008)

^{*} Backup methods include male and female condoms.

[†] Where a visit 6 weeks after childbirth is routinely recommended and other opportunities to obtain contraception limited, some providers and programs may give COCs at the 6-week visit, without further evidence that the woman is not pregnant, if her monthly bleeding has not yet returned.

12.10 Client Counselling Instructions

Explain about side effects

- Describe the most common side effects:
 - In the first few months, bleeding at unexpected times (irregular bleeding); then lighter, shorter, and more regular monthly bleeding
 - Headaches, breast tenderness, weight change, and possibly other side effects.
- Explain about these side effects:
 - Side effects are not signs of illness.
 - Most side effects usually become less or stop within the first few months of using COCs.
 - Side effects are common, but some women do not have them.
- Explain what to do in case of side effects:
 - Keep taking COCs. Skipping pills risks pregnancy and can make some side effects worse.
 - Take each pill at the same time every day to help reduce irregular bleeding and also help with remembering.
 - Take pills with food or at bedtime to help avoid nausea.
- The client can come back for help if side effects bother her.

Give pills

- Give two pill packs.
- Show the packs.

Explain the COC pill pack

- Show her the kind of pack she will be using (21 pills or 28 pills). With 28-pill packs, point out that the last 7 pills are a different colour and do not contain hormones.
- Show her how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills.

Give key instructions on how to take pills

- Take one pill each day until the pack is empty.
- Discuss cues for taking a pill every day. Linking pill-taking to a daily activity, such as cleaning her teeth, may help her remember.
- Taking pills at the same time each day helps a client remember them and may help reduce some side effects.

Explain starting next pack

- 28-pill packs: When she finishes one pack, she should take the first pill from the next pack on the very next day.
- 21-pill packs: After she takes the last pill from one pack, she should wait 7 days, no more, and then take the first pill from the next pack.
- It is very important to start the next pack on time. Starting a pack late risks pregnancy.

Provide backup method and explain use

- Sometimes she may need to use a backup method, such as when she misses pills.
- Backup methods include male and female condoms. Give her condoms, if possible.

Explain what to do if she misses pills (see "How to Manage Missed Pills," Section 12.14)

Give reasons to return

- Assure every client that she is welcome to come back any time. For example:
 - If she has problems, questions, or wants another method
 - If she has any major change in health status
 - If she thinks she might be pregnant
 - If she lost her pills or started a new pack more than 3 days late and also had sex during this time. She may wish to consider ECPs.
- General health advice: Anyone who suddenly feels that something is seriously wrong with her health should immediately seek medical care from a provider. Her contraceptive method is most likely not the cause of the condition, but she should tell the nurse or doctor what method she is using.

Plan the next visit

- Encourage her to come back for more pills before she uses up her supply of pills.
- Agree on a date for the next visit—in 2 to 3 months depending on how many pill packs you give her.
- Some women can benefit from contact after 3 months of COC use. This offers an opportunity to answer any questions, help with any problems, and check on correct use.

12.11 Warning Signs of Complications

- Blood clot in deep veins of legs or lungs (deep vein thrombosis or pulmonary embolism).
 Warning signs include a sharp pain in the leg or abdomen.
- Stroke—warning signs include severe headache with vision problems.
- Heart attack—warning signs include severe chest pain or shortness of breath.

12.12 Helping Continuing Users

- 1. Ask how the client is doing with the method and whether she is satisfied. Ask if she has any questions or anything to discuss.
- 2. Ask especially if she is concerned about bleeding changes. Give her any information or help that she needs (see Managing Side Effects, Section 12.15).
- 3. Ask if she often has problems remembering to take a pill every day. If so, discuss ways to remember, making up missed pills, ECPs, or choosing another method.
- 4. Give her more pill packs—a full year's supply (13 packs), if possible. Plan her next resupply visit before she will need more pills.
- 5. Every year or so, check blood pressure if possible.
- 6. Ask a long-term client if she has had any new health problems since her last visit. Address problems as appropriate. See New Health Problems that may Require Switching Methods, Section 12.16.
- 7. Ask a long-term client about major life changes that may affect her needs—particularly plans for having children and her STI/HIV risk. Follow up as needed.

12.13 Extended and Continuous Use of COCs

Some COC users do not follow the usual cycle of 3 weeks taking hormonal pills followed by one week without hormones. Some clients take hormonal pills for 12 weeks without a break, followed by one week of non-hormonal pills (or no pills). This is **extended use**. Other women take hormonal pills without any breaks at all. This is **continuous use.** Monophasic pills are recommended for such use (see Question 16 in Section 12.17).

Women easily manage taking COCs in different ways when properly advised how to do so. Many women value controlling when they have monthly bleeding—if any—and tailoring pill use as they wish.

Benefits

- Women have vaginal bleeding only 4 times a year or not at all.
- COCs reduce how often some women suffer headaches, premenstrual syndrome, mood changes, and heavy or painful bleeding during the week without hormonal pills.

Disadvantages

- Irregular bleeding may last as long as the first 6 months of use—especially among women who have never before used COCs.
- More supplies are needed—15 to 17 packs every year instead of 13.

Extended use instructions



Illustration by Rafael Avila and Rita Meyer

- Skip the last week of pills (without hormones) in 3 packs in a row. (21-day users skip the 7-day waits between the first 3 packs.) No backup method is needed during this time.
- Take all 4 weeks of pills in the 4th pack. (21-day users take all 3 weeks of pills in the 4th pack.) Expect some bleeding during the 4th week.
- Start the next pack of pills the day after taking the last pill in the 4th pack. (21-day users wait 7 days before starting the next pack.)

Continuous use instructions

The woman should take one hormonal pill every day for as long as she wishes to use COCs. If bothersome irregular bleeding occurs, a woman can stop taking pills for 3 or 4 days and then start taking hormonal pills continuously again.

12.14 How to Manage Missed Pills

It is easy to forget a pill or to be late in taking it. COC users should know what to do if they forget to take pills. If a woman misses one or more pills, she should follow these instructions:

Key Instructions	 Take a missed hormonal pill as soon as possible. Keep taking pills as usual, one each day. (She may take 2 pills at the same time or on the same day.)
Missed 1 or 2 pills? Started new pack 1 or 2 days late?	 Take a hormonal pill as soon as possible. There is little or no risk of pregnancy.
Missed 3 or more pills in the first or second week? Started new pack 3 or more days late?	 Take a hormonal pill as soon as possible. Use a backup method for the next 7 days. Also, if she had sex in the past 5 days, can consider taking ECPs (See Emergency Contraceptive Pills, Unit 14)
Missed 3 or more pills in the third week?	 Take a hormonal pill as soon as possible. Finish all hormonal pills in the pack. Throw away the 7 non-hormonal pills in a 28-pill pack. Start a new pack the next day. Use a backup method for the next 7 days. Also, if she had sex in the past 5 days, she can consider taking ECPs.
Missed any non- hormonal pills? (last 7 pills in 28-pill pack)	 Discard the missed non-hormonal pill(s). Keep taking COCs, one each day. Start the new pack as usual.
Severe vomiting or diarrhoea	 If she vomits within 2 hours after taking a pill, she should take another pill from her pack as soon as possible, then keep taking pills as usual. If she has vomiting or diarrhoea for more than 2 days, follow instructions for 1 or 2 missed pills above.

12.15 Managing Side Effects

Problems Reported as Side Effects or Problems With Use

Problems with side effects affect women's satisfaction and use of COCs. They deserve the provider's attention. If the client reports side effects or problems, listen to her concerns, give her advice, and, if appropriate, provide treatment.

Side Effect	How to Manage
Missed pills	See "How to Manage Missed Pills," Section 12.14
Irregular bleeding (bleeding at unexpected times that bothers the client)	 Reassure her that many women using COCs experience irregular bleeding. It is not harmful and usually becomes less or stops after the first few months of use. Other possible causes of irregular bleeding: Missed pills; taking pills at different times every day; vomiting or diarrhoea; taking anticonvulsants or rifampicin To reduce irregular bleeding: Take a pill each day and at the same time each day. Make up for missed pills properly, including after vomiting or diarrhoea. For modest short-term relief, she can take 800 mg ibuprofen 3 times daily after meals for 5 days, or another nonsteroidal anti-inflammatory drug (NSAID), beginning when irregular bleeding starts. NSAIDs provide some relief of irregular bleeding for implants, progestin-only injectables, and IUCDs, and they may also help for COCs. If she has been taking the pills for more than a few months and NSAIDs do not help, give her a different COC formulation, if available. Ask her to try the new pills for at least 3 months. If irregular bleeding continues or starts after several months of normal or no monthly bleeding, or you suspect that something may be wrong for other reasons, consider underlying conditions unrelated to method use.
No monthly bleeding	 Ask if she is having any bleeding at all. (She may have just a small stain on her underclothing and not recognize it as monthly bleeding.) If she is, reassure her. Tell her that some women using COCs stop having monthly bleeding, and this is not harmful. There is no need to lose blood every month. It is similar to not having monthly bleeding during pregnancy. She is not infertile. Blood is not building up inside her. Ask if she has been taking a pill every day. If so, reassure her that she is not likely to be pregnant. She can continue taking her COCs as before. If she skipped the 7-day break between packs (21-day packs) or skipped the 7 non-hormonal pills (28-day pack), reassure her that she is not pregnant. She can continue using COCs. If she has missed hormonal pills or started a new pack late: She can continue using COCs.

	Tell a woman who has missed 3 or more pills or started a new pack 3 or more days late to return if she has signs and symptoms of early pregnancy.
Ordinary headaches (non- migrainous)	 Try the following (one at a time): Suggest aspirin (300–600 mg), ibuprofen (200–400 mg), paracetamol (500–1000 mg), or other pain reliever. Some women get headaches during the hormone-free week (the 7 days a woman does not take hormonal pills). Consider extended use (see Extended and Continuous Use of Combined Oral Contraceptives, Section 12.13). Any headaches that get worse or occur more often during COC use should be evaluated.
Nausea or dizziness	 For nausea, suggest taking COCs at bedtime or with food. If symptoms continue, consider locally available remedies. Consider extended use if her nausea comes after she starts a new pill pack
Breast tenderness	 Recommend that she wear a supportive bra (including during strenuous activity and sleep). Try hot or cold compresses. Suggest aspirin (300–600 mg), ibuprofen (200–400 mg), paracetamol (500–1000 mg), or other pain reliever.
Weight change	Review diet and counsel as needed.
Mood changes or changes in sex drive	 Some women have changes in mood during the hormone-free week (the 7 days when a woman does not take hormonal pills). Consider extended use (See Section 12.13). Ask about changes in her life that could affect her mood or sex drive, including changes in her relationship with her partner. Give her support as appropriate. Clients who have serious mood changes such as major depression should be referred for care. Consider locally available remedies.
Acne	 Acne usually improves with COC use. It may worsen for a few women. If she has been taking pills for more than a few months and acne persists, give her a different COC formulation, if available. Ask her to try the new pills for at least 3 months. Consider locally available remedies.

12.16 New Problems That May Require Switching Methods

May or may not be due to the method

Unexplained vaginal bleeding (that suggests a medical condition not related to the method) or heavy or prolonged bleeding

- Refer or evaluate by history and pelvic examination. Diagnose and treat as appropriate. She can continue using COCs while her condition is being evaluated.
- If bleeding is caused by sexually transmitted infection or pelvic inflammatory disease, she can continue using COCs during treatment.

Starting treatment with anticonvulsants or rifampicin

- Barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, and rifampicin may make COCs less effective. If using these medications long-term, she may want a different method, such as progestin-only injectables or a copper-bearing IUCD.
- If using these medications short-term, she can use a backup method along with COCs.

Migraine headaches

• Regardless of her age, a woman who develops migraine headaches, with or without aura, or whose migraine headaches become worse while using COCs should stop using COCs. Help her choose a method without oestrogen.

Circumstances that will keep her from walking for one week or more

- If she is having major surgery, or her leg is in a cast, or for other reasons she will be unable to move about for several weeks, tell her to:
 - Stop taking COCs and use a backup method during this period.
 - Restart COCs 2 weeks after she can move about again.

Certain serious health conditions (suspected heart or liver disease, high blood pressure, blood clots in deep veins of legs or lungs, stroke, breast cancer, damage to arteries, vision, kidneys or nervous system due to diabetes, or gall bladder disease)

- Tell her to stop taking COCs.
- Give her a backup method to use until the condition is evaluated.
- Refer for diagnosis and care if not already under care.

Suspected pregnancy

- Assess for pregnancy.
- Tell her to stop taking COCs if pregnancy is confirmed.
- Assure her there are no known risks to a foetus conceived while a woman is taking COCs.

12.17 Questions and Answers about COCs

1. Should a woman take a "rest" from COCs after taking them for a time?

No. There is no evidence that taking a "rest" is helpful. In fact, taking a "rest" from COCs can lead to unintended pregnancy. COCs can safely be used for many years without having to stop taking them periodically.

2. If a woman has been taking COCs for a long time, will she still be protected from pregnancy after she stops taking COCs?

No. A woman is protected only as long as she takes her pills regularly.

3. How long does it take to become pregnant after stopping COCs?

Women who stop using COCs can become pregnant as quickly as women who stop using nonhormonal methods. COCs do not delay the return of a woman's fertility after she stops taking them. The bleeding pattern a woman had before she used COCs generally returns after she stops taking them. Some women may have to wait a few months before their usual bleeding pattern returns.

4. Do COCs cause abortion?

No. Research on COCs finds that they do not disrupt an existing pregnancy.

5. Do COCs cause birth defects? Will the foetus be harmed if a woman accidentally takes COCs while she is pregnant?

No. Good evidence shows that COCs will not cause birth defects and will not otherwise harm the foetus if a woman becomes pregnant while taking COCs or accidentally starts to take COCs when she is already pregnant.

6. Do COCs cause women to gain or lose a lot of weight?

No. Most women do not gain or lose weight due to COCs. Weight changes naturally as life circumstances change and as people age. Because these changes in weight are so common, many women think that COCs cause these gains or losses in weight. Studies find, however, that, on average, COCs do not affect weight. A few women experience sudden changes in weight when using COCs. These changes reverse after they stop taking COCs. It is not known why these women respond to COCs in this way.

7. Do COCs change women's mood or sex drive?

Generally, no. Some women using COCs report these complaints. The great majority of COC users do not report any such changes, however, and some report that both mood and sex drive improve. It is difficult to tell whether such changes are due to the COCs or to other reasons. Providers can help a client with these problems (see "Mood changes or changes in sex drive" under Managing Side Effects, Section 12.15.). There is no evidence that COCs affect women's sexual behaviour.

8. What can a provider say to a client asking about COCs and breast cancer?

The provider can point out that both COC users and women who do not use COCs can have breast cancer. In scientific studies breast cancer was slightly more common among women using COCs and those who had used COCs in the past 10 years than among other women. Scientists do not know whether or not COCs actually caused the slight increase in breast

cancers. It is possible that the cancers were already there before COC use but were found sooner in COC users.

9. Can COCs be used as a pregnancy test?

No. A woman may experience some vaginal bleeding (a "withdrawal bleed") as a result of taking several COCs or one full cycle of COCs, but studies suggest that this practice does not accurately identify who is or is not pregnant. Thus, giving a woman COCs to see if she has bleeding later is not recommended as a way to tell if she is pregnant. COCs should not be given to women as a pregnancy test of sorts because they do not produce accurate results.

10. Must a woman have a pelvic examination before she can start COCs or at follow-up visits?

No. Instead, asking the right questions usually can help to make reasonably certain that a woman is not pregnant (see Pregnancy Checklist, Section 12.8). No condition that could be detected by a pelvic examination rules out COC use.

11. Can women with varicose veins use COCs?

Yes. COCs are safe for women with varicose veins. Varicose veins are enlarged blood vessels close to the surface of the skin. They are not dangerous. They are not blood clots, nor are these veins the deep veins in the legs where a blood clot can be dangerous (deep vein thrombosis). A woman who has or has had deep vein thrombosis should not use COCs.

12. Can a woman safely take COCs throughout her life?

Yes. There is no minimum or maximum age for COC use. COCs can be an appropriate method for most women from onset of monthly bleeding (menarche) to menopause.

13. What if a client wants to use COCs but it is not reasonably certain that she is not pregnant after using the pregnancy checklist?

If pregnancy tests are not available, a woman can be given COCs to take home with instructions to begin their use within 5 days after the start of her next monthly bleeding. She should use a backup method such as male or female condoms until then.

14. Can COCs be used as ECPs after unprotected sex?

Yes. As soon as possible, but no more than 5 days after unprotected sex, a woman can take COCs as ECPs. Progestin-only pills, however, are more effective and cause fewer side effects such as nausea and stomach upset.

15. Is it important for a woman to take her COCs at the same time each day?

Yes, for 2 reasons. Taking the pill at the same time each day may reduce some side effects. Also, taking a pill at the same time each day can help women remember to take their pills more consistently. Linking pill taking with a daily activity also helps women remember to take their pills.

(WHO/RHR and CCP, Knowledge for Health Project 2008)

Combined Oral Contraceptives Teaching Resources

Case Studies

(Adapted from Jhpiego, no date)

Case Study 1

The client is a 19-year-old mother of two, the younger of whom is 9 months old. Her last pregnancy was a difficult one, and she does not want another child for several years. She came to the clinic two months ago and after initial counselling decided to use COCs as her family planning method.

She has now returned to the clinic complaining of spotting and nausea since taking her first packet of pills. She is very worried that she is losing too much blood from the spotting, and she is also losing weight because she isn't eating due to the nausea. She is thinking about switching to another method.

Questions			
1.	What are the possible causes of her spotting and nausea?		
2.	What else do you need to know to identify the cause of her spotting and nausea? What questions would you ask her, and what examinations would you perform?		
3.	Finding no other causes, what would you tell her about spotting and nausea and use of COCs?		
4.	How would you manage this client?		
5.	If the client decides she would prefer to use another family planning method, which one(s) may be appropriate for her? Why?		

Case Study 2

The client is a 31-year-old mother of five. While she is not certain that she has all the children she wants, she does know that she is not interested in having another child for at least several years. She is frightened of injections, and her husband does not like to use condoms. She has heard that COCs are easy to use and effective; she'd like to give them a try.

You conduct some basic screening and obtain the following information: BP 140/90; she was diagnosed with tuberculosis 8 months ago; she smokes 6–8 cigarettes a day; you observe mild varicosities on both lower legs.

Qı	uestions
1.	What other information do you need to obtain in order to assess whether COCs are the best choice for her?
2.	The rest of the client's history and assessment do not reveal any precautions for COC use. Are COCs an appropriate choice for this client? Why or why not?
3.	If she does use COCs, what counselling and information does she need?
4.	If COCs are not an appropriate choice, what other methods might be? Why?

COC Case Studies Answer Key

Case Study 1

Questions

1. What are the possible causes of her spotting and nausea?

Taking pills at different times each day; taking pills without food; missed pills; taking anticonvulsants or rifampicin; pregnancy

2. What else do you need to know to identify the cause of her spotting and nausea? What questions would you ask her, and what examinations would you perform?

When does she usually take pills? Does she take them at the same time each day? Does she have difficulty remembering to take the pills, and, if so, how many has she missed? How does she make up for missed pills, if any? Is she taking any anti-convulsants or rifampicin?

3. Finding no other causes, what would you tell her about spotting and nausea and use of COCs?

That irregular bleeding is common in the first few months of taking COCs. It is harmless and usually becomes less and stops after a few months. Nausea may be a result of taking pills without food or missing pills.

4. How would you manage this client?

Suggest that she take the pills at the same time each day to lessen both nausea and spotting. She could take them at bedtime with food. She should make up for missed pills promptly, according to instructions.

For short-term relief of spotting, she could take 800 mg ibruprofen three times a day, after meals, for 5 days.

She may also try Continuous Use of COCs (see Section 12.13).

5. If the client decides she would prefer to use another family planning method, which one(s) may be appropriate for her? Why?

Because she does not want another child for several years, contraceptive implants or an IUCD may be good choices. With either, she would not have to remember to take a pill every day. Also, implants don't have oestrogenic side effects, though she would need to be aware about the possible side effects of bleeding changes and spotting. IUCDs don't have hormonal side effects, though spotting is possible with these as well.

Case Study 2

Questions

1. What other information do you need to obtain in order to assess whether COCs are the best choice for her?

Nothing else is needed. Elevated blood pressure of 140/90 is a contraindication for COC use (MEC category 3).

2. The rest of the client's history and assessment do not reveal any precautions for COC use. Are COCs an appropriate choice for this client? Why or why not?

No. Because she has elevated blood pressure, she is not a good candidate for COCs.

3. If she does use COCs, what counselling and information does she need?

She should not use COCs.

4. If COCs are not an appropriate choice, what other methods might be? Why?

Implants or IUCDs would be good, long-term choices since she does not want another child for at least several years.

Note: for additional case studies, see the Pathfinder International website: http://www.pathfind.org/pf/pubs/module4.pdf

COC Role Plays

Role Play 1

(Adapted from Jhpiego, no date)

Participant roles

Clinician: The clinician is an experienced family planning provider, who is skilled in counselling.

Client: The client is 31 years old and began taking COCs after the birth of her fifth child 2 years ago. At that time, she was screened for medical conditions that might be a precaution for COC use, but none were found. She has had no problems with COCs, once she got over the initial nausea and breast tenderness. Her husband died several months ago, and she has had to take a second job in order to provide for her children. She never gets more than 4 hours of sleep each night.

Situation

The client has now returned to the clinic complaining of headaches that she believes are caused by the COCs. She is very nervous. Her mother-in-law told her about someone who, after using COCs for years and suffering bad headaches, died because the COCs caused something in her head to burst.

Focus of the role play

The focus of the role play is on the interaction between the clinician and the client. The clinician needs to assess the extent of the client's headaches and their possible relationship with COCs. She needs to counsel and reassure the client and recommend a plan of management. The client should remain adamant in her belief that the COCs are causing her headaches until the clinician provides her with the information and management plan that will calm her concerns.

Observer discussion questions

- 1. How did the clinician approach the client?
- 2. How did the client respond to the clinician? Did the clinician change her approach based on this response? If so, was it appropriate?
- 3. Did the clinician accurately assess the relationship of the headaches to the COCs? Did she outline an appropriate management plan?
- 4. How might the clinician improve her interaction with the client?

(The following role plays are adapted from Solter, Cathy 1999)

Role Play 2

Participant roles

Clinician: The clinician is an experienced family planning provider who is skilled in counselling.

Client: A 24-year-old woman comes to see her provider because she has heavy menstrual periods lasting 7 to 8 days each month and feels "run down" since the birth of her last child. She has 4 children: a boy of 7 months and 3 daughters, ages 2 years, 3 years, and 4½ years. She has never used a contraceptive method, and she and her husband want to have at least 1 more son.

Suggested questions to address during role play simulation

- 1. How would the provider introduce the topic of family planning, and what might s/he say to counsel this client about adopting a child-spacing method?
- 2. What questions might the client raise in regard to child-spacing methods (including some rumours she has heard)?
- 3. What information regarding benefits, advantages, and risks should the provider give to guide this client to select an appropriate method for her?
- 4. What specific method instructions should the provider give the client, including possible side effects and warning signs, and returning for follow-up?

Role Play 3

Participant roles

Clinician: The clinician is an experienced family planning provider who is skilled in counselling.

Clients: A young couple, wife age 18 and husband age 22, married for 7 weeks, come to the clinic because they want to postpone their first child until they both have completed their university studies in 2 years. They are currently using condoms, but neither like this method. The wife has heard about COCs and wants to use this method. The husband is against this, as he has heard that the pill could cause his wife to become sterile.

Suggested questions to address during role play simulation

- 1. What should the provider say to the husband with regard to the question of the COCs causing sterility?
- 2. What should the provider say regarding the effectiveness, safety, advantages, disadvantages, and possible side effects of the COCs when counselling this couple?
- 3. What other contraceptive options might the provider suggest?

Role Play 4

Participant roles

Clinician: The clinician is an experienced family planning provider who is skilled in counselling.

Clients: A married woman, age 22, comes to your office accompanied by her mother-in-law. She has 3 small children under the age of 5. She wants to use the pill, but her mother-in-law is very much opposed to this; she has heard that the pill causes cancer.

Suggested questions to address during role play simulation

- 1. How should the provider respond to the mother-in-law with regard to the COCs causing cancer?
- 2. What should the provider say regarding the effectiveness, safety, advantages, disadvantages, and possible side effects of COCs when dealing with the mother-in-law and client?
- 3. What specific instructions should the provider give with regard to the use of the pill?
- 4. What other contraceptive options might the provider suggest?

Role Play 5

Participant roles

Clinician: The clinician is an experienced family planning provider who is skilled in counselling.

Client: A 41-year-old woman with 3 teenage boys and a 12-year-old girl wants contraceptive protection. She used an IUCD in the past for about 4 months but had it removed because of heavy bleeding, cramping, and pain. She absolutely refuses to consider sterilisation or another IUCD. She has heard that she is too old to take the pill.

Suggested questions to address during role play simulation

- 1. How should the clinician respond to this client's belief that she is too old for the pill?
- 2. What important questions should the clinician ask this client to ascertain if COCs are appropriate for her?
- 3. What benefits of COCs should the clinician discuss with this client?
- 4. What other contraceptive options might the provider suggest?

Role Play 6:

Participant roles

A 23-year-old man and his 19-year-old wife, 6 months postpartum, bring their baby in to see the paediatrician because the baby has a cold and fever. The mother is partially breastfeeding. She uses this visit to ask how she could prevent another pregnancy for a year or two. She would like to try COCs, but her husband is not in favour of the idea; he believes the pill could harm the baby through the mother's milk.

Suggested questions to address during role play simulation:

- 1. What should the clinician say to the husband regarding his belief that the pill would harm the baby?
- 2. What guidance regarding the effectiveness, safety, advantages, disadvantages, possible side effects, and warning signs should the doctor discuss with this couple?

Role Play 7

Participant roles

Three physicians (one obstetrician/gynaecologist, one general practitioner, and one paediatrician) are having lunch together and discussing various family planning methods. The paediatrician and general practitioner are not generally in favour of COCs. The paediatrician states, "I don't like pills, because you have to take them into your body. If used for a long time, they can cause cancer or infertility." The general practitioner agrees with this statement and adds that he is "too busy to bother with family planning; treatment of illness is more important." Both claim they never initiate discussion of family planning with patients or advise couples to consider spacing their children. They would be concerned about offending patients by bringing up a sensitive topic.

The obstetrician is upset by the views of her colleagues.

Suggested questions to address during role play simulation:

What would the obstetrician say to convince the others that their views do not conform to scientific facts, such as the clearly established benefits of family planning to mother and child health, and facts regarding the safety and effectiveness of low-dose COCs?

COC Quiz Questions

Questions 1-7: Circle all answers that apply.

- 1. Actual/typical use effectiveness of the COC is:
 - a. No pregnancies per 100 women
 - b. 1 pregnancy per 100 women
 - c. 2 pregnancies per 100 women
 - d. 8 pregnancies per 100 women
 - e. 5 pregnancies per 100 women
- 2. Major advantages of COCs include that they:
 - a. Are highly effective if taken correctly
 - b. Protect against HIV/AIDS
 - c. Protect against ovarian and endometrial cancer
 - d. Decrease the risk of ectopic pregnancy
 - e. Protect against breast cancer
- 3. The COC may be an appropriate choice for:
 - a. A woman who desires a prompt return of fertility
 - b. A nulliparous woman
 - c. A woman over 35 who smokes
 - d. A woman who is breastfeeding a newborn baby
 - e. A woman with a history of benign, functional ovarian cysts
- 4. COCs are not appropriate for the following women:
 - a. A woman with suspected pregnancy
 - b. A woman with liver disease (cirrhosis)
 - c. A woman age 36 and a heavy smoker
 - d. A woman with family history of ovarian cancer
 - e. A woman with high blood pressure
 - f. A woman with breast cancer
 - g. A woman living with HIV
- 5. Common side effects of COCs include:
 - a. Spotting
 - b. Severe vaginal bleeding
 - c. Dysmenorrhoea
 - d. Amenorrhea
 - e. Nausea
 - f. Breast tenderness
 - g. Hypotension
 - h. Insomnia
 - i. Anaemia
- 6. A woman comes to the clinic on day 7 of her menstrual cycle and requests COCs. She has not had intercourse since the first day of her period. Which of the following is medically appropriate? (Circle the correct answer.)
 - a. Advise her to return to clinic on the first day of her next period.
 - b. Provide her with pills and tell her that she can start now without any further precautions.

- c. Provide her with pills and tell her that she can start now, but she should abstain from sex or use additional contraceptive protection for the next 7 days.
- 7. If a client forgets to take 1 pill, she should:
 - a. Take the forgotten pill as soon as she remembers
 - b. Discard the forgotten pill
 - c. Take 2 pills as soon as she remembers
 - d. Take the next pill at the regular time
 - e. Continue to take 1 pill a day until the package is finished
 - f. Start a new pack of pills

Questions 8–18: Tick either "Yes" or "No" in the space provided.

8.	Is it appropriate to counsel a client that spotting increases after the first several cycles on the COC? Yes No
9.	If a client has taken a cycle of COCs perfectly (every day) and misses her period (no bleeding at all), can she start her next package of pills on schedule? Yes No
10.	Is it appropriate to prescribe COCs for a 20-year-old woman whose sister has hypertension and whose father had a heart attack at age 48? Yes No
11.	Can women with cyclic cystic breast changes use COCs? Yes No
12.	If a client had a blood pressure of 120/80 prior to using COCs that increased to 150/98 after 3 months on COCs, is it advisable for her to continue the pills? Yes $_$ No $_$
13.	COCs may be prescribed for a 20-year-old smoker. Yes No
14.	It is usually recommended that fully breastfeeding women use COCs for the first 6 months postpartum. Yes No
15.	Rifampin decreases the effectiveness of COCs. Yes No
16.	COCs should not be prescribed for a 45-year-old woman. Correct? Yes No
17.	COCs should not be prescribed for an anaemic, malnourished woman. Correct?
	Yes No
18.	It is recommended that women using COCs take a break from the pill every few months. Yes No

COC Quiz Questions Answer Key

Questions 1-7: Circle all answers that apply.

- 1. Actual/typical use effectiveness of the COC is:
 - d. 8 pregnancies per 100 women
- 2. Major advantages of COCs include that they:
 - a. Are highly effective if taken correctly
 - c. Protect against ovarian and endometrial cancer
 - d. Decrease the risk of ectopic pregnancy
- 3. The COC may be an appropriate choice for:
 - a. A woman who desires a prompt return of fertility
 - b. A nulliparous woman
 - e. A woman with a history of benign, functional ovarian cysts
- 4. COCs are not appropriate for the following women:
 - a. A woman with suspected pregnancy
 - b. A woman with liver disease (cirrhosis)
 - c. A woman age 36 and a heavy smoker
 - e. A woman with high blood pressure
 - f. A woman with breast cancer
- 5. Common side effects of COCs include:
 - a. Spotting
 - e. Breast tenderness
- 6. A woman comes to the clinic on day 7 of her menstrual cycle and requests COCs. She has not had intercourse since the first day of her period. Which of the following is medically appropriate? (Circle the correct answer.)
 - c. Provide her with pills and tell her that she can start now, but she should abstain from sex or use additional contraceptive protection for the next 7 days.
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 - a. Take the forgotten pill as soon as she remembers
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