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مشروع تعزيز تنظيم الأسرة
Strengthening Family Planning Project



Family Planning Counseling On Oral Contraceptives: COMBINED ORAL CONTRACEPTIVES AND PROGESTIN-ONLY PILLS



**BOLD
THINKERS
DRIVING
REAL-WORLD
IMPACT**

2012

Objectives

By the end of the training workshop participants will be able to:

1. Describe the oral contraceptive (OC) as an effective and safe family planning method.
2. Counsel clients seeking oral contraceptives.
3. Describe the mechanism of action and effectiveness of the pills.
4. Name the contraindications for use of the COCs and POPs.
5. Identify and manage side effects and warning signs of pills use.
6. Manage missed pills.
7. Name at least 3 non contraceptive benefits of the pills.
8. Utilize the performance checklist to assure adherence to clinical guidelines

Outline of the Presentation

1. **FP situation in Jordan**
2. **Review of EBM/ CATs and steps of counseling**
3. **Introduction on menstrual cycle, basics of hormones and pills preparations, effectiveness**
4. **Mechanism of action**
5. **Advantages and disadvantages**
6. **Indications and contraindications-WHO MEC**
7. **Side effects, warning signs and management of side effects**
8. **Initiation and continuation**
9. **Management of missed pills**
10. **Effect on breast cancer, return to fertility and cardiovascular disease.**
11. **Summary-take Home Messages.**
12. **Performance Checklist.**

Family Planning Situation In Jordan

DHS 2009

- Total fertility rate is **3.8** compared to 3.7 in 2002.
- It is expected that Jordan's population by the year 2020 will increase by 2.8 million births and overall population number will double by the year 2030.
- Public healthcare facilities provide contraceptives to about **46%** of current users, while private hospitals and clinics provide various methods to **54%** of users. (JAFPP 12%, UNRWA 8%)
- The contraceptive prevalence rate (CPR) among married women in reproductive age is **59%**, and **42%** are using a modern method.
- Among the 42 % of users, **IUD is the most common** method and accounts for 53 %(**JAFPP are the primary source for IUDs (23%)**), pills 19.5 %, condoms 15 %,Injectables 1.7 %, Implants 0.2 and Tubal Ligation 6.2 %.
- 11% of married women have an unmet need for family planning.

Family Planning Situation In Jordan

DHS 2009

- Among reasons behind the increase in TFR for 2009 are:
 - **Providers' bias** against some modern methods especially long acting and hormonal methods
 - Increased **discontinuation rate** of family planning due to improper counseling and managing of side effects.

The data reflected from the DHS 2009 show that the discontinuation rate of Injectables is 64.30 %, Pills is 50.9% and IUD is 15.1%.

Healthcare Quality in Family Planning

FP success can be achieved by providing high quality care

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge- EBM (Institute of Medicine

Proper family planning counseling based on evidence enables the woman to choose the most appropriate method for herself given her reproductive plan, preferences, personal circumstances and *enhances method satisfaction and use.*

Evidence Based Medicine

EBM is a new paradigm:

- from authority to evidence
- from anecdotes to outcomes
- maximizes relevance, validity
- minimizes work (use of pre-validated concise summaries that are the CATs)



A CAT (Critically Appraised Topic) is a concise evidence based summary that answers a question that emerges in clinical practice *all in a page or so.*

It is based on the appraisal of articles that were chosen after an extensive literature search because of their relevance in addressing the question or problem that we have

Importance of EBM for Health providers

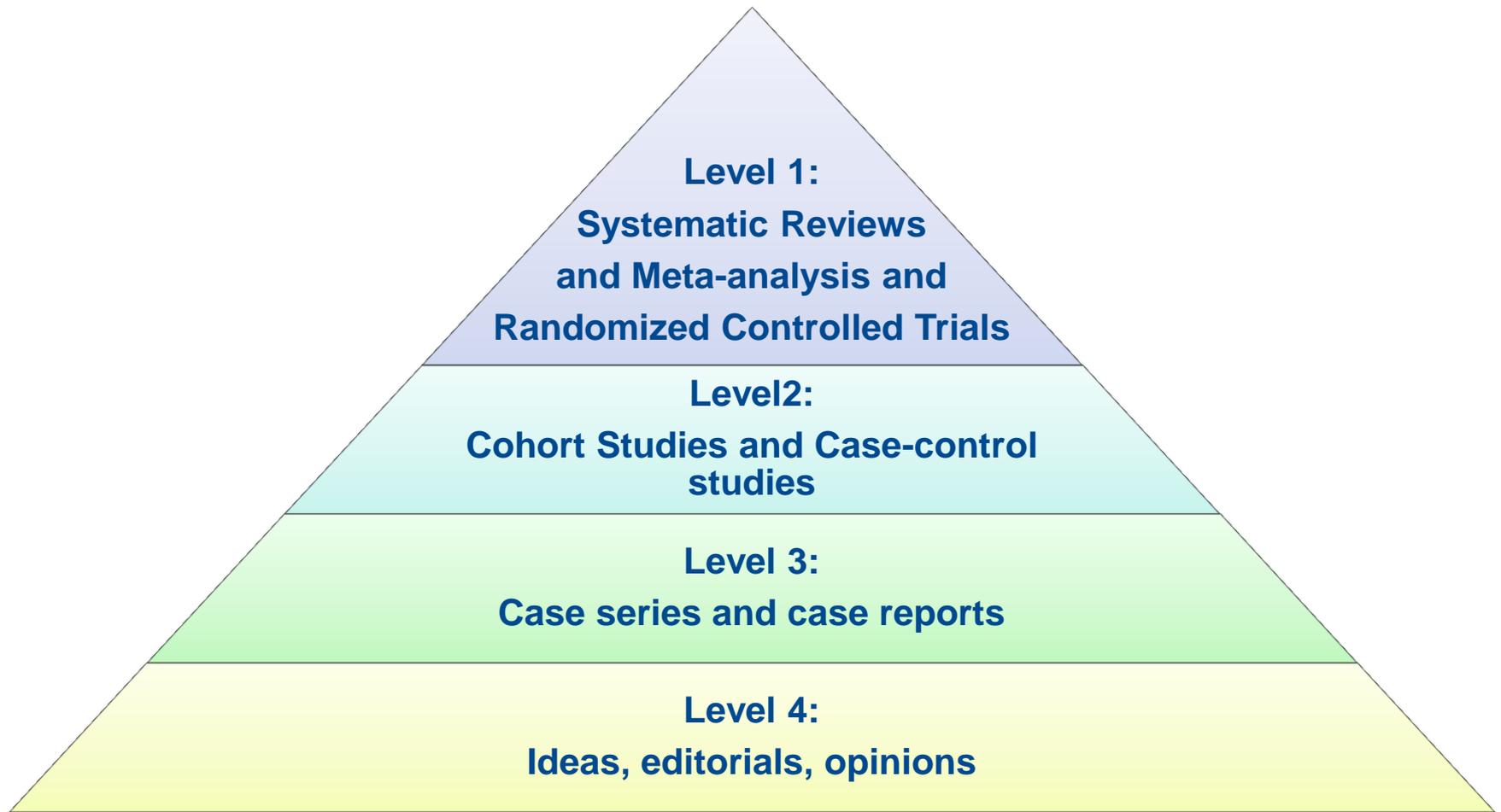
- It is important in life-long learning
- Avoids the “ping-pong”; Helps resolve clinical dilemmas/ controversies
- Offers research information to providers
- Answers to some clinical questions
- Uses evidence to respond to questions
- Offers quick access to relevant information



EBM Cycle



The Hierarchy Of Evidence



There is no evidence supporting an association between COCs and weight gain.

Declarative title

Conclusion

This systematic review of randomized controlled trials suggests that there is no evidence available to determine the effect of COCs on the weight, neither an association between weight gain in women and use of combined oral contraceptives.

Conclusion

Clinical Question

Do women taking combination oral contraceptives have greater weight gain than women not taking them?

The question

Search Terms

Contraceptives, oral contraceptives, contraception, weight gain.

Citation

Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight. (Cochrane Review). In: The Cochrane Library, Issue 1, 2006. Oxford: Update Software.

The article used

Object of research

Use of combined oral contraceptives compared to another combined oral contraceptive or a placebo.

Subject of research

Change in weight

Study Features

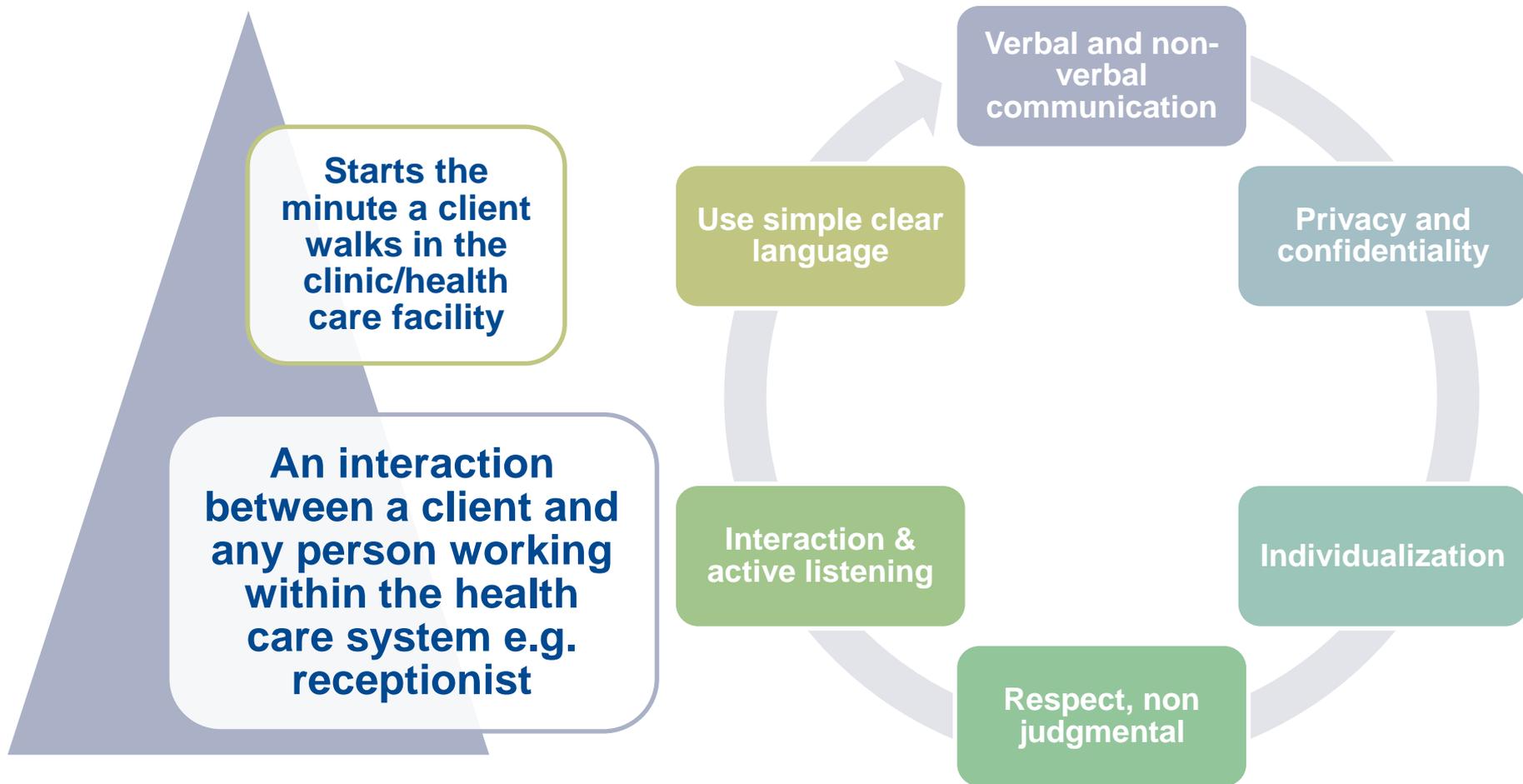
This systematic review evaluated the association between COCs and weight change. 570 randomized controlled trials comparing COC use to placebo or a second COC were found. After eliminating those studies that failed to follow patients beyond three cycles of therapy and those that with insufficient data regarding weight change, a final analysis was performed on 44 studies

Decision Making **about FP choice**

- *The evidence is not the only basis for making decisions.*
- **Client's** patient's preference and **Physician's** Clinical judgment should also be considered.
- Other factors to be considered in decision making.
 - Available resources
 - Access to expertise/skills
 - Laboratory, treatment and other phases in the patient or a clinical problem
 - Cost
 - Others



Client Provider Interaction (CPI)



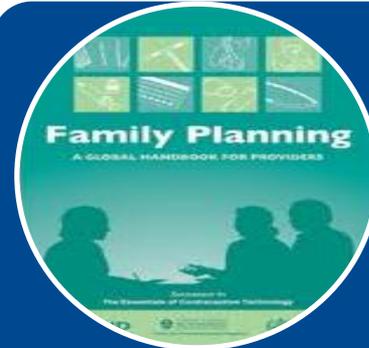
Steps of Counseling



1. Identify category (new client vs returning)
2. Assess reproductive plans
3. Assess previous experiences
4. Identify preference



Clinical Assessment:
Personal Hx
Medical Hx
Physical Exam



1. Based on the WHO MEC decide which methods can be used (limit her choices)
2. Explain briefly about each method & in detail the chosen method



1. Encourage client's participation in decision making
2. Encourage asking questions
3. Dispel rumors
4. Implement the shared decision
5. Plan return visit

Establish a rapport, put the client at ease, use CPI skills appropriately

Points to Discuss During Counselling for Oral Contraception Use

Mechanism of action



The effectiveness



Side effects and complications



Advantages and disadvantages including non contraceptive benefits



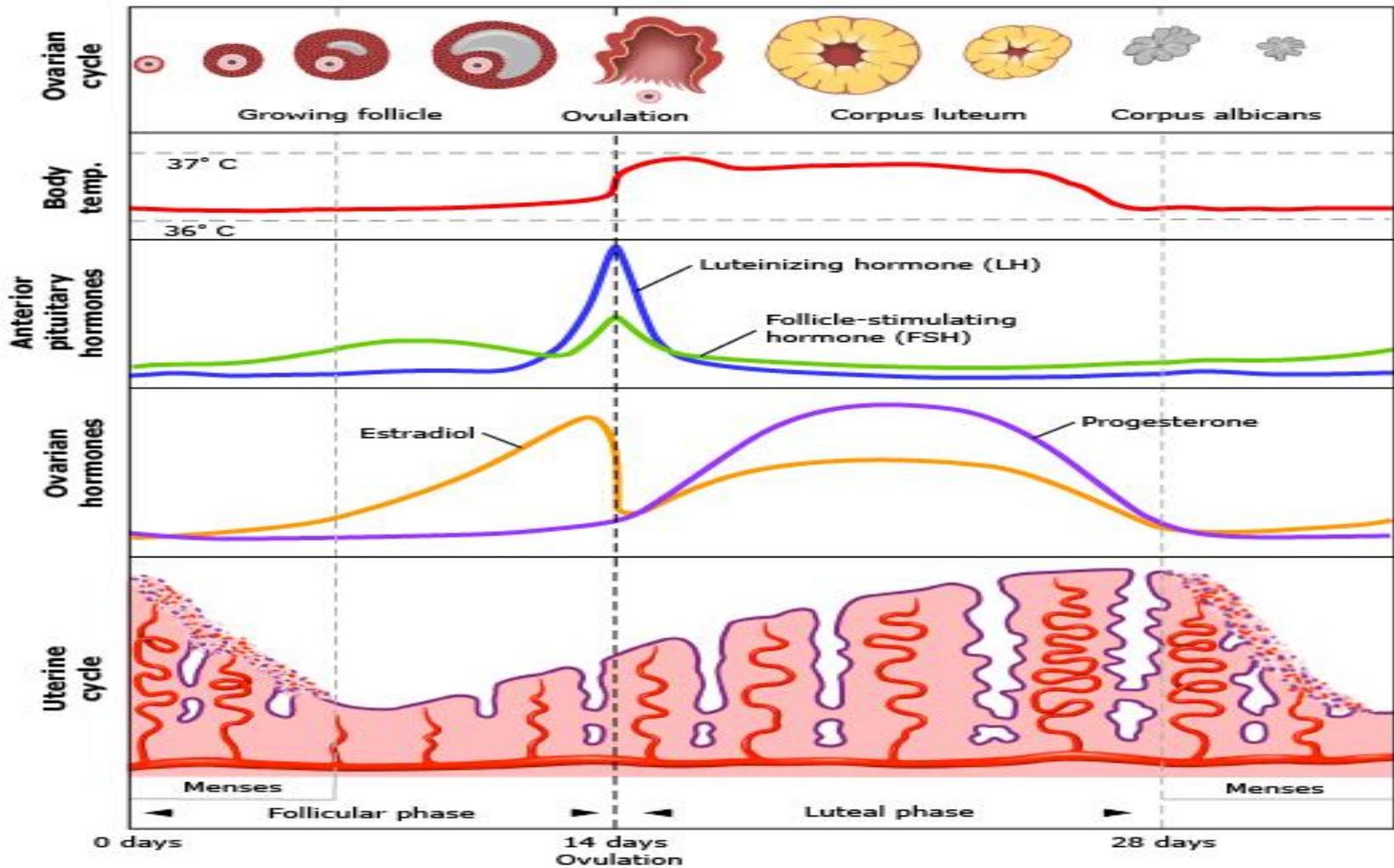
How and when to use
What to do in case of missed pill/pills

Session III

Family Planning Counseling On Oral Contraceptives: Menstrual Cycle and Hormone Basics



Menstrual Cycle



Where are Sex Hormones made?

- **Sex hormone are steroid hormones**
 - Steroid hormones are produced primarily in the **ovaries** and **adrenal** glands or by conversion from other sex steroids in other tissue such as liver or fat (aromatization).
 - They are manufactured from **cholesterol**.
- **Steroids hormones:**
 - **Estrogen:** Estradiol (E2), Estriol (E3), Estrone(E1)
 - **Progesterone**
 - **Androgen:** Testosterone, DHEA, Androstenedione
 - **Cortisol** (Glucocorticoids)
- **Estrogens and Progestagens** are considered "**female sex hormones**".
- **Androgens** are considered "**male sex hormones**", since they have masculinizing effects

Estrogen

Endogenous estrogen is produced by the ovaries in the form of **estradiol (E2)**. E2 is the strongest of estrogens and is responsible for building up the endometrium

- **Effects on reproductive system**
 - Acts as a growth hormone for tissue of the reproductive organs.
 - Responsible for the development of secondary sex characteristics.
- **Effect on CVS**
 - Antioxidant effects and improved endothelial cell injury recovery
 - A rapid vasodilatory response via nitric oxide
 - Reduces low-density lipoprotein cholesterol (LDL-C) oxidation and binding and platelet aggregation, and increases cyclooxygenase-2 activity.
- **Ethinyl Estradiol**, is the estrogen in nearly all OCs currently used.

Progesterone

Endogenous progesterone is secreted by the corpus luteum to prepare the endometrium for implantation of the fertilized egg.

Progestin: any natural or synthetic substance that has properties similar to natural progesterone.

Effects:

1. Progestational Effects
2. Androgenic Effects
3. Estrogenic Effects

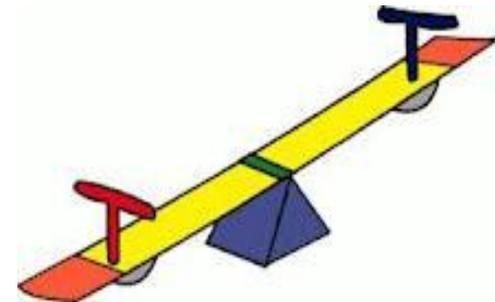
Cyproterone acetate, a progestin and androgen receptor antagonist, presented in (Diane) in addition to ethinyl estradiol, has *antiandrogenic* effect

Kinds of progestins

Generation	Kinds	Properties
First generation	<ol style="list-style-type: none">1. Norethindrone2. Norethindrone Acetate3. Ethynodiol Diacetate	low progestational and slight estrogenic activity, tends to be less androgenic than the second-generation progestins
Second generation	<ol style="list-style-type: none">4. Levonorgestrel5. Norgestrel.	varying degrees of androgenic and estrogenic activities and high progestational effects
Third generation	<ol style="list-style-type: none">6. Desogestrel7. Norgestimate	high progestational selectivity, minimizing androgenic effects and estrogenic activity, possibly higher risk of non-fatal <u>venous thrombosis</u> with desogestrel
Fourth generation	<ol style="list-style-type: none">8. Drospirenone	the newest progestin, the only progestin derived from 17 α -spiro lactones, also has low androgenic activity, may cause higher potassium levels, so women with kidney, liver, or adrenal disease should not use it

Estrogene and Progesterone

- Estrogene and Progesterone receptors are found in cells throughout the body.
 - **Bone, brain, blood vessels, bladder, breast, thyroid and reproductive organs.**
- **Excess estrogen** causes weight gain at the hips, fluid retention, tender breasts, fibrocystic breasts, migraine, irritability, mood swings, anxiety, bleeding changes, loss of sex drive.
- **Excess progesterone** causes nausea, depression, drowsiness, breast swelling, oily skin, increased acne, excess facial hair and “shuts off” the effect of estrogen.



Hormonal contraceptives

- Hormonal contraceptives contain artificial (synthetic) versions of hormones.
- They mimic the action of estrogen and progesterone and interfere with normal monthly cycle to prevent pregnancy.

Oral Hormonal Contraceptives

There are two types of oral contraceptive pills:

Combination pills:

contain both estrogen and progestin and are packaged in 21-day, classification depends on **Ethinyl Estradiol** content and kind of progestin

Progestin-only pill (also referred to as the "mini-pill") packed in 28-day cycles, classification depends on kind of progestin



Formulation OCPs

- **COCs:**

- **30 µg Ethinyl estradiol**

- 150 µg levonorgestrel (Microgynon) *2rd. gen.*
- 150 µg desogestrel (Marvelon) *3^{ed}. gen*
- 3000 µg drospirenone (Yasmin) *4th . gen*

- **35 µg Ethinyl estradiol**

- 2000 µg cyproterone acetate (Diane 35)

- **POPs**

- 350 µg norethindrone (Micronor)
- 500 µg ethynodiol diacetate (Femulen)
- 75 µg desogestrel (Cerazette)

❖ The decrease in both hormones has led to a reduction in both side effects and cardiovascular complications.



Types of Combination Pills

- **Monophasic pills** contain the same dose of estrogen and progestin in each of the 21 hormonally active pills.
- (Marvelon)
- **Multiphasic** preparations alter the dosage of both the estrogen and progestin components periodically throughout the pill-taking schedule.
- Gracial

Mechanism of Action

- OCs have several mechanisms of action.
 - The most important action is estrogen/progestin-induced **inhibition of the mid-cycle LH surge** of gonadotropin secretion “ *negative feedback mechanism*”, so that **ovulation is suppressed**.
 - They also alter **endometrial receptivity** and inhibit the ability of sperm to access the upper genital tract.
 - Another potential mechanism of contraceptive action is suppression of gonadotropin secretion during the **follicular phase** of the cycle, thereby preventing follicular maturation.

Effectiveness

The effectiveness of a method is expressed as both the ***theoretical*** efficacy and the ***actual*** effectiveness

- **Theoretical** (perfect use) refers to the pregnancy rate among those who use the method **correctly AND** on every occasion
- **Actual** (typical use) effectiveness is usually lower due to inconsistent or incorrect use
 - Actual effectiveness is also influenced by frequency of intercourse, age, and regularity of menstrual cycles

Effectiveness

- Effectiveness is often quantitated by the **Pearl Index or life table technique (failure rate)**.
- Pearl Index is the number of **unintended pregnancies per hundred women per year** (i.e., the number of pregnancies in 1200 observed months of use).
- Method effectiveness vs use-effectiveness.
- The most effective methods in typical use are those that do not depend upon regular user action.

Rates of Unintended Pregnancies per 100 Women in the First-Year

Family planning method	Consistent and correct use	As commonly used	Key
Implants	0.05	0.05	0–0.9 Very effective
Vasectomy	0.1	0.15	
Levonorgestrel IUD	0.2	0.2	1–9 Effective
Female sterilization	0.5	0.5	10–25
Copper-bearing IUD	0.6	0.8	Moderately effective
Combined oral contraceptives	0.3	8	26–32
Progestin-only oral pills	0.3	8	Less effective

Couple Years of Protection (CYP)

- CYP is the **estimated protection** provided by contraceptive methods during a one-year period, based upon the volume of all contraceptives sold or distributed free of charge to clients during that period.
- The CYP is calculated by **multiplying the quantity of each method distributed to clients by a conversion factor**, to yield an estimate of the duration of contraceptive protection provided per unit of that method.
- CYP conversion factors are based on how a method is used, failure rates, wastage, and how many units of the method are typically needed to provide one year of contraceptive protection for a couple.

First-year Pill Discontinuation Rates

- Discontinuation rates were separately calculated for each method based on use of a method within 12 months after beginning the method.
- In Jordan only the IUD surpass pills use in Jordan 23% vs 8%
- The overall discontinuation rate among **pill users is 50.9 % VS Injectable is 64.30 %**, and IUD is 15.1% percent

Reason	%
Method failure	8.1
Desire to become pregnant	11.8
Switched to another method	19.5
Other reason	11.5
Total	50.9

Discontinuation

- **It is important to counsel the client about potential side effects**, and reassure her that break through bleeding/spotting will decrease after the first 3-4 months and can be easily managed.
- **Advise the client not to stop taking COCs unless she has another method to use** or she wants to become pregnant.

Combination Pills -- COCs

- The **low-dose combined estrogen-progestin pills** are one of the most popular reversible contraceptives developed to date and is used safely by at least **10 million** women in the United States and **100 million** women worldwide.

(source: Diana B. Petitti, M.D., M.P.H. N Engl J Med 2003; 349:1443-1450 Oct 2003)

Combination Pills

- **Ethinyl Estradiol**, is the estrogen in nearly all OCs currently used.
- **Low-dose COCs** are defined as containing **less than 50** micrograms of estrogen (Ethinyl estradiol) and substantially lower progestin, ranging from 0.05 mg to 2.0 mg).
- The current pills contain on average **30 to 35 mcg of ethinyl estradiol (EE)**.
- Both the estrogen and progestin components of combined contraceptives provide contraceptive actions, but the estrogen component also provides cycle control (i.e., reduces the frequency and duration of scheduled and unscheduled bleeding), which is beneficial.
- Another benefit is that estrogen maintains or improves bone density .

Effectiveness

The theoretical failure rate is **0.1%**

The actual failure rate is **8%** due primarily to missed pills or failure to resume therapy after the seven-day pill-free interval

Advantages

- Highly **effective** if taken correctly.
- **Safe** for most women.
- **Reversible**; fertility returns soon after discontinuing
- No need to do anything at the time of sexual intercourse.
- Can be used as long as a woman wants to prevent pregnancy. **No rest periods needed.**
- Can be used at any age from adolescence to menopause.
- Will not affect a woman's lactation after it is well established.
- Has non-contraceptive benefits

Non Contraceptive Benefits

- **Disorders related to menstrual cycle**
 - Menorrhagia
 - Dysmenorrhea
 - Premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD) (continuous pills or pills with shortened pill-free interval)
 - Prevention of menstrual migraine (continuous pill)
- **Gynecologic disorders**
 - Bleeding due to leiomyomas
 - Pelvic pain due to endometriosis
 - Reduces risk of functional ovarian cysts, benign breast cysts, fibroadenoma, and ectopic pregnancy
 - Symptoms of PCO

Non Contraceptive Benefits

- **Cancer risk reduction**
 - Decreased risk of endometrial cancer and ovarian cancer
 - Decreased risk of colon cancer
- **Hyperandrogenism**
 - Acne
 - Hirsutism
- **Others:**
 - Decreases risk of iron-deficiency anemia

Disadvantages

- Requires **regular supply**.
- **Client dependent**; strong motivation needed to take pills correctly.
- Expensive for some women.
- Offers no protection against STIs/HIV.
- Not appropriate choice for lactating women.
- Minor side effects common in first 3 months may include spotting, amenorrhea, nausea and others.
- May cause **rare and life threatening** circulatory complications.
- Increased risk to users over 35 who are heavy smoker and have other health problems.

COC Method-specific Clinical Assessment

- Age
- Smoking
- Last delivery; childbirth in past 21 days
- Breastfeeding
- Last menstrual cycle/possible pregnancy
- Severe headaches with blurred vision or temporary loss of vision
- History of stroke and heart disease
- History of venous thromboembolism
- Hypertension
- Lumps in breast/breast cancer
- Past or current history of liver disease or Gallbladder disease
- Diabetes mellitus
- SLE
- Planning surgery

Reproductive system:

Parity, Menstrual cycle pattern, bleeding pattern, dysmenorrhea, history of ectopic, ovarian cyst, fibroids, endometriosis....etc.

Medications:

- Medication for tuberculosis (TB), fungal infections, or seizures
- ACEI, heparin, long term use of NSAID (with drospiridone)

A physical (blood pressure measurement /pelvic/breast) **exam is desirable** for all women **but not essential**.

Medical Eligibility Criteria- الأهلية الطبية



Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use –
to initiate or continue use of combined oral contraceptives (COCs), depot-medroxyprogesterone acetate (DMPA), progestin-only implants, copper intrauterine device (Cu-IUD)

CONDITION		COC	DMPA	Implants	Cu-IUD
Pregnancy		NA	NA	NA	NC
Breastfeeding	Less than 6 weeks postpartum	NC	NC	NC	NC
	6 weeks to < 6 months postpartum	NC	NC	NC	NC
	6 months postpartum or more	NC	NC	NC	NC
Postpartum	Less than 21 days, non-breastfeeding	NC	NC	NC	NC
	< 48 hours including immediate post-placental	NC	NC	NC	NC
	≥ 48 hours to less than 4 weeks	NC	NC	NC	NC
	Puerperal sepsis	NC	NC	NC	NC
Postabortion	Immediate post-septic	NC	NC	NC	NC
Smoking	Age ≥ 35 years, < 15 cigarettes/day	NC	NC	NC	NC
	Age ≥ 35 years, ≥ 15 cigarettes/day	NC	NC	NC	NC
Multiple risk factors for cardiovascular disease					
Hypertension	History of (where BP cannot be evaluated)	NC	NC	NC	NC
	BP is controlled and can be evaluated	NC	NC	NC	NC
	Elevated BP (systolic 140 - 159 or diastolic 90 - 99)	NC	NC	NC	NC
	Elevated BP (systolic ≥ 160 or diastolic ≥ 100)	NC	NC	NC	NC
	Vascular disease	NC	NC	NC	NC
Deep venous thrombosis (DVT) and pulmonary embolism (PE)	History of DVT/PE	NC	NC	NC	NC
	Acute DVT/PE	NC	NC	NC	NC
	DVT/PE established on anticoagulant therapy	NC	NC	NC	NC
	Major surgery with prolonged immobilization	NC	NC	NC	NC
Known thrombogenic mutations					
Ischemic heart disease (current or history of) or stroke (history of)					
Known hyperlipidemias					
Complicated valvular heart disease					
Systemic lupus erythematosus	Positive or unknown antiphospholipid antibodies	NC	NC	NC	NC
	Severe thrombocytopenia	NC	NC	NC	NC
	Immunosuppressive treatment	NC	NC	NC	NC
Headaches	Non-migrainous (mild or severe)	NC	NC	NC	NC
	Migraine without aura (age < 35 years)	NC	NC	NC	NC
	Migraine without aura (age ≥ 35 years)	NC	NC	NC	NC
	Migraines with aura (at any age)	NC	NC	NC	NC
Vaginal bleeding patterns	Irregular without heavy bleeding	NC	NC	NC	NC
	Heavy or prolonged, regular and irregular	NC	NC	NC	NC
	Unexplained bleeding (prior to evaluation)	NC	NC	NC	NC

- 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 consulting access to clinical services are required for use.
- Category 4 The method should not be used.

CONDITION		COC	DMPA	Implants	Cu-IUD
Gestational trophoblastic disease	Regressing or undetectable β-hCG levels	NC	NC	NC	NC
	Persistently elevated β-hCG levels or malignant disease	NC	NC	NC	NC
Cancers	Cervical (awaiting treatment)	NC	NC	NC	I C
	Endometrial	NC	NC	NC	I C
	Ovarian	NC	NC	NC	I C
Breast disease	Undiagnosed mass	*	*	*	NC
	Current cancer	NC	NC	NC	NC
	Past w/ no evidence of current disease for 5 yrs	NC	NC	NC	NC
Uterine distortion due to fibroids or anatomical abnormalities					
STIs/PID	Current purulent cervicitis, chlamydia, gonorrhea	NC	NC	NC	I C
	Vaginitis	NC	NC	NC	I C
	Current pelvic inflammatory disease (PID)	NC	NC	NC	I C
	Other STIs (excluding HIV/hepatitis)	NC	NC	NC	I C
	Increased risk of STIs	NC	NC	NC	I C
Pelvic tuberculosis		NC	NC	NC	I C
		NC	NC	NC	I C
Diabetes	Non-vascular disease	NC	NC	NC	NC
	Vascular disease or diabetes for > 20 years	NC	NC	NC	NC
Symptomatic gall bladder disease (current or medically treated)					
Cholestasis (history of)	Related to pregnancy	NC	NC	NC	NC
	Related to oral contraceptives	NC	NC	NC	NC
Hepatitis	Acute or flare	I C	NC	NC	NC
	Chronic or client is a carrier	NC	NC	NC	NC
Cirrhosis	Mild	NC	NC	NC	NC
	Severe	NC	NC	NC	NC
Liver tumors (hepatocellular adenoma and malignant hepatoma)					
HIV	High risk of HIV or HIV-infected	NC	NC	NC	NC
AIDS	No antiretroviral therapy (ARV)	NC	NC	NC	I C
	Clinically well on ARV therapy	see drug interactions	NC	NC	NC
	Not clinically well on ARV therapy	see drug interactions	NC	NC	I C
Drug interactions, including use of:	Nucleoside reverse transcriptase inhibitors	NC	NC	NC	NC
	Non-nucleoside reverse transcriptase inhibitors	NC	NC	NC	NC
	Ritonavir, ritonavir-boosted protease inhibitors	NC	NC	NC	NC
	Rifampicin or rifabutin	NC	NC	NC	NC
	Anticonvulsant therapy**	NC	NC	NC	NC

Unlike previous versions of the MEC Quick Reference Chart, this version includes a complete list of all conditions classified as Category 3 and 4 by WHO.

I/C (Initiation/Continuation): A woman may fall into either one category or another, depending on whether she is initiating or continuing to use a method. For example, a client with current PID who wants to initiate IUD use would be considered as Category 4, and should not have an IUD inserted. However, if she develops PID while using the IUD, she would be considered as Category 2. This means she could generally continue using the IUD and be treated for PID with the IUD in place. Where I/C is not marked, the category is the same for initiation and continuation.

NC (not applicable): Women who are pregnant do not require contraception.

NC (not classified): The condition is not part of the WHO classification for this method.

* Evaluation of an undiagnosed mass should be pursued as soon as possible.

** Anticonvulsants include: phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, and lamotrigine. Lamotrigine is a category 1 for implants.

Source: Adapted from Medical Eligibility Criteria for Contraceptive Use, Geneva: World Health Organization, updated 2008. Available: <http://www.who.int/reproductive-technologies/publications/mec/>

Indications

COCs may be an appropriate method for a woman who:

- Wants an effective, reversible family planning/spacing method.
- Is anemic because of heavy menstrual bleeding.
- Is nulliparous. COCs provide temporary, reversible protection for women wishing to postpone a first pregnancy.
- Are of any age.
- Has a history of ectopic pregnancy.
- Has a history of benign functional ovarian cysts.
- Has a family history of ovarian cancer (in mother or sister).
- Has severe menstrual cycle symptoms (heavy bleeding, severe cramping, irregular cycles.....etc.).
- Has acne or hirsutism.
- Has varicose veins.

Contraindications to COCs Use:

- **Smoking:** Women over age 35 years who smoke heavily (greater than 15 cigarettes per day).
- **Breast feeding:** exclusively up to 6 months, partially up to 6 weeks.
- **Migraine:** Women over age 35 with migraines, or in women of any age with migraines with aura
- **Cardiovascular:**
 - Multiple cardiac risk factors.
 - Previous or current thromboembolic event (MI, stroke, TIA, DVT or PE).
 - Uncontrolled hypertension.
 - Complicated valvular heart disease.

Contraindications to COCs Use:

- Known dyslipidemia
- **Breast:** current or past cancer or undiagnosed breast mass.
- **GI:** Active liver or gall bladder disease/ cirrhosis or tumor
- **Reproductive system:**
 - Pregnancy
 - Undiagnosed abnormal uterine bleeding
- **Endocrine:** diabetes mellitus for more than 20 years or with complications.
- **SLE**
- **Medications:** anticonvulsants, rifampin or griseofulvin

COCs Side Effects

- Side effects are common in the first 3 months and then decrease.
- Several are similar to, but milder than symptoms in early pregnancy.
- Some of the following side effects may also be caused by conditions not due to COCs.
- Some side effects can be managed by switching pills to change the **dose of estrogen or to change the dose and type of progestin.**
- Good counseling regarding possible side effects, and encouraging the client to persevere for the first 3 months lead to greater continuation.
- If side effects persist and the client does not want to continue, help her choose another method.

Common Side Effects

Related to estrogen component:

1. **Nausea**
2. **Breast tenderness**
3. **Mild Headaches**
4. **Spotting/breakthrough bleeding**
5. **Amenorrhea or scanty period:**
 - Due to Inadequate endometrial buildup due to low dose COC. Bleeding may return after next cycle of COCs.
 - ***Post-pill amenorrhea***: women who do not menstruate 3 months after discontinuing an OC should undergo the same evaluation for amenorrhea as any woman with amenorrhea.
6. **Depression/mood changes**
 - Can be related to both estrogen and progestin.

Less Common Side Effects

- **Elevated blood pressure:**
 - Estrogen or progestin component of COCs
- **Chloasma** (brown under eyes, or “mask of pregnancy”): Cause may be estrogens.
- **Reduced Libido:**
 - In some women vaginal secretions are altered and free testosterone is decreased, which may decrease the sex drive.

Management of Side Effects

Side effects	Management
Nausea	Reassurance, keep taking the pills, take the pill before bedtime or with meals
Mild headache	Reassurance, keep taking the pills, analgesia
Breast tenderness	Reassurance, keep taking the pills, supportive bra, analgesia, cold or hot compresses
Spotting	Reassurance, keep taking the pills exactly on time
Moodiness	Reassurance, keep taking the pills
Weight gain	Reassurance, keep taking the pills, monitor diet and exercise

Management Of Side Effects

1. Irregular bleeding:

1. Take the pill each day at the same time.
2. Manage missed pills properly
3. Try NSAID
4. If persists after 3 months try another formulation
5. Consider other underlying conditions

2. Amenorrhea

1. R/O pregnancy
2. Reassurance

3. Acne

Switch to another formulation

Warning Signs

- Complications are very rare in low-dose 30- 35 mcg (or less) pills.
- Every client should be informed of the COC warning signs and that she should come to the clinic immediately if she experiences any one of them.
- Present the information in a non-alarming way.
- Question for warning signs at each follow-up visit.
- Heavy smoking appears to be the most significant risk factor for development of major cardiovascular disease.

Warning Signs /ACHES

- **Severe abdominal pain** could be a sign of thrombosis of major intra-abdominal vessels such as the hepatic veins or mesenteric artery or veins.
- **Severe chest pain** could be a myocardial infarction or PE.
- **Severe calf pain** of one leg might indicate a DVT.
- **Severe headaches** may be the major warning sign that precedes a cerebrovascular accident (stroke).
- **Acute loss of vision in one eye** could be caused by retinal artery or vein thrombosis or hemorrhage. Loss of a field of vision may signify transient cerebral ischemia.
- **Jaundice** may be related to active hepatitis, gallbladder disease, or liver tumors (rare).

Initiation

- COCs may be started **anytime you can be reasonably sure that the client is not pregnant.**
- The best time to start the pills is the first **5 days** of the menstrual cycle.
- If the chosen start day for the first pack is on or after the 5th day of the client's normal menses, she must use a **back-up method for 7 days.**
- **Immediately** if she is switching from an IUD or hormonal method that has been used correctly.

A three-month follow-up visit can be useful to measure blood pressure and discuss satisfaction and side effects

Continuation

- Continue taking a pill everyday at the same time for **21 days.**
- Wait **7 days** before starting a new packet.
- Women do **not** need a “**rest**” from taking COC.



When Can COCs Be Started Postpartum?

- If **non breast feeding** she can start after the **4th week**.
 - If **partially breast feeding** she can start at **6 weeks**.
 - If **exclusively** breast feeding, she can start COCs at **6 months** postpartum.
- **3 weeks, 6 weeks, 6 months**
- After 6-8 weeks postpartum, exclusively breastfeeding women desiring hormonal contraception should be encouraged to use POPs or Injectable or implants.
 - If her monthly bleeding has not returned postpartum, she can start if she is sure she is not pregnant however need to use backup method for 7 days.

Post Abortion Initiation

May COCs be begun immediately post abortion?

- **Yes. COCs are appropriate for use immediately** after a first or second trimester abortion and should be initiated **within the first 7 days post abortion**

Rationale:

- **Ovulation returns almost immediately post abortion** within 3 weeks for first trimester abortion and within 4 weeks for second trimester abortion.

Is There a Minimum Age to Receive COCs or a Maximum Age?

- **COCs may be used at any age at which a woman is at risk of pregnancy** (i.e., past menarche and through menopause).
- **Women over 40 can take COCs**, provided other risk factors have been considered (e.g. smoking, high blood pressure, diabetes).

Rationale:

- **Cardiovascular risks from COC use are minimal in healthy, non-smoking, older women.**
- The risk of amenorrhea after discontinuing COCs is small and more common in women who had irregular menses prior to COC use. Women who have irregular menses are more likely to develop secondary amenorrhea whether they take COCs or not.

Missing One or Two COC Pills

- The woman should **take one pill as soon as possible** and then continue taking one pill each day as prescribed. She may take two pills on the same day or at the same time.
- If **seven or more** pills are left in the pack after the last missed pill, she should finish the pack and have the usual seven day break.
- If **less than seven** pills are left in the pack after the missed pill, she should finish the pack and begin a new pack the next day (omit hormone-free days).

Missed Pills –summary

	Missed 1-2	Missed 3 or more pills
First or second week	<ul style="list-style-type: none"> ✓ Take one pill as soon as possible ✓ Continue taking one pill each day ✓ Have the usual seven day break. 	<ul style="list-style-type: none"> ✓ Take one pill as soon as possible ✓ Continue taking one pill each day. ✓ Have the usual seven day break. ✓ Use a backup method for 7 days.
Third week	<ul style="list-style-type: none"> ✓ Take one pill as soon as possible ✓ Continue taking one pill each day ✓ Finish the pack and begin a new pack the next day (Omit hormone-free days). 	<ul style="list-style-type: none"> ✓ Take one pill as soon as possible ✓ Continue taking one pill each day ✓ Finish the pack and begin a new pack the next day (Omit hormone-free days). ✓ Use a backup method for 7 days.

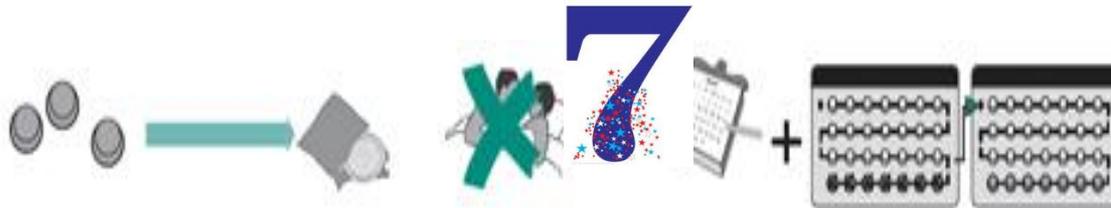
Missing Three Pills

- **Three or more missed pills on the first or second week or if the woman start a pack 3 days or more late:**
 - She should take one pill as soon as possible and then continue taking one pill each day as prescribed.
 - She may take two pills on the same day or at the same time and use a **back up** method for 7 days.



Missing Three Pills

- **Three missed pills or more in the third week:**
 - Women should take one pill as soon as possible and then continue taking one pill each day until you finish the pack then **immediately start a new pack** and use a **back up** method for 7 days.



Vomiting and Diarrhea

- If the woman vomits within 2 hours after taking the pill, she should take another pill as soon as possible and then continue taking the pill as usual.
- If vomiting or diarrhea continues for more than 2 hours follow the instructions for missed 1 or 2 pills.

Overcoming Barriers To The Provision Of COCs

- Throughout the world, **many myths and rumors have surrounded the provision of combined oral contraceptives.**
- Excellent candidates for COCs have been denied pills because of well-intended but inappropriate decisions by health providers.
- Examples:
 1. Use of COC for nulliparous before the having a first child.
 2. Use of COC by women with varicose veins.
 3. Use of COCs by healthy, non-smoking women throughout their reproductive lives.
 4. Use of COC for women in their forties.
 5. The overall effect of COCs on the risk of breast cancer.
 6. Having a rest period.

Facts About COC and Cancer

Ovarian and endometrial cancers:

- COC s has protective effect.
- Use for **at least 12 months** reduces the risk of endometrial cancer by 50% with the greatest protection by use for more than 3 years.
- This protection persists for **20 or more years** after discontinuation and is greatest in women with high risk.
- Protection is seen with all monophasic formula.
- The risk of developing ovarian cancer is reduced by 40%
- This protective effect increases with duration of use and **20 or more years** after discontinuation

Facts About COC and Cancer

Breast cancer:

- Current and recent use of oral contraceptives may be associated with a slight increase of breast cancer.
- There is no effect of past use or duration of use on the risk of breast cancer.
- Women who have used COC more than 10 years ago are at the same risk of non users.
- When current or former user is diagnosed with breast cancer the cancer is usually less advanced than in non users.
- COC use does not increase the risk of breast cancer in women with positive family history.

Facts About COC and Cancer

Cancer of the cervix:

- Studies indicated that the risk for dysplasia and carcinoma in situ of the uterine cervix increases with the use of COC for more than one year.
- Invasive Cx cancer may be increased with long term use.
- Use of COC for 5 years or more appears to speed up the development of persistent HPV infection into cervical cancer.

Risk of Myocardial Infarction

It has been suggested that **low-dose** OCs may **not increase** the risk for acute myocardial infarction, even in smokers.

Cardiovascular **morbidity and mortality** data for low-dose pill use in **older smokers** are **conflicting** showing an increased risk vs no effect .

The relationship between smoking, OC use, and cardiovascular disease may be related to high plasma **fibrinogen** concentrations and intravascular **fibrin** deposition, and enhanced **monocyte tissue factor expression**. ([PubMed](#))

Newer "third-generation" OCs (eg, Marvelon) have more favorable effects on the lipid profile than second generation preparations.

However, because MI is an extremely rare event in otherwise healthy women of reproductive age, even a doubling of the risk would result in an extremely low attributable risk.

Risk of Myocardial Infarction and Ischemic

- A consensus panel reviewing the benefit of use of OC in women over 35 who smoke fewer than 15 cigarettes per day outweighs the risk, since the risks of pregnancy in this age group are greater than the risks associated with OC use.
- Women who have taken an OC are not at increased risk for coronary heart disease later in life.
- **Low-dose OC** may be associated with a **small increase in ischemic stroke risk**, although available studies have significant methodological limitations. If present, the absolute increase in **risk is extremely low**, particularly in healthy women under age 35.
- Risk appears to be **the same for second and third generation progestins**, and the risk of **hemorrhagic stroke does not appear to be increased**.

Venous Thromboembolic Disease (VTE)

- An **increase in the risk of VTE** is seen with both high and low dose estrogen OC preparations.
- The absolute excess risk is extremely small, and may be outweighed by the many benefits of Ocs.
- There have been concerns that **newer progestins** may be associated with a **greater risk** of VTE when compared to earlier progestins.
- **Desogestrel (Marvelon)** and gestodene, but not norgestimate were at **greater risk** for VTE when compared with women taking OCs containing **levonorgestrel**.
- **Acquired resistance to activated protein C** has been suggested as one mechanism by which the third generation OCs could predispose to VTE.

Do COC Cause Weight Gain?

- **No.** most women do not gain or lose weight because of COC.
- A few women experience sudden changes in weight that are reversible after stopping the pills.
- Some women seem to gain weight on the pill, but research has shown that it is not due to pill use.
- The **estrogen** in the pill can make some women feel **bloated**, but this typically goes away. The **progestin** found in the pill may **increase appetite**, resulting in weight gain. Water retention; it can often be reduced by switching to a lower dose pill.

Do COCs Cause Birth Defect?

- **No.** good evidence showed that COCs will not cause birth defects and will not harm the fetus if a woman becomes pregnant while taking COCs.



Planning Surgery

- Tell the surgeon the woman is using COCs
- Stop COC 3-4 weeks pre-operative
- Use back up method
- Restart 2 weeks after full ambulation

Key Messages

1. **Compliance is increased** in COC users **when clients are active participants in the counseling process**, when they are given thoughtful replies to their questions and concerns, and when accurate and detailed Evidence based information is provided.
2. The COC is safe, effective, and reversible, and is one of the most extensively studied medications ever used by human beings.
3. Serious side effects are very rare.
4. The **non-contraceptive benefits of COCs** are significant
5. COCs appear to have no apparent overall effect on the risk of breast cancer.
6. **COCs may be used by healthy, non-smoking women throughout their reproductive lives**, starting in the teenage years and into their forties.

Introduction

- The minipills contain a small dose of progestational agent and must be taken daily in a continuous fashion.
- Desogestrel available in a **75 mcg** (Cerazette) is different and has low failure rate, suppresses ovulation and intake delay of up to 12 hours does not affect efficacy.



Effectiveness

- Failure rates range from 1 to 10 per 100 women in the first year of use.
- **Breastfeeding women:**
 - As commonly used POP s are **99%** effective.
- **Non breast feeding; less effective:**
 - As commonly used about 3-10 pregnancies per 100 women over the first year. This mean it is **90-97%** effective.
- The failure rate is higher in younger women compared with women over 40.

Advantages/Benefits

- Can be used by breast feeding mothers starting 6 weeks after childbirth (partially). Quality and quantity of breast milk do not seem harmed.
- No estrogen side effects. Does not increase risk of estrogen-related complications.
- Women take one pill every day with no break.
- Can be very effective during breastfeeding.
- Even less risk of progestin-related side effects, such as acne and weight gain, than with the COC.
- Can be stopped any time.
- Return to fertility is immediate.
- Do not interfere with sex.

Disadvantages/Risks

- For women who are **not breastfeeding**, a common side effect is a change in menstrual bleeding.
 - include irregular periods, spotting or bleeding between periods (common), and amenorrhea possibly for several months.
- POPs may lengthen amenorrhea during breastfeeding.
- Less common side effects include headaches and breast tenderness.
- Must be taken at about the same time each day to be effective.

Disadvantages/Risks

- Offers no protection against STIs/HIV.
- Requires regular, dependable supply.
- Expensive for some women.
- Effectiveness may be lowered when certain drugs are taken for epilepsy(phenytoin and barbiturates)
or
tuberculosis (rifampin).



Indications

POPs may be an **appropriate method** for a woman who:

- **Is breastfeeding and wants a contraceptive.**
- **Has high blood pressure.** POPs are unlikely to affect blood pressure.
- **Has had estrogen-related contraindication or side effects from**
- **COCs**, including migraine headaches, nausea, high blood pressure or breast tenderness.
- **Is over 35 and smokes heavily**, but does not want to use an IUD or other method.
- Nullipara or multipara
- Has varicose veins

Contraindications to POPs Use:

1. **Breast feeding:** exclusively breast feeding less than 6 weeks
2. **CVS:** Ischemic heart disease, stroke and current DVT.
3. **GI:** liver tumors, cirrhosis or viral hepatitis
4. **Reproductive system:**
 1. Pregnancy
 2. Unexplained and abnormal vaginal bleeding
5. **Diabetes Mellitus** over 20 years or with complications.
6. **Breast:** current or past history of breast cancer.
7. **Medications:** anticonvulsants, rifampin or griseofulvin

Side Effects

1. Changes in bleeding pattern:

- For breast feeding; longer delay to monthly bleeding
- Frequent bleeding
- Irregular bleeding
- Amenorrhea
- Infrequent bleeding
- Prolonged bleeding
- Spotting

2. Headaches

3. Dizziness

4. Mood changes

5. Breast tenderness

6. Abdominal pain

7. Nausea

Management of Side Effects

- **Spotting or bleeding between periods** (very common with POPs)
 - Perform an examination to R/O a gynecologic abnormality. e.g. tumors, pregnancy, abortion, and PID. If present, refer or manage as appropriate. If PID or abortion is causing bleeding, POPs can be continued.
 - Reassure the client that spotting or bleeding between periods is a very common side effect of POPs.
 - Reassure her that the total blood loss is likely to be less than normal monthly blood loss.
 - If the client still sees spotting as a problem, help her to make an informed choice of another contraceptive method.

Management of Side Effects

- **Moderate bleeding** (equivalent to normal menses) or **irregular bleeding**

Moderate bleeding may occur for non-breastfeeding women, but is uncommon when breastfeeding. If client is not satisfied after counseling and reassurance, two treatment options may be considered:

1. Give a cycle of low-dose COCs if she is not breastfeeding and has no other condition for which use of COCs is inadvisable.
2. Give ibuprofen (up to 800 mg three times daily for 5 days) or another NSAID.

Management of Side Effects

- **Heavy or prolonged bleeding** (twice as much or longer than 8 days) very rare, especially for breastfeeding women.
 - Rule out ectopic pregnancy, abortion, PID, and other gynecologic problems. Refer as appropriate.
 - If PID or abortion is causing bleeding, POPs can be continued.
 - Reassurance, it usually becomes less or stops after a few months.
 - Try NSAIDS, suggest iron tablets.
- **Amenorrhea**
 - Pregnancy must be ruled out.
 - If a diagnosis of pregnancy cannot be made, ask the client to continue POPs and return in one month for a re-exam.
 - Reassure her that this is normal and not harmful.
 - If the client is bothered by lack of menses, switch to combined oral contraceptives (COCs), or another reliable non-hormonal method.

Management of Side Effects

- **Headaches:** suggest ASA, NSAID or paracetamol.
- **Breast tenderness:** if not breast feeding,
 - Recommend wearing supportive Bra
 - Try hot or cold compresses
 - Suggest analgesia
- **Severe lower abdominal pain:**
 - This could be due to an ovarian cyst or ectopic pregnancy
 - Do not stop the pills while evaluating
 - Enlarged follicles or cysts usually disappear spontaneously
 - Re-evaluate in 6 weeks
 - If ectopic is suspected/diagnosed, refer

Warning Signs

Ask the client to come to the clinic if she has any of the following **symptoms or problems**:

- **Abdominal pain, tenderness, or fainting**

(This could be due to an ovarian cyst or ectopic pregnancy). Do not stop the pills, but come to the clinic right away.

- **Extremely heavy or prolonged bleeding** (twice as long or twice as much as usual).
- **Severe headache** (that start or become worse after taking POPs).
- **Jaundice.**
- **If she thinks she might be pregnant.**

Initiation

- **Start within the first 5 days of the cycle.** No back up method is needed.
- If started after 5 days, use back up method for 2 days.
- She can start immediately if switching from another reliable method that has been used correctly and consistently.
- If **breast feeding** she can start as early as **6 weeks.**
- If **not breast feeding** she can start **immediately.**
- If no monthly bleeding she can start as soon as pregnancy is ruled out. Use back up method for 2 days.
- Immediately after first or second trimester abortion.

Continuation

- Take one pill each day at the same time, any time of the day.
- Upon completion of the cycle open a new packet and continue taking one pill each day at the same time.
- No breaks between packs.



If a Woman is Using POPs During Breastfeeding, When Should She Switch to Another Method?

- Women can rely on POPs after the first 6 weeks and safely use them during the entire duration of breastfeeding.
- Without the additional protection of breast feeding POPs become less effective.
- Women can continue using POPs after they stop breastfeeding, provided that they have been informed of the advantages and disadvantages of the method and are willing to use the POPs correctly and consistently.
- Breastfeeding women using POPs should be advised not to switch to COCs or other methods containing estrogen until at least 6 months postpartum.
- Breastfeeding women can switch to non hormonal methods at any time, as appropriate.

Missed Pills

Missed one pill within the preceding 3 hours :

- Take the pill as soon as possible, take the next pill at regular time, continue taking the pills as usual.

Missed one pill but more than 3 hours (12 hours for Desogestrel containing POPs):

- Take the pill as soon as possible, take the next pill at regular time, continue taking the pills as usual and use back up method for 2 days.

If she vomits within 2 hours after taking the pill, she should take another pill as soon as possible and continue taking the pills as usual.

Do POPs Increase The Risk Of Ectopic?

- **No.** on the contrary, POPs reduce the risk of ectopic pregnancy. The rate of ectopic pregnancy among women using POPs is **48 per 10,000** women per year. The rate of ectopic in women not using contraceptive is **65 per 10,000 women** per year.
- On the uncommon occasions that POPs fail and pregnancy occurs, **5-10 of every 100** are ectopic.
- Thus the great majority after POPs fail are not ectopic.
- Past history of ectopic does not contraindicate POP use.

Source: WHO Family Planning global handbook 2011

Do POPs Cause Birth Defect?

- **No.** good evidence showed that POPs will not cause birth defects and will not harm the fetus if a woman becomes pregnant while taking POPs.

New Client: First Visit

**New
Client**

- **Check that client's understanding of method is accurate.**
- **Support client's choice, if client is medically eligible for the method.**
- **Discuss how to use method.**
- **Tell client about possible side effects and how to cope with them.**
- **Provide method/supplies.**
- **Schedule return visit.**

The best method is the method that the woman prefers

Return Follow-up Visit

Returning client

- Check that the client is using the method correctly
- Perform physical examination
- Ask her to repeat the instructions and what she should do if she misses 1 or more pills
- Ask if she has started any new medication
- Remind her of the warning signs
- Discuss the reason behind switching or discontinuation if she is unhappy with the pills
- Manage any side effects or problems if found
- Switch to another method if problems persist
- Counsel on the new method
- Dispel any rumors or concerns
- Respect her wishes if she wants to become pregnant and offer pre-conception counseling
- Provide supplies and plan a return visit

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