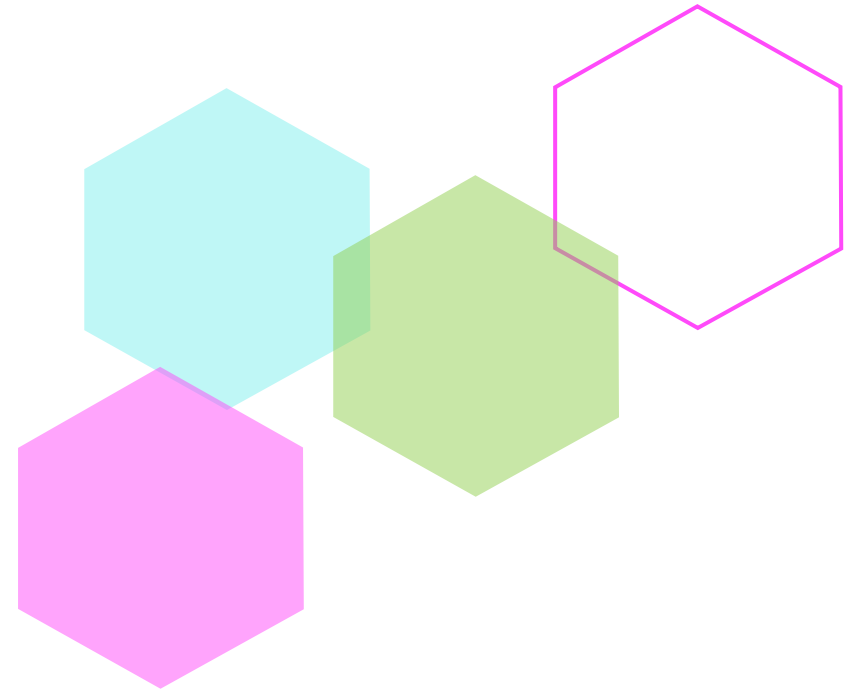


Focusing on women issues: reproductive care, pregnancy and lactation



Stephanie Pagán-Rodríguez, Pharm.D., BCPS
August 24, 2024

Disclosure to Learners

Stephanie Pagán-Rodríguez, faculty for this CE activity, has no relevant financial relationship(s) with ineligible companies to disclose.



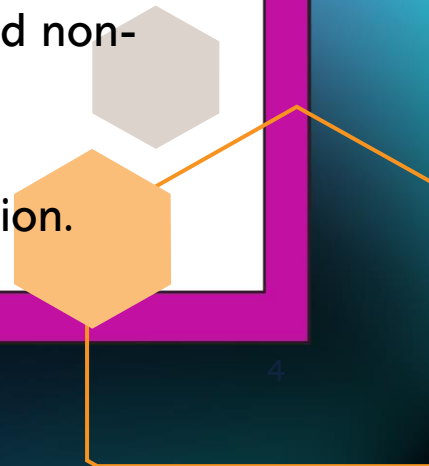
“The Colegio de Farmacéuticos de Puerto Rico is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.”

Provider Number: 0151

Objectives

At the conclusion of the activity, pharmacists, should be able to:

1. Describe the social determinants that impact women health and reproductive care, pregnancy, and lactation.
2. Identify access barriers for services and medications needed for reproductive care, pregnancy, and lactation.
3. Discuss medications used for reproductive care, during pregnancy and lactation.
4. Identify contraindications, and special precautions with the use of pharmacological and non-pharmacological interventions during reproductive care, pregnancy, and lactation.
5. Value the role of the pharmacy team during reproductive years, pregnancy, and lactation.



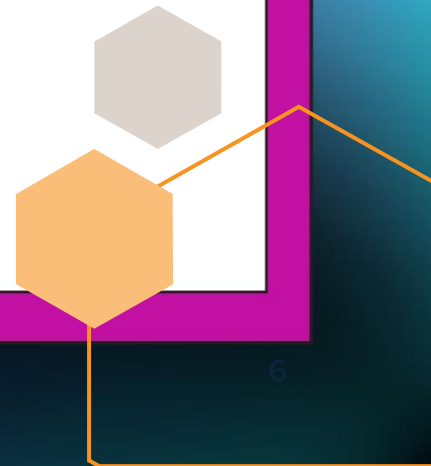
Objectives

At the conclusion of the activity, pharmacy technicians, should be able to:

1. Describe the social determinants of health that impact women health and reproductive care, pregnancy, and lactation.
2. Identify access barriers for services and medications needed for reproductive care, pregnancy, and lactation.
3. List medications used for reproductive care, during pregnancy and lactation.
4. Identify contraindications, and special precautions with the use of pharmacological and non-pharmacological interventions during reproductive care, pregnancy, and lactation.
5. Value the role of the pharmacy team during reproductive years, pregnancy, and lactation.

Social Determinants of Women Health

- Nonmedical factors in a person's life that influence their health outcomes
- Some social determinants:
 - Poverty
 - Social exclusion
 - Unemployment
 - Unequal gender
 - Lack of insurance
 - Access to obtain medical appointment or reaching a clinic
 - Fear of lack of services



Women's Health Issues

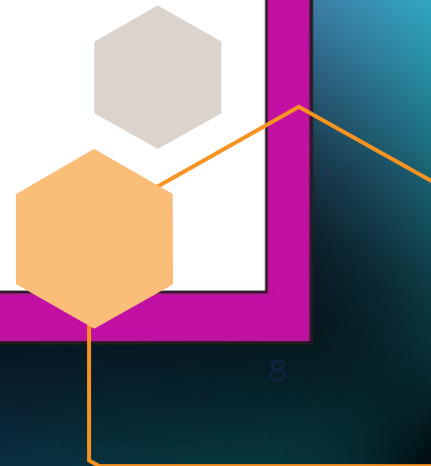
- As per National Institute of Health (NIH) Office of Research on Women's Health:

Women's health equity refers to the state in which all individuals who are women and/or were assigned female at birth have a fair and just opportunity to attain their highest level of health.

- Racial and ethnics disparities in women's health have existed for decades
- Social-level public policy such as *The Patient Protection and Affordable Care Act* has strengthened reproductive health care, close gaps in services and outcomes, and decrease racial–ethnic reproductive health disparities
- Challenges continue to threatened the potential of current social-level policies
- Barriers to reproductive health continue to increase

Women's Health Issues and Pharmacy Teams

- Health care members and systems need to be aware of the needs and considerations of women's reproductive health
- Pharmacy teams can help reduce barriers by:
 1. Increasing access for medications
 2. Provide pre-conception care to all women child-bearing potential
 3. Contraception prescribing and/or education
 - Prescribing authority in some states
 4. Prevention of pregnancy
 5. Pharmacological precautions during pregnancy and lactation



Reproductive Health

Menarche → Menopause

Preventive gynecologic care	Immunizations	Mental health	Female genital mutilation	Pregnancy and lactation	Uterine fibroids
Anatomy	Nicotine	Sexually transmitted infections	Abortion	Infertility	Gynecologic Cancer
Menstruation	Healthy relationships and consent	Contraception and pregnancy prevention	Hormone therapy and menopause	Endometriosis	Interstitial Cystitis

Reproductive Health

Menarche → menopause

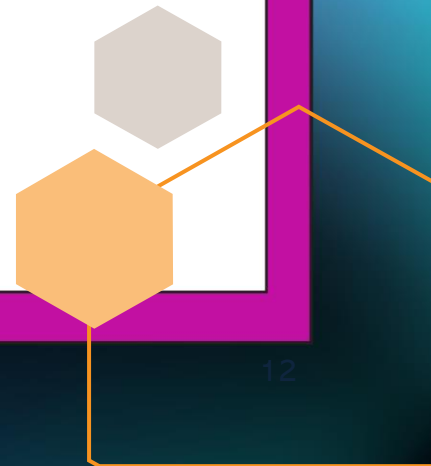
Preventive gynecologic care	Immunizations	Mental health	Female genital mutilation	Pregnancy and lactation	Uterine fibroids
Anatomy	Nicotine	Sexually transmitted infections	Abortion	Infertility	Gynecologic Cancer
Menstruation	Healthy relationships and consent	Contraception and pregnancy prevention	Hormone therapy and menopause	Endometriosis	Interstitial Cystitis

The slide features a decorative arrangement of five hexagons on the left side. There is a large orange hexagon in the center, a smaller light blue hexagon above it, a smaller light orange hexagon below it, a white hexagon with a black outline to the left, and a very small light orange hexagon at the bottom center. The entire slide is framed by a thick magenta border.

Contraception and Pregnancy Prevention

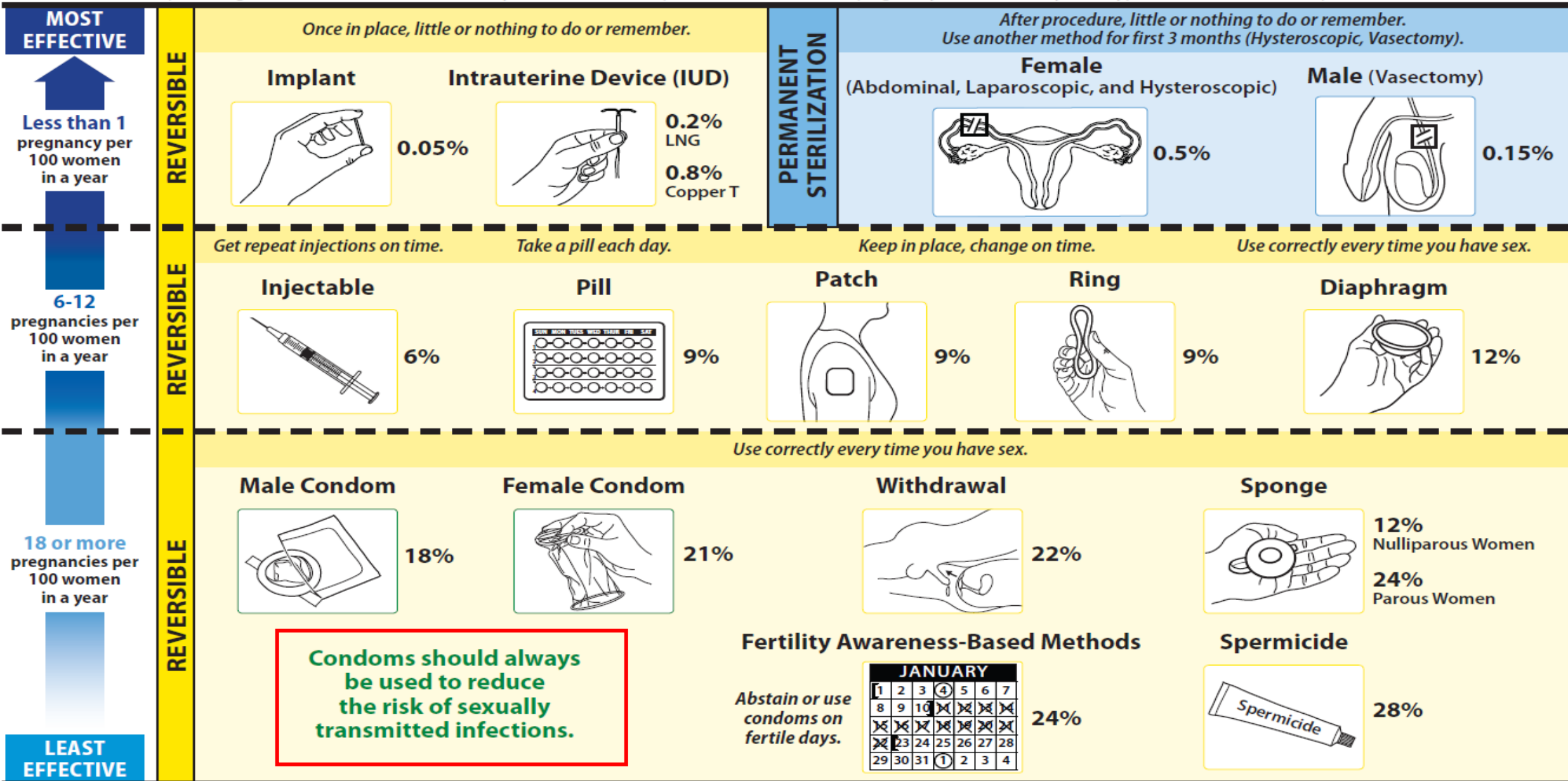
Reversible Methods of Contraception

- **Hormonal methods**
 - Combined hormonal contraceptives
 - Oral
 - Patch
 - Ring
 - Progestin only pill
 - Implant
 - Injection
- **Intrauterine device contraception (IUD)**
 - Levonorgestrel intrauterine system
 - Copper T intrauterine device
- **Barrier methods**
 - Diaphragm or cervical cap
 - Sponge
 - Male or female condom
 - Spermicides
- **Fertility awareness-based methods**
- **Lactational amenorrhea methods**
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EFFECTIVENESS OF FAMILY PLANNING METHODS*

*The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.



Other Methods of Contraception: (1) Lactational Amenorrhea Method (LAM): is a highly effective, temporary method of contraception; and (2) Emergency Contraception: emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy. Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. *Contraception* 2011;83:397-404.

EFFECTIVENESS OF FAMILY PLANNING METHODS*

*The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

MOST EFFECTIVE

Once in place, little or nothing to do or remember.

After procedure, little or nothing to do or remember.
Use another method for first 3 months (Hysteroscopic, Vasectomy).

External condoms are the **only** over the counter contraception that can protect against sexually transmitted infections spread by genital fluids.

18 or more pregnancies per 100 women in a year

REVERSIBLE

LEAST EFFECTIVE

Male Condom



18%

Female Condom



21%

Withdrawal



22%

Sponge



12% Nulliparous Women
24% Parous Women

Condoms should always be used to reduce the risk of sexually transmitted infections.

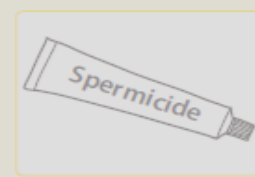
Fertility Awareness-Based Methods

Abstain or use condoms on fertile days.



24%

Spermicide



28%

Other Methods of Contraception: (1) Lactational Amenorrhea Method (LAM): is a highly effective, temporary method of contraception; and (2) Emergency Contraception: emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy. Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD: Geneva, Switzerland: CCP and WHO: 2011; and Trussell J. Contraceptive failure in the United States. *Contraception* 2011;83:397-404.

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Reversible Methods of Contraception

Hormonal Methods → Combined Hormonal Contraceptives → Oral



- Contains estrogen + progestin
 - Estrogen: ethinyl estradiol, estradiol valerate, mestranol
 - Progestin: norethindrone, norgestrel, desogestrel, etonogestrel, drospirenone, ect
- Content of hormones varies (bi-phasic, tri-phasic, quadri-phasic)
- Most common contain:
 - 20-32 ethinyl estradiol + progestin
 - 3 weeks active and 1 week inactive
- Mechanism of action:
 - Estrogen: suppress FSH/ovulation + increase aldosterone + increase sex hormone
 - Progestin: suppress LH surge/ovulation + thickens cervical mucus + endometrial atrophy
- Failure rate: 7%

Reversible Methods of Contraception

Hormonal Methods → Combined Hormonal Contraceptives → Oral

Table 1
Activity of Progestin Agents

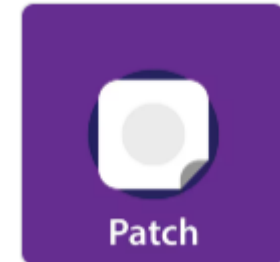
Generation	Progestin	Estrogenic	Progestational	Androgenic
First	Norethindrone	++	++	++
	Ethinodiol diacetate	++	+++	+
	Norgestrel	-	+++	+++
	Norethindrone acetate	++	++	++
Second	Levonorgestrel	-	++++	++++
Third	Norgestimate	-	++	++
	Desogestrel	+/-	++++	++
Fourth	Drospirenone	-	+/-	-

*+/- indicates low to no activity.
- indicates no activity.
Source: References 3, 8, 18.*

Reversible Methods of Contraception

Hormonal Methods → Combined Hormonal Contraceptives → [Patch](#)

- Contains ethinyl estradiol (EE) + norelgestromin or levonorgestrel
 - EE 30-35 mcg
- Presentation and measure varies
- EE exposure is > 50% higher compared to oral
- Applied once per week x 3 weeks → 1 week off
- Application area: buttock, abdomen, or upper torso
- Failure rate: 7%



Reversible Methods of Contraception

Hormonal Methods → Combined Oral Contraceptives → **Ring**



- Contains ethinyl estradiol (EE) + etonogestrel or segestorone acetate
 - EE 13-15 mcg
- Inserted 3 weeks, then one week ring free
- Concentration of EE lower than with other combined hormonal contraceptives
- Special considerations:
 - Refrigeration required for EE/etonogestrel ring
 - EE/segestrerone acetate ring is reusable for 13 cycles and is latex free
- Failure rate: 7%



Reversible Methods of Contraception

Hormonal Methods → Combined Oral Contraceptives

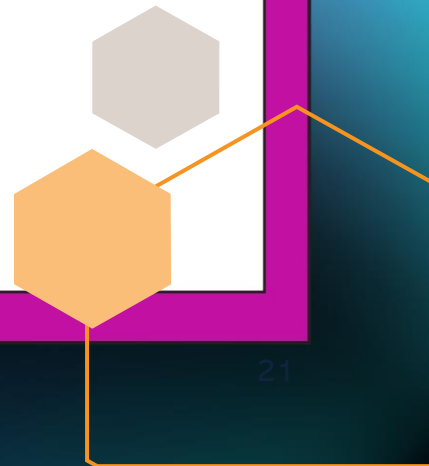
- The U.S Medical Eligibility Criteria (USMEC) for Contraceptive Use, 2016 medical eligibility criteria are separated in 4 categories based on risk vs benefit.

Key:	
1 No restriction (method can be used)	3 Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	4 Unacceptable health risk (method not to be used)

- Some contraindications of combined oral contraceptives :
 - < 21 days post-partum
 - Smoker (> 15 cigg/day)
 - Uncontrolled hypertension (>160/100mmHg)
 - Current breast cancer
 - Migraine with aura
 - Current deep vein thrombosis or pulmonary embolism
 - Vascular disease
 - Current or history ischemic heart disease

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Reversible Methods of Contraception

Hormonal Methods → Progestin Only

- Contains only progestin
 - Norethindrone:
 - Drospirone
 - Norgestrel – 1st OTC oral contraception (approved 07/2023)
- Mechanism of action: thickening cervical mucus, thins uterus lining, suppress LH/FSH
 - Minimal ovulation inhibition
- May be beneficial for patients unable to tolerate and/or use combined hormonal contraceptives
- Failure rate: 4% - 7%
- Effectiveness with typical use: 91%



Reversible Methods of Contraception



Hormonal Methods → Progestin Only → Norgestrel (OTC)

- Norgestrel is **the first over the counter** oral contraceptive approved by the FDA
- Dose: one tablet once daily at the same time each day in the order presented in the blister pack
 - No hormone free interval
- Advantages:
 - No estrogen
 - Safe in breastfeeding
 - Improved dysmenorrhea/endometriosis
 - May be started on any day during the month
- Disadvantages:
 - **Strict timing of administration**
 - late > 3hrs = missed dose
 - back up method needed for the first 48 hrs after the missed dose

Reversible Methods of Contraception



Hormonal Methods → [Progestin Only](#) → [Norgestrel \(OTC\)](#)

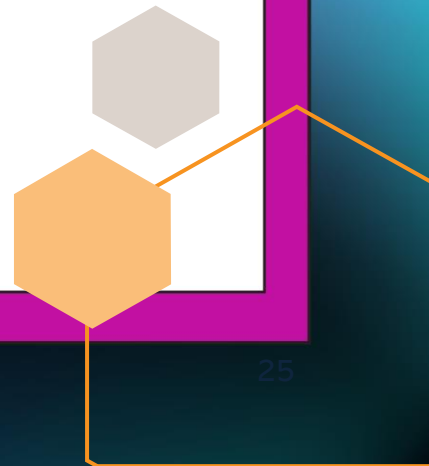
Over-the-Counter Access to Hormonal Contraception Committee Opinion by the by the American College of Obstetricians and Gynecologists

Recommendation and Conclusions:

- The American College of Obstetricians and Gynecologists **supports** over-the-counter access to hormonal contraception without age restrictions.
- Over-the-counter access has continuation rates of hormonal contraception comparable to prescription-only access and has the potential to decrease unintended pregnancy.
- Data support that progestin-only hormonal methods are generally safe and carry no or minimal risk of venous thromboembolism (VTE).
- **Pharmacist-provided contraception** may be a necessary intermediate step to increase access to contraception, but over-the-counter access to hormonal contraception should be the ultimate goal.

Reversible methods of birth control

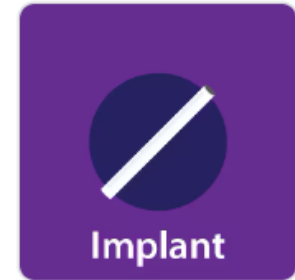
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Reversible Methods of Contraception

Hormonal Methods → [Implant](#)

- Contains only progestin (estrogen free)
 - 68mg etonogestrel
 - Slow release and gradual dose reduction
- Inserted subdermal in the inner upper arm (clinic insertion)
- Mechanism of action: suppress ovulation and thickening of cervical mucus
- Special considerations:
 - Desired long-term contraception
 - Contraindicated in breast cancer and liver disease
 - FDA approved 3 years (effective up to 5 years)
 - Return to fertility 3-4 weeks
- Failure rate: 0.1%



Reversible methods of contraception

- **Hormonal methods**
 - Combined hormonal contraceptives
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- **Emergency Contraception**
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 - IUD
 - Combined oral contraception



Reversible methods of contraception

Hormonal Methods → Injection



- Contains only progestin (estrogen free)
 - Depot Medroxyprogesterone Acetate (DMPA)
 - 150 mg intramuscular or 104 mg subcutaneous (SQ self-administration)
 - Administered every 3 months (max 15-week interval)
- Mechanism of action: suppress ovulation and thickening of cervical mucus
- Special considerations:
 - Contraindicated in breast cancer
 - Safe in breastfeeding
 - Delayed return to fertility 7-9 weeks
- Failure rate: 4%



For accessible version, please see the summary of classifications at <https://www.cdc.gov/contraception/hcp/usmec/>

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC)



Updated in 2024. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see: <https://www.cdc.gov/contraception/hcp/usmec/>. Most contraceptive methods do not protect against STIs. Consistent and correct use of the external (male) latex condom reduces the risk of STIs and HIV. Please see NIH guidelines for up to date recommendations on hormonal contraception and ARVs: <https://clinicalinfo.hiv.gov/en/guidelines/perinatal/prepregnancy-counseling-childbearing-age-overview?view=full#table-3> and <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/drug-interactions-overview?view=full>.

KEY: 1 = No restriction (method can be used) 2 = Advantages generally outweigh theoretical or proven risks 3 = Theoretical or proven risks usually outweigh the advantages 4 = Unacceptable health risk (method not to be used)

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Age	Menarche to <20 yrs:	2		2		1		2		1		2	
	Menarche to <18 yrs:	2		2		1		2		1		2	
	Menarche to <40 yrs:	1		1		1		1		1		1	
Anatomical abnormalities	a. Distorted uterine cavity	4		4									
	b. Other abnormalities	2		2									
Anemia, iron-deficiency		2		1		1		1		1		1	
Benign ovarian tumors	(including cysts)	1		1		1		1		1		1	
Breast disease	a. Undiagnosed mass	1		2*		2*		2*		2*		2*	
	b. Benign breast disease	1		1		1		1		1		1	
	c. Family history of cancer	1		1		1		1		1		1	
	d. Breast cancer [†]												
	i. Current	1		4		4		4		4		4	
ii. Past and no evidence of current disease for 5 years	1		3		3		3		3		3		
Breastfeeding	a. <21 days postpartum					2*		2*		2*		4*	
	b. 21 to <30 days postpartum												
	i. With other risk factors for VTE					2*		2*		2*		3*	
	ii. Without other risk factors for VTE					2*		2*		2*		3*	
	c. 30-42 days postpartum												
i. With other risk factors for VTE					1*		2*		1*		3*		
ii. Without other risk factors for VTE					1*		1*		1*		2*		
d. >42 days postpartum					1*		1*		1*		2*		
Cervical cancer	Awaiting treatment	4	2	4	2	2		2		1		2	
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		1		2		2		2		1		2	
Chronic kidney disease ^a	a. Current nephrotic syndrome	1	1	2	2	2		3		2/4*		4	
	b. Hemodialysis	1	1	2	2	2		3		2/4*		4	
	c. Peritoneal dialysis	2	1	2	2	2		3		2/4*		4	
Cirrhosis	a. Compensated (normal liver function)	1		1		1		1		1		1	
	b. Decompensated (impaired liver function)	1		2		2		3		2		4	
Cystic fibrosis [†]		1*		1*		1*		2*		1*		1*	
Deep venous thrombosis (DVT)/Pulmonary embolism (PE) ^a	a. Current or history of DVT/PVE, receiving anticoagulant therapy (therapeutic dose)	2*		2*		2*		2*		2*		3*	
	b. History of DVT/PE, receiving anticoagulant therapy (prophylactic dose)												
	i. Higher risk for recurrent DVT/PE	2*		2*		2*		3*		2*		4*	
	ii. Lower risk for recurrent DVT/PE	2*		2*		2*		2*		2*		3*	
	c. History of DVT/PE, not receiving anticoagulant therapy												
	i. Higher risk for recurrent DVT/PE	1		2		2		3		2		4	
	ii. Lower risk for recurrent DVT/PE	1		2		2		2		2		3	
d. Family history (first-degree relatives)	1		1		1		1		1		2		
Depressive disorders		1*		1*		1*		1*		1*		1*	

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Diabetes	a. History of gestational disease	1		1		1		1		1		1	
	b. Nonvascular disease												
	i. Non-insulin dependent	1		2		2		2		2		2	
	ii. Insulin dependent [†]	1		2		2		2		2		2	
	c. Nephropathy, retinopathy, or neuropathy [†]	1		2		2		3		2		3/4*	
d. Other vascular disease or diabetes of >20 years' duration [†]	1		2		2		3		2		3/4*		
Dysmenorrhea	Severe	2		1		1		1		1		1	
Endometrial cancer [†]		4	2	4	2	1		1		1		1	
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		2		1		1		1		1		1	
Epilepsy [†]	(see also Drug Interactions)	1		1		1*		1*		1*		1*	
Gallbladder disease	a. Asymptomatic	1		2		2		2		2		2	
	b. Symptomatic												
	i. Current	1		2		2		2		2		3	
ii. Treated by cholecystectomy	1		2		2		2		2		2		
iii. Medically treated	1		2		2		2		2		2		
Gestational trophoblastic disease (GTD) [†]	a. Suspected GTD (immediate postevacuation)												
	i. Uterine size first trimester	1*		1*		1*		1*		1*		1*	
	ii. Uterine size second trimester	2*		2*		1*		1*		1*		1*	
	b. Confirmed GTD												
	i. Undetectable or non-pregnant β-hCG levels	1*	1*	1*	1*	1*		1*		1*		1*	1*
	ii. Decreasing β-hCG levels	2*	1*	2*	1*	1*		1*		1*		1*	1*
	iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2*	1*	2*	1*	1*		1*		1*		1*	1*
	iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4*	2*	4*	2*	1*		1*		1*		1*	1*
Headaches	a. Nonmigraine (mild or severe)	1		1		1		1		1		1	1*
	b. Migraine												
	i. Without aura (includes menstrual migraine)	1		1		1		1		1		1	2*
ii. With aura	1		1		1		1		1		1	4*	
History of bariatric surgery [†]	a. Restrictive procedures	1		1		1		1		1		1	
	b. Malabsorptive procedures			1		1		1		3		3	
History of cholestasis	a. Pregnancy related	1		1		1		1		1		2	
	b. Past COC related	1		2		2		2		2		3	
History of high blood pressure during pregnancy		1		1		1		1		1		2	
History of pelvic surgery	(see also Postpartum [including cesarean delivery])	1		1		1		1		1		1	
HIV	a. High risk for HIV	1*	1*	1*	1*	1		1		1		1	
	b. HIV infection												
	i. Clinically well receiving ARV therapy	1	1	1	1								
ii. Not clinically well or not receiving ARV therapy ^a	2	1	2	1									

Abbreviations: ARV = antiretroviral; C = continuation of contraceptive method; CHC = combined hormonal contraceptive (pill, patch, and ring); COC = combined oral contraceptive; Cu-IUD = copper intrauterine device; DMPA = depot medroxyprogesterone acetate; I = initiation of contraceptive method; LNG-IUD = levonorgestrel intrauterine device; NA = not applicable; POP = progestin-only pill; P/R = patch/ring; SSRI = selective serotonin reuptake inhibitor; STI = sexually transmitted infection; VTE = venous thromboembolism. ^aCondition associated with increased risk as a result of pregnancy. [†]Please see the complete guidance for a clarification to this classification: <https://www.cdc.gov/contraception/hcp/usmec/>.

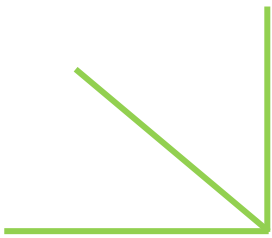
Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC)



Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a. Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b. Elevated blood pressure levels (properly taken measurements)												
	i. Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii. Systolic ≥160 or diastolic ≥100 ²	1*		2*		2*		3*		2*		4*	
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)		1		1		1		2		2		2/3*	
	Ischemic heart disease ² Current and history of	1	2	3	2	3	3	2	3	3	2	3	4
Liver tumors	a. Benign												
	i. Focal nodular hyperplasia	1		2		2		2		2		2	
	ii. Hepatocellular adenoma ²	1		2		2		3		2		4	
	b. Malignant ² (hepatocellular carcinoma)	1		3		3		3		3		4	
Malaria			1		1		1		1		1		1
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)			1		2		2*		3*		2*		3/4*
Multiple sclerosis	a. Without prolonged immobility	1		1		1		2		1		1	
	b. With prolonged immobility	1		1		1		2		1		3	
Obesity	a. Body mass index (BMI) ≥30 kg/m ²	1		1		1		1		1		2*	
	b. Menarche to <18 years and BMI ≥30 kg/m ²	1		1		1		2		1		2*	
Ovarian cancer ²		1		1		1		1		1		1	
Parity	a. Nulliparous	2		2		1		1		1		1	
	b. Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		1		1		1		2		1	
Pelvic inflammatory disease	a. Current	4	2*	4	2*			1		1		1	
	b. Past												
	i. With subsequent pregnancy	1	1	1	1	1		1		1		1	
	ii. Without subsequent pregnancy	2	2	2	2	1		1		1		1	
Peripartum cardiomyopathy ²	a. Normal or mildly impaired cardiac function												
	i. <6 months	2		2		1		2		1		4	
	ii. ≥6 months	2		2		1		2		1		3	
	b. Moderately or severely impaired cardiac function	2		2		2		3		2		4	
Postabortion (spontaneous or induced)	a. First trimester abortion												
	i. Procedural (surgical)	1*		1*		1*		1*		1*		1*	
	ii. Medication	1*		1*		1*		1/2*		1*		1*	
	iii. Spontaneous abortion with no intervention	1*		1*		1*		1*		1*		1*	
	b. Second trimester abortion												
	i. Procedural (surgical)	2*		2*		1*		1*		1*		1*	
	ii. Medication	2*		2*		1*		1*		1*		1*	
iii. Spontaneous abortion with no intervention	2*		2*		1*		1*		1*		1*		
c. Immediate postseptic abortion	4		4		1*		1*		1*		1*		
Postpartum (nonbreastfeeding)	a. <21 days					1		2		1		4	
	b. 21 days to 42 days												
	i. With other risk factors for VTE					1		2		1		3*	
	ii. Without other risk factors for VTE					1		1		1		2	
c. >42 days					1		1		1		1		
Postpartum (including cesarean delivery, breastfeeding, or nonbreastfeeding)	a. <10 minutes after delivery of the placenta	2*		2*									
	b. 10 minutes after delivery of the placenta to <4 weeks	2*		2*									
	c. ≥4 weeks	1*		1*									
	d. Postpartum sepsis	4		4									
Pregnancy			4*		4*		NA*		NA*		NA*		NA*

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Rheumatoid arthritis	a. Not on immunosuppressive therapy	1		1		1		2		1		2	
	b. On immunosuppressive therapy	2	1	2	1	1		2/3*		1		2	
Schistosomiasis	a. Uncomplicated	1		1		1		1		1		1	
	b. Fibrosis of the liver ¹ (if severe, see also Cirrhosis)	1		1		1		1		1		1	
Sexually transmitted infections (STIs)	a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1		1		1		1	
	b. Vaginitis (including Trichomonas vaginalis and bacterial vaginosis)	2	2	2	2	1		1		1		1	
	c. Other factors related to STIs	2*	2	2*	2	1		1		1		1	
Sickle cell disease ¹		2		1		1		2/3*		1		4	
Smoking	a. Age <35	1		1		1		1		1		2	
	b. Age ≥35, <15 cigarettes/day	1		1		1		1		1		3	
	c. Age ≥35, ≥15 cigarettes/day	1		1		1		1		1		4	
Solid organ transplantation ¹	a. No graft failure	1	1	1	1	2		2/3*		2		2*	
	b. Graft failure	2	1	2	1	2		2/3*		2		4	
Stroke ²	History of cerebrovascular accident	1		2		2	3	3		2	3	4	
	a. Varicose veins	1		1		1		1		1		1	
Superficial venous disorders	b. Superficial venous thrombosis (acute or history)	1		1		1		2		1		3*	
	a. Minor surgery without immobilization	1		1		1		1		1		1	
Surgery	b. Major surgery												
	i. Without prolonged immobilization	1		1		1		1		1		2	
	ii. With prolonged immobilization	1		1		1		2		1		4	
	a. Positive (or unknown) antiphospholipid antibodies	1*	1*	2*		2*		3*	3*	2*		4*	
Systemic lupus erythematosus ¹	b. Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*	
	c. Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*	
	d. None of the above	1*	1*	2*		2*		2*	2*	2*		2*	
	Thalassemia		2		1		1		1		1		1
Thrombophilia ¹		1*		2*		2*		3*		2*		4*	
Thyroid disorders	Simple goiter, hyperthyroid, or hypothyroid	1		1		1		1		1		1	
Tuberculosis ² (see also Drug Interactions)	a. Nonpelvic	1	1	1	1	1*		1*		1*		1*	
	b. Pelvic	4	3	4	3	1*		1*		1*		1*	
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation		4*	2*	4*	2*	3*		3*		2*		2*	
Uterine fibroids		2		2		1		1		1		1	
Valvular heart disease	a. Uncomplicated	1		1		1		1		1		2	
	b. Complicated ²	1		1		1		2		1		4	
Vaginal bleeding patterns	a. Irregular pattern without heavy bleeding	1		1		2		2		2		1	
	b. Heavy or prolonged bleeding	2*		1*		2*		2*		2*		1*	
Viral hepatitis	a. Acute or flare	1		1		1		1		1		3/4*	2
	b. Chronic	1		1		1		1		1		1	1
Drug Interactions													
Antiretrovirals (ARVs) used for prevention (PrEP) or treatment of HIV ¹	Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*		2*		2*		2*	3*
	All other ARVs are 1 or 2 for all methods												
Anticonvulsant therapy	a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		2*		1*		3*		3*	
	b. Lamotrigine	1		1		1		1		1		3*	
Antimicrobial therapy	a. Broad-spectrum antibiotics	1		1		1		1		1		1	
	b. Antifungals	1		1		1		1		1		1	
	c. Antiparasitics	1		1		1		1		1		1	
	d. Rifampin or rifabutin therapy	1		1		2*		1*		3*		3*	
SSRIs		1		1		1		1		1		1	
St. John's wort		1		1		2		1		2		2	

Patient Counseling for Hormonal Contraceptives



- Timing – when to start
 - Amenorrhea
 - Postpartum (breastfeeding pr non-breastfeeding)
 - Postabortion
- Need for back-up method
- What to do if late, missed, or delayed dose of oral contraceptive
- Management of bleeding irregularities while using contraception
- What to expect and possible side effects
- Condom use

Patient Case

28-year-old female patient with pertinent medical history of hypertension, anxiety, depression, chronic low back pain, and migraine with aura, among others. Patient was referred to the clinical pharmacist for contraception counseling and recommendations.

Denies smoking and alcohol use.

Patient states doing well, and she wants to have a children in one year

Which is the best contraceptive agent?

- a. Levonorgestrel IUD
- b. Oral tablet norethindrone
- c. Transdermal ethinyl estradiol/etonogestrel
- d. Oral ethinyl estradiol/desogestrel tablet

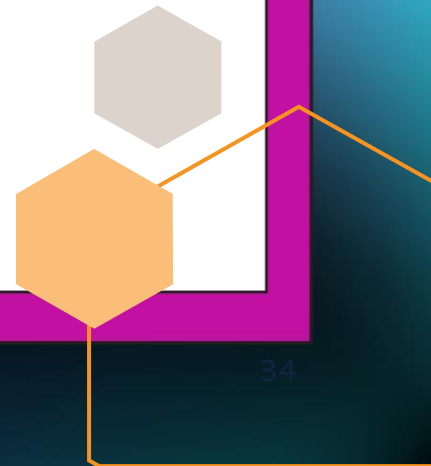
Reversible methods of contraception

- **Hormonal methods**
 - Combined hormonal contraceptives
 - Oral
 - Patch
 - Ring
 - Progestin only pill
 - Implant
 - Injection
- **Intrauterine device contraception**
 - Levonorgestrel intrauterine system
 - Copper T intrauterine device
- **Barrier methods**
 - Diaphragm or cervical cap
 - Sponge
 - Male or female condom
 - Spermicides
- **Fertility awareness-based methods**
- **Lactational amenorrhea methods**
- **Emergency Contraception**
 - Oral
 - IUD
 - Combined oral contraception

Reversible methods of contraception

Hormonal Methods → Emergency Contraception

- Therapy used to prevent pregnancy after unprotected or inadequately protected act of sexual intercourse
 - Under protected
 - Oral contraceptive pill missed or taken incorrectly
 - Barrier method failure
 - Medroxyprogesterone acetate shot is late
 - Contraceptive patch dislodged/expulsion of IUD
- Does not interfere/end pregnancy
 - NOT abortifacient
- Does not interfere with implantation of fertilized egg
- Does not encourage risk sexual behavior



Reversible methods of contraception

Hormonal Methods → [Emergency Contraception](#) → Oral

Levonorgestrel 1.5mg

Mechanism	Dosing	ADRs	Efficacy	Clinical Pearls
<ul style="list-style-type: none">Thickening of cervical mucus and inhibition of ovulation.	<ul style="list-style-type: none">1 tab PO x1	<ul style="list-style-type: none">Irregular mensesNauseaBreast tendernessFatigueDizzinessAbdominal pain	<ul style="list-style-type: none">Failure rate: 2-3%Less efficacious at higher BMIs (>25); may not work BMI >30	<ul style="list-style-type: none">Best if taken within 3 days of unprotected intercourseModerately effective up to 5 daysAvailable over the counterCan resume regular contraceptive immediatelyRecommend back up contraception 7 days after use

Reversible methods of contraception

Hormonal Methods → [Emergency Contraception](#) → [Oral](#)

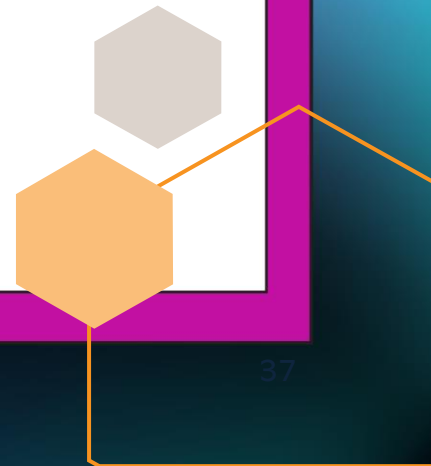
Ulipristal Acetate 30mg

Mechanism	Dosing	ADRs	Efficacy	Clinical Pearls
<ul style="list-style-type: none">• Selective progesterone receptor modulator.• Delays or inhibits ovulation; also inhibits follicular rupture.• May also alter normal endometrium, impairing implantation	<ul style="list-style-type: none">• 1 tab PO x1	<ul style="list-style-type: none">• Suppress menstruation• Abdominal pain• Nausea• Dysmenorrhea• Headache	<ul style="list-style-type: none">• Failure rate: 1.4%	<ul style="list-style-type: none">• Can be used up to 5 days after unprotected intercourse• Resume/start hormonal contraception no sooner than 5 days

Reversible methods of contraception

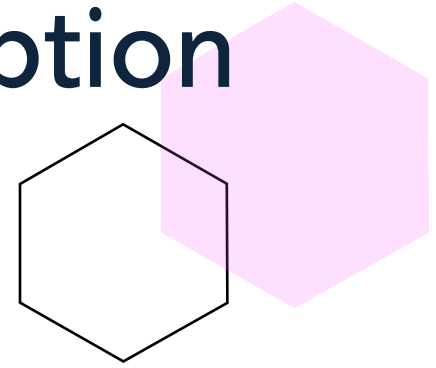
Hormonal Methods → Emergency Contraception → IUD and Combined Oral Contraception

- Copper IUD/LNG 52mg IUD
 - ****Off-label use****
 - Access: MD appointment and insertion by clinician
 - Failure rate 0.1%
 - Considered in obese women
 - Use within 5 days of unprotected intercourse
- Combined oral contraception
 - Access: requires prescription and guidance
 - Infrequently used
 - Use within 72 hours of unprotected intercourse



Reversible methods of contraception

Hormonal Methods → Emergency Contraception



- Who is candidate for emergency contraception?
 - Any person who has unprotected/under protected/uninvited intercourse and wishes to reduce risk of pregnancy
 - No conditions in which risk of EC use outweigh the benefits
 - Patient on oral contraception/advance provision
 - ACOG recommends advance prescription EC be provided to all reproductive age women
 - Does NOT require physical exam, lab testing or pregnancy test prior to dispensing

Reversible methods of contraception

Hormonal Methods → [Emergency Contraception](#)

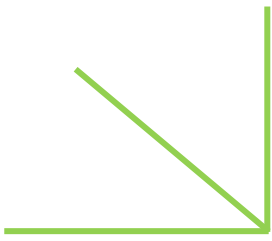
Emergency Contraception Committee Opinion by the by the American
College of Obstetricians and Gynecologists

Recommendations and conclusion (Level A):

- Ulipristal acetate is more effective than the levonorgestrel-only regimen and maintains its efficacy for up to 5 days.
- The levonorgestrel-only regimen for emergency contraception is more effective than the combined hormonal regimen and is associated with less nausea and vomiting.
- Insertion of a copper IUD is the most effective method of emergency contraception.

ACOG = American College of Obstetricians and Gynecologists.

Patient Counseling for Emergency Contraception



- Does not protect against pregnancy with subsequent unprotected intercourse after EC use
- Oral EC may be used multiple times in the same menstrual cycle
- Not adequate form of contraception
- EC doesn't interfere with future fertility
- Start date for regular contraception resumption
- Expected adverse effects
- Notify provider/pharmacist if vomits occurs (may need re-dosing)

Patient Case

26-year-old female patient who comes to community pharmacy and asks about emergency contraception. States she was out in a weekend getaway at Culebra and forgot to take her oral contraceptive pills. She had unprotected intercourse 4 days ago and is concerned about becoming pregnant.

Which is the best recommendation?

- a. Recommend to see her primary care provider for a levonorgestrel 1.5mg prescription
- a. Recommend emergency contraception, may still be effective because she is within the 120-hour time window
- a. Do not recommend emergency contraception and re-start her oral contraceptive regimen as emergency contraceptive



Pregnancy is unlikely if....

No signs/symptoms of pregnancy and one of the following:

- ≤ 7 days after start of normal menses
- No sexual intercourse since start of last normal menses
- ≤ 7 days after spontaneous/induced abortion
- < 4 weeks postpartum
- Fully or nearly fully breastfeeding, amenorrheic and < 6 months postpartum
- Correctly and consistently using reliable contraceptive method

Clinical Decision Tools

Resources for contraception use:

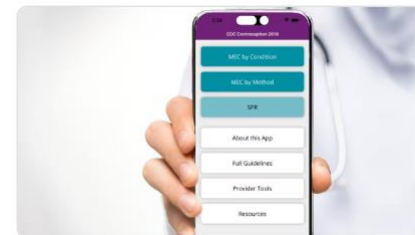
The 2024 U.S. Selected Practice
Recommendations for Contraceptive Use
(U.S. SPR)

The 2024 U.S. Medical Eligibility Criteria for
Contraceptive Use (U.S. MEC)

Contraception APP

US SPR

US MEC



Reproductive Health

Menarche → Menopause

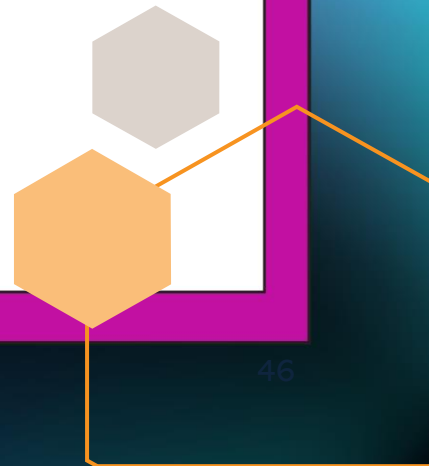
Preventive gynecologic care	Immunizations	Mental health	Female genital mutilation	Pregnancy and lactation	Uterine fibroids
Anatomy	Nicotine	Sexually transmitted infections	Abortion	Infertility	Gynecologic Cancer
Menstruation	Healthy relationships and consent	Contraception and pregnancy prevention	Hormone therapy and menopause	Endometriosis	Interstitial Cystitis

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Medication Abortion

Medication Abortion

- What is medication abortion?
 - Therapy that involves the use of pharmacological agents rather than uterine aspiration to induce abortion
 - FDA approved medications include mifepristone and misoprostol
 - Medications can be provided up to 70 days (10 weeks) of gestation
 - Combined regimen is preferred over misoprostol-only regimen



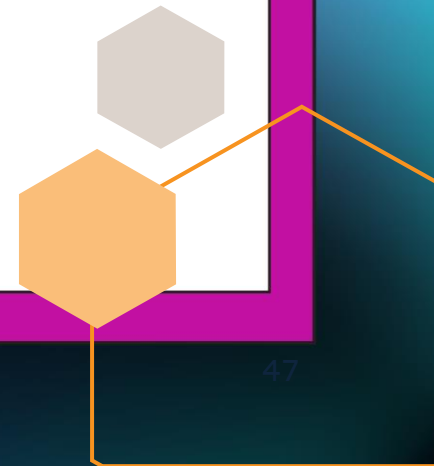
Medication Abortion Alternatives

1. Mifepristone 200mg

- Mechanism of action: Selective progesterone receptor modulator that binds to the progesterone
 - Causes decidual necrosis, cervical softening, and increased uterine contractility and prostaglandin sensitivity
 - Restriction under **REMS** program
 - The ACOG advocates for the removal of REMS restriction

2. Misoprostol 800mg:

- Mechanism of action: prostaglandin E1 analogue that causes cervical softening and uterine contractions.



Medication Abortion Alternatives

Table 1. Medication Abortion Regimens Up to 70 Days of Gestation

Regimen	Mifepristone Dose	Misoprostol Dose	Interval Between Drugs
Preferred			
Combination, FDA-approved*	200 mg (orally)	800 micrograms (buccally)	24–48 h
Combination, WHO recommended†	200 mg (orally)	800 micrograms (vaginally, sublingually, or buccally)	24–48 h
Alternative			
Misoprostol only	N/A	800 micrograms (vaginally, sublingually, or buccally)	Repeat every 3 h for up to 3 doses‡

Abbreviations: h, hours; FDA, U.S. Food and Drug Administration; N/A, not applicable; WHO, World Health Organization.

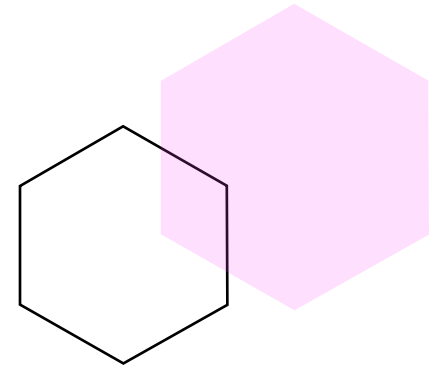
*U.S. Food and Drug Administration. Mifeprex (mifepristone) information. Postmarket drug safety information for patients and providers. Silver Spring, MD: FDA; 2018. Available at: <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm>. Retrieved March 3, 2020.

†World Health Organization. Medical management of abortion. Geneva: WHO; 2018. Available at: <https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1>. Retrieved March 3, 2020.

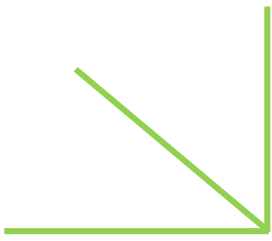
‡Although studies typically use no more than three doses for the initial treatment regimen, the World Health Organization guidelines do not specify a maximum number of misoprostol doses (Raymond EG, Harrison MS, Weaver MA. Efficacy of misoprostol alone for first-trimester medical abortion: a systematic review. *Obstet Gynecol* 2019;133:137-47 and World Health Organization. Medical management of abortion. Geneva: WHO; 2018. Available at: <https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1>. Retrieved March 3, 2020).

Medication Abortion

- Who is candidate?
 - Most patients at 70 days of gestation or less who desire abortion
 - Medication abortion over uterine aspiration is preferred:
 - Uterine fibroids
 - Congenital uterine abnormalities
 - Multiple gestation pregnancy is not a contraindication
 - NOT recommended:
 - Confirmed or suspected ectopic pregnancy
 - IUD in place
 - Current long-term systemic corticosteroid therapy
 - Intolerance/allergy to any misoprostol/mifepristone



Patient Counseling for Medication Abortion



- Pain management
 - Self-resolving ~ 24 hrs
 - NSAIDS are drug of choice
- Medication abortion does not have an adverse effect on future fertility or pregnancy outcomes
- Contraception initiation (if desired)
 - Almost all contraceptive methods can be safely initiated immediately on day 1 of medication abortion
 - All contraceptives can safely be initiated after successful medication abortion

Medication Abortion

Medication Abortion Up to 70 Days of Gestation

Committee Opinion by the by the American College of Obstetricians and Gynecologists (ACOG)

Recommendations and Conclusions (Level A):

- Combined mifepristone–misoprostol regimens are recommended as the preferred therapy for medication abortion because they are significantly more effective than misoprostol-only regimens. If a combined mifepristone–misoprostol regimen is not available, a misoprostol-only regimen is the recommended alternative.
- Clinicians should counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks.
- Any clinician with the skills to screen patients for eligibility for medication abortion and to provide appropriate follow-up can provide medication abortion.

Medication Abortion

Medication Abortion Up to 70 Days of Gestation
Committee Opinion by the by the American College of Obstetricians and Gynecologists (ACOG)

Recommendations and Conclusions (Level A):

- Patients can safely and effectively use mifepristone at home for medication abortion.
- Patients can safely and effectively self-administer misoprostol at home for medication abortion.
- Nonsteroidal anti-inflammatory drugs are recommended for pain management in patients who undergo a medication abortion.

Medication Abortion

Medication Abortion Up to 70 Days of Gestation
Committee Opinion by the by the American College of Obstetricians and Gynecologists (ACOG)

Recommendations and Conclusions (Level A):

- Routine in-person follow-up is not necessary after uncomplicated medication abortion. Clinicians should offer patients the choice of self-assessment or clinical follow-up evaluation to assess medication abortion success. If medically indicated or preferred by the patient, follow-up evaluation can be performed by medical history, clinical examination, serum human chorionic gonadotropin (hCG) testing, or ultrasonography.
- If an ultrasound examination is performed at follow-up after medication abortion, the sole purpose is to determine whether the gestational sac is present or absent. The measurement of endometrial thickness or other findings do not predict the need for subsequent uterine aspiration.

Reproductive Care

Menarche → Menopause

Preventive gynecologic care	Immunizations	Mental health	Female genital mutilation	Pregnancy and lactation	Uterine fibroids
Anatomy	Nicotine	Sexually transmitted infections	Abortion	Infertility	Gynecologic Cancer
Menstruation	Healthy relationships and consent	Contraception and pregnancy prevention	Hormone therapy and menopause	Endometriosis	Interstitial Cystitis



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Pregnancy and Lactation

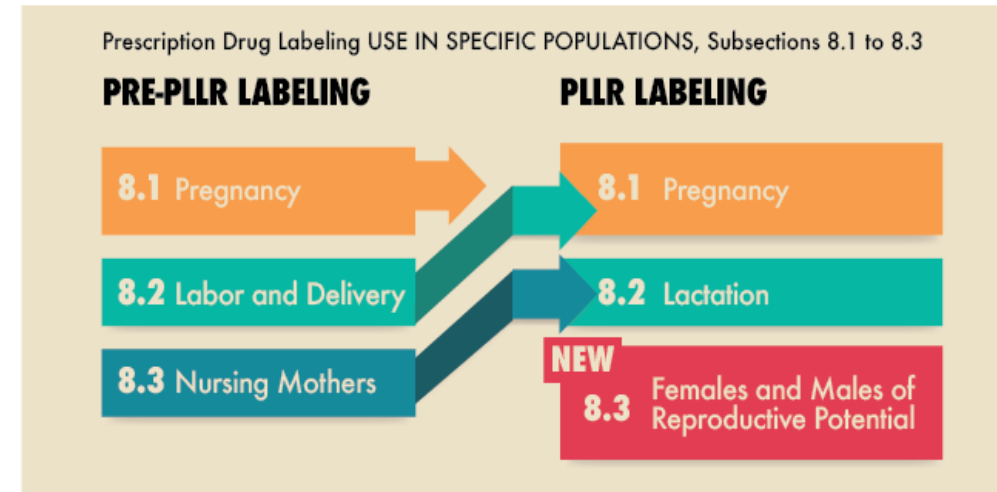
Pregnancy and Lactation

- What we know about safe and effective use of medication during pregnancy and lactation?
 - Are commonly used in pregnancy
 - No robust data or information about known or potential maternal or fetal harm
 - Limited medications approved by the FDA has sufficient data to determine risk of congenital anomalies
 - Risk vs benefit of medications use in child-bearing age is key
 - patient-centered and share-decision process
 - Medications that are safe in pregnancy are not always safe in breast-feeding mothers



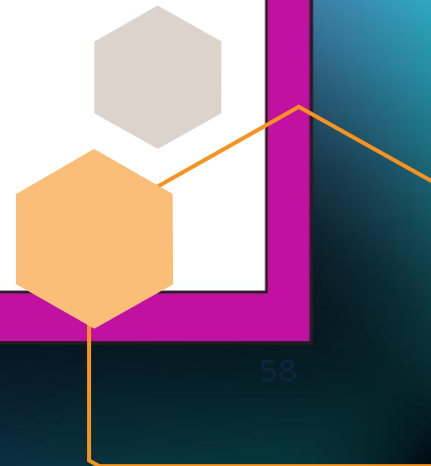
Pregnancy and Lactation

- 2014 – FDA published the *Pregnancy and Lactation Rule (PLLR)*
- Requires
 - summary of the risks of using a drug during pregnancy and lactation
 - discussion of the data supporting that summary
 - relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation
- Removes letter categories (A,B,C,D and X)



Pregnancy and Lactation

- Pregnancy and medications considerations:
 - Placental barrier and passive diffusion – drug specific factors
 - Protein binding
 - Lipophilicity
 - Size
 - Oral bioavailability
 - Half life
 - Avoid drug when possible
 - Topical therapy preferred over systemic
 - Medication exposure risk to consider
 - Teratogenesis
 - Neonatal symptoms
 - Long term effects



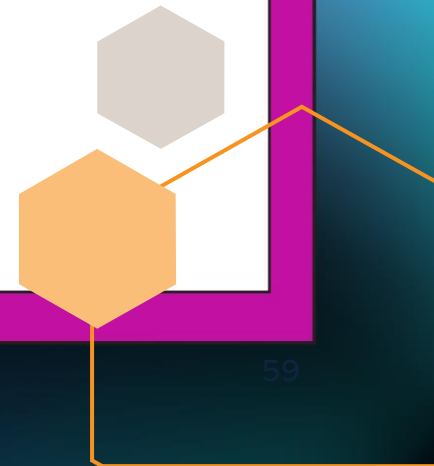
Pregnancy and Lactation

Some known teratogens:

- Angiotensin-converting enzyme inhibitor
- Angiotensin II receptor blockers
- Isotretinoin
- Methotrexate
- Statin
- Tetracyclines
- Thalidomide
- Warfarin

Some with known pregnancy risk:

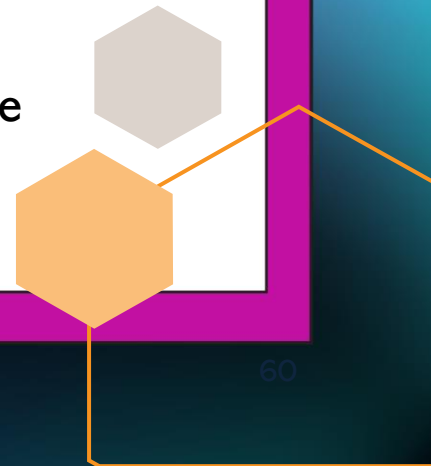
- Aspirin
- Diuretics
- Narcotic analgesics
- NSAIDS
- B-blockers



Pregnancy and Lactation

Lactation and medication considerations:

- Passive diffusion
- How to select a medication?
 - Shortest half-life
 - Highest protein binding
 - Well studied in infants
 - Poorest bioavailability
 - Less hydrophilic
 - Daily dosing
 - schedule it with infant bedtime
 - if multiple day dosing is required, advise to breast feed immediately before dose



Pregnancy and Lactation

Some drugs not to be used in breast-feeding according to *American Academy of Pediatrics*:

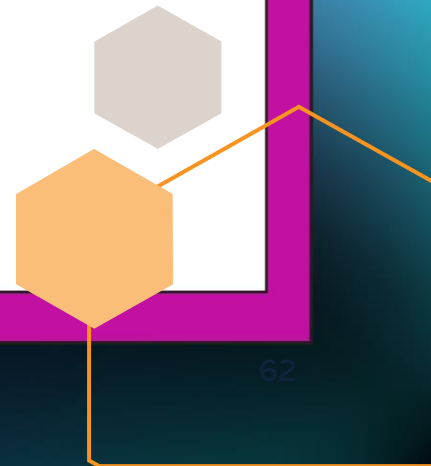
- Antineoplastic agents
- Bromocriptine
- Ergotamine
- Lithium
- Methotrexate
- Radiopharmaceuticals



Pregnancy

Complications in pregnancy and management:

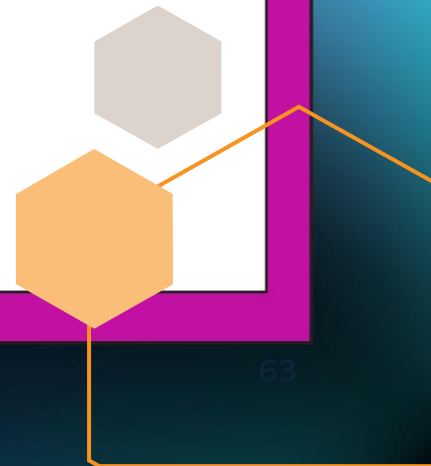
- Morning sickness:
 - First line: lifestyle modifications
 - Second line: doxylamine + pyridoxine (B6)
 - Third line: metoclopramide, phenothiazines, diphenhydramine, ondansetron
- Heartburn:
 - First line: lifestyle modifications
 - Second line: antacids (Mg-, Al-, or Ca-)
 - Third line: sucralfate, proton pump inhibitor, H-2 receptor antagonist
- Constipation:
 - First line: lifestyle modifications
 - Second line: bulk laxatives, stool softeners
 - Drugs to avoid mineral oil



Pregnancy

Complications in pregnancy and management:

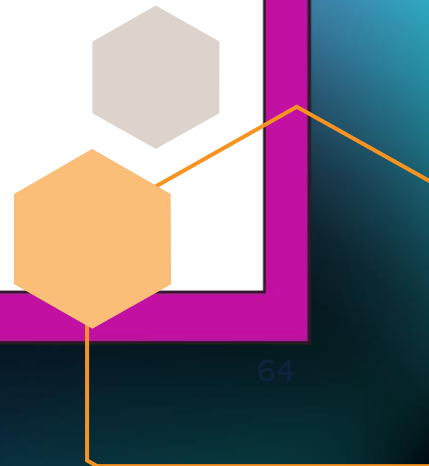
- Headache:
 - First line: lifestyle modifications + 1000mg acetaminophen
 - Second line: APAP/caffeine, diphenhydramine, metoclopramide
 - Drugs to avoid aspirin, NSAIDS, triptans, ergotamine
- Hemorrhoids:
 - First line: lifestyle modifications, stool softener



Pregnancy

Management of chronic conditions during pregnancy:

- Diabetes mellitus:
 - First line: lifestyle modifications
 - Second line: insulin
 - Second line: metformin, glyburide
 - Drug to avoid: GLP1-Ra associated with increased risk of birth defects in animal studies
- Hypertension:
 - First line: labetalol and methyldopa
 - Second line: nifedipine SA, hydrochlorothiazide
 - Drugs to avoid: ACEi, ARB, atenolol



Patient Case

25-year-old female veteran women request appointment with clinical pharmacist to assess her medications since she wants to get pregnant soon. Past medical history of obesity BMI 28 kg/m², hypertension, seasonal allergy, and constipation, among others. Active medications include multivitamins, fluticasone nasal spray, hydrochlorothiazide and lisinopril.

VS at clinic: 119/73 mmHg p61

Which is the best option to treat her hypertension while she is trying to conceive?

- a. Continue lisinopril
- a. Discontinue lisinopril and all other medications
- a. Discontinue lisinopril and start labetalol
- a. Discontinue hydrochlorothiazide and add atenolol

Pregnancy and Lactation

Key takeaways:

1. Individualized approach
2. Share decision process considering clinical practice, available data, and patient's preference
3. Close monitoring is generally recommended to reduce maternal and fetal complications during pregnancy
 - Access?
4. Lifestyle modifications is generally considered first line treatment
5. Start low and go slow with medications
6. Consider the risk to the mother and infant if the disease state is left untreated



Clinical Decision Tools

Resources for medication use during pregnancy and regarding lactation:

Reprotox

**MotherToBaby
Fact Sheets**

TERIS
(Teratogen Information System)

**Drugs in
Pregnancy and
Lactation**

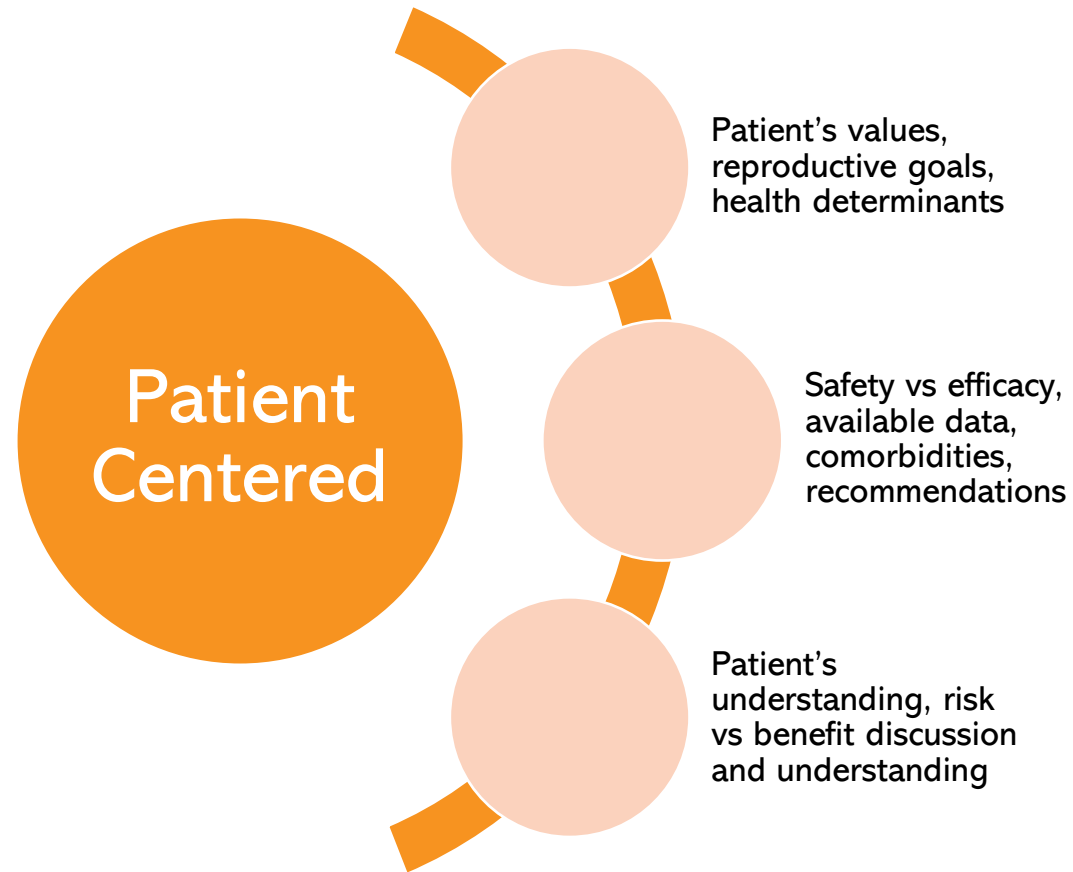
LactMed

Package Insert

UptoDate

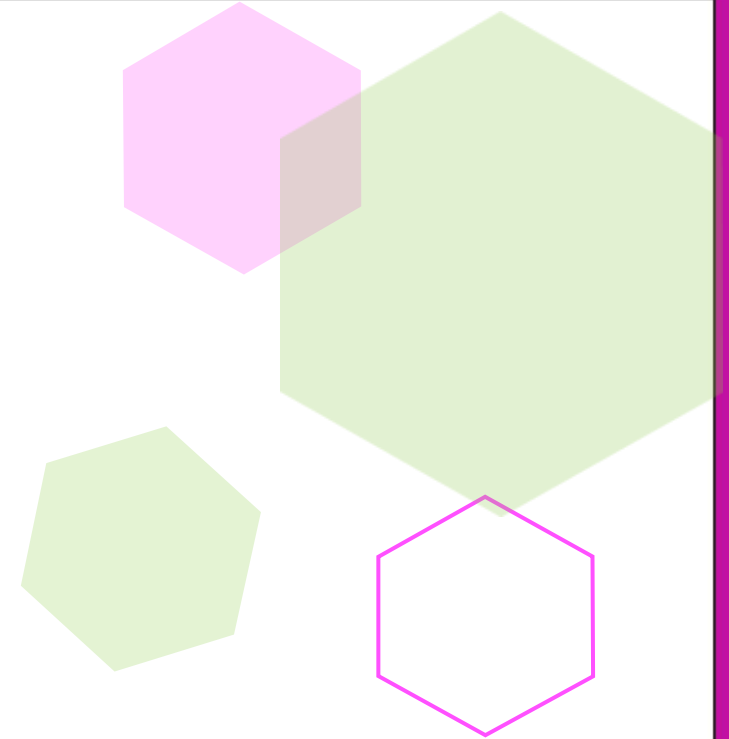
OTIS
(Organization of Teratology
Information Specialist)

Shared Decision Making

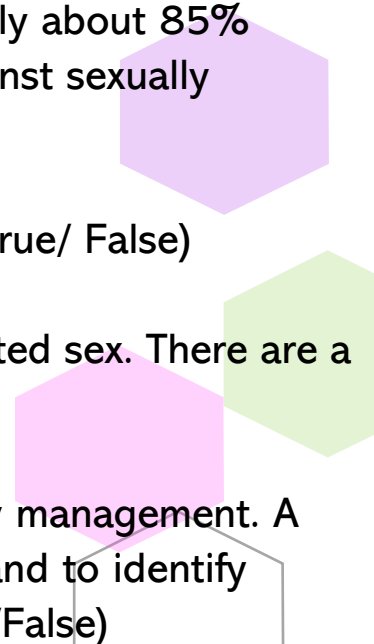


Conclusion

- Expanding pharmacy practice and pharmacy team is an important and critical resource to improve access of women health reproductive care and reduce health disparities.
 - Direct patient care
 - Leadership
 - Public policies
 - Informatics
- Awareness is key



POST TEST QUESTIONS

1. By including a package of women's preventive services, access through the ACA includes Pap tests, mammograms, and some contraceptives without copays for women which improves comprehensive care and access for all women and may ultimately help reduce reproductive health disparities. (True/False)
 2. There are several over the counter (OTC) birth control options; external condoms are typically about 85% effective for preventing pregnancy and are the only OTC contraceptive that can protect against sexually transmitted infections (STIs). (True/False)
 3. Norgestrel (Optill) is an OTC birth control pill that's about 91% effective with typical use. (True/ False)
 4. Emergency contraception (EC) is a type of birth control to use shortly after having unprotected sex. There are a few EC options, but only levonorgestrel (Plan B One-Step) is available OTC. (True/False)
 5. The delivery of preconception care can easily be incorporated as part of medication-therapy management. A medication review can be conducted to ensure optimal management of chronic conditions and to identify medications that may potentially pose a risk to the fetus if a pregnancy should occur. (True/False)
- 
- A decorative graphic consisting of several overlapping hexagons in various colors (purple, pink, green, light blue) is located on the right side of the slide, partially overlapping the text of the questions.

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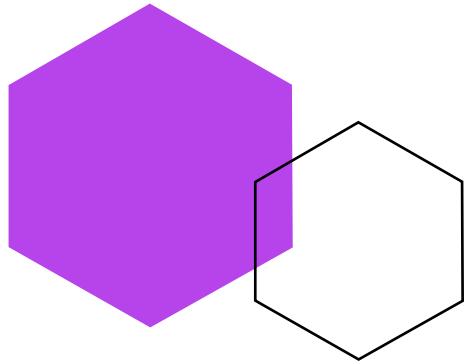
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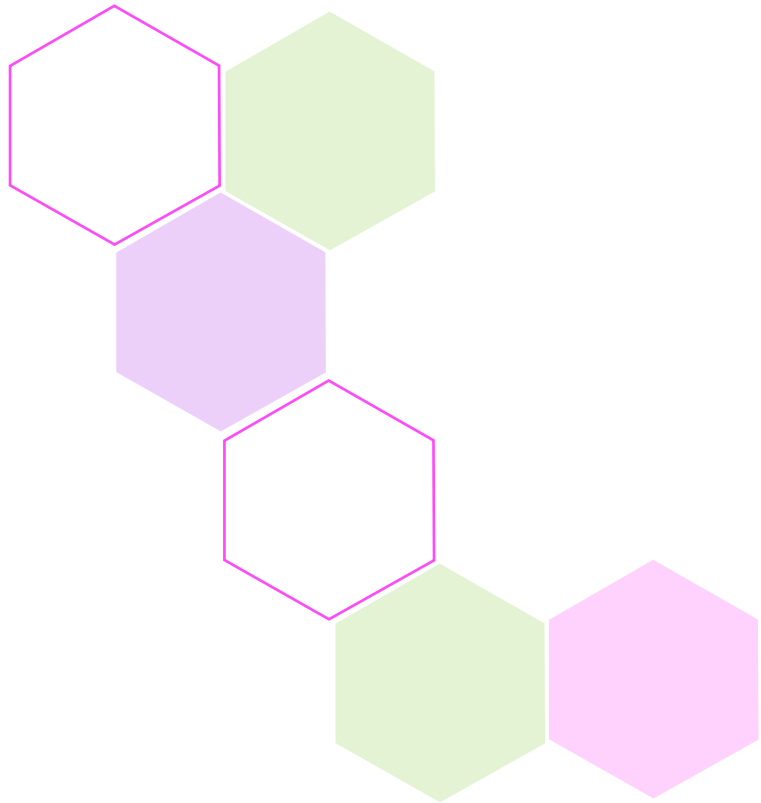


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Thank you!

Contact Information:

stephanie.pagan-rodriquez@va.gov

Please reach out if you have ANY questions!