PHARMACISTS' ROLE IN WOMEN'S HEALTH

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DISCLOSURES

None to disclose

PHARMACIST OBJECTIVES

- Discuss the history of oral contraceptives and the different options available
- Outline the best treatment option for a given patient
- Discuss the pharmacist's role in women's health care
- Describe the recent federal and state changes to providing women's health care
- Explain how different states are implementing new changes and how this affects pharmacists
- Identify the benefits to patient care with the advancements

TECHNICIAN OBJECTIVES

- Discuss the history of oral contraceptives and the different options available
- Discuss the technician's role in assisting the pharmacist
- Describe the recent federal and state changes to providing women's health care
- Explain how different states are implementing new changes and how this affects technicians
- Identify the benefits to patient care with the advancements

AGENDA

- Introduction
- Pharmacist Role
- Background on state and federal changes
- Illinois Updates
- Rolling out new legislation
- Benefits & Barriers
- Future Impact

PRE-ASSESSMENT

- What is your comfort level in prescribing oral contraception?
- How well prepared are you in dispensing?
- How much training are you willing to do? How many hours of training is reasonable?
- What type of training?
 - Self study, in person, combination?

Question 1

Currently how many states allow pharmacists to prescribe hormonal contraception?

- A. 13
- B. 29
- c. 42
- D. All states and the District of Columbia allow pharmacists to prescribe hormonal contraception

Question 2 Select all that apply

In Illinois, a pharmacist can dispense hormonal contraceptives:

- A. As part of a collaborative practice agreement
- B. As long as the patient has completed a self screening assessment
- C. For a period up to 12 months
- D. As long as the prescriber has completed a training program through ACPE
- E. For any patient, regardless of health status

Question 3 Select All that Apply

Which resource can be consulted to determine if a patient is eligible for hormonal contraception?

- A. No tools necessary, only one treatment option
- B. CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use
- C. Patient Self Assessment Form
- D. Pharmacist's Personal Clinical Knowledge

PATIENT CASE MEET KE

- K E is a 27 yof who has been coming to your pharmacy once or twice monthly for levonorgestrel 1.5 mg for the past 6 months.
- What questions do you have for K E?
 - What are KR reproduction goals? (ie time to return to ovulation)
 - Health history
 - Other medications/disease states
 - Patient Preferences
 - route of administration
 - length of action
 - Hormonal component

USE OF CONTRACEPTIVES

Contraception is defined as any means of preventing pregnancy

2017-2019 Data from National Survey of Family Growth

- Approx. 65.3% of women between ages 15-49 use contraception
 - Female sterilization 18.1%
 - Oral contraceptives 14.0%
 - Long-acting reversible contraception 10.4%
 - Male condom 8.4%
 - Injection, vaginal ring, or transdermal patch 3.1%
- 38% of pregnancies were reported as unplanned/unwanted

SOCIAL CONDITIONS PRIOR TO LEGALIZATION OF ANY CONTRACEPTIVE METHOD

- Margaret Sanger was a nurse angered by the fact that:
 - those with more money had fewer children and better health
 - By law only doctors (not nurses) could discuss birth control
 - Barrier methods only ones available
 - Condoms and diaphragms
- Led to her creation of Planned Parenthood in 1916
- Federal and state law prohibited info to exist in print
- 1914 published "birth control" for 1st time in newspaper The Woman Rebel
- New York State Court of Appeals broadened the law's definition of disease to include the risks of pregnancy and thus began the process of legalizing contraception

THE MAKING OF "THE PILL"

- Carl Djerassi chemist who first synthesized a steroid oral contraceptive in October 1951
- Gregory Pincus encouraged cell division in rabbit embryos
 - Subsequently not given tenure at Harvard
- Worked with Dr. John Rock an OBGYN
 - Clinical trials done in Puerto Rico clinics
 - Involuntary patient population
 - Many RNs at clinic involved in trial quit due to side effects
 - Headache, nausea, cervical erosion, breakthrough bleeding, dizziness
- Approved May 11, 1960 one of main ingredients Enovid (already approved for severe menstrual bleeding)
 - first OCP to be approved by FDA, but use was limited to 2 years
 - First on the market in June 1957

BARRIERS AND TRIUMPHS

Barrier

- Religious entities like Roman Catholic Church
 - Led to marketing as cycle regulator as opposed to pregnancy prevention
- Worries that sexual activities of young people would increase
- Sex was considered a private activity
- Clinical trials done in Puerto Rico and Mexico lacking informed consent
- Conservative companies not wanting to manufacture such a drug

Triumphs

- Decoupling of sexual activities and reproduction
- Sex was made more public
- Contraceptive method that was independent of sexual activity
 - Contraception was a private activity
- More women attended and graduated from college

CONTEMPORARY DEVELOPMENTS

- Still puts burden of contraception the on female
- Lack of need for a menses
- Continual development of lower concentration of hormones in pills
 - 2012 average progestin dose was 0.1 to 3 mg progestin and 20 to 50 mcg estrogen
- Increase in alternative dosage forms vs. just oral
 - including extended regimens
 - patches
 - vaginal inserts
- Male Pill?
 - WHO Group on Fertility Control- Male Task Force

TYPES OF HORMONAL CONTRACEPTIVES

- Oral contraceptives--21 or 28 day
- Transdermal Patches--wear weekly for 3 weeks and off 1 week
- Vaginal Rings--insert 1 ring for 21 days and remove for 7
- Injections--monthly

Often determined by patient preference, history, adherence, etc.

In the state of Illinois, pharmacists may dispense any of these forms

HORMONAL COMPONENTS

Estrogens

- Inhibits ovulation by suppressing FSH & LH
- Always in combination with progestin
 - Can be monophasic or multiphasic
- Forms
 - Vaginal Ring
 - Tablets
 - Transdermal Patch

Progesterones

- Inhibits ovulation by suppressing LH
- Can be monotherapy
 - Only monophasic
- Forms
 - Tablet
 - Intrauterine device (IUD)
 - Intramuscular Injection
 - Implant
- Administration timing is very important

PHARMACIST ROLE

- Counseling
 - Starting contraceptives (Sunday start vs day 1) Adherence and administration

 - Missed doses and using backup methods Venous Thromboembolism risk Side Effects

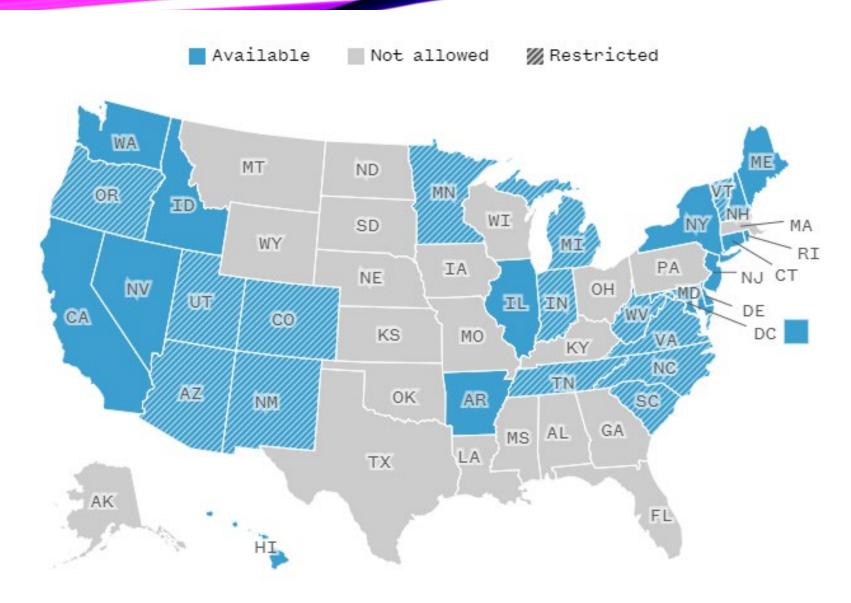
 - Drug interactions
- Evaluation of therapy & use
 - Primary use: Preventing pregnancy
 - Secondary Uses: Dermatological improvement, PMDD, menstrual suppression, regulation of cycle, risk reduction of certain cancers, PCOS management, reduction of menstrual bleeding
- Access to care

STATE AND FEDERAL CHANGES

- The Dobbs Decision--Brought the decision of reproductive health services back to the state level
 - Abortion banned in 14 states.
 - Limited to 6-12 weeks in 3 states
 - Limited to 15-22 weeks in 8 states
 - Legal beyond 22 weeks in 25 states including DC
 - Illinois falls here

Comparing states

- Oregon and California were first states to allow RPH prescribing of contraceptives in 2016
- Currently, 29 states allow pharmacist dispensing
- Some with restrictions--such as age, forms, duration, etc.



Where Pharmacists can prescribe contraceptives

ROLLING OUT NEW LEGISLATION-ILLINOIS

- One of the most accessible states for women's health
- Pharmacists in Illinois can dispense hormonal contraceptives to a patient through a standing order
- Pharmacist may dispense no more than 12 month supply
- Must complete an educational training program accredited through the ACPE
- Provide patient with self-screening risk assessment
- Use CDC's Medical Eligibility Criteria for Contraceptive Use
- Pharmacist will use results of screening and their own professional/clinical judgement to determine treatment or necessity for referral to another healthcare provider
- Will require CE, training, etc.

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



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	Menarche	Menarche	Menarche	Menarche	Menarch
		to	to	to	to	to	to
		<20 yrs: 2	<20 yrs: 2	<18 yrs: 1	<18 yrs: 2	<18 yrs: 1	<40 yrs:
		≥20 yrs:1	≥20 yrs:1	18-45 yrs:1	18-45 yrs:1	18-45 yrs:1	≥40 yrs:
				>45 yrs:1	>45 yrs:2	>45 yrs:1	
Anatomical	a) Distorted uterine cavity	4	4				
abnormalities	b) Other abnormalities	2	2				
Anemias	a) Thalassemia	2	1	1	1	1	1
	b) Sickle cell disease‡	2	1	1	1	1	2
	c) Iron-deficiency anemia	2	i	i	i	i	1
Benign ovarian tumors	(including cysts)	1	1	i	i	i	i
Breast disease	a) Undiagnosed mass	1	2	2*	2*	2*	2*
or cast discase	b) Benign breast disease	1	1	1	1	1	1
	c) Family history of cancer	1	1	1	1	1	i
	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*	1*	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		1	2	2	2	1	2
neoplasia						1	
Cirrhosis	a) Mild (compensated)	1	1	1	1	1	1
	b) Severe [‡] (decompensated)	1	3	3	3	3	4
Cystic fibrosis [‡]		1*	1*	1*	2*	1*	1*
Deep venous thrombosis							
(DVT)/Pulmonary	anticoagulant therapy						
embolism (PE)	i) Higher risk for recurrent DVT/PE	1	2	2	2	2	4
	ii) Lower risk for recurrent DVT/PE	1	2	2	2	2	3
	b) Acute DVT/PE	2	2	2	2	2	4
	 c) DVT/PE and established anticoagulant therapy for at least 3 months 						
	i) Higher risk for recurrent DVT/PE	2	2	2	2	2	4*
	ii) Lower risk for recurrent DVT/PE	2	2	2	2	2	3*
	d) Family history (first-degree relatives)	1	1	1	1	1	2
	e) Major surgery						
	i) With prolonged immobilization	1	2	2	2	2	4
	ii) Without prolonged immobilization	1	1	1	1	1	2
	f) Minor surgery without immobilization	1	1	1	1	1	1
Depressive disorders		1*	1*	1*	1*	1*	1*

Condition	Sub-Condition		IUD	LNG-IUD		Implant	DMPA	POP	CHC	
		- 1	С	1	С	I C	I C	I C	I C	
Diabetes	a) History of gestational disease	1	1	1		1	1	1	1	
	b) Nonvascular disease									
	i) Non-insulin dependent	1	1	2		2	2	2	2	
	ii) Insulin dependent	1	1	2		2	2	2	2	
	c) Nephropathy/retinopathy/neuropathy [‡]	1	1	2		2	3	2	3/4*	
	d) Other vascular disease or diabetes of >20 years' duration [‡]	1	1	2	2	2	3	2	3/4*	
Dysmenorrhea	Severe	-	2	1	1	1	1	1	1	
Endometrial cancer [‡]		4	2	4	2	1	1	1	1	
Endometrial hyperplasia				-	_	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) Symptomatic									
	i) Treated by cholecystectomy	•	1	- 2	2	2	2	2	2	
	ii) Medically treated		1	- 2	2	2	2	2	3	
	iii) Current		1	2		2	2	2	3	
	b) Asymptomatic	-	1			2	2	2	2	
Gestational trophoblastic disease [‡]										
	i) Uterine size first trimester	1	1*	1	*	1*	1*	1*	1*	
	ii) Uterine size second trimester		2*	2*		1*	1*	1*	1*	
	b) Confirmed GTD									
	i) Undetectable/non-pregnant ß-hCG levels	1*	1*	1*	1*	1*	1*	1*	1*	
	ii) Decreasing ß-hCG levels	2*	1*	2*	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*	
	 iv) Persistently elevated ß-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease 	4*	2*	4*	2*	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	2*	
	ii) With aura	1		1		1	1	1	4*	
History of bariatric	a) Restrictive procedures	1	1	1		1	1	1	1	
surgery [‡]	b) Malabsorptive procedures	1	1	1	1	1	1	3	COCs: 3 P/R: 1	
History of cholestasis	a) Pregnancy related		1	1	1	1	1	1	2	
	b) Past COC related	1	1		2	2	2	2	3	
History of high blood pressure during pregnancy		1		1		1	1	1	2	
History of Pelvic surgery		1	1	1		1	1	1	1	
HIV	a) High risk for HIV	1*	1*	1*	1*	1	1	1	1	
	b) HIV infection					1*	1*	1*	1*	
	i) Clinically well receiving ARV therapy	1	1	1	1	If on tr	eatment, se	e Drug Intera	actions	
	ii) Not clinically well or not receiving ARV	2	1	2	1	If on tr	eatment co	e Drug Inter	actions	
	therapy*	-				If on treatment, see Drug Interactions				

Abbreviations: ARV = antiretroviral; C=continuation of contraceptive method; CHC=combined hormonal contraception (pill, patch, and, ring); COC=combined oral contraceptive; Cu-ILU=copper-containing intrauterine device; DMR = depot medioayprogesterone acetate; 1=initiation of contraceptive method; ING-IUD=levonorgestref-releasing intrauterine device; NA=not spificable; POP=progestrie-only pill; P/R=patch/ring; SSRI=selective serotonin reputate inhibitor; \$ Condition than to increased risk as a result of pregnancy. *Please see the complete guidance for a clarification to this classification: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm.

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



Condition	ion Sub-Condition Cu-IUD		IUD	LNG-IUD		Implant		DMPA		POP		CHC
		1	С	- 1	C	ı	C	- 1	С	- 1	С	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‡		1*		2*		2*		3*		2*	4*
	c) Vascular disease		1*		2*	2*		3*		2*		4*
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	1			1		1		2		2	2/3*
Ischemic heart disease‡	Current and history of		1	2 3		2	3		3	2 3		4
Known thrombogenic	,					_						
mutations [‡]			1*		2*		2*		2*		2*	4*
Liver tumors	a) Benign											
	i) Focal nodular hyperplasia		1		2		2		2		2	2
	ii) Hepatocellular adenoma‡		1		3		3		3		3	4
	b) Malignant ⁺ (hepatoma)		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) With prolonged immobility		1		1		1		2		1	3
	b) Without prolonged immobility		1		1		1		2		1	1
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/m²	1		1			1	2			1	2
Ovarian cancer [‡]		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	a) Past											
disease	i) With subsequent pregnancy	1	1	1	1		1		1		1	1
	ii) Without subsequent pregnancy	2	2	2	2		1		1		1	1
	b) Current	4	2*	4	2*		1		1		1	1
Peripartum	a) Normal or mildly impaired cardiac				_	$\overline{}$				$\overline{}$		
cardiomyopathy [‡]	function											
	i) <6 months	2		2		1		1			1	4
	ii) ≥6 months	2		2		1		1			1	3
	b) Moderately or severely impaired cardiac function	2		2		2			2		2	4
Postabortion	a) First trimester		1*	1*			1*		1*		1*	1*
	b) Second trimester	2*		2*		1*		1*			1*	1*
	c) Immediate postseptic abortion	4		4				1*			1*	1*
Postpartum	a) <21 days						1		1		1	4
(nonbreastfeeding women)	b) 21 days to 42 days											
	i) With other risk factors for VTE						1		1		1	3*
	ii) Without other risk factors for VTE						1		1		1	2
	c) >42 days						1		1		1	1
Postpartum (in breastfeeding or non- breastfeeding women,	a) <10 minutes after delivery of the placenta											
	i) Breastfeeding	1*			2*							
	ii) Nonbreastfeeding	1*			1*							
including cesarean delivery)	b) 10 minutes after delivery of the placenta to <4 weeks	2*			2*							
	c) ≥4 weeks	1*			1*							
	d) Postpartum sepsis		1	4								

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant	DMPA		POP	CHC	
	1 0		С	1	С	I C	I C		I C	I C	
Pregnancy		4	*	4	*	NA*	N	A*	NA*	NA*	
Rheumatoid	a) On immunosuppressive therapy	2 1		2 1		1	2/3*		1	2	
arthritis	b) Not on immunosuppressive therapy	_	-	1		1	2		1	2	
Schistosomiasis	a) Uncomplicated	_	i	_	1	1		1	1	1	
	b) Fibrosis of the liver [‡]		i	_	i	1	i		1	i	
Sexually transmitted diseases (STDs)	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 relating to STDs	2*	2	2*	2	1		1	1	1	
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	a) Complicated	3	2	3	2	2		2	2	4	
transplantation [‡]	b) Uncomplicated		2	- :	2	2		2	2	2*	
Stroke [‡]	History of cerebrovascular accident		1		2	2 3		3	2 3	4	
Superficial venous	a) Varicose veins		1		1	1		1	1	1	
disorders	b) Superficial venous thrombosis (acute or history)		1		1	1		1	1	3*	
Systemic lupus erythematosus [‡]	 a) Positive (or unknown) antiphospholipid antibodies 	1*	1*	3*		3*	3*	3*	3*	4*	
	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*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid		1		1	1		1	1	1	
Tuberculosis [‡]	a) Nonpelvic	1	1	1	1	1*		1*	1*	1*	
(see also Drug Interactions)	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	a) Uncomplicated		1	1		1	1		1	2	
disease	b) Complicated [‡]		1		1	1		1	1	4	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding		1	1	1	2		2	2	1	
	b) Heavy or prolonged bleeding		2*	1*	2*	2*		2*	2*	1*	
Viral hepatitis	a) Acute or flare		1		1	1		1	1	3/4* 2	
·	b) Carrier/Chronic		1		1	1		1	1	1 1	
Drug Interactions											
Antiretrovirals used for prevention (PrEP) or	Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*	:	2*	2*	3*	
treatment of HIV	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	3*	
Antimicrobial therapy	Broad spectrum antibiotics	_	i	_	i	i	_	i	i	1	
	b) Antifungals	_	1		<u>-</u>	i	i i		i	i	
	c) Antiparasitics		-	- i -		- i -	 i		1	<u> </u>	
	d) Rifampin or rifabutin therapy		-		-	2*	_	*	3*	3*	
SSRIs	a,a.i or madden dictapy	_	-	_		1	_	1	1	1	
JJ1113					-	2	_	-	2	2	

Updated in 2020. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see: https://www.cdc.cou/reproductivehealth/contaception-guidance.htm. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condomreduces the risk of STDs and HIV.

CS314239-/

APhA EDUCATION

APhA Increasing access to hormonal contraceptive products training

- Open to all pharmacists in all practice settings
- knowledge and application-based modules

- Module 1: Hormonal Contraceptive Products
- Module 2: Assessing Women for Hormonal Contraception
- Module 3: Communicating About Hormonal Contraceptives
- Module 4: Pharmacy Practice Operations

BENEFITS

PATIENT BENEFITS

- Better access to care especially in low income or underserved communities
- 1-stop for services
- Continuation of care
- Reduces stigma of contraceptive use

PHARMACIST BENEFITS

- Increases ability to serve patients
- Growth opportunities for pharmacists
- Use of expanded clinical knowledge

FUTURE IMPACT

- This opens new opportunities for further advancements in pharmacy
 - CGM, Test and Treat, Antibiotics, etc.
 - Individualized disease state collaboration with practitioners
 - Better care for patients

Together we can advance the future of pharmacy!

POST-ASSESSMENT

- Do you feel more prepared?
- Revisiting patient case
 - Are you more prepared to help KE?
 - What would you recommend?

Take Home Points

- Contraception has been a concern since the beginning of recorded history, but the most accessible healthcare provider is poised to _____ fill the gap(?)
- Prescribing contraceptives is not scary, there are resources to help you
- Pharmacists ability to provide access to medications is expanding
- Pharmacy is always advancing, be prepared for more changes to come



QUESTIONS?



CE CREDIT SLIDE

And the code is:

SOURCES

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Thank you!