


SCHOOL OF MEDICINE

EVIDENCE-BASED UPDATE ON CONTRACEPTION

NEW MEXICO PHARMACISTS ASSOCIATION 2023 94TH ANNUAL CONVENTION
AMBER TRUEHART MD, MS




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Financial Disclosures

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:


No relationships to disclose



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Learning Objectives

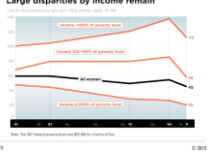
1. Explain the advantages, disadvantages, and characteristics of combined hormonal contraceptive methods
2. Explain the advantages, disadvantages, and characteristics of progestin-only contraceptive methods
3. Describe what new contraceptive methods are available and for who each method may be ideal for



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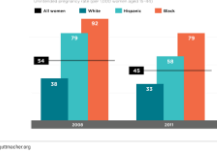
Background

The U.S. unintended pregnancy rate is at its lowest in 30 years




Large disparities by income remain

Despite recent declines, unintended pregnancy rates in the U.S. remain high among women of color



Disparities by race/ethnicity remain

<https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states>



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Background



Inequity in US Abortion Rights and Access: The End of Roe Is Deepening Existing Divides



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Expanding Access

REPORT JAN 31, 2023

Advancing Contraception Access in States with Expanded Pharmacist Prescribing

New Mexico requires plans to reimburse any participating pharmacist who is certified to prescribe contraceptives at the same rate provided to other health care providers.



This is the second installment in the Center for American Progress' series highlighting best practices to improve and expand access to contraception at the state level.

<https://www.americanprogress.org/article/advancing-contraception-access-in-states-through-expanded-pharmacist-prescribing>



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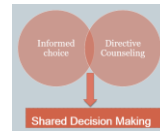
What is the goal of contraceptive counseling?

- A. To inform people about all contraceptive options
- B. To have a person who desires contraception leave a visit with a contraceptive plan that they feel comfortable with
- C. To allow people to make the contraceptive choices that are best for them
- D. To remind people that there is not one perfect method for everyone

E. All of the above!

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Shared decision making



"Shared medical decision-making is a process where both patients and [clinicians] share information, express treatment preferences, and agree on a treatment plan. The process is applicable if two or more reasonable medical options exist."

- ACOG Committee Opinion #587, Effective Patient-Physician Communication

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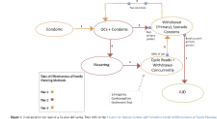
5 components of shared decision-making

1. **Focus on interpersonal relationship.**
2. **Elicit patient preferences for methods.**
3. **Be attuned to diverse patient preferences.**
4. **Provide relevant information in accordance with patient preferences.**
5. **Be aware of and responsive to patient preferences during counseling.**

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Provider's Role

To give needed information and to rule out significant medical risk, not to make the contraceptive choices



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Contraceptive Evidence



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Reviewing Contraceptive Evidence

- World Health Organization's Medical eligibility criteria for contraceptive use
https://www.who.int/reproductivehealth/publications/family_planning/en/
 - US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016
<https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html>
 - ACOG practice bulletin/committee opinions
<https://www.acog.org/clinical/clinical-guidance/practice-bulletin>
 - Expert opinions
- UNM Family Planning Service through PALS Line 505-272-2000

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U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

- Target Audience: Health care providers
- Purpose: To assist health care providers when they counsel patients about contraceptive use and to serve as a source of clinical guidance
- Content: More than 1800 recommendations for over 120 conditions and sub conditions

Why is evidence-based guidance for contraceptive use needed?

- To base family planning practices on the best available evidence
- To address misconceptions regarding who can safely use contraception
- To remove unnecessary medical barriers
- To improve access and quality of care in FP

U.S. MEC

MEC Example

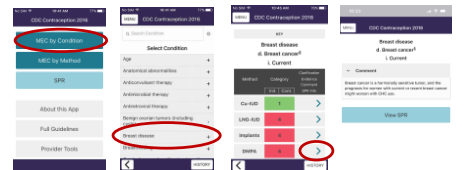
Condition	Sub-Condition	C/I		U/A		A		C	
		I	C	U	A	A	C	I	C
Age		Menarche to <20 yrs.2	Menarche to <20 yrs.2	Menarche to <18 yrs.1	Menarche to <18 yrs.1	Menarche to <18 yrs.1	Menarche to <18 yrs.1	Menarche to <18 yrs.1	Menarche to <18 yrs.1
		>30 yrs.3	>30 yrs.4	>45 yrs.1	>45 yrs.2	>45 yrs.1	>45 yrs.2	>45 yrs.1	>45 yrs.2

- 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)

The Categories

- No restriction for the use of the contraceptive method for a woman with that condition
- Advantages of using the method generally outweigh the theoretical or proven risks
- Theoretical or proven risks of the method usually outweigh the advantages – not usually recommended unless more appropriate methods are not available or acceptable
- Unacceptable health risk if the contraceptive method is used by a woman with that condition

U.S. MEC App



- Look by "condition" in MEC app

HOW WELL DOES BIRTH CONTROL WORK?

90% pregnancy rate in one year with NO method.

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Combination hormonal contraceptives

- All combined hormonal contraceptives contain:
 - Progestin
 - Ethinyl Estradiol (EE) OR Estetrol
- All combined hormonal contraceptives work by:
 - ↓ Ovulation by blocking LH surge
 - Thickening cervical mucus
 - ↓ Tubal epithelial motility

SPOILER ALERT!

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Combined Methods - MOA

- Progestin: contraceptive effects
 - suppresses midcycle estrogen and LH surge = no ovulation
- Estrogen: stabilize endometrium, decrease unwanted spotting

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Estrogen dose

- High-dose combined oral contraception (50 mcg and greater) is associated with higher risks of VTE than lower-dose formulations
- Modern Estrogen containing contraception has 2 fold increased risk of VTE
- There is fair evidence that COCs containing EE doses lower than 35 mcg have similar VTE risk to 35 mcg formulations
- Highest risk in the first one year
 - Does not increase with continuous use

WHO/FDA: use "lowest dose pill to decrease potential side effects"

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Comparative Risks of VTE

Group	Incidence of VTE per 100,000 woman-years
General population	60
Low-dose OC	20-30
High-dose OC	15
Pregnancy	5

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Combined Methods - progestins

PROGESTIN NAME	PROGESTING ACTIVITY	ANDROGENIC ACTIVITY	ANTI-ANDROGENIC ACTIVITY	ANTI-MINERALOCORTICOID ACTIVITY
Progesterone	(+)	(-)	(+/-)	(+)
Medroxy-progesterone acetate	(+)	(+/-)	(-)	(-)
Norethandrone	(+)	(+)	(-)	(-)
Norethindrol	(+/-)	(+)	(-)	(-)
Levonorgestrel	(+)	(+)	(-)	(-)
Norgestimate	(++)	(+)	(+)	(-)
Desogestrel	(++)	(+)	(-)	(-)
Clotrimol	(++)	(+)	(-)	(+)
Drospirenone	(+)	(-)	(+)	(++)

- Spirolactone derivative
- Levonorgestrel: most androgenic
- Norgestimate: most progestational

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First generation progestins

- Derived from testosterone
- Low potency, short half life
- Side effects: unscheduled bleeding
- Norethindrone, norethindrone acetate

Contraceptive Technology, 20th edition

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Second generation progestins

- Developed with the aim of addressing unscheduled bleeding
- 19-norprogesterone derivative: Gonanes
- 19-carbon, derived from testosterone
- High potency, longer half-life
- Androgenic
- Side effects: androgenic side effects (acne, oily skin, facial hair, adverse lipids)
- Norgestrel, levonorgestrel

Contraceptive Technology, 20th edition

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Third generation progestins

- Developed to maintain potency, but decrease androgenic side effects
- 19-norprogesterone derivative: Gonanes
- 19-carbon, derived from testosterone
- High potency, longer half-life
- Less androgenic
- Desogestrel, etonogestrel, norgestimate

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Fourth generation progestins

- Derived from spironolactone
- High potency
- Anti-androgenic, anti-mineralocorticoid activity (no increase in arrhythmias, no need to test K)
- FDA approved to treat PMDD, Acne
- Drospirenone

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Combined Methods – Pills

- Pills Pills Pills....
- Know one for various estrogen dosing

20 mcg 30 mcg 35 mcg

Adolescents => Low-Ogestrel (norgestrel/30 mcg EE)
 Ovarian cyst suppression => Loestrin 24 (norethindrone/20 mcg EE)
 => Sprintec (norgestimate/35 mcg EE)
 PCOS => pill with norgestimate or Drospirenone (Yaz)
 Extended cycle => Any pill (not multiphasic)

Get information about previous pill use

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Combined Methods – Patch

- Weekly transdermal patch
 - Continuous delivery to systemic circulation
 - 20 mcg EE + 150 mcg norelgestromin daily
- Not as effective in women who weigh greater than 90kg (198 lbs)

How the Patch is Used

	Month						
1st Patch =>	1	2	3	4	5	6	7
2nd Patch =>	8	9	10	11	12	13	14
3rd Patch =>	15	16	17	18	19	20	21
4th Patch =>	22	23	24	25	26	27	28

Each patch is worn for a 7-day period. After using three patches in a row, no patch is worn during the fourth week.

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Combined Methods – Ring

- Monthly vaginal ring
 - 15 mcg/day EE and 120 mcg/day etonogestrel
- Compared with COCs there is less irregular bleeding in first 2 cycles
- Can be removed for 3 hours without compromising effectiveness
- Does not need to be removed for intercourse

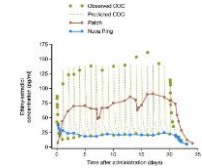


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Combined Methods

- The ring produces lower exposure to EE than the transdermal patch and a COC containing 30 mcg EE
- Less estrogen side effects



van den Heuvel et al. 2005 Contraception

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Contraindications to Estrogen Therapy

- Contraindications
 - Migraine with aura
 - Diabetes with end organ disease
 - Solid organ transplant, complicated
 - Active thrombosis
 - Severe cirrhosis
 - Poorly controlled HTN
 - Thrombogenic mutations
- > Check their medications (Topamax used for everything)

US MEC
US SPR
CDC



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Progestin only Methods

- Various kinds of progestin
- Progestin only contraceptives work by:
 - Thickening cervical mucus
 - Thinning the lining of the uterus
 - ↓ Ovulation to varying degrees
- Common side effect = 3-6 months of irregular bleeding



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Progestin only Methods

- Norethindrone 0.35 mcg
- Taken continuously with no hormone-free week
- Can be taken by patients with contraindications to estrogen:
 - Breastfeeding women/immediately post partum
 - Smokers over age 35
- Must be taken at *exactly* the same time every day or decreased efficacy
- Poor bleeding profile



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Progestin only Methods

- IM injection of 150 mg medroxyprogesterone acetate
- Subq 104 mg medroxyprogesterone acetate
- Advantages – less frequent dosing, amenorrhea
- Special populations - improved seizure control, fewer sickle cell crises
- Disadvantages – Weight gain, delay in return to fertility, change in BMD



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Dianet et al. Contraception, 2019, Jinakittikul et al., J Clin Med Res 2019


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What's new in Contraception?

- Annovera®**
(ethinyl estradiol/segesterone acetate)
- Slynd®**
(drospirenone)
- Nextstellis®**
(estrelol/drospirenone)
- Phexxi®**
(lactic acid, citric acid and potassium bitartrate)

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Annovera®



- Monthly vaginal ring
 - 13 mcg/day EE and 150 mcg/day segesterone acetate
- Goal to decrease "resupply challenges" and enhance consistent use
- 56mm in diameter, 8.4mm in cross sectional diameter
- Does not require refrigeration
- Same ring can be used for up to a full year
 - Not evaluated for continuous use

Compared to Etonogestrel Ring
 54 mm in diameter, 4.0 mm cross sectional
 Needs refrigeration
 Can be used continuously (change every 3 weeks)
 Less bleeding and spotting

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Sergesterone Acetate

- Novel progestin – 4th generation
- Derived from progesterone
- Lacks androgenetic and glucocorticoid activity
- Not orally active


The most common side effects with Annovera are:

- Headache 38.8%
- Nausea/Vomiting 25%
- Vaginal Infections 14.5%
- Dysmenorrhea 12.0%
- Vaginal Discharge 11.8%

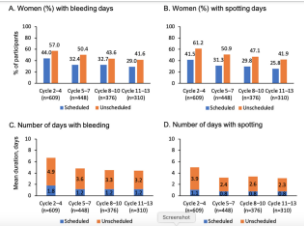
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Slynd®

- Option for patients who have contraindications to estrogen use
- Drospirenone 4 mg has 24 active and 4 inactive tablets
 - *minimizes breakthrough bleeding*
- Contraindications - kidney failure, adrenal insufficiency (Due to risk of hyperkalemia)



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A. Women (%) with bleeding days

Group	Cycle 1-3	Cycle 4-6
Scheduled	57.0%	26.4%
Unscheduled	61.4%	40.3%

B. Women (%) with spotting days

Group	Cycle 1-3	Cycle 4-6
Scheduled	61.2%	25.4%
Unscheduled	61.2%	40.3%

C. Number of days with bleeding

D. Number of days with spotting

Scheduled bleeding - Cycle 1 to Cycle 3 was 81.2% to 26.4%
 Unscheduled bleeding - Cycle 1 to Cycle 3 was 61.4% to 40.3%

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Nextstellis®

- FDA approved in 2021
- New combined oral contraceptive with 3 mg drospirenone and 14.2 mg estrelol
- New type of estrogen

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Estetrol

- First plant-based estrogen to ever be approved for birth control
- Longer half life
- Selective action in tissues
- Minimal first pass metabolism

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Drospirenone (DRSP):

- Antimineralocorticoid (*decreased bloating/water weight gain*)
- Antiandrogenic (*decreased acne/hirsutism*)
- Half life 25-30 hrs → *more "wiggle room" than norethindrone*

Compared to Norethindrone pills
20 active tablets
More progestin related side effects
(weight gain, mood)

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Phexxi®

- Only FDA approved contraceptive gel on the market
- Non-hormonal, patient-controlled, prescription vaginal gel used to prevent pregnancy
- Does not contain nonoxonyl-9
- Must be inserted within 1 hour before vaginal sex



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Phexxi® - How does it work

- Normal vaginal pH: 3.5 to 4.5
- Designed to maintain the acidic vaginal environment even in the presence of alkaline semen
- Phexxi controls vaginal pH > reduces sperm mobility
- Designed to stay in place in the vagina during intercourse - high bio adhesive and viscosity-retaining properties



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Phexxi®

- If **more than one** act of vaginal intercourse occurs within one hour, an additional dose must be applied
- Avoid use with vaginal rings!
- The **most common side effects:**
 - Vaginal burning and itching,
 - Vaginal yeast infection, Bacterial vaginosis and vaginal discharge
 - Urinary tract infection

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Things to remember

- Write refills for all methods for one year
- NM requires insurance to cover 6 month dispensing of self administered methods
- Counsel on condom use regardless of contraception method a person chooses
- Any age person can be given contraception and/or EC without parental involvement
- Offer EC "just in case" to any patient who chooses a short acting method
- End all visits by encouraging questions – "What questions do you have?"

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Summary

- Contraceptive choices are personal and patient specific
- Important to know how to find and use the evidence
- "Standard" birth control options are not going anywhere but new methods offer patients more options

Thank you!



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