


What's new and on the horizon in contraception?


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Disclosures


- None
- Will discuss brand names as pertinent for new contraceptive methods



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Objectives

1. Review updates and recent research on contraception.
2. Describe novel contraceptive methods and technologies in development.
3. Discuss contraceptive provision in the current landscape of reproductive health care.



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Contraceptive options

Category	Method	Effectiveness (%)
REVERSIBLE (Most Effective)	IMPLANT	99%
	IUD (LNG-0.20, MNU-0.20, COPPER T-3.8)	99%
PERMANENT	FEMALE STERILIZATION	99%
REVERSIBLE	INJECTION (DEPO)	96%
	THE PILL	93%
	PATCH	93%
	RING	93%
	DIAPHRAGM	92%
	EXIT (Female Condom)	92%
REVERSIBLE (Least Effective)	MALE CONDOM	85%
	FEMALE CONDOM	82%
	WITHDRAWAL OR PULL OUT	80%
	SPONGE	78%
	FERTILITY-BASED APPROACHES	75%

Using condoms can reduce the risk of sexually transmitted infections.

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Newest options!

2019: Innovera (first reversible vaginal system)

2020: Slynra (first reversible vaginal system)

2021: [Product]

2022: [Product]

2023: Opil (Norgestrel 0.075mg Daily Oral Contraceptive)

2024: [Product]

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Over-the-counter progestin-only pill

- Norgestrel 0.075 mg daily (Opil™)
- FDA approved July 2023 with planned availability in early 2024
- No age restrictions
- 28 pill pack, no placebo pills

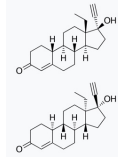
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Allen and Bartz, *Obstet Gynecol* 2024

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Norgestrel

- Synthetic 2nd generation progestin
- Racemic mixture of active levonorgestrel (LNG) and inactive dextronorgestrel
 - Half as potent as LNG
- Weak androgenic activity
- Available in combined OCP



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Over-the-counter progestin-only pill

- Current breast cancer is only absolute contraindication
- Relative contraindications:
 - Benign or malignant liver tumors
 - Severe cirrhosis
 - Acute liver disease
 - Positive antiphospholipid antibodies
 - Past breast cancer
 - Malabsorptive bariatric surgery
 - Drug-drug interactions



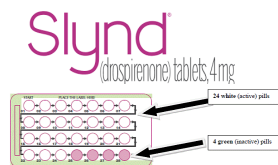
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Allen and Bartz, *Obstet Gynecol* 2024

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How does the Opill® compare to other POPs?

- Norethindrone 0.35 mg (Micronor®)
 - 1st generation progestin
- Drospirenone 4 mg (Slynd®)
 - 4th generation, derived from spironolactone

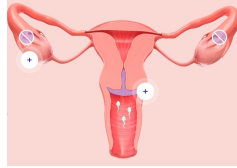


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Mechanism of action

- OTC POP
 - Primary = thickens cervical mucus
 - Secondary = ovulation suppression (50-66%)
- DRSP only pill is similar except for higher ovulation suppression (99+%)
- NET only pill does not reliably suppress ovulation



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Over-the-counter progestin-only pill

- Recommended to take at the same time/within 3 hours
 - Small study showed no changes in cervical mucus by 6 hours of missing OTC POP
- If late or miss a pill, need back-up for 48 hours
 - NET only pill: same
 - DRSP only pill: given long half-life, back-up is only needed if 2+ tabs are missed



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Contraceptive efficacy

- OTC POP: Pearl Index 4.4 (95% CI, 1.9-8.8)
- Perfect use of POPs – 99.5%, typical use – 95%
- DRSP only pill typical use – 98%



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Bleeding profiles

- OTC POP: 48% BTB/spotting, up to 1/4 were amenorrheic
- DRSP only pill: 30% BTB/spotting, <5% prolonged bleeding, up to 1/3 amenorrheic
- NET only pill: 70% BTB/spotting, 33-50% prolonged bleeding



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FDA Drug Label: Norgestrel
Archer et al, *Contraception* 2015
Kovacs, *Hum Reprad* 1996

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OTC POP: side effects

- 17.4% discontinued due to side effects
 - 2/3 were due to bleeding
- Headache
- Breast tenderness
- GI side effects
- Acne



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Comparison

DRSP only pill:	OTC pill:	NET only pill:
• Highest ovulation suppression	• Decent ovulation suppression	• Inconsistent ovulation suppression
• 24hr delayed intake window (t1/2 = 30+hr)	• 3hr delayed intake window (t1/2 = 12 hr)	• 3hr delayed intake window (t1/2 = 9 hr)
• Anti-androgenic	• Not yet available	• Most bleeding side effects
• High cost without insurance coverage*		• Cheap

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*Fall 2023: improved CO Medicaid coverage with no PAT needed

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Take home points: progestin-only pills

- DRSP only pill is the most forgiving, anti-androgenic pill with high ovulatory suppression and good bleeding profile
- But over a 1/3 of OCP users have missed pills due to issues with getting their next supply, making the OTC pill important!



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OTC approval

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OTC approval

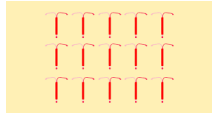
- ACCESS study of >1200 users
 - >99% correctly self-selected if they were appropriate users
 - 93% adherence to daily use
 - No difference in adolescents or individuals with low health literacy
 - 97% used back-up if a pill was missed
- Modeled data suggests potential to reduce up to 34,000 unintended pregnancies per year
- Zena® combined oral contraceptive pill seeking approval



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Extended use of LARCs

- Offering when appropriate is patient centered
- Avoids barriers to accessing contraceptive care



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Extended use of IUDs

- 8-year approval for 52 mg LNG IUD obtained in 2022
 - Year 7 (478 users): 1 ectopic, 1 implantation 4 days post-removal
 - Year 8 (343 users): 0 pregnancies
 - Amenorrhea rates 39% at years 7 & 8
- Mean LNG levels 119 pg/mL at 8.5 years (58.6 pg/mL at 3 years with 13.5 mg LNG IUD)
- Trials are ongoing up to 10 years

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Extended use of IUDs

- 52 mg LNG IUD likely effective beyond 8 years to 10 years, can offer with joint decision making due to limited data
- Extended use not recommend for the 19.5 mg or 13.5 mg LNG IUD
- Good data supporting 12 years for 380 mm² copper IUD with some evidence up to 15 years

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Extended use of ENG implant

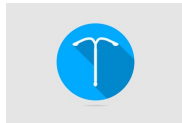


- Data for extended use up to 5 years
- Limited data in patients with class 3 obesity (BMI >40)
 - Association between lower ENG levels and higher BMI
- Caution in patients using CYP3A4 inducers
- Nexplanon® extension trial is underway looking at up 5 years to support an updated FDA label

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Extended use of LARC

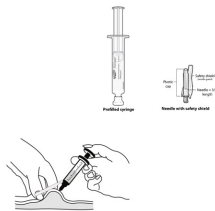
- Safe, effective, and desirable for many patients
- Need to shift thinking away from "expiring" devices
- Pharmacokinetic and prospective trials are ongoing for extended use



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DMPA-SQ

- 104 mg subcutaneous injection every 13-15 weeks
- Self-administration is off-label
- Pre-filled syringe, need rx for other supplies
- Patient education materials are available online (bedsider.org, Reproductive Health Access Project)



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DMPA-SQ



- Long history of use globally
- Sayana Press®
 - Created for easy self-administration
 - Not approved or available in the US

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DMPA-SQ

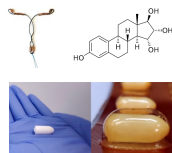
- Increasing data that self-administration is safe, effective, and can improve continuation rates (10-30% higher)
- Renewed interest during COVID-19 pandemic, but availability is still limited



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Novel contraceptive methods

- Enhance existing methods
- Use new delivery systems
- Alter hormonal composition
- Use multipurpose prevention technologies (MPT)
- Create novel agents and targets



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Nonhormonal ring

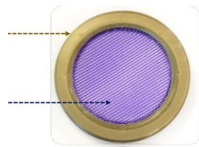
- Ovaprene®
- “One size fits most” ring inserted at the end of menses and removed at the start of next menses
- Phase 3 contraceptive efficacy trial started



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Nonhormonal ring

- Spermistatic, silicone ring
 - Ferrous gluconate – immobilizes sperm
 - Ascorbic acid – increases cervical mucus
 - Polyglycolide – increases vaginal pH
- Physical barrier
 - Non-braided, fluid-permeable mesh barrier



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Contraception in development

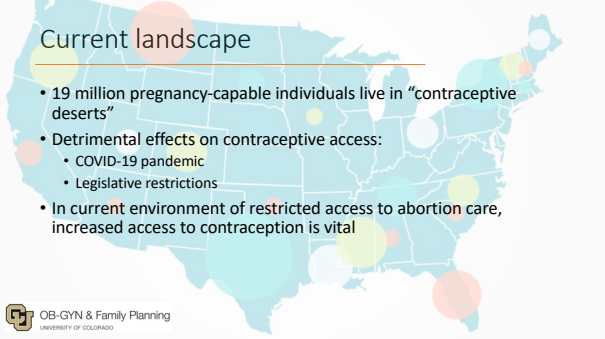
- IUD with NSAID reservoir
- Microneedle patch
- Monthly pill
- Six-month injectable
- Non-hormonal vaginal capsule to thicken vaginal mucus
- Hormonal contraceptives for sperm-producing people



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Current landscape

- 19 million pregnancy-capable individuals live in “contraceptive deserts”
- Detrimental effects on contraceptive access:
 - COVID-19 pandemic
 - Legislative restrictions
- In current environment of restricted access to abortion care, increased access to contraception is vital




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Summary

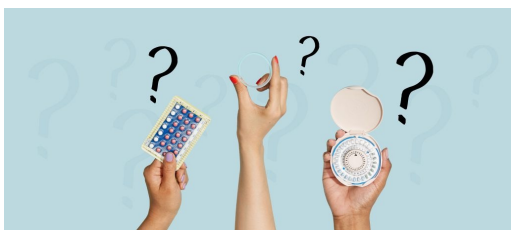
- Understanding the differences in new methods can help guide their use
- While the OTC pill itself is not novel, the approval is important for access
- Increasing data support extended LARC use and self-administration of DMPA-SQ
- New developments are on the horizon!



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Questions?



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