Current Topics in Contraception

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Objectives

- **The pharmacist participant will be able to:**
  - List the principles of reproductive justice.
  - Discuss recent FDA approvals of new and emerging hormonal and non-hormonal contraceptive options.
  - Given a patient case, describe how to engage in shared decision-making with a patient about contraceptive options.
- **The pharmacy technician participant will be able to:**
  - List the principles of reproductive justice.
  - Discuss recent FDA approvals of new and emerging hormonal and non-hormonal contraceptive options.
  - Refer patients for pharmacist counseling on contraceptive choices and management.

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Reproductive Justice

The human right to…

- maintain bodily autonomy
- have children
- not have children
- parent the children we have in safe & sustainable communities

For more information:
https://www.sistersong.net/reproductive-justice

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Reproductive Justice

How can we apply this to contraception discussions in the pharmacy?

- Avoid making assumptions and judgments about patients' plans to have or not have children
- Counsel on all available contraceptive methods
- Avoid coercing/pressuring patients into choosing certain methods

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Contraception Management

- Nearly half of U.S. pregnancies are described as "unintended" (wanted later or never)
- 54% of unintended pregnancies occur in patients who **did not use** a contraceptive method
- 41% of unintended pregnancies occur in patients who **inconsistently used** a contraceptive method
- 5% of unintended pregnancies in patients who consistently used a contraceptive method

Source: Guttmacher.org

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Contraception Management

- Contraception as a chronic condition
  - Average age at menarche in U.S. is ~12.5 years old
  - Average of menopause in U.S. ~51 years old
  - "Childbearing age" defined by CDC as 15-44 years old
- Patient's reproductive life plan, preferences, and the safety of methods – may change throughout childbearing years
- Should be re-evaluated and managed appropriately throughout patient's entire reproductive lifetime

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Contraception Management

- Effectiveness/efficacy
- Safety
- Patient lifestyle & preferences

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POLL QUESTION

Are you currently certified to prescribe hormonal contraception?

A. Yes
B. No
C. Not applicable

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Pharmacy access to contraception can help prevent unintended pregnancy

- **Oregon Medicaid**
  - January 2016—December 2017
  - 1,313 RXs for patients in Oregon Medicaid program
  - Estimated to prevent 51 unintended pregnancies
  - Estimated $1.6 million dollars saved
  - Authors projected New Mexico could save $2.3 million

Source: Rodriguez, et al. https://www.ncbi.nlm.nih.gov/pubmed/31083123

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Pharmacist prescribing patterns may improve contraception adherence and reach patients in need

- **California, Hawaii, Colorado, and Oregon**
  - January 2019—November 2019
  - 410 patients presenting for contraception
  - Compared to patients seeking contraception from other providers:
    - Lower levels of education
    - Younger
    - More likely to be uninsured
  - Pharmacists were more likely to prescribe 6-month or greater supplies

Source: Rodriguez, et al. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766072

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Patients trust pharmacists to help them make decisions about contraception

- **Direct Access Study**
  - 195 patients in Seattle
  - 97.7% "satisfied" or "very satisfied"
  - 97.1% would recommend the pharmacist to a friend
  - 96.6% felt they could ask the pharmacist any questions

Source: Gardner, et al. https://www.ncbi.nlm.nih.gov/pubmed/18359734

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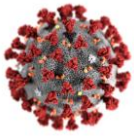
The CDC has identified pharmacy access to contraception as an important service during the COVID-19 pandemic

For more info:

https://www.cdc.gov/reproductivehealth/contraception/covid-19-family-planning-services.html



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Contraception during COVID

- Encourage contactless pick-up (mail, drive-through, curbside)
- Promote OTC products such as emergency contraception and pregnancy tests
- Optimize maximum quantities and refills for birth control prescriptions
- Recommend methods that require less screening (e.g., progestin-only methods)

Source: https://www.pharmacytimes.com/news/pharmacy-best-practices-for-contraceptive-care-during-covid-19

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POLL QUESTION

Which emergency contraception is most effective for women with a BMI >30?

A. Plan B
B. Ella
C. Copper IUD
D. None of the above
E. Not sure

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Emergency Contraception

Method	Mechanism of Action	How to Use	Notes
Levonorgestrel (Plan B One Step; Next Choice; My Way, etc.)	Prevention of ovulation	1 tablet taken within 72 hours of unprotected intercourse (more effective the earlier it is taken; may use up to 120 hrs but less effective)	- Should be offered to all women using short-acting hormonal contraception to have on hand in the event of missed doses ~98-99% effective; **less effective in women who are overweight/obese or ≥165 lbs**

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Emergency Contraception

Method	Mechanism of Action	How to Use	Notes
Ulipristal acetate 30 mg (Ella)	Progesterone receptor modulator; inhibits or delays ovulation; may prevent implantation	1 tablet taken within 120 hours (5 days) of unprotected intercourse	~98-99% effective; less effective in obese women

McKesson now has ella®, NDC code 73302-456-01, available for purchase at their main DCs.

Additionally, ella® is available at the DCs of Cardinal where there is demand for ella®. If the Cardinal DC you order from does not have stock, please:
1. Place an order which will trigger the DC to order ella® OR
2. Call Cardinal at 855-855-0708 to place the order for ella®.

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Emergency Contraception

Method	Mechanism of Action	How to Use	Notes
Copper IUD ***not included in prescriptive authority**	Prevent fertilization through effect of copper ions on sperm; may interfere with implantation	Place within 5 days of unprotected intercourse	Most effective emergency contraceptive method (1/1000 failure rate) Effective for women who are overweight/obese

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POLL QUESTION

Have you prescribed or dispensed depo medroxyprogesterone acetate (Depo Provera) for <u>subcutaneous</u> injection?

A. Yes
B. No
C. Not sure / not applicable

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Depomedroxyprogesterone (DMPA)
150 mg (IM); 104 mg (SQ)

99.8% effective perfect use
94% effective typical use

Mechanism of Action	How to Use	Notes
Progestin-only method Prevention of ovulation Thinning of endometrium	IM or SQ injection every 3 months *(11-15 weeks)*	High discontinuation rate compared to other methods (~44-77% in various studies) Slow baseline return to fertility (~10 months avg; up to 18+ months)

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Depo Sub-Q

- "Off label" self-injection
- No generic available (vs. IM formulation)
- Higher rates of continuation with self-administration vs. provider administration
- No difference in pregnancy rates
- Increase in injection site reactions with self-administration; no other difference in adverse effects

Source: https://gh.bmj.com/content/4/2/e001350

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POLL QUESTION

Which of the following are considered "LARC"?

A. Mirena
B. Nexplanon
C. Nuvaring
D. All of the above
E. A & B only

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LARC (long-acting reversible contraception)

- **IUD**
  - **Non-hormonal:** Copper IUD (Paragard)
  - **Hormonal:** all contain levonorgestrel (a progestin)
    - Mirena
    - Liletta
    - Kyleena
    - Skyla
- **Implant** – Nexplanon
- >99% effective

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Pharmacists may not be referring patients for LARC

- **California & Oregon**
  - August 2016—February 2017
  - 381 pharmacists; 2,117 visits
  - Did not identify any referrals for long-acting reversible contraception (LARC)
  - Reasons unknown
    - Women may self-select for pharmacy services
    - Pharmacist counseling may guide women

Source: Lu, et al. https://www.ncbi.nlm.nih.gov/pubmed/30562478

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Pharmacists and LARC

- IUDs and implants are not included in pharmacist prescriptive authority
- LARC use remains low in the U.S. but is increasing
- Half of women surveyed expressed concern about side effects & safety of LARC
- Pharmacists should be prepared to discuss risks and benefits

Sources: Teal & Romer. https://www.ncbi.nlm.nih.gov/pubmed/23535055
Burns, et al. https://www.ncbi.nlm.nih.gov/pubmed/23535055

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FDA approvals for extensions of IUD use

- Liletta IUD approved for **6 years** of use in Fall 2019
- Mirena IUD approved for **6 years** of use in August 2020

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Implant

Mechanism of Action	Notes
Contains 68mg etonorgestrel Thickening of cervical mucus; alteration of endometrium; some anovulatory effects	• FDA approved for 3 years; **remains effective for 4-5 years** • Irregular bleeding is common (~33%) & frequent cause of discontinuation

Sources: Managing Contraception; Nexplanon prescribing information

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Copper IUD

Mechanism of Action	Notes
Copper ions inhibit sperm; inflammatory reaction in endometrium	• FDA approved for 10 years; **effective 12+ years** • May increase menstrual bleeding/cramping

Source: https://www.sciencedirect.com/science/article/pii/S0010782497001868

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Levonorgestrel (LNG) IUD

Mechanism of Action: Thickening of cervical mucus; alteration of endometrium; some anovulatory effects

Name	Levonorgestrel content	Replace after _ years FDA / *off-label*
Mirena ®	52 mg (20 mcg/day)	6 years / **7 years**
Liletta ®	52 mg (18.6 mcg/day)	6 years / **7 years**
Kyleena ®	19.5 mg (17.5 mcg/day)	5 years
Skyla ®	13.5 mg (14 mcg/day)	3 years

Sources: Mirena; Skyla; Kyleena; and Liletta prescribing information
https://www.sciencedirect.com/science/article/pii/S0010782419304445 / https://pubmed.ncbi.nlm.nih.gov/26916172/

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Recent FDA Approvals

Chat: What new contraceptive methods have patients asked you about in the pharmacy?

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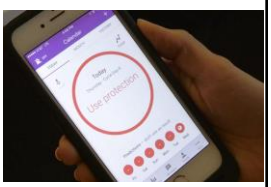
Behavioral Method

Natural Cycles App

- FDA approved August 2018
- Users track temperature daily and enter readings
- Abstain from intercourse when "use protection" displayed on app
- **Typical use:** ~93% effective



Source: https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy

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Barrier Method

Phexxi™

- FDA approved in May 2020
- **Typical use:** 86% effective
- Lactic acid, citric acid, and potassium bitartrate 1.8%, 1%, 0.4% vaginal gel
- 5 grams in pre-filled applicator vaginally up to 1 hour before intercourse

Source: Phexxi prescribing information

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Barrier Method

Phexxi™

- Lowers vaginal pH to reduce sperm motility
- May be used in combination with other vaginal products (e.g., miconazole)
- Some cases (0.36%) of cystitis, pyelonephritis, UTIs in clinical studies

Source: Phexxi prescribing information

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Progestin-Only Method

Norethindrone 0.35mg
Drosperinone 4mg – Slynd
Approved June 2019

99.7% effective (perfect use)
91% effective (typical use)

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Progestin-Only Method

Mechanism of Action	How to Use	Notes
Primarily works by thickening cervical mucus; ovulation suppressed in ~60% of users	**Norethindrone:** 1 tablet by mouth every day at the SAME TIME (>3 hours late = "missed dose") No placebo tablets; take continuously **Drosperinone:** 1 tablet daily (24 hour window) 24 active + 4 inactive tablets	As effective as combined oral contraceptives with correct use Drosperinone has anti-androgenic effects; may be more desirable for patients with acne, PCOS Use drosperinone with caution in hyperkalemia

Sources: Slynd prescribing information; Norethindrone prescribing information; Managing Contraception

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Combined Hormonal Method

Nuvaring® etonogestrel/ethinyl estradiol 120/15 mcg/day
Annovera® segesterone acetate/ethinyl estradiol 150/13 mcg/day
Approved August 2018

Nuvaring: >99% effective (perfect use); 91% effective (typical use)
Annovera (clinical trial): 97.5% effective

Source: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209627Orig1s000TOC.cfm

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Combined Hormonal Method

Mechanism of Action	How to Use	Notes
Progesterone and estrogen combination Prevention of ovulation; thickening of cervical mucus, inhibiting sperm Estrogen component also helps to stabilize endometrium, decreasing breakthrough bleeding	Nuvaring 1 ring inserted into the vagina for 3 weeks, then removed for 1 week *(off-label: use continuously for 4 weeks, then replace with new ring)* Annovera 1 ring inserted into vagina for 3 weeks, then removed for 1 week; clean, dry, and store ring during off week; repeat. Can be used for 13 cycles.	Continuous, steady release of hormones & lowest serum levels of hormones vs. other combined hormonal methods (similar levels in both products) Avoid use of oil-based lubricants or vaginal products Annovera has not been adequately evaluated in women with a BMI > 29 Annovera does not require refrigeration

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Combined Hormonal Method

Twirla™ (120 mcg/d levonorgestrel & 30mcg/d ethinyl estradiol)
Approved February 2020

99.7% effective (perfect use)
91% effective (typical use)

Source: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/204017Orig1s000TOC.cfm

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Combined Hormonal Method

Mechanism of Action	How to Use	Notes - Twirla
Progesterone and estrogen combination Prevention of ovulation; thickening of cervical mucus, inhibiting sperm Estrogen component also helps to stabilize endometrium, decreasing breakthrough bleeding	1 patch applied to lower stomach, buttock, or upper torso each week for 3 weeks, then 1 week off If patch is detached for >24 hours, use backup method for next 7 days	Indicated for women with BMI <30 Reduced effectiveness in BMI ≥25 or weight >92 kg (similar to Xulane) In clinical trials, 5% of patches detached; patients indicated abdomen was best site for application Lower estrogen exposure than Xulane (30mcg vs. 35mcg per day) Slightly larger than Xulane; circular vs. square Like Xulane, only available in beige

Sources: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/204017Orig1s000TOC.cfm; *Twirla prescribing information*

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CASES

Discuss what you would recommend for each of the following patients…

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Case 1: "I know I'm out of time on my IUD, and I cannot get pregnant right now!"

- 33-year-old female
- Married with two children, ages 6 and 8; she is a teacher and reports feeling very stressed by all the online teaching
- Has been using Mirena IUD for the last 5 years; does not have regular periods; satisfied with method
- Medications: Lisinopril 5mg once daily for high blood pressure; BP in pharmacy is 126/78 mmHg
- Presents to the pharmacy asking if you can prescribe birth control because she can't get in to see her OB/GYN

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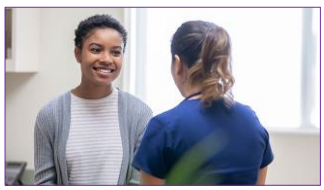
Case 1: "I know I'm out of time on my IUD, and I cannot get pregnant right now!"

Chat: What would you discuss with the patient?



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Case 2: "I want to use something without hormones."

- 22-year-old female; student at UNM
- In a monogamous relationship with her partner of two years
- No known medical conditions
- Does not take any medications
- Interested in contraceptive methods, but does not want to take anything that contains hormones

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Case 2: "I want to use something without hormones."

Chat: What would you discuss with the patient?

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Case 3: "Which of these morning-after pills should I buy?"

- 28-year-old female; previously worked as a restaurant sever, currently unemployed
- Not in a monogamous relationship, but has been quarantining with a friend with benefits since March, and the condom broke during intercourse last night
- No medication allergies
- Seasonal allergies; takes loratadine as needed
- While chatting with her, she tells you: "I've really put on some weight during quarantine! All the stress-eating has me in the 200s now. I'm going on a run after this."

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Case 3: "What morning-after pill do you think I should buy?"

Chat: What would you discuss with the patient?

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Thank you!

Questions?

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