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.

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

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

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

Contraception as a chronic condition
• Average age at menarche in U.S. is ~12.5 years old
• Average of menopause in U.S. is ~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
Contraception Management

- Effectiveness/efficacy
- Safety
- Patient lifestyle & preferences

POLL QUESTION

Are you currently certified to prescribe hormonal contraception?
A. Yes
B. No
C. Not applicable

Pharmacy access to contraception can help prevent unintended pregnancy

- Oregon Medicaid
  - January 2016—December 2017
  - 1,313 Rx's for patients in Oregon Medicaid program
  - Estimated to prevent 51 unintended pregnancies
  - Authors projected New Mexico could save $2.3 million

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
    - Lower levels of education
    - Younger
    - More likely to be uninsured
  - Pharmacists were more likely to prescribe 6-month or greater supplies

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

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

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)


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

Emergency Contraception

<table>
<thead>
<tr>
<th>Method</th>
<th>Mechanism of Action</th>
<th>How to Use</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonorgestrel (Plan B One Step, Next Choice, My Way, etc.)</td>
<td>Prevention of ovulation</td>
<td>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)</td>
<td>Should be offered to all women using short-acting hormonal contraception to have on hand in the event of missed doses</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>Prevent fertilization through effect of copper ions on sperm; may interfere with implantation</td>
<td>Place within 5 days of unprotected intercourse</td>
<td>Most effective emergency contraceptive method (1/1000 failure rate) Effective for women who are overweight/obese</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>*not included in prescriptive authority</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulipristal acetate 30 mg (Ella)</td>
<td>Progestrone receptor modulator; inhibits or delays ovulation; may prevent implantation</td>
<td>1 tablet taken within 120 hours (5 days) of unprotected intercourse</td>
<td>~98-99% effective; less effective in obese women</td>
</tr>
</tbody>
</table>

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®
2. Call Cardinal at 855-855-0708 to place the order for ella®.

POLL QUESTION

Have you prescribed or dispensed depo medroxyprogesterone acetate (Depo Provera) for subcutaneous injection?
A. Yes
B. No
C. Not sure / not applicable
**Depomedroxyprogesterone (DMPA)**
- **150 mg (IM); 104 mg (SQ)**
- 99.8% effective perfect use
- 94% effective typical use

**Mechanism of Action**
- Progestin-only method
- Prevention of ovulation
- Thinning of endometrium

**How to Use**
- 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)

**Notes**
- "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

**POLL QUESTION**
Which of the following are considered “LARC”?
A. Mirena
B. Nexplanon
C. Nuvaring
D. All of the above
E. A & B only

**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

**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

**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
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

Implant

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
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</thead>
<tbody>
<tr>
<td>Contains 68mg etonorgestrel</td>
<td>• FDA approved for 3 years; remains effective for 4-5 years</td>
</tr>
<tr>
<td>Thickening of cervical mucus; alteration of endometrium; some anovulatory effects</td>
<td>• Irregular bleeding is common (~33%) &amp; frequent cause of discontinuation</td>
</tr>
</tbody>
</table>

Copper IUD

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Copper ions inhibit sperm; inflammatory reaction in endometrium</td>
<td>• FDA approved for 10 years; effective 12+ years</td>
</tr>
<tr>
<td>May increase menstrual bleeding/cramping</td>
<td></td>
</tr>
</tbody>
</table>

Levonorgestrel (LNG) IUD

<table>
<thead>
<tr>
<th>Forma</th>
<th>Levonorgestrel content</th>
<th>Replace after _years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mirena®</td>
<td>52 mg (20 mcg/day)</td>
<td>6 years / 7 years</td>
</tr>
<tr>
<td>Liletta®</td>
<td>52 mg (18.6 mcg/day)</td>
<td>6 years / 7 years</td>
</tr>
<tr>
<td>Kyleena®</td>
<td>19.5 mg (17.5 mcg/day)</td>
<td>5 years</td>
</tr>
<tr>
<td>Skyla®</td>
<td>13.5 mg (14 mcg/day)</td>
<td>3 years</td>
</tr>
</tbody>
</table>

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: ~53% effective

Recent FDA Approvals

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

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

Progestin-Only Method

Norethindrone 0.35mg
Drosperrinone 4mg – Slynd
Approved June 2019
- 99.7% effective (perfect use)
- 91% effective (typical use)

Mechanism of Action
- Primarily works by thickening cervical mucus; ovulation suppressed in ~60% of users

How to Use
- Norethindrone: 1 tablet by mouth every day at the SAME TIME (>3 hours late = “missed dose”)
- No placebo tablets; take continuously
- Drosperrinone: 1 tablet daily (24 hour window)
- 24 active + 4 inactive tablets

Notes
- As effective as combined oral contraceptives with correct use
- Drosperrinone has anti-androgenic effects; may be more desirable for patients with acne, PCOS
- Use drosperrinone with caution in hyperkalemia

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

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

Mechanism of Action
- Progestrone and estrogen combination
- Prevention of ovulation; thickening of cervical mucus, inhibiting sperm
- Estrogen component also helps to stabilize endometrium, decreasing breakthrough bleeding

How to Use
- 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; can be used for 13 cycles

Notes
- 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 > 20
- Annovera does not require refrigeration

Sources:
- https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209627Orig1s000TOC.cfm
- Managing Contraception
Combined Hormonal Method

**Twirla™ (120 mcg/d levonorgestrel & 30 mcg/d ethinyl estradiol)**
Approved February 2020
99.7% effective (perfect use)
91% effective (typical use)

**Mechanism of Action**
- Progesterone and estrogen combination
- Prevention of ovulation; thickening of cervical mucus, inhibiting sperm
- Estrogen component also helps to stabilize endometrium, decreasing breakthrough bleeding

**How to Use**
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

**Notes**
- 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

**Source:** [https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/204017Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/204017Orig1s000TOC.cfm)

**CASES**
Discuss what you would recommend for each of the following patients...

**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

**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

**Source:** [https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/204017Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/204017Orig1s000TOC.cfm); Twirla prescribing information
**Case 2:** “I want to use something without hormones.”

Chat: What would you discuss with the patient?

**Case 3:** “Which of these morning-after pills should I buy?”

- 28-year-old female; previously worked as a restaurant server, 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.”

**Case 3:** “What morning-after pill do you think I should buy?”

Chat: What would you discuss with the patient?

Thank you!

Questions?