Objectives

The pharmacist participant will be able to:

- Describe various contraceptive options, to include non-hormonal and hormonal long-acting reversible contraception (LARC), short-acting hormonal contraception, emergency contraception, and barrier and behavioral methods.
- Describe differences in efficacy and safety among contraceptive options.
- Recognize and manage adverse effects of various contraceptive options.
- Engage in shared decision making with a patient about contraceptive choices.

Objectives

The pharmacy technician participant will be able to:

- Describe various contraceptive options, to include non-hormonal and hormonal long-acting reversible contraception (LARC), short-acting hormonal contraception, emergency contraception, and barrier and behavioral methods.
- Describe differences in efficacy and safety among contraceptive options.
- Refer patients for pharmacist counseling on contraceptive choices and management.

Overview

Contraception Management

Selecting a Method

Adverse Effects: Identification & Management

Resources & Questions

In the absence of ANY form of contraception, how many pregnancies would the average woman experience during her lifetime?

A 2

B 7

C 10

D 15

Source: Vienna Museum of Contraception & Abortion (Museum für Verhütung und Schwangerschaftsabbruch)

Take a virtual tour:

http://en.mvvi.org/museum/tour/
**Contraception Management**

- Undesired fertility: 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 – may change throughout childbearing years
- Patient’s preferences for contraception – may change
- Safety of contraceptive options – may change
- Should be re-evaluated and managed appropriately throughout patient’s entire reproductive lifetime.

**Contraception Management**

- Unintended pregnancy
- Nearly half of U.S. pregnancies are described as “unintended”
- 41% of unintended pregnancies occur in women who did not use a contraceptive method
- 4% of unintended pregnancies occur in women who inconsistently used a contraceptive method
- 5% of unintended pregnancies in women who consistently used a contraceptive method
- Pregnancy ambivalence
  - Do you want to become pregnant? Yes / No / Maybe
- Other influences choice of method (especially re: effectiveness)

Source: Guttmacher.org

**Contraception Management**

- Shared, informed decision making helps a patient choose the most effective option that is safe for her and fits her lifestyle and preferences
- The best contraceptive method is one that is medically appropriate, that the patient will use consistently, and the patient is happy with

**Selecting a Method**

- Effectiveness
  - Sterilization
  - Long-acting reversible contraception (LARC)
  - IUD, implant, shot (e.g., Depo Provera)
  - Short-acting reversible hormonal contraception
    - Pill, patch, ring, shot
  - Barrier & behavioral methods
- Safety
- Lifestyle & preferences

**Selecting a Method**

- Effectiveness
- Safety
- Medical conditions
- U.S. Medical Eligibility Criteria (MEC) for contraceptive use:
  - [www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html](http://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html)
- App available for iOS and Android systems
- Lifestyle & preferences
Example of the MEC – many more disease states are included in full document

Selecting a Method

- Effectiveness
- Safety
- Lifestyle & preferences
  - A method that worked in the past
  - A method she heard about from a friend/family member/etc.
  - Adherence
  - Convenience
  - Periods or no periods
  - Need to keep method hidden?
  - Return to fertility/desire for future pregnancies
  - Timing and spacing of pregnancies

Selecting a Method

- The pill and female sterilization are the most popular forms of contraception in the U.S.
- In the Contraceptive CHOICE Project, participants were offered a contraceptive method of their choice at no cost for 2-3 years
- 78% of participants chose LARC (IUD or implant)
- LARC methods were 20 times more effective than non-LARC methods
- LARC methods had higher continuation rates at 12 & 24 months
- The Contraceptive CHOICE Project in Review:

What percentage of sexually active women of childbearing age in the U.S. have ever used at least one contraceptive method?

Source: https://www.guttmacher.org fact sheet/contraceptive-use-united-states

CONTRACEPTIVE METHOD CHOICE

What percentage of sexually active women of childbearing age in the U.S. have ever used at least one contraceptive method?

Source: https://www.guttmacher.org fact sheet/contraceptive-use-united-states
Selecting a Method

- IUD (>99% effective)
  - Non-hormonal: Copper IUD (Paragard)
  - Hormonal: all contain levonorgestrel (a progestin)
  - Vary in amount of hormone & how many years they are approved for use, and size

<table>
<thead>
<tr>
<th>Name</th>
<th>Levonorgestrel dose (mg)</th>
<th>Replacement after years (FDA)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mirena</td>
<td>52 mg (20 mcg/day)</td>
<td>5</td>
</tr>
<tr>
<td>Skyla</td>
<td>13.5 mg (4 mcg/day)</td>
<td>3</td>
</tr>
<tr>
<td>Kyleena</td>
<td>19.5 mg (7.5 mcg/day)</td>
<td>5</td>
</tr>
<tr>
<td>Liletta</td>
<td>52 mg (18.6 mcg/day)</td>
<td>4</td>
</tr>
</tbody>
</table>

Source: Mirena, Skyla, Kyleena, and Liletta prescribing information

- Implant (>99% effective)
  - Nexplanon®
  - Contains 68 mg etonogestrel (a progestin)
  - Releases ~40-70 mcg daily
  - Implanted under the skin in the upper arm
  - FDA approved for 3 years of use; evidence that it remains effective for 4-5 years


- Barrier Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Effectiveness – perfect use</th>
<th>Effectiveness – typical use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Condom</td>
<td>98%</td>
<td>82%</td>
</tr>
<tr>
<td>Female Condom</td>
<td>91%</td>
<td>79%</td>
</tr>
<tr>
<td>Sponge</td>
<td>80-91%</td>
<td>70-88%</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>N/A</td>
<td>71-81%</td>
</tr>
<tr>
<td>Spermicide</td>
<td>82%</td>
<td>72%</td>
</tr>
</tbody>
</table>

Source: Bedsider.org

- Sterilization (>99% effective)
  - Male sterilization: vasectomy (no anesthesia)
  - Female sterilization
    - Essure (no surgery or anesthesia)
    - Tubal ligation (laproscopic surgery, requires anesthesia)

- Behavioral Methods

- Abstinence
- Rhythm Method
- Withdrawal
  - 95% effective with perfect use; 78% effective typical use
- Fertility Awareness
  - 90-95% effective with perfect use; 76-88% effective typical use
- Involves observation of signs of fertility such as cervical mucus and body temperature
- Lactational
  - Effective for up to 6 months after birth if exclusively breastfeeding at least 4xh during the day and 6xh at night, and amenorrhea

Focus in on choosing a hormonal method covered by our prescriptive authority

- Pill, patch, ring, shot, EC
- Pill: combined hormonal or progestin-only
- Patch: combined hormonal
- Ring: combined hormonal
- Shot: progestin-only
- EC: Plan B; Ella
Selecting a Method

Pill (combined: estrogen and progestin)
- 99.7% effective perfect use
- 91% effective typical use
- Contain ethinyl estradiol and a progestin
- Picking a pill to start
  - How much estrogen?
  - Monophasic vs. multiphasic?
  - Which bleeding pattern?
  - Which progestin?

In general, start with 30-35 mcg EE (low estrogen content)
- Lower EE = possible lower risk of VTE; increase in breakthrough bleeding
- High estrogen content = 50 mcg EE
- Very low estrogen content = <20 mcg EE

Monophasic vs. multiphasic?
- In general, start with monophasic
- No evidence that multiphasic pills are "better" with respect to side effects
- Multiphasic pills may be confusing when pills are missed

Picking a pill to start
- Which bleeding pattern?
  - Patient preference
  - 28-day/21-day active pills, 7 days placebo = "normal" withdrawal bleeding pattern
  - Bicycling/tricycling: Skipping placebos for 1-2 packs; less frequent withdrawal bleeding
  - Continuous use: Take only active pills with no placebos; no withdrawal bleeding
- Use monophasic pills
- Breakthrough bleeding may be more common
- May provide better protection against pregnancy
- No current evidence of increased health risks
- Limited information on long-term outcomes

True or False: Progestin-only pills are less effective than combined pills which contain an estrogen and a progestin.
Selecting a Method

- Picking a pill to start
  - Which progestin?
  - Most progestin in oral contraceptives is derived from 19-nortestosterone
  - Drospirenone derived from 17-a-spirolactone
  - “Generation” may relate to structure, year approved for marketing, or activity (estrogenic, androgenic, progestational)
  - Grouping often inconsistent; not standardized

Sources:

Selecting a Method

- Pill (progestin-only)
  - Most women are appropriate candidates, but generally used by women who can’t or don’t want to take estrogen
  - History of DVT/PE
  - Postpartum
  - Breastfeeding
  - Smokers over age 35
  - Cardiovascular risk factors
  - Lupus

- Ring
  - Nuvaring® (etonogestrel/ethinyl estradiol 120/15 mcg/day)
  - 99.7% effective with perfect use
  - 91% effective with typical use
  - 1 ring inserted into the vagina for 3 weeks, then removed for 1 week (pill label use continuously for 4 weeks, then replace)
  - Adherence may be higher vs. pill
  - Easier to hide than patch or pill
  - Continuous, steady release of hormones & lowest serum levels of hormones vs. other combined hormonal methods
Selecting a Method

- **Patch**
  - Xulane (norelgestromin and ethinyl estradiol 150/35 mcg/day)
  - 99.7% effective with perfect use
  - 91% effective typical use
  - Less effective in women >90 kg (198 lbs)
  - 1 patch applied each week for 3 weeks, then 1 week off
  - Adherence may be higher vs. pill
  - Higher estrogen exposure than pills or ring » may increase VTE risk

- **Shot**
  - Depomedroxyprogesterone (DMPA) 150 mg (IM), 104 mg (SQ)
  - 99.8% effective perfect use
  - 94% effective typical use
  - 1 injection every 13-15 weeks
  - Progestin-only method, so good option for women who can’t/won’t take estrogen
  - Easier to keep hidden vs. other methods
  - High discontinuation rate compared to other methods (~44-77% in various studies)

Selecting a Method

- **Emergency Contraception**
  - Levonorgestrel (Plan B One Step; Next Choice; My Way, etc.)
  - Levonorgestrel EC should be offered to all women using hormonal contraception such as pills, patches, rings, and shot to have on hand in the event of missed doses
  - Ella
  - Upright acetate 35 mg
  - Progesterone receptor modulator
  - Cooper IUD is the most effective emergency contraceptive method (1/1000 failure rate)

Adverse Effects: CHC

- Adverse effects of combined hormonal contraceptive methods (pill, patch, ring) are similar
- VTE, MI, stroke among the most serious complications
- Increased risk of MI/stroke occur in smokers >35 years old; women with hypertension, diabetes, hyperlipidemia, or obesity; women with migraine with aura (stroke risk)
  - Abdominal pain
  - Chest pain
  - Headaches (severe; visual problems)
  - Eye problems (tunnel vision; partial/complete loss of vision)
  - Severe leg pain

<table>
<thead>
<tr>
<th>Population</th>
<th>VTE Rate (women/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-COC user</td>
<td>50/100,000</td>
</tr>
<tr>
<td>CDC user</td>
<td>100/100,000</td>
</tr>
<tr>
<td>Pregnant/postpartum</td>
<td>200/100,000</td>
</tr>
</tbody>
</table>

- Desogestrel & increased VTE risk – mixed data – no recommendation to switch
- Higher estrogen content (50 mcg pills) increases VTE risk
- Higher estrogen concentrations

True or False: Women should take periodic breaks from hormonal contraception to minimize adverse effects.

- True
- False

**Hint:** Use the bar graph to determine the correct answer.
Adverse Effects

- Offer reassurance, education & counseling
- Respect patient choice to discontinue any method at any time
- Refer to PCP or OB/GYN provider when needed

Adverse Effects: CHC

- No significant differences in formulations shown in RCTs
- Switching to a different formulation may resolve issues, but no clear algorithm
- Nausea, vomiting – take with food
- Breakthrough bleeding – usually resolves in 3–6 cycles; take at same time each day; adherence and smoking cessation more common with very low dose EE, may be less among women; consider PCP
- Weight gain – no evidence that CHCs promote weight gain vs. placebo; consider lifestyle factors
- Acne – consider anti-androgenic progestin (e.g., drospirenone); avoid levonorgestrel
- Mood changes/depression – in clinical trials, no different than vs. placebo; consider referral for assessment

Adverse Effects: POP

- Nausea/vomiting – take with food
- Irregular menses/spotting – assess adherence
- If heavy bleeding, refer to rule out other causes

Adverse Effects: Shot

- Irregular menses – reassurance; at 1 year, 50% of women are amenorrheic
- Weight gain – Average 3.4 lbs in first year; 6.5 lbs after 5 years; adolescents may be more likely to gain weight. Assess lifestyle factors.
- Decrease in bone mineral density – in women using for >2 years; similar to that experienced by lactating women; 12 months after discontinuation, similar to non-users. Encourage calcium supplementation/diet, regular weight-bearing exercise.

Resources

- New Mexico Prescriptive Authority Training Toolkit
  - Links and documents including protocol, questionnaire, consent form, CDC US MEC, counseling guide, and more
- Reproductive Health ECHO Clinic
  - https://echo.unm.edu/nm-telehealth-clinic/reproductive-health/
  - Pharmacy CE credits starting in July 2018
  - Didactic presentation & patient cases
- Upcoming topics:
  - How to pick a pill, initiation and counseling
  - Combined hormonal methods – indications and contraindications
  - Monograde effects of pills/patches
  - DMPA as contraception
  - Emergency contraception

Questions?