A Pharmacist’s Update on the Efficacy, Safety and Role of Long-acting Reversible Contraception

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Educational Objectives

At the completion of this activity, the participant will be able to:

• Explore the efficacy and safety of various types of non-hormonal and hormonal long-acting reversible contraception (LARC) measures

• Identify the role of the pharmacist in the education and management of patients who elect to use LARCs

U.S. Pregnancies

Unintended vs Intended

- Intended Pregnancies: 55%
- Unintended Pregnancies: 45%
- Abortion: 19%
- Births: 26%


Ideal Contraceptive

- Very effective
- Easily accessible
- Long duration of action
- No adverse effects
- Reversible
- Discrete in use
- STI Protection


Patient Case

TL is a 32-year-old woman who is 38 weeks pregnant and is scheduled for a planned repeat C-section at 39 weeks. She is seeking contraception postpartum. She has 3 children, and she and her husband have decided not to have anymore children in the near future, but may consider having another child again in a few years.

She has a history of GERD, TMJ and seasonal allergies, but, otherwise, she is healthy. Her medications prior to pregnancy include omeprazole 20 mg PO daily, fluticasone 50 mcg 2 sprays intranasally daily, carbamazepine 200 mg PO BID for TMJ. Her BMI is 34. She has used condoms in the past but would like something more long-term. She plans to breastfeed and prefers to stay away from hormonal contraception for concerns with hormones in the breastmilk and because her mother had a DVT in the past. TL works full-time and is very busy. She is thinking about an intrauterine device and asks her pharmacist if it is a good option for her.

What are some contraceptive options for TL and some considerations regarding therapy choice for TL?
Factors in Choosing a Contraceptive

- Effectiveness
  - Theoretical (Perfect) vs Actual (Typical)

- Accessibility
  - Cost
  - Adherence ability

- Patient Factors
  - Age
  - Health/conditions and lifestyle choices
  - Medication history
  - Frequency of intercourse
  - Importance of not becoming pregnant
  - Perceptions and misperceptions

- Acquisition
  - Advise effects
  - Duration of action
  - Return to fertility time
  - Risks vs benefits

- Adverse effects

- Duration of action

- Return to fertility time

- Risks vs benefits

- Cost

- Adherence ability

- Acquisition

Contraceptive Methods

- Female/male sterilization

- Long-acting (IUD: copper, progestin; progestin implant)

- Shorter-acting hormonal contraceptives: combined, progestin-only

- Emergency contraceptives

- Barrier contraceptives

- Spermicides

- Natural family planning

Types of Long-Acting Reversible Contraception (LARC)

- Non-hormonal LARC
  - Intrauterine copper contraceptive

- Hormonal LARC
  - Progestin intrauterine systems
  - Progestin implant

Characteristics of LARC

<table>
<thead>
<tr>
<th>Ideal Contraceptive</th>
<th>Characteristics of LARC</th>
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<tbody>
<tr>
<td>Highly Effective?</td>
<td>Yes</td>
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<tr>
<td>Long Duration of Action?</td>
<td>3 to 10 years</td>
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<tr>
<td>Easily Reversible?</td>
<td>Yes</td>
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<tr>
<td>Adverse Effects?</td>
<td>Yes</td>
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<td>Privacy of Use?</td>
<td>Yes</td>
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<tr>
<td>STI Protection?</td>
<td>No</td>
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<tr>
<td>Easily Accessible (able to attain, cost, availability)</td>
<td>Depends</td>
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</table>

Who is a Candidate for LARC?

Any healthy reproductive age woman who is seeking effective, reversible contraception. Includes those that are:

- Nulliparous or parous
- Adolescents
- History of sexually-transmitted infection (STI)
- Postpartum

Intrauterine Copper Contraceptive

- US product name: ParaGard T 380A

- Description
  - T-shaped IUD (32 mm x 36 mm), frame - polyethylene with barium sulfate
  - 2 flexible arms for insertion that open in uterus to hold solid sleeves of copper against fundus
  - Surface area of copper: 380 mm²

- Effectiveness
  - Works for 10 years
  - Perfect use failure rate: 0.6%
  - Typical use failure rate: 0.8%
Intrauterine Copper Contraceptive: Mechanism of Action

- Primary action: spermicide
- Copper ions
  - Inhibit sperm motility by inhibiting acrosomal enzyme activation
- Presence of device may prevent implantation
- Does not interfere with ovulation

Types of LARC

- Non-hormonal LARC
  - Intrauterine copper contraceptive
- Hormonal LARC
  - Progestin intrauterine systems
  - Progestin implant

LARC - Progestins

<table>
<thead>
<tr>
<th>Progestin</th>
<th>Description</th>
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<tr>
<td>Levonorgestrel</td>
<td>Used in intrauterine systems, oral combined hormonal contraception, OTC emergency contraception, Second generation progestin</td>
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<tr>
<td>Etonogestrel</td>
<td>Found in contraceptive implant, contraceptive vaginal ring, Active metabolite of desogestrel, Third generation progestin</td>
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</table>

Levonorgestrel Intrauterine Systems

<table>
<thead>
<tr>
<th>System</th>
<th>Mechanisms of action</th>
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| 5-yr. LNG-IUS [Mirena] | - Releases 15 mcg/day  
                          |  - Increased irregular bleeding          |
| 5-yr. LNG-IUS [Liletta] | - Releases 13 mcg/day  
                          |  - Increased bleeding  
                          |  - Increased scheduled bleeding          |
| 5-yr. Low dose LNG-IUS [Skyla] | - Releases 12 mcg/day  
                                       |  - Amenorrhea                         
                                       |  - Abdominal pain                      
                                       |  - Headache/migraine                   
                                       |  - Intrauterine conception             |

Some Adverse Reactions of IUDs

- Uterine bleeding
- Irregularities
  - Unscheduled bleeding
  - Decreased bleeding
  - Increased scheduled bleeding
- Amenorrhea
- Abdominal pain
- Headache/migraine
- Intrauterine conception

Some progestin adverse effects

- Headache
- Increased appetite
- Depression
- Changes in libido
- Hair loss*
- Hirsutism*
- Acne, oily skin*
- Androgen-mediated

Levonorgestrel - LNG-IUS Failure Rates: Typical Use = Perfect Use (0.2%)

- Effective for 5 years
- Releases 20 mcg/day
- Also has indication for heavy menses in women who would like contraception
- Size = 32 mm wide/32 mm

Etonogestrel - LNG-IUS Failure Rates: Typical Use = Perfect Use (0.2%)

- Effective for 3 years
- Releases 18.6 mcg/day
- Also has indication for heavy menses in women who would like contraception
- Size = 32 mm wide/32 mm

*Androgen-mediated
Contraindications for IUDs
Per Package Labeling
• Pregnancy or suspected pregnancy
• Distortion of the uterus
• Acute pelvic inflammatory disease or current high risk
• Postpartum/postabortal endometritis in last 3 months
• Uterine or cervical cancer
• Unknown etiology of vaginal bleeding
• Mucopurulent cervicitis or vaginitis
• Allergic to product
• Current IUD that has not yet been removed
• Acute liver disease or liver tumor (benign or malignant)
• Breast cancer or other progestin-sensitive cancer
*Purple denotes levonorgestrel IUD

IUD: Patient Counseling
• PAINS
  – P – Period late; abnormal spotting or bleeding
  – A – Abdominal pain, pain with intercourse
  – I – Infection exposure (STI); abnormal vaginal discharge
  – N – Not feeling well, fever, chills
  – S – String missing, shorter or longer
• Anticipated menstrual changes
• If expulsion occurs, back up contraception must be used

Contraindications for Progestin Implant
Per Package Labeling
• Pregnancy or suspected pregnancy
• Unknown etiology of vaginal bleeding
• History of thrombosis or thromboembolic disease
• Allergic to product
• Acute liver disease or liver tumor (benign or malignant)
• Breast cancer or other progestin-sensitive cancer

Progestin Implant
Product Name
• Nexplanon (etonogestrel)
  • Inserted subdermally in upper arm

Description
• Single, soft, radiopaque, rod implant
• 4 cm x 2 mm
• Made of ethylene vinyl acetate
• Contains 68 mg of etonogestrel and 15 mg of barium sulfate
• Releases 25-45 mcg/day over 3 years

Effectiveness
• Typical use failure rate: 0.05%
• Perfect use failure rate: 0.05%

Studies: Decrease in Abortions/Pregnancy/Births
• Contraceptive CHOICE Project – St. Louis
  -Over 9,000 women enrolled for 3 years, 75% chose LARC method
  -Continuation rates higher than for short-acting methods
    – 86% vs 55% at 12 months
    – 77% vs 41% at 24 months
    – 71% of participants reported no change in partners at 6 and 12 months
Studies: Decrease in Abortions/Pregnancy/Births

- Contraceptive CHOICE Project – continued
  - Failure rates for pill, patch and ring users were higher (4.8–9.4%) than for LARC users (<1%) over the 3 years
  - Birth and abortion rates decreased by half compared to nation rates
    - Pregnancy: 3.4% vs 5.74% (all US teens 15–19), 15.85% (sexually active US teens)
    - Abortion: 0.97% vs 1.47% (all US teens 15–19), 4.15% (sexually active US teens)
    - Birth: 1.97% vs 3.44% (all US teens 15–19), 9.4% (sexually active US teens)

- National Survey of Family Growth 2006-2010
  - 13% of postpartum women using short-acting contraceptives were pregnant within 18 months compared to 0.5% using LARC


Studies: Same Day IUD/ Implant Placement and Infection Risk

- Same day IUD/Implant placement
  - Increases uptake and decreases pregnancy rate
  - One study showed only 54% uptake for women requiring a second visit for IUD placement
  - Other studies show decreased short-term pregnancy rates with same-day insertion, including postpartum and post-abortion

- Infection risk
  - Infection rates considered low
  - Study at Kaiser Permanente Northern California – over 57,000 participants looked at safety of IUD placement with STI testing
    - Overall PID rates were 0.5%
    - No difference in infection rates between those in the same-day STI tested group, those screened 3 months later or those no screening
  - Other studies have confirmed low infection rates, similar findings PID rates ~0.5%, consistent even in women with high risks for STIs


Patient Case

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Pharmacist’s Role in LARC Patient Care

- Determine type of LARC
- Determine if it is a levonorgestrel based
- Other things to consider/to counsel on
  - Very important when taking a medical history to also ask about LARC therapies to assess the following issues:
    - Drug-drug interactions
    - Adverse drug reactions
    - Prevention of STIs
    - Teratogenicity

Pharmacist’s Role in LARC Patient Care

- Other things to consider/to counsel on
  - Open dialog is key. May phrase question as:
    - “Are you currently using any forms of birth control such as over-the-counter spermicides, condoms, oral tablets, patch, vaginal ring, intrauterine device or implant?”
    - Open-ended, “What forms of birth control are you using, if any, such as over-the-counter spermicides, condoms, oral tablets, patch, vaginal ring, intrauterine device or implant?”

CDC Medical Eligibility Criteria for Contraceptive Use (MEC)

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

Contraindications for LARC
Based on CDC Medical Eligibility Criteria
4 categories:

Category 1. A condition for which there is no restriction for the use of the contraceptive method.

Category 2. A condition where the advantages of using the method generally outweigh the theoretical or proven risks.

Category 3. A condition where the theoretical or proven risks usually outweigh the advantages of using the method.

Category 4. A condition that represents an unacceptable health risk if the contraceptive method is used.

CDC Medical Eligibility Criteria (MEC) I vs C

Initiation “I”
- Condition present when initiating the contraceptive agent

Continuation “C”
- Condition presents while woman is using the contraceptive agent

CDC MEC for LARC

<table>
<thead>
<tr>
<th>Condition</th>
<th>LNG-IUD</th>
<th>Implant</th>
<th>Cu-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Hypertension (controlled)</td>
<td>2</td>
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<tr>
<td>Hypertension (uncontrolled)</td>
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<tr>
<td>Diabetes</td>
<td>2</td>
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<tr>
<td>History of DVT/PE/thrombogenic mutation</td>
<td>2</td>
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<tr>
<td>Awaiting DVT/PE or anticoagulant therapy</td>
<td>2</td>
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<tr>
<td>Stroke</td>
<td>2</td>
<td>3</td>
<td>1</td>
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<tr>
<td>Malignant neoplasm</td>
<td>2</td>
<td>1</td>
<td>1</td>
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<tr>
<td>HIV infection (CD4 &lt; 200)</td>
<td>2</td>
<td>2</td>
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<tr>
<td>HIV infection (CD4 &gt; 200)</td>
<td>3</td>
<td>3</td>
<td>1</td>
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Other Contraindications

Copper IUD
- Wilson’s disease
- Systemic lupus erythematosus with severe thrombocytopenia

Progestin LARC
- Acute liver disease or liver tumor (benign or malignant)
- Ischemic heart disease
- Systemic lupus erythematosus with positive or unknown antiphospholipids
- Solid organ transplant (initiation)

DVT and Hormonal LARC

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<tr>
<th>Method</th>
<th>Adjusted Relative Risk of DVT (95% CI)</th>
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<tbody>
<tr>
<td>Non-user</td>
<td>Reference (1)</td>
</tr>
<tr>
<td>Transdermal patch</td>
<td>7.9 (3.54 to 17.85)</td>
</tr>
<tr>
<td>Vaginal ring</td>
<td>6.48 (4.89 to 8.94)</td>
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<tr>
<td>COC with norgestimate</td>
<td>3.57 (2.98 to 4.27)</td>
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<tr>
<td>COC with LNG and 30-40 mcg of estrogen</td>
<td>3.21 (2.71 to 3.81)</td>
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<tr>
<td>Implant</td>
<td>7.49 (3.76 to 9.87)</td>
</tr>
<tr>
<td>Levonorgestrel IUD</td>
<td>9.57 (6.41 to 13.81)</td>
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Risk of DVT


DVT and LARC

Postpartum and LARC Use
CDC Medical Eligibility Criteria

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</table>
| Recommendations for Drug Interactions with LARC

- Copper IUD
  - No known drug interactions (CDC Category 1, CDC 1/2 for ARVs)

- Levonorgestrel IUDs
  - No known interactions with ARV therapy (Category 1/2) or antiepileptic medication (CDC Category 1), but inducers or inhibitors of CYP3A4 are known to affect progestin levels.

- Progestin Implant
  - Concomitant use of drugs that decrease effectiveness progestin levels requires a back-up birth control method, such as condoms. (CDC Category 2)

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| Drug Interactions
Summary Chart for U.S. CDC Medical Eligibility Criteria for Contraceptive Use

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| CYP3A4 Inducers may decrease progestin effectiveness:
  - Examples: Itraconazole, ketoconazole

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| Recommendations for Drug Interactions with LARC

- Copper IUD
  - No known drug interactions (CDC Category 1, CDC 1/2 for ARVs)

- Levonorgestrel IUDs
  - No known interactions with ARV therapy (Category 1/2) or antiepileptic medication (CDC Category 1), but inducers or inhibitors of CYP3A4 are known to affect progestin levels.

- Progestin Implant
  - Concomitant use of drugs that decrease effectiveness progestin levels requires a back-up birth control method, such as condoms. (CDC Category 2)

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  - Examples: Itraconazole, ketoconazole

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Return to Fertility

- Pilot data from Contraceptive CHOICE project
  - Return to fertility time with IUDs is similar to shorter-acting contraceptive methods
  - Looked at 69 IUD users (19 copper and 50 LNG IUDs) vs 42 non-users
  - Found pregnancy rates similar at 12 months, 81% of users vs 70% of non-users
- Copper IUD – ovulation is not suppressed
- LARC methods do not cause infertility

Adolescents and LARC: ACOG Recommendations

- LARC methods should be considered for all adolescents, and accessibility to these methods should be assured
- Counseling about LARC methods should be provided to sexually active adolescents at every health care provider visit.
  - Low failure rates, easy adherence
  - High satisfaction and continuation
  - Also discuss importance of condom use for STI prevention
- Complications are low, expulsion may be higher in adolescents

Conclusion

- Pharmacists play an important role with LARC in:
  - Providing information
  - Identifying and referring appropriate patients
  - Taking comprehensive medication histories
  - Managing drug-drug interactions
  - Recommending additional contraception for STI protection
  - Manage and assess side effects
  - Working with institutions to encourage provision
- LARC therapies are:
  - Very effective in preventing pregnancy
  - Quickly reversible
  - Have high continuation rates
  - Cost-effective

Additional Resources

- Centers for Disease Control and Prevention
- ACOG/LARC Clinical Education and Training
- American Reproductive Health Professionals
  - www.arhp.org
- Bedsider
  - www.bedsider.org
- Guttmacher Institute
  - www.guttmacher.org
- The Choice Project
  - www.choiceproject.wustl.edu
- LARC First
  - www.larcfirst.com