The Essentials on Long Acting and Reversible Contraception

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Presentation Disclosures

- As faculty of an OB/GYN program, I have been certified to teach our residents insertion of the Nexplanon implantable device.
- I have no relevant financial relationship with the manufacturers of any of the commercial products discussed in this presentation.
- I will not be discussing any off label uses of any product/device during this presentation.
Learning Objectives

- Describe the potential for Long Acting Reversible Contraception (LARC) to help prevent unintended pregnancies and reduce health care costs.
- Compare the clinical effects of the different types of LARC's including Nexplanon, Paragard IUD, and Mirena IUD.
- Discuss the selection of appropriate candidates for LARC and adverse effects using the principles of body unity, self regulation, and the interrelationship of structure and function.
Unintended pregnancies

- Women of childbearing age, particularly adolescents (age 15-19) and young women (age 20-24) are at risk for an unintended pregnancy.
- Approximately 50% of pregnancies in this country are unintended.
- 82% of adolescent pregnancies are unplanned and this accounts for 1/5 of all unintended pregnancies in this country.
- Potential implications are the increased risk for poor maternal and infant outcomes and the financial burden on our health care system.
Unintended pregnancies

**Declines in Birth Control Education**

Fewer teens are learning about methods of birth control from formal sex education sources, while more are being taught how to say no to sex without any birth control information.

<table>
<thead>
<tr>
<th>Instruction about Methods of Birth Control</th>
<th>Say No to Sex, No Birth Control Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Female</strong> 2006–2010 70%</td>
<td><strong>Female</strong> 2011–2013 22%</td>
</tr>
<tr>
<td><strong>Male</strong> 2006–2010 61%</td>
<td><strong>Male</strong> 2011–2013 29%</td>
</tr>
<tr>
<td><strong>Female</strong> 2006–2010 60%</td>
<td><strong>Female</strong> 2011–2013 28%</td>
</tr>
<tr>
<td><strong>Male</strong> 2006–2010 55%</td>
<td><strong>Male</strong> 2011–2013 35%</td>
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</tbody>
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www.guttmacher.org
LARC's and their impact on health care costs.

- In 2010, unintended pregnancies resulted in $21 billion dollars in direct medical costs in the United States.
- Even if the LARC method is not used for the full duration of efficacy, they become cost saving relative to short acting contraceptive methods within three years of use.
- According to the CDC, for every public dollar spent on pregnancy prevention, $4.02 was shown to be saved on maternity and infant care among Medicaid eligible women.
- A 2003 national survey showed that an estimated $15.7 billion was saved over one year by preventing unplanned births.
The legal ability of minors to consent to health care services, including sexual and reproductive health, has increased dramatically over the past 30 years.

Many states explicitly permit all or some minors to obtain contraceptive, prenatal, and STI services without parental involvement.

Nearly every state permits minor parents to make important decisions regarding their own children.

In terms of contraception services, 26 states and the District of Columbia allow minors (12 and older) to consent to contraceptive services. 20 states allow only certain categories of minors to consent and 4 states have no relevant policy or case law (North Dakota, Ohio, Rhode island, and Wisconsin). In these states, physicians commonly provide medical care without parental consent to minors they deem mature.
Effectiveness of contraception methods
Long-Acting Reversible Contraception: Implants and Intrauterine Devices

- Safe and appropriate contraceptive methods for most women and adolescents.
- Many boast a pregnancy rate of <1% per year for typical use.
- They have the highest rate of satisfaction and continuation of all reversible contraceptives.
- Approximately 4.5% of women age 15-19 who are currently on birth control are using a LARC with Mirena IUD being the most common.
Medical Eligibility Criteria for Contraceptive Use

<table>
<thead>
<tr>
<th>MEC categories for contraceptive eligibility</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A condition for which there is no restriction for the use of the contraceptive method</td>
</tr>
<tr>
<td>2</td>
<td>A condition where the advantages of using the method generally outweigh the theoretical or proven risks</td>
</tr>
<tr>
<td>3</td>
<td>A condition where the theoretical or proven risks usually outweigh the advantages of using the method</td>
</tr>
<tr>
<td>4</td>
<td>A condition that represents an unacceptable health risk of the contraceptive method is used.</td>
</tr>
<tr>
<td>CONDITION</td>
<td>SUBCONDITION</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Hypertension (continued)</td>
<td>a) Systolic ≤160 or diastolic ≤100 mm Hg</td>
</tr>
<tr>
<td>c) Vascular disease</td>
<td></td>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
<td>a) Intestinal obstruction (Crohn’s disease)</td>
</tr>
<tr>
<td>Liver tumors</td>
<td>a) Benign</td>
</tr>
<tr>
<td>a) Hepatocellular adenoma</td>
<td></td>
</tr>
<tr>
<td>b) Malignant *</td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>Multiple risk factors for severe cardiovascular disease (such as older age, smoking, diabetes and hypertension)</td>
</tr>
<tr>
<td>Obesity</td>
<td>a) ≥30 kg/m² body mass index (BMI)</td>
</tr>
<tr>
<td>a) ≥30 overweight adults</td>
<td></td>
</tr>
<tr>
<td>b) Menarche ≤18 years and ≥30 kg/m²</td>
<td></td>
</tr>
<tr>
<td>Ovarian cancer *</td>
<td></td>
</tr>
<tr>
<td>a) Nulliparous</td>
<td></td>
</tr>
<tr>
<td>b) Parous</td>
<td></td>
</tr>
<tr>
<td>Pelvic inflammatory disease</td>
<td>a) Past (assuming no current risk factors of STI)</td>
</tr>
<tr>
<td>a) with subsequent pregnancy</td>
<td></td>
</tr>
<tr>
<td>a) without subsequent pregnancy</td>
<td></td>
</tr>
<tr>
<td>b) Current</td>
<td></td>
</tr>
<tr>
<td>Peripartum cardiomyopathy *</td>
<td>a) Normal or mildly impaired cardiac function</td>
</tr>
<tr>
<td>i) &lt;6 mo</td>
<td></td>
</tr>
<tr>
<td>a) ≥6 mo</td>
<td></td>
</tr>
<tr>
<td>b) Moderately or severely impaired cardiac function</td>
<td>4</td>
</tr>
<tr>
<td>Postpartum</td>
<td>a) First 24 hours (immediate up to 48 h)</td>
</tr>
<tr>
<td>a) Second trimester</td>
<td></td>
</tr>
<tr>
<td>a) Immediately post-septic abortion</td>
<td></td>
</tr>
<tr>
<td>Postpartum (in nonbreastfeeding women)*</td>
<td>b) ≥21 d to 42 d</td>
</tr>
<tr>
<td>a) With other risk factors for VTE (such as age ≥30 y, previous VTE, thrombophilia, immediate thrombinogenemia at delivery, BMI ≥30 kg/m², postpartum hemorrhage, postcesarean delivery, pre-eclampsia or smoking)</td>
<td>3</td>
</tr>
<tr>
<td>b) Without other risk factors for VTE</td>
<td></td>
</tr>
<tr>
<td>Postpartum (breastfeeding)</td>
<td>b) ≥21 d to 30 d</td>
</tr>
<tr>
<td>a) With other risk factors for VTE (such as age ≥30 y, previous VTE, thrombophilia, immediate thrombinogenemia at delivery, BMI ≥30 kg/m², postpartum hemorrhage, postcesarean delivery, pre-eclampsia or smoking)</td>
<td>2</td>
</tr>
</tbody>
</table>
There's an App for That

*US Medical Eligibility Criteria for Contraceptive Use*

This may make things easier...
Nexplanon: etonogestrel contraceptive implant

- A 4cm flexible implantable birth control made with 68 mg of etonogestrel.
- Currently approved for three years of pregnancy prevention.
- Radiopaque
- Contraindications
  - Known or suspected pregnancy
  - History of thrombus or thromboembolic disorder
  - Liver disease
  - Known or suspected breast cancer
  - Allergies to any component of Nexplanon device
Nexplanon

• Very quick insertion time (approximately 30 seconds).
• Insertion is safe at any time in non-breast feeding women after childbirth and theoretically no less than 4 weeks for breast feeding mothers (concern for milk production and growth of child).
• Can be inserted anytime during the menstrual cycle.
• Providers should exclude pregnancy.
• Use a back up form of birth control for seven days unless inserted:
  • Within five days of menses
  • Immediately post partum or post abortion
  • Immediately upon switching from one form of birth control to another
Implant bleeding patterns

Bleeding/Spotting Episodes During the First 2 Years’ Use of Non-radiopaque Etonogestrel Implant IMPLANON

<table>
<thead>
<tr>
<th>Bleeding Patterns</th>
<th>% of 30-day intervals with this pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrequent</td>
<td>33.6%</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>22.2%</td>
</tr>
<tr>
<td>Prolonged</td>
<td>17.7%</td>
</tr>
<tr>
<td>Frequent</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

Based on 3,315 recording periods of 90 days’ duration in 780 women, excluding the first 90 days after implant insertion. Bleeding/spotting episode=one or more consecutive days during which bleeding or spotting occurred.
Adolescents who use the contraceptive implant may have changes in their menstrual patterns throughout the duration of use.

Because of the potential for infrequent menstrual bleeding, hemoglobin levels in patients with the etonorgestrel implant are often higher.

Some studies have shown a reduction in dysmenorrhea and pelvic pain in users.

The contraceptive implant has shown less weight gain than Depo Provera injections in overweight adolescents.
Nexplanon – Patient Counseling

- Give patients realistic expectations regarding their potential bleeding patterns and tell them to give the it a good 90 days worth of an adjustment period.
- Women with favorable bleeding profiles in the first 3 months of use were likely to continue with that bleeding pattern for the first two years.
- Women who started with an unfavorable pattern had a 50% chance of improving.
- Women with a low body weight had fewer bleeding and spotting days than women with a higher body weight.
Copper IUD (Paragard)

- T-shaped device of polyethylene wrapped with copper wire around the stem and arms.
- FDA has approved the copper IUD for up to 10 continuous years.
- Proposed mechanism of actions include:
  - Inhibits sperm migration and viability
  - Change in transport speed of the ovum
  - Damage to or destruction of the ovum
  - All effects (pre and post fertilization) occur prior to implantation.
LNG intrauterine device (Mirena)

- 99% effective and releases approximately 20 mcg/day of levonorgestrel.
- FDA approved for up to five years.
- Also approved for patients with heavy vaginal bleeding.

**Mechanism of action**
- Thickens cervical mucus
- Inhibition of implantation
- Thinning the lining of the uterus
LNG- IUD contra-indications

- Pregnancy or suspicion of pregnancy (cannot be used for post coital contraception)
- Congenital or acquired anomalies that distort the uterine cavity
- Acute pelvic inflammatory disease
- Post partum endometritis or septic abortion within the past 3 months
- Known or suspected uterine or cervical cancer
- Known or suspected breast cancer
- Active liver disease
- Uterine bleeding of unknown etiology
IUD insertion timing

- Okay to insert anytime during menstrual cycle.
- You must reasonably exclude pregnancy prior to insertion.
- There's really no major benefit to inserting the IUD while patient is on her menses in terms of ease of administration.
- Routine antibiotic prophylaxis is not recommended prior to insertion.
- For women at low risk, data does not support routine screening of STI's prior to insertion.
- Treat known STI prior to insertion.
IUD insertion timing: high risk patients

- It is reasonable to screen for STI's and place IUD at the same visit.
- Treat with IUD in place if the result is positive.
- Risk of PID remains low
  - 0-2% when no cervical infection is present
  - 0-5% when insertion occurs with an undetected infection
IUD's and postpartum insertion

- Appears safe and effective.
- Should be placed within 10 minutes of placental separation.
- May want to cut strings 1-2 weeks after insertion due to continued involution of the uterus.
- Expulsion rates are higher immediately postpartum but the benefits of this LARC may be worth the risk. This risk may also be less if IUD is placed after a patient has had a cesarean section.
- Remember that there is a theoretical risk of affecting breastfeeding with the Mirena IUD and not the Copper IUD.
- Insertion of an IUD immediately following an abortion is safe and effective. Almost half the abortions performed in this country are repeat abortions. This habit may be reduced if an IUD (or implant) is immediately inserted.
IUD's and other issues

Ectopic pregnancy

- You can use an IUD in the patient with a history of an ectopic pregnancy.
- A patient has a higher risk of having an ectopic pregnancy with an IUD in place, but her overall risk of getting pregnant is lower.

IUD with concurrent pregnancy

- Both the FDA and the WHO recommend removing the IUD in the event of an intrauterine pregnancy.
- This should be done without an invasive procedure (no hooks!)
- A retained IUD during pregnancy increases a patient’s risk of septic abortion.
IUD's are safe to use among adolescents.

They may be inserted without any more difficulty as compared with an older patient.

IUD expulsion is uncommon in adolescents.

Adolescents should be routinely screened for STI's (gonorrhea and chlamydia) at the time of insertion.

Adolescents should be counseled on the changes in their bleeding patterns, especially during the first few months of use.
SKYLÁ

- Releases 14 mcg levonorgestrel per day and smaller than the Mirena IUD.
- The “answer” to the nulliparous cervix.
- Effective for 3 years.
- Does not carry the approval for heavy menses at this time.
- Insert within the first seven days of menses or immediately after a first trimester abortion. When inserted with these parameters, a back-up for birth control is not needed.
CDC's 6/18 Initiative

- The CDC is partnering with health care payers, purchasers, and providers to improve health and health care costs.
- They are targeting 6 common and costly health care conditions and 18 proven specific interventions.
- One of these health care conditions is unintended pregnancies.
CDC's 6/18 Initiative - Proposed payer interventions

- Reimburse providers for the full range of contraceptive services (screening, counseling, insertion, removal, and follow-up) for women of child bearing age.

- Reimburse providers or systems for the actual cost of LARC in order to provide the full range of contraceptive methods (high up front cost but overall cost effective).

- Reimburse for immediate postpartum insertion of long acting reversible contraception by unbundling payment for LARC from other post partum services (coding modifiers have been successful in at least 13 states as of July 2015).

- Remove administrative and logistical barriers to long-acting reversible contraceptives (pre-approval requirements or step therapy restriction, and manage high acquisition and stocking costs).
• LARC methods should be offered as **first-line contraceptive methods and encouraged as options for most women**

• LARC methods have few contraindications

• Almost all women are eligible for the implant and IUDs


ACOG initiative and immediate post partum placement of LARCs

- ACOG has a variety of resources on it’s site which are designed to help physicians and health systems navigate the process of inserting and billing for LARCs placement immediately postpartum.

- The resource digest is downloadable and discussed clinical guidance and implementation, billing and reimbursement, capacity building and systems change, and publications on safety, efficacy, barriers to access and breast feeding.

- 21 states have currently provided guidance for Medicaid reimbursement for immediate postpartum placement.
• Despite the continued research and ACOG recommendations, relatively few LARC's are prescribed by OB/GYNs and even fewer are inserted on a same day basis.

• A study examining OB/GYN practices and opinions about the use of IUD's in adolescents, nulliparous patients, and other patient groups reported:
  • 95.8% report providing IUDs but only 66.8% considered nulliparous women and 43% considered adolescents as appropriate candidates.
  • 87% of OB/GYNs studied require two or more visits for IUD insertion. Years of experience and professional title significantly predicted attitudes about the number of visits required to get a LARC.
  • 67.3% agreed that IUD can be inserted immediately post partum, however very few provide these services.
Even Peds acknowledges that it’s the right thing to do!
What can you do?

- Review your office or hospital practices to see where you can improve providing LARC for your patients.
- Examine your own bias toward contraception.
- Review your counseling with patients and ensure that you give them all of their options.
- Consider being trained on the insertion of all LARC devices.
- Continue being an advocate for your patients and their health.
References


- www.cdc.gov/sixeighteen/

- www.guttmacher.org/print/state-policy/explore/overview-minors-consent-law

- www.guttmacher.org/fact-sheet/facts-american-teens-sources-information-about-sex/

- ACOG Committee Opinion Number 539 October 2012; Adolescents and Long Acting Reversible Contraception: Implants and Intrauterine Devices.

- ACOG Practice Bulletin Number 121, July 2011; Long-Acting Reversible Contraception: Implants and Intrauterine Devices