CONTRACEPTIVE UPDATES: A HIGHLIGHT ON POSTPARTUM CONTRACEPTION

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DISCLOSURE
Dr. Sadia Haider reports no financial relationships that would pose a conflict of interest in preparing or delivering this presentation.

OBJECTIVES
• Discuss contraceptive updates in the setting of the ACA.
• Discuss new FDA-approved methods as of 2015: Skyla and Liletta.
• Identify common myths, misconceptions about contraceptives and strategies for overcoming them.
• Describe the importance of postpartum contraception and counseling.
CASE STUDY

- Ms. JD, a 16 y/o nulliparous adolescent
- Currently sexually active, one partner 17 y/o, using condoms
- Seeking contraception
- Medicaid managed program insurance
- Wants to have periods each month
- Concerned with weight gain due to contraceptive method

WHAT’S NEW IN CONTRACEPTION?

CONTRACEPTIVE USE IN THE U.S.
CONTRACEPTIVE SAVINGS IN MN

Unintended Pregnancy Prevention

<table>
<thead>
<tr>
<th>Year</th>
<th>All health centers</th>
<th>Title X centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>294,200</td>
<td>132,100</td>
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<tr>
<td>2012</td>
<td>221,000</td>
<td>62,300</td>
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Public Cost Savings

<table>
<thead>
<tr>
<th>Year</th>
<th>All health centers</th>
<th>Title X centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$13,810,000</td>
<td>$1,700,000</td>
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<tr>
<td>2012</td>
<td>$11,280,000</td>
<td>$1,150,000</td>
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</table>

CONTRACEPTIVE NEED IN MN

- In 2013, 294,200 MN women were in need of publicly supported contraceptive services
CONTRACEPTION PROVISION IN MN

Sources of Funding: Minnesota
Public funding for family planning services in Minnesota by funding source in 2010

- Other federal sources: 20%
- Medicaid: 62%
- Title X: 10%

www.guttmacher.org

CONTRACEPTION & THE ACA

- Contraceptive methods and counseling must be covered at no cost by plans in the Health Insurance Marketplace when provided by an in-network provider

- All FDA-approved methods must be covered

CONTRACEPTION & THE ACA

The Affordable Care Act’s contraceptive coverage guarantee is working...

Privately insured women are increasingly paying $0 out of pocket for a range of contraceptive methods.

- IUD: 62%
- Male sterilization: 59%
- Injectable: 44%
- Pills: 44%
- Pessary: 27%

- Percent of privately insured women who paid $0 out of pocket for each method:
  - Half of 2012 to 2014
  - Less than 1% 2014

...and soon even more women will benefit.

*Based on combined data from 2010, 2012, and 2014 because the number of S.I. cases increased each year.
WE STILL NEED TITLE X

IMMEDIATE IMPACT

In the first year of the Affordable Care Act’s recent coverage expansions, participating centers collectively saw an increase in both publicly and privately insured family planning users.

<table>
<thead>
<tr>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>60%</td>
</tr>
</tbody>
</table>

But what about the remaining 36%???

NEW LARC METHODS

• What do you need to know about the newest approved IUDs?

SKYLA

• LNG IUS (Skyla®)
• 13.5 mg levonorgestrel (Bayer)
• Releases average 6mcg / day of levonorgestrel
• FDA Approved January 2013
• Approved for 3 years
• Smaller size device than Mirena
• Marketed as easier insertions in nulliparous women
• 6% of users develop amenorrhea after 1 year of use
LILETTA

- Liletta® - An Alternative to Mirena
- FDA Approved February 27, 2015
- 52 mg levonorgestrel, average 15.6 mcg/day release
- Cumulative 3 year efficacy: 99.45%
- Reduced pricing for 340B programs – including Title X
- Expected to reduce costs to patients

LILETTA PRICING

<table>
<thead>
<tr>
<th>NUMBER OF UNITS</th>
<th>VOLUME DISCOUNTS</th>
<th>ACQUISITION COST</th>
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<tbody>
<tr>
<td>1-9</td>
<td>4.1%</td>
<td>$0506.88</td>
</tr>
<tr>
<td>6-11</td>
<td>6.2%</td>
<td>$0503.75</td>
</tr>
<tr>
<td>16-24</td>
<td>8.0%</td>
<td>$0183.00</td>
</tr>
<tr>
<td>25-30</td>
<td>10.0%</td>
<td>$0502.00</td>
</tr>
<tr>
<td>40-60</td>
<td>12.0%</td>
<td>$0500.00</td>
</tr>
<tr>
<td>800+</td>
<td>14.0%</td>
<td>$0507.00</td>
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</table>

- 340B pricing - $50
- If commercially insured, patient savings program may reduce costs of device to $75 out-of-pocket. Max discount $500. Program expires 9/30/15.

LILETTA PATIENT SAVINGS

- Patients must:
  - Have commercial health insurance
  - Not participate in Medicaid, Medicare, TRICARE, or any other federal or state healthcare program
  - Have an out-of-pocket expense for LILETTA greater than $75
  - Reside in the U.S. or Puerto Rico
- Patients can receive a LILETTA card that can be used to pay the office for device, up to $500 savings.
- Patients who paid in full at time of insertion, can get a rebate check
**IUD PRICING COMPARISON**

<table>
<thead>
<tr>
<th>Number of Devices</th>
<th>Mirena</th>
<th>Skyla</th>
<th>Paragard</th>
<th>Liletta</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4/5</td>
<td>$770</td>
<td>$618</td>
<td>$739.00</td>
<td>$599.38</td>
</tr>
<tr>
<td>5/6-8</td>
<td>$770</td>
<td>$618</td>
<td>$702.05</td>
<td>$593.75</td>
</tr>
<tr>
<td>9-14</td>
<td>$770</td>
<td>$618</td>
<td>$683.58</td>
<td>$593.75</td>
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<td>15-24</td>
<td>$750</td>
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<td>25-39</td>
<td>$730</td>
<td>$585</td>
<td>$665.10</td>
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<td>40-99</td>
<td>$713</td>
<td>$572</td>
<td>$665.10</td>
<td>$550.00</td>
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<tr>
<td>100+</td>
<td>$697</td>
<td>$559</td>
<td>$650.32</td>
<td>$537.50</td>
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</tbody>
</table>

**LOADING LILETTA**

1. Area of hole receives the string
2. Pull string until fully inserted
3. Press string until fully inserted

**INSERTING LILETTA**

4. Ensure the device is fully inserted
5. Insert the device into the canal
6. Ensure the device is fully inserted
7. Hold the device in place for 5-7 seconds
COMMON MYTHS & MISCONCEPTIONS ABOUT CONTRACEPTIVES

**MYTH**

IUDs are abortifacients because they prevent implantation

**PARAGARD**

- The exact mechanism of action is not known.
- Most likely mechanisms include:
  - Prevention of fertilization (primary mechanism)
  - ↓ Motility/viability of sperm
  - Disrupts oocyte division and fertilization
- Inhibition of implantation (secondary mechanism)
MIRENA

- Fertilization inhibition:
  - Cervical mucus thickened
  - Sperm motility/function inhibited
  - Endometrium suppressed
  - Weak foreign body reaction induced
  - Ovulation inhibited (in some cycles)

MYTH

IUDs cause Pelvic Inflammatory Disease (PID)

FACT

IUDs and PID

- PID incidence for IUD users same as for general population
  - ↑ Incidence only during 1st month after insertion

- Preexisting STI at time of insertion, NOT IUD itself
  - ↑ Incidence of PID
    - No ↑ risk chlamydia acquisition
    - ↑ Risk upper genital tract infection at insertion, compared to women with no STI
    - Comparable PID rates between women with STI and IUD insertion vs STI and no insertion (case series only)

- LNG IUD may ↓ PID
IUDs AND INFERTILITY

Tubal Infertility by Prior Copper-T IUD Use and Presence of Chlamydia Antibodies Among Nulligravid Women

- IUDs NOT associated with tubal infertility
- Chlamydia is associated with infertility

FERTILITY RATES

After Discontinuation of Contraception

- IUC
- OC
- Diaphragm
- Other methods
Nulliparous women can’t / shouldn’t use IUDs

IUDS AND NULLIPS

- High acceptability rate (60%)
- No concern for future infertility
- Expulsion rate same for nullips/multips (5%)
- Slightly higher insertion pain
  - Same as for parous women without labor or SVD
  - Pain scores low regardless (2.7 vs. 1.9)
- Similar rates of continuation/satisfaction between nullips and multips (80% and 88% respectively)

SUPPORTING GUIDELINES

Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research


COUNSELING TIPS

• Important to prepare adolescent/nullip for the procedure
  — Be honest about what they can expect – pain, length of procedure, vaginal exam, etc.
  — Options available to them for reducing pain

• Explain side effects they may experience before initiating method to prevent early discontinuation
  — Changes in menstrual bleeding patterns

• Know your local laws for protecting adolescents’ confidentiality
  — Can minors consent for contraceptives, pregnancy or STI testing independently? Do you need to notify parents? Can you bill confidentially?

MYTH

Providers over-emphasize LARC methods when counseling patients

LARC FIRST COUNSELING

• Shift in our strategy of how we counsel patients, to promote LARC as “first-line” methods for all women

• Should not replace comprehensive counseling techniques


**How do providers counsel patients?**

- Audio recorded 342 contraceptive counseling visits in the August ’09 and January ’12.

- Investigate who is counseled about IUDs and what providers discuss in the counseling session.

**Counseling findings**

- Patients initiated discussion of IUDs in 17 visits
  - In 11 visits, providers recited information about IUD side effects.
  - In 3 cases, they also discussed IUD benefits.
  - In 2 additional cases, providers focused only on benefits.
  - Patients independently determined whether to use an IUD.
  - Providers’ involvement was minimal unless patients explicitly requested their opinions.

- Providers initiated discussion of IUDs in 25 visits
  - In 18 visits, IUDs were included among a list of methods.
  - IUDs were emphasized in only 8 of these visits.
  - Providers were more likely to mention potential negative aspects of the bleeding patterns expected with IUDs (8 visits) than the potential positive aspects of these patterns (5 visits).
  - Superior efficacy was mentioned in only 2 visits.
  - Convenience was mentioned in only 3 visits.

**Conclusions**

- “Overall, providers allowed women complete independence in assessing the method’s appropriateness for them. Given previous findings that women desire decision support from their providers when choosing a contraceptive method, this suggests that, if anything, providers in our sample could have been more proactive in informing women about and helping them to assess IUDs.”

- “Counseling about IUDs could be improved through increased use of a patient-centered approach.”
CHOICE STUDY

- Study to remove financial barriers to the most effective methods of birth control & reduce unintended pregnancy in St. Louis
- Comprehensive, “LARC-first” counseling
- Enrolled 9,256 women over 4 years.

http://www.choiceproject.wustl.edu

86% of those using LARC still used it at 1 year, vs. 55% of those using other methods

Women using LARC had highest reported satisfaction levels at 1 year

http://www.choiceproject.wustl.edu

REPRODUCTIVE LIFE PLANNING AND APPROACHES TO COUNSELING
DEFINING CLIENT CENTERED CARE

• Care that is respectful and responsive to client’s preferences, needs, and values
  – Whole-person care
  – Coordination and Communication
  – Support & Empowerment
  – Autonomy-voluntary/zero coercion
• Educating and counseling on all methods with most effective first
  – Provide referrals if not offered at your health center, includes permanent sterilization

QUALITY COUNSELING – SUPPORTING REPRODUCTIVE LIFE GOALS

• Establish & maintain rapport with client, use open ended questions, listen, show empathy and acceptance
• Assess client’s needs and personalize discussion – ambivalence is normal, rephrase to clarify (it sounds like you... I hear you saying...)
• Work with the client interactively and establish a plan together (identify potential barriers)
• Provide easy to understand facts with multiple mediums (risks & benefits)
• Confirm client understands, consider teach back method

FAMILY PLANNING VISIT

• Subjective/Chief Complaint (CC)/History of Present Illness (HPI)/Review of Systems (ROS)/Past family social history (PFSH): Why is patient here today?
  – CC: “I need to prevent a pregnancy; I’m not happy with how the pill makes me feel; I have itching and burning.”
  – HPI: “White discharge for one week, seems to be worse after sex, not painful and using OTC meds didn’t help (4)
  – ROS: “Denies fever, no abdominal pain” (2-9)
  – PFSH: Review of medical history/sexual health history/family history and psychosocial history. Should include IPV, substance abuse and depression screen at minimum annually (2)
  – Regardless of CC, ask Reproductive Life Questions (see next two slides)
  – Always ask if client has any other source for primary healthcare
REPRODUCTIVE LIFE PLANNING (RLP) DOCUMENTATION

- Do you have children now?
  - Document G/P or G/TPAL

- Do you want to have (more) children?

- How many (more) children do you want and when?

- Clarify client’s motivation regardless if wanting or preventing pregnancy

RLP LEADS TO COUNSELING FOR ONE OF THE THREE

1. **Contraception**: tiered approach, offering all methods regardless if your site offers
   - Client centered approach

2. **Preconception**: biomedical, behavioral and social risk, 0.4-0.8mg of folic acid

3. **Basic infertility**: peak fertility days, basic labs, semen analysis, medical history

POSTPARTUM CONTRACEPTION – IMPORTANCE & COUNSELING TIPS
IMPORTANCE OF PP CONTRACEPTION

- Rapid repeat pregnancy (RRP) = Pregnancy within 18 months of prior live birth

- Risks associated with RRP:
  - **MOTHER**
    - Pre-Eclampsia
    - Anemia
    - Uterine rupture during TOLAC
    - Death
  - **INFANT**
    - Low birth weight
    - PPROM
    - SGA
    - Preterm birth
    - Congenital anomalies
    - Fetal, neonatal, or infant death

IMPORTANCE OF PP CONTRACEPTION

Interpregnancy Interval Length

- 60+ mos, 15.5%
- 24 to 59 mos, 44.5%
- 12 to 17 mos, 16.6%
- 6 to 11 mos, 12.4%
- 0 to 5 mos, 6.7%
- 35% of total in RRP range

CDC MEC

- Based on WHO MEC, with some adaptations for U.S. context
- Available online and as an App for iPhone and iPad

- Can my patient use this method?
  - 1 Can use the method
  - 2 Can use the method
    - Advantages generally outweigh theoretical or proven risks.
  - 3 Should not use method
    - unless no other method is appropriate
    - Theoretical or proven risks generally outweigh advantages
  - 4 Should not use method
    - Unacceptable health risk
RESOURCES FOR PP COUNSELING

- Medical Eligibility Criteria for Contraceptive Use
  - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm
  - Describes methods of contraception

- Practice Recommendations for Contraceptive Use, 2013
  - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm
  - Describes how contraception may be used including:
    - Timing
    - Need for back-up contraception
    - Special considerations (postpartum, breastfeeding)
    - Exams and tests needed before initiation
    - Follow-up requirements
    - Bleeding changes

- CHOICE Project
  - http://www.larcfirst.com/sessions.html

- Association of Reproductive Health Professionals

2010 U.S. MEC: POST-PARTUM IUD INSERTION

<table>
<thead>
<tr>
<th>Postpartum (BF or non-BF women) including post-cesarean section</th>
<th>LNG-IUC</th>
<th>Cu-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10 min after delivery of placenta</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>10 min after delivery of placenta to &lt; 4 wks</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>&gt; 4 wks</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Puerperal sepsis</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
**DO PATIENTS WANT LARC PP?**

- Chart review of 2982 patients with plan for PP LARC at UIC
  - 59% never got a LARC within 18 months of delivery, as planned
  - 11.5% experienced a RRP

- Prospective cohort study of 800 PP women in Texas
  - 34% would prefer LARC PP, but only 12% using LARC at 6 mo. PP

- Analysis of baseline survey data assessing predictors of PP desire for LARC among 800 women in N. Carolina
  - 38% planned to use LARC as their PP contraception

- Prospective observational study of 396 adolescents in Colorado to assess effect of immediate PP implant on RRP
  - 43% of participants received implant immediately PP and 86% continued at 12 mo. PP
  - Pregnancy by 12 mo. PP = 2.6% in implant group, 18.6% in control group (RR 5.0 [95% CI, 1.9–12.7])

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**POSTPARTUM IUD TIMING**

- Expulsion rates vary widely, but rates as high as 24% are still considered acceptable based on current literature
- Expulsion rates have been found to decrease as provider proficiency at insertions increases

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**IPP LARC**

- Sonalker & Kapp 2015: Systematic review of 18 studies
  - Confirmed that IPP IUD insertion is safe and effective
  - Expulsion rates vary widely, but rates as high as 24% are still considered acceptable based on current literature
  - Expulsion rates have been found to decrease as provider proficiency at insertions increases
BARRIERS TO IPP

• IUDs currently offered IPP or 4-6 weeks PP
  – The likelihood of a new mother receiving a LARC device falls dramatically if it is delayed

• Billing
  – Most state Medicaid programs pay for all L&D services using a single Diagnosis Related Group (DRG) code that does not allow for reimbursement of individual procedures on a fee-for-service basis

• Different technique

PP LARC REIMBURSEMENT

• 13 states have published final or proposed guidance regarding reimbursement for postpartum LARC as of July 28, 2015.

PATIENT RISKS & BENEFITS

• Risks
  – Increased risk of expulsion from interval placement

• Benefits
  – No delay for starting PP contraception

"Although all six states have postpartum LARC Medicaid policies in place, it has sometimes been difficult to implement the policies in hospitals because of a lack of provider awareness about the policies, provider misperceptions about the use of LARCs postpartum, and lack of provider training. In addition, many hospitals do not have protocols in place to offer and implement postpartum LARC."

"Cumulative probability of pregnancy within 18 months after delivery by contraceptive method:"
PP IUD PLACEMENT

- Immediate PP – within 10 minutes of delivery of placenta
- It is safe & effective
- No difference in risk of infection
- Provider experience may be relevant to expulsion risk

HOW TO PLACE?

- Figure 25.2 Two techniques of postplacental IUD insertion and proper location of IUD after insertion

  A) IUD strings placed in palm of hand
  B) Manual insertion at top of uterus
  C) Use of ring forceps to insert IUD

FOLLOW-UP

- Monthly string checks
- Offer to see patient back in 2-3 months
- If develop cervical infection or PID, may treat with IUD in place
- Pregnancy
  - Pull IUD if can do so without instrumenting uterus
  - Counsel about increased risk for preterm labor/delivery
- Abnormal Pap
  - Tuck/cut strings and treat with IUD in place
  - Actinomyces
WHAT IF...?

- Lets think back to the case of Ms. JD

  What does counseling look like?
  - LARC first, comprehensive counseling
  - What has she used in the past? What do her friends use?
  - Honest counseling of risks and benefits of all methods
  - STI risk and prevention

  Skyla

  - Anticipatory guidance for insertion
  - Can you do same day insertion?
  - What is her out of pocket cost?

Questions??
THANK YOU!