Long Acting Reversible Contraception (LARC): An Overview for Primary Care Settings

Meredith M Warden MD, MPH

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Meredith M Warden MD, MPH

- Assistant Professor, Department of Obstetrics and Gynecology, University of New Mexico
- Completed Ob/Gyn residency and Family Planning fellowship at the University of California, San Francisco
- Associate Program Director, Fellowship in Family Planning at the University of New Mexico
Learning Objectives

• Understand comparative effectiveness of contraceptive methods
• Understand risks and benefits of LARC
• Find evidence about contraception for women with possible contraindications
• Understand barriers to LARC contraceptive use
6.6 Million Pregnancies Annually

51% Unintended

49% Intended

Finer et al., 2014
How is New Mexico doing?

Unintended Pregnancy Rates, by State, in 2008

*Rates for Arizona, Indiana, Kansas, Montana, Nevada, New Hampshire, North Dakota and South Dakota estimated by multiple regression.
Modern Contraception Works

The two-thirds of U.S. women at risk of unintended pregnancy who practice contraception consistently and correctly account for only 5% of unintended pregnancies.

Women at Risk (43 Million in 2008)
- 14% Nonuse or long gaps in use
- 18% Inconsistent use
- 68% Consistent use

Unintended Pregnancies (3.1 Million)
- 5% Consistent use
- 54% Nonuse
- 41% Inconsistent use

By consistency of method use all year
By consistency of method use during month of conception

Sonfield et al., 2014
The small proportion of women who do not use contraceptives ... account for roughly half of all unintended pregnancies.

[Pie chart showing:]
- **Using 89%**
  - Women at risk of unintended pregnancy,
- **Not using 11%**
  - Women experiencing unintended pregnancies,

[Another pie chart showing:]
- **Using 53%**
- **Not using 47%**
Contraceptive use & non-use in the US, 2006-2010 NSFG

Women ages 15-44

- None: 38%
- OCP: 17%
- Female sterilization: 17%
- Condom: 10%
- Vasectomy: All other methods = 18%
- IUD
- Withdrawal
- DMPA
- Ring
- Implant, Patch

Vital Health Statistics, 23(29); 2010
Contraception Methods

- Episodic
- Daily
- Weekly
- Monthly
- 3 Months
- 3 yrs
- 5 yrs
- 10 yrs
- Permanent

- OCPs
- Patch
- Ring
- DMPA (IM or SQ)
- Progestin Implant (Implanon)
- Progestin IUC (Mirena)
- Copper IUC
- BTL
- Essure
- Vasectomy

Least effective

Most effective

Barrier

Combined Hormonal

Progestin Only

IUC

Sterilization
Contraceptive Efficacy

Perfect Use ≠ Typical Use

Lowest expected failure rate
From clinical trials

What happens in real life
Effectiveness: The difference between “perfect use” and “typical use”

% estimates of unplanned pregnancy in the first year of use

- **PILL**: 8% typical, 0.3% perfect
- **Injectable**: 3% typical, 0.3% perfect
- **Copper T**: 0.8% typical, 0.6% perfect

## Continuation rates

<table>
<thead>
<tr>
<th>% Continuation at one year</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pills, patch, ring</td>
<td>68%</td>
</tr>
<tr>
<td>Condoms</td>
<td>60%</td>
</tr>
<tr>
<td>Depo-provera</td>
<td>56%</td>
</tr>
<tr>
<td>ParaGard (copper T)</td>
<td>78%</td>
</tr>
<tr>
<td>Mirena (LNG)</td>
<td>81%</td>
</tr>
<tr>
<td>Nexplanon</td>
<td>82%</td>
</tr>
</tbody>
</table>
Traditional IUD candidate

- Parous
- Completed childbearing
- Not an adolescent
- Not a candidate for birth control pills
- Not ready for permanent sterilization
Who is a candidate for an IUD? Or an implant?

Almost every woman!
Who is a candidate for an IUD?

✓ Women with past history of PID
✓ Women with prior ectopic pregnancy
✓ Teens
✓ Nulliparous women
✓ Women with more than one sexual partner
IUDs do NOT cause PID

Risk of PID by duration of IUD use

Baseline PID risk: 1-2 cases /women yrs

n=~20,000 women.

IUDs do NOT Cause PID

- Pre-existing STI at time of insertion, not the IUD itself, increases risk
- No reason to restrict use based on sexual behaviors
- STI/PID risk similar with and without the IUD

Grimes, DA, Lancet, 2000
STI screening before insertion? 

*Routine* screening NOT necessary!

- Retrospective cohort, n=57,728 IUDs
- Evidence-based screening (CDC)¹

1. **Low Risk Women** - Risk of PID:
   - Non-screening = Screening
   - OR= 1.05 (0.78, 1.43)

2. **Screened Women** - Risk of PID:
   - Same day = Pre-insertion
   - OR=.997 (.64, 1.54)

- No cases of PID when PP switched to same day screening²
- No benefit to prophylactic antibiotics³
- ACOG: no routine screen⁴

1. Sufrin 2010 *Reproductive Health ACM*
2. Goodman 2008 *Contraception*
3. Grimes 1999 *Contraception*
4. ACOG Practice Bull #59, 2005
Who should be screened?

- Use CDC and USPSTF guidelines for STI screening

1. Annually < 26 yo and sexually active
   OR
2. If RFs present (new partner, sx, another STI)
IUDs do not cause infertility

- Large cohort study showed no impairment of fertility after discontinuing IUDs
  - Included women discontinuing to conceive AND women discontinuing because of problems with IUD
- Consistent among studies is that women discontinuing IUD because of problems is a resultant high rate of abortion
IUDs and nulliparous women

- IUDs safe and effective in nulliparous women
- No increase in infertility
- LNG-IUS appropriate for nulliparous women with menorrhagia and/or dysmenorrhea
- IUD expulsion, bleeding, and pain are slightly more likely among nulliparous women
## FDA labeling

<table>
<thead>
<tr>
<th>OLD LABEL</th>
<th>NEW LABEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute PID or history of PID</td>
<td>Acute PID or current behavior suggesting high risk of PID</td>
</tr>
<tr>
<td>Postpartum or postabortal endometritis in past 3 months</td>
<td>Postpartum or postabortal endometritis in past 3 months</td>
</tr>
<tr>
<td>Uterine or cervical cancer or unresolved Pap smear</td>
<td>Known or suspected uterine or cervical malignancy</td>
</tr>
<tr>
<td>Untreated acute cervicitis/vaginitis</td>
<td>Mucopurulent cervicitis</td>
</tr>
<tr>
<td>Patient or partner w/multiple partners</td>
<td>REMOVED</td>
</tr>
<tr>
<td>Increased susceptibility to infection (AIDS, leukemia, etc)</td>
<td>REMOVED</td>
</tr>
</tbody>
</table>
## Old vs. new package insert

<table>
<thead>
<tr>
<th>OLD LABEL</th>
<th>NEW LABEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy or suspicion of pregnancy</td>
<td>No change</td>
</tr>
<tr>
<td>Distorted uterine cavity</td>
<td>No change</td>
</tr>
<tr>
<td>Current IUD in place</td>
<td>No change</td>
</tr>
<tr>
<td>Genital bleeding of unknown source</td>
<td>No change</td>
</tr>
<tr>
<td>Wilson’s disease (Paragard only)</td>
<td>No change</td>
</tr>
</tbody>
</table>
Key messages: FDA-approved new ParaGard label

<table>
<thead>
<tr>
<th>OLD LABEL</th>
<th>NEW LABEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>ParaGard recommended for women who have had at least one child</td>
<td>ParaGard appropriate for nulliparous women</td>
</tr>
<tr>
<td>ParaGard recommended for women in a stable, mutually monogamous relationship</td>
<td>ParaGard appropriate for women without a relationship requirement</td>
</tr>
</tbody>
</table>
IUDs and ectopic pregnancy

<table>
<thead>
<tr>
<th>Ectopic pregnancy rates</th>
<th>per 1,000 Woman Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non contraceptive users</td>
<td>2.00-4.50</td>
</tr>
<tr>
<td>Levonorgestrel IUD</td>
<td>0.20</td>
</tr>
<tr>
<td>Tcu-380A IUD</td>
<td>0.20</td>
</tr>
</tbody>
</table>

• IUD users have LOWER risk of ectopic pregnancy . . . Because they are less likely to become pregnant!

• If pregnancy occurs, risk of ectopic pregnancy is elevated

## Will abdominal sterilization become obsolete?

<table>
<thead>
<tr>
<th>We thought…</th>
<th>Now we know…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormones dangerous &gt; 35</td>
<td>OK to use till menopause</td>
</tr>
<tr>
<td>IUDs dangerous</td>
<td>IUDs safe till menopause</td>
</tr>
<tr>
<td>Tubal the most effective method</td>
<td>IUDs, Implanon as effective as tubal</td>
</tr>
<tr>
<td>Laparoscopy safer than laparotomy</td>
<td>IUD, hysteroscopy safer than either</td>
</tr>
<tr>
<td>Regret is rare</td>
<td>40% young women request info about reversal</td>
</tr>
<tr>
<td>Tubal most cost-effective method over time</td>
<td>IUD most cost effective method over 2-5 years</td>
</tr>
</tbody>
</table>
Nexplanon™

• Subcutaneous implant x 3 years
• Etonogestrel 60mcg/day (Progestin only)
• Perfect use = typical use
• Rapid return to fertility
  – 94% of women ovulate within 2-3 weeks after removal
Contraindications

• Known/suspected pregnancy
• Cirrhosis
• Undiagnosed vaginal bleeding
• Known or suspected breast cancer, or P-sensitive breast cancer
Nexplanon™

• Training required to insert/remove
• Easier than Implanon!
• Unlike Implanon, can be visualized on XRay
ETG Implant & Bleeding

Bleeding parameters for the reference period analysis group.

- Infrequent: 34%
- Amenorrhea: 22%
- Prolonged bleeding: 18%
- Frequent bleeding: 7%

17 bleeding-spotting days/90d

Overall, women experience less bleeding!

Darney 2009 Fertil Steril
Mansour 2010 Contraception
Mansour 2008 Eur J Contr Repro Health Care
Implant & Bleeding

- First three months predict bleeding pattern?
- Overall less bleeding
- Less dysmenorrhea
- Counseling important!
One approach...

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Evidence?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. COC x 21d/7d (3 mo)</td>
<td>Minimal</td>
</tr>
<tr>
<td>2. Cyclic progestin (MPA 10bid) x 21d/7d (3mo)</td>
<td>Anecdotal</td>
</tr>
<tr>
<td>3. POP daily up to 3 mo</td>
<td>Anecdotal</td>
</tr>
<tr>
<td>4. NSAIDs (COX-2 inhibitor), daily x 5-10 d</td>
<td>Minimal Anecdotal</td>
</tr>
<tr>
<td>5. Tranexamic acid 500 bid x 5d</td>
<td>Minimal Anecdotal</td>
</tr>
</tbody>
</table>

Adapted from Mansour et al 2011 Contraception
In practice . . .

- Benefit of any intervention may be short-lived
- If other methods unacceptable, and bleeding intolerable, consider co-administering long-term 30mcg EE OCP
  - IF EE not contraindicated for patient
Skyla is a small T-body made of soft, flexible plastic. Skyla is designed to be inserted into the uterus to provide long-term birth control. It contains 99.95% pure silver ring that differentiates each patient on ultrasound. It contains 13.5 mg of LNG and provides effective contraception.

**Actual measurements:**
- **Width:** 28 mm
- **Height:** 30 mm

**Description:**
- **Arms:** The arms of Skyla are designed for easy insertion into the uterus.
- **Removal threads:** These threads are used to remove the device after use.
- **Hormone reservoir:** Contains 13.5 mg of LNG.

**Important note:**
- If you plan to get an MRI, please consult with your provider as Skyla may not be suitable for MRI due to the metallic components.

**Skyla inserter:** The Skyla inserter is designed for single-handed loading into the insertion tube. It simplifies the insertion process, making it more comfortable for patients.
LNG-IUS Update

• Smaller device, smaller inserter might be more comfortable for placement
  – Marketed for nullips
• Lower dose of LNG (14 mcg/day) may decrease progestin-related side effects
• Effective for three years
  – Target fears that 5 years is “too long”
LNG-IUS Update

Mean number of bleeding or spotting days per 90-day reference period during the 3 years of the intrauterine system use (reference periods 1–12). Drop-outs were not accounted for in this analysis; the results are based on subjects participating during the respective reference period. The drop-out rates (for any reason) were 27.2%, 29.0%, and 28.3% in the LNG-IUS12, LNG-IUS16, and Mirena arms, respectively. It is possible that subjects dropping out as a result of changes in bleeding patterns may have influenced these results. LNG-IUS = levonorgestrel intrauterine system.

LNG-IUS Update

Table 1: Bleeding Patterns Reported with Skyla in Contraception Studies (by 90-day reference periods)

<table>
<thead>
<tr>
<th>Skyla</th>
<th>First 90 days N=1,531</th>
<th>Second 90 days N=1,475</th>
<th>End of year 1 N=1,329</th>
<th>End of year 3 N=903</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhea</td>
<td>&lt;1%</td>
<td>3%</td>
<td>6%</td>
<td>12%</td>
</tr>
<tr>
<td>Infrequent bleeding</td>
<td>8%</td>
<td>19%</td>
<td>20%</td>
<td>22%</td>
</tr>
<tr>
<td>Frequent bleeding</td>
<td>31%</td>
<td>12%</td>
<td>8%</td>
<td>4%</td>
</tr>
<tr>
<td>Prolonged bleeding</td>
<td>59%</td>
<td>17%</td>
<td>9%</td>
<td>3%</td>
</tr>
<tr>
<td>Irregular bleeding</td>
<td>42%</td>
<td>28%</td>
<td>23%</td>
<td>_8%</td>
</tr>
</tbody>
</table>

- Compared to Mirena:
  - 50% amenorrhea by 12 mo
  - 25% oligomenorrhea throughout 2 y
  - Spotting 25% @ 6mo -> 8% @ 18 mo-> 11% @ 24 mo.

LNG-IUS Update: Skyla Hype

• Awaiting data on whether Skyla is associated with less insertion pain, fewer hormonal side effects . . .

• Appears to have a slightly worse bleeding profile
  – More bleeding/spotting days
  – Less amenorrhea

• May appeal to more women given its smaller size and shorter duration of use . . .
What are we missing?

IUD use throughout Europe vs. USA

- Austria: 15%
- Baltic states: 14%
- Czech Republic: 10%
- Denmark: 18%
- France: 17%
- Germany: 10%
- Norway: 27%
- Spain: 6%
- Sweden: 21%
- United Kingdom: 11%
- United States: 2%

% of female contraceptive users:
- copper IUD
- hormonal IUD
- any IUD

2014 IHS NCC Meeting
What are we missing?

• Training: Many primary care providers do not receive training in IUD/implant provision
  – Majority of family medicine residents reported no training
  – Rural PCPs also report receiving no training
    • 9% provide implants, 35% place IUDs
    • Maternity providers, female gender associated w/provision
  – Only 12% of primary care NPs reported receiving training

Steinauer et al. 1997. Fam Plan Perspect
Lunde et al. 2014 J Womens Health
What are we missing?

• Training
• Access: Up front cost of LARC prohibitive
  – For patients
    • Cost affects method choice
    • Many women use methods inconsistently to save money
  – For providers
  – ACA has helped!

Trussell et al. 2009. Contraception
Frost JJ et al. 2008 Perspect Sex Repro Health
Finer LB et al. 2014. Contraception
What are we missing?

• Training
• Access
• Patient concerns/myths
  – Fears about pain with insertion
  – Fears about fertility
  – Fears about “foreign body”
  – Perception that IUD/implant are not appropriate for young women or first time users

Rubin et al. 2010. J Womens Health
Asker C et al. 2006. J Fam Plann Repro Health Care
What are we missing?

• Training
• Us (providers) . . . Wait, what?
• Access
  – Lack of counseling about LARC
• Patient concerns/myths
  – Overly restrictive provision of LARC
  – Misconceptions about risk of infection, infertility, nullips
  – We ALL do it!
    • Pediatricians
    • Family medicine
    • Ob/Gyns

Callegari et al. 2014 J Am Board Fam Med
Luchowski et al. 2014. Contraception
Utilizing the evidence

- CDC Medical Eligibility Criteria for Contraceptive Use

  Clear criteria for method selection based on patient characteristics (HTN, VTE, smoking, etc.)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Sub-condition</th>
<th>Combined pill, patch, ring</th>
<th>Progestin-only pill</th>
<th>Injection</th>
<th>Implant</th>
<th>LNG-IUD</th>
<th>Copper-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic inflammatory disease</td>
<td></td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>a) Past, (assuming no current risk factors of STIs)</td>
<td></td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>(i) with subsequent pregnancy</td>
<td></td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(ii) without subsequent pregnancy</td>
<td></td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>b) Current</td>
<td></td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

2014 IHS NCC Meeting
Utilizing the evidence

• Guidance for common management issues around initiation and use of specific contraceptive methods . . .
  – When to start a method and follow up
  – What to do if late, delayed, missed method
  – Management of IUD in setting of PID
  – Much more

• Practical, clinical guidance
Counseling

The most effective method of birth control is one a woman is actually going to use
Conclusions

• LARC should be offered as first line methods for virtually all women
• Contraceptive clinical guidance is easily accessible and should be utilized
• Providers should offer evidence based, patient centered contraceptive counseling
Thank You

- Eve Espey
- UNM RH PALS Pager: 272-2000

www.managingcontraception.org

http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm
http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm
http://www.who.int/reproductivehealth/topics/family_planning/en/index.html