Long Acting Reversible Contraception Methods (LARC): Improving Family Planning

Mark Hathaway MD,MPH
Community Outreach Program
Dept of Ob/Gyn
Washington Hospital Center/Unity Health Care
Washington DC

Reproductive Health Update
Baltimore, Maryland
April 27, 2012

Learning Objectives

> Describe the three LARC methods available in the United States
> Rank efficacy & mechanism of action associated with LARC methods compared with other contraceptive methods
> Describe counseling strategies for increasing LARC uptake & follow up
> Identify selection criteria and appropriate candidates for LARC use
> Explain why effective family planning is important and needed

Acknowledgment of Support

This educational program is funded through an unrestricted educational grant from Bayer Healthcare Pharmaceuticals, Inc. and TEVA Pharmaceuticals.

Disclosures: Dr Hathaway is a speaker and trainer for MERCK, TEVA, & Bayer
Long Acting Reversible Contraceptive Methods (LARC)

> Copper-T IUD (10-12 yrs)
> Levonorgestrel Intrauterine system (LNG IUS) (5-7 yrs)
> Single Rod Hormonal Implant (Implanon) (3 yrs)
> “long” can mean even just a year

Why LARC?

> Abortions: more than 1/3 of all U.S. women will have had an induced abortion by age 45
> Sterilization is permanent: 20% of women selecting sterilization at age 30 years or younger later express regret
> Effective: couples need an effective contraceptive method that is “forgettable” or “hands-off”.
> Unintended pregnancies are preventable

LARCs Are An Important Choice

LARCs will help reduce the number of unintended pregnancies due to contraceptive failures.

- LARCs are very effective--more than many other methods, because no “user-failure” issues, aka “forgettable”
- Project Choice (St Louis, MO) has reached 70% LARC uptake with a simple counseling and “no-barriers” strategy
Unintended Pregnancies in the United States

Data from 2002 National Survey of Family Growth

- Intended: 51%
- Elective abortions: 22%
- Fetal losses: 7%
- Unintended 49%

6.4 Million Pregnancies


Why an Update on Intrauterine Contraception? (continued)

> Myths: many exist about intrauterine contraception, and selection of candidates is unduly restrictive
> Misinformation: lack of knowledge & understanding about intrauterine contraception is very common even among providers...


Contraceptive Use

- % of US women 15-44 years
  - Sterilization: 23%
  - OC: 19%
  - Male Condom: 11%
  - Injectable: 3.3%
  - Withdrawal: 2.5%
  - IUD: 1.3%
  - Other Non-hormonal: 0.8%
  - Other Hormonal: 0.8%

Worldwide Use of IUC

~ Use for Married Women of Reproductive Age

<table>
<thead>
<tr>
<th>Region</th>
<th>% Using IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia</td>
<td>18</td>
</tr>
<tr>
<td>Europe</td>
<td>15</td>
</tr>
<tr>
<td>Latin America &amp; Caribbean</td>
<td>8</td>
</tr>
<tr>
<td>Africa</td>
<td>5</td>
</tr>
<tr>
<td>Oceania</td>
<td>2</td>
</tr>
<tr>
<td>North America</td>
<td>1</td>
</tr>
</tbody>
</table>


A starting point: pregnancy and risks

> Average number of desired children in US is two. Therefore a woman will spend approximately 30 years of her life avoiding pregnancy
> Key to having a healthy child is to get as healthy as possible before becoming pregnant
> Recognize that all contraceptive methods have far, far fewer risks than pregnancy

Characteristics of Intrauterine Contraception

> Highest patient satisfaction among methods
> Rapid return of fertility
> Safe
> Immediately effective
> Long-term protection
> Highly effective

Why IUDs are Underused in the United States

- Dearth of trained and willing professionals to insert devices
- Negative publicity
- Misconceptions
- Fear of litigation
- Upfront cost
- Lack of awareness of method among women


Appropriate Candidates for LARC?

Any women (including adolescents and nulliparous women) of any reproductive age seeking a long-term, discreet, highly effective, convenient, safe, and reversible contraceptive.

- Few contraindications
- Risk of PID and subsequent infertility is dependent on non-IUC factors
- One year should be considered “long term”


What Do Women Find Unacceptable About IUDs?

- Lack of objective information
- Reported side effects
- Anxiety about IUD insertion
- Unfounded fear of infection risk
- Lack of personal control of IUD after insertion

Factors Influencing a Woman’s Use of Contraceptives

Use of IUDs by Female Ob/Gyns vs. All Women in the United States

Counseling and Education

> Get a good sense of your patients, then counsel accordingly..
> What are your reproductive health plans, or how long do you want to wait 'til pregnancy?
> What methods have you heard of?
> What methods have you tried in the past?
> What did you like or dislike?
> What are your periods like now?

Dispelling Common Myths About IUDs

In fact, IUDs:
> Are not abortifacients
> Do not cause ectopic pregnancies
> Do not cause pelvic infection
> Do not decrease the likelihood of future pregnancies
> Are small in size

(continued)

Dispelling Common Myths About IUDs

In fact, IUDs:
> Can be used by nulliparous women
> Can be used by women who have had an ectopic pregnancy
> Do not need to be removed for PID treatment
> Do not have to be removed if actinomyces-like organisms (ALO) are noted on a Pap test
Ways to Discuss Contraception

- **Effectiveness**
- Duration of use (permanent vs LARC vs condoms)
- Hormonal vs non-hormonal
- Estrogen and progestins
- Barrier vs non barrier
- Options now abound…need to provide them to our patients

Considerations in Choice of Contraceptive Methods

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>Reversibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side effects</td>
<td>Non-contraceptive benefits</td>
</tr>
<tr>
<td>Convenience</td>
<td>Cost</td>
</tr>
<tr>
<td>Duration of action and childbearing plans</td>
<td>Privacy</td>
</tr>
<tr>
<td>Patient choice</td>
<td></td>
</tr>
</tbody>
</table>

IUDs Available in the United States

- **LNG IUD**
  - 20 mcg levonorgestrel/day
  - Approved for 5 years’ use

- **Copper T 380A IUD**
  - Copper ions
  - Approved for 10 years’ use
### IUC Methods: A Comparison

<table>
<thead>
<tr>
<th>Copper T380A IUD</th>
<th>Levonorgestrel-Releasing Intrauterine System</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Approved in 1984; marketed in 1988</td>
<td>• Approved in 2000</td>
</tr>
<tr>
<td>• Copper ions</td>
<td>• Releases 20 μg of levonorgestrel/day</td>
</tr>
<tr>
<td>• Approved for 10 years of use</td>
<td>• Approved for 5 years of use</td>
</tr>
<tr>
<td>• Data show effectiveness for up to 20 years</td>
<td>• Data show effectiveness for up to 7 years</td>
</tr>
</tbody>
</table>

Sivin I. Contraception. 2007.

### IUC Methods: Mechanisms of Action

<table>
<thead>
<tr>
<th>Copper T IUD</th>
<th>LNG IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Continuous, low-dose release of Cu inhibits fertilization, implantation by:</td>
<td>• Continuous, low-dose of LNG inhibits fertilization, implantation by:</td>
</tr>
<tr>
<td>• Reduction of sperm motility, viability</td>
<td>• Thickening of cervical mucus</td>
</tr>
<tr>
<td>• Inhibition of ovum development</td>
<td>• Inhibition of sperm motility, function</td>
</tr>
<tr>
<td>• Effects on endometrium</td>
<td>• Effects on endometrium</td>
</tr>
</tbody>
</table>


### IUC Methods: Side Effects

<table>
<thead>
<tr>
<th>Copper T IUD</th>
<th>LNG IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Abdominal/pelvic pain</td>
<td>• Abdominal/pelvic pain</td>
</tr>
<tr>
<td>• Increased menstrual bleeding</td>
<td>• Spotting/irregular bleeding</td>
</tr>
<tr>
<td>• Spotting between periods</td>
<td>• Acne</td>
</tr>
<tr>
<td></td>
<td>• Breast tenderness</td>
</tr>
</tbody>
</table>

Timing of Insertion of Intrauterine Contraception

<table>
<thead>
<tr>
<th>Timing</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>With menses</td>
<td>Ensures patient not pregnant</td>
<td>Scheduling; interim pregnancy</td>
</tr>
<tr>
<td>Midcycle anytime</td>
<td>Convenience; low rate of expulsion</td>
<td>Must rule out pregnancy</td>
</tr>
<tr>
<td>Emergency contraception (copper IUD)</td>
<td>Convenience; pregnancy prevention</td>
<td>Pregnancy</td>
</tr>
</tbody>
</table>


Timing of Insertion for Copper T IUD

- First day of LMP:
  - ≤5 days ago: Insert IUD today
  - >5 days ago: Urine pregnancy test negative
  - First instance of unprotected sex since LMP:
    - ≤5 days ago: Insert IUD today
    - >5 days ago: Insert IUD within 5 days of next menses


Timing of Insertion for LNG IUS

- First day of LMP:
  - ≤5 days ago: Insert LNG IUS today
  - >5 days ago: Urine pregnancy test negative
  - Offer pill/patch/cap as bridge to LNG
    - Yes: Inserts LNG IUS today
    - No: Unprotected sex since LMP?
      - Yes: Patient declines pill/patch/cap, uses barrier instead
      - No: 2 weeks later, pregnancy test is negative

Hormone-Releasing IUD - Decreases Bleeding

> LNG-IUD users initially experience more bleeding and spotting after insertion, but bleeding gradually decreases after three months.
> - 25% to 35% of LNG-IUD users have no bleeding at all by the end of the first year of use.
> Counseling about bleeding changes is key to successful use.
> LNG-IUD has several therapeutic applications because it reduces bleeding:
> - Increases blood iron levels
> - Treatment for menorrhagia
> - Progestin component of hormone replacement therapy

Copper-Bearing IUDs - Can Increase Bleeding

> Copper-bearing IUDs can increase blood flow volumes by 20% to 50%.
> Most common complaint among IUD users
> But many women still keep their IUDs.
> - Rates of removal because of bleeding or pain range from 1 to 17 per 100 women.
> Increased bleeding could decrease blood iron levels.

Efficacy: 1st Year Failure Rates of Select Contraceptives (Typical Use)

<table>
<thead>
<tr>
<th>Contraceptive</th>
<th>Failure Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Contraception</td>
<td>0.1</td>
</tr>
<tr>
<td>Spermicides</td>
<td>0.8</td>
</tr>
<tr>
<td>Condom - Male</td>
<td>3</td>
</tr>
<tr>
<td>Pill - Combined</td>
<td>8</td>
</tr>
<tr>
<td>Injectable (DMPA)</td>
<td>15</td>
</tr>
<tr>
<td>IUD - Copper T</td>
<td>29</td>
</tr>
<tr>
<td>IUD - LNG</td>
<td>65</td>
</tr>
</tbody>
</table>

IUDs are one of the Most Effective Methods of Contraception

- Women who become pregnant during first year of use:
  - TCu-380A: 3 to 8 per 1,000 (0.3% to 0.8%)
  - LNG-IUD: 1 to 3 per 1,000 (0.1% to 0.3%)
- Comparable to effectiveness of female sterilization

- LNG-IUD is slightly more effective than TCu-380A …
  - After 6 years of use, 20 women per 1,000 (2%) became pregnant while using the TCu-380A,
  - 5 women per 1,000 (0.5%) became pregnant while using the LNG-IUD.
- … But LNG-IUD has lower continuation rates, largely because of removals due to lack of bleeding.

Cost for Patient

- Patient costs are a factor in choosing contraceptive methods including up-front costs
- Costs of side effects associated with IUC are minimal compared to other many other methods, especially unintended pregnancy costs
- Title X clinic systems and/or pharmaceutical patient assistance programs exist for low-income or uninsured patients


IUC is Very Cost Effective

Five year costs of contraceptives.

Screening & Counseling Goals for Providers

1. Review contraceptive options with patients
2. Allow patients to hold contraceptive devices
3. Promote successful use of chosen method
4. Allow time for questions
5. Provide written materials in the appropriate language and literacy level

Contraindications or Poor Candidates for Intrauterine Contraception

- Known or suspected pregnancy
- Puerperal or post abortion sepsis (TAB/SAB)
- Unexplained vaginal bleeding
- Malignancy of genital tract (cervical or uterine)
- Uterine fibroids that distort uterine cavity
- Acute PID, diagnosed cervicitis (current gonorrhea, chlamydia, or cervicitis within last 3 mos.)
- Copper allergy or Wilson’s Disease

IUD Use During Lactation

Effectiveness not decreased
Uterine perforation risk unchanged
Expulsion rates unchanged
Decreased insertional pain
Reduced rate of removal for bleeding and pain
LNG comparable to copper T in breastfeeding parameters


Copper T IUD Insertion as Emergency Contraception

Can be inserted up to 5 days after unprotected intercourse to prevent pregnancy
More effective than use of emergency contraceptive pills (Plan B)


IUD Insertion Tricks of the Trade

For women with narrow cervical canal
  > Apply gentle traction of cervix at time of insertion
  > Utilize “verbicaine”
For pain management
  > Oral NSAID 400-800mg PO and/or
  > Explain 3 “twinges”
  > The sampler can be used instead of sound to measure depth of uterus
IUD Insertion Tricks of the Trade (continued)

If trouble visualizing cervix
> Use large speculum
> Use full vertical opening of speculum
> If vaginal walls obscure cervix, cut off end of condom and slip over metal speculum
> Get better light

IUD Use and Follow-up Visits

Schedule follow-up visits at:
> Around 3–6 weeks, at clinician’s discretion
> Routine well-woman care
Advised return visit earlier or any time if there is:
> Possible expulsion or displacement
> Severe cramping or bleeding
No data on routine thread checks by patient


Signs of Possible Complications

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe bleeding or abdominal cramping 3–5 days after insertion</td>
<td>Perforation, infection</td>
</tr>
<tr>
<td>Irregular bleeding and/or pain every cycle</td>
<td>Dislocation or perforation</td>
</tr>
<tr>
<td>Fever, chills, unusual vaginal discharge</td>
<td>Infection</td>
</tr>
</tbody>
</table>
Signs of Possible Complications (continued)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain during intercourse</td>
<td>Infection, perforation, partial expulsion</td>
</tr>
<tr>
<td>Missed period, other signs of pregnancy, expulsion</td>
<td>Pregnancy (uterine or ectopic)</td>
</tr>
<tr>
<td>Shorter, longer, or missing threads</td>
<td>Partial or complete expulsion, perforation</td>
</tr>
</tbody>
</table>

Possible Complications & Management of Cramping &/or Bleeding

Mild: recommend NSAIDs
Severe or prolonged:
> Examine for partial expulsion, perforation, or PID
> Remove IUD if severe cramping is unrelated to menses or unacceptable to patient

Management of Heavy Bleeding Lasting more than 3 Months

> Examine for infection or fibroids
> Check for signs of anemia and treat, if needed
> Prescribe NSAIDs
> Prescribe trial of oral contraceptives if not contraindicated
> Remove device if medical indication or unacceptable to patient
Expulsions are Uncommon

- Most expulsions occur in the first three months after insertion.
  - First-year expulsion rates vary from 2 to 8 per 100 women.
- Reduce chance of expulsion by:
  - Correct insertion, with the IUD placed up to the top of the uterus.
  - Insertion within 10 minutes after delivery of the placenta during postpartum insertion.

Management of Missing String

- Rule out pregnancy
- Probe for strings in cervical canal (can use cervical brush)
- Prescribe back-up contraceptive method
- Obtain ultrasound or x-ray, as needed
- Copper T IUD or LNG-IUS in abdomen should be referred for consultation

Management of STIs

If STI diagnosed:
- Treat infection
- IUD removal is not necessary if symptoms improve within 72 hours of treatment
- Counsel patient about prevention of STI transmission

WHO. Selected Practice Recommendations for Contraceptive Use. 2002.
Management of PID

If PID diagnosed:
> Treat infection
> IUD removal may not be necessary
> Recommendations to remove IUD are not evidence-based


Risk of Uterine Perforation

Rare: 1 per 1,000 insertions
Perforation linked to:
> Uterine position and consistency
> Skill and experience of provider with technique required
> Time of insertion after childbirth
  * Risk doubled within first 12 weeks postpartum
Perforations reduced through directed training and observation


Management of Perforation at Insertion

If perforation occurs at insertion:
> Remove device
> Provide alternative contraception
> Monitor for excessive bleeding
> Follow up as appropriate
> Can insert another device after next menses
Pregnancy with IUD In Situ

Determine site of pregnancy (intrauterine or ectopic)
Remove IUD if threads available
Removal may decrease risk of
  > Spontaneous abortion
  > Premature delivery


Implanon

> Brand name: Implanon/Neplanon
> Contains etonogestrel
> Effective for 3 years
> Placed in upper arm
> FDA mandated training required for clinicians


Levonorgestrel-Releasing Intrauterine System

Noncontraceptive Uses:
  • Heavy menstrual bleeding
  • Dysmenorrhea*
  • Postmenopausal hormone replacement therapy* (when combined with estrogen)

*Non–FDA-approved indications.
Mgmt of Bleeding Issues

- Counseling and reassurance
- Side effect vs “nuisance” or “bothersome” issues
- Ibuprofen 800mg po tid for 5 days
- Estradiol 1-2mg po qd for 10 days
- OCP’s for 2-3 cycles

IUC for Adolescents, Nulligravidas

Advantages:
• Long-term, highly effective method
• No action required at time of intercourse or on a daily basis
• Well tolerated by appropriately selected and counseled patients

Case Presentation: Nulligravid Adolescent

- “Anna,” 17-year-old high-school senior
- Has been sexually active with boyfriend for 3 months
- Has been using condoms for birth control
- Does not want to use hormonal method of contraception

Consider: Copper T IUD or LNG IUS*

* After first few months, very little LNG enters the circulation.
Nulligravid Adolescent Case: Clinical Considerations

> Insertion difficulty (smaller os and uterus than in parous woman)
> Insertion pain
> Possible increased risk of STIs (chlamydia) and PID (because of age <25 years)


Nulligravid Adolescent Case: Practice Tips

To reduce insertion pain:
- Misoprostol:
  • 200–800 μg a few hours before insertion
  • Can be given orally, buccally, or vaginally
  • Consider stocking in clinician’s office
  • Medication may be dispensed early in the day and patient asked to return for insertion

Clinical Pearl

Nulligravid Adolescent Case: Practice Tips (continued)

> Same-day chlamydia testing (with normal clinical exam):
  • No need to wait for test results before insertion
  • Positive tests should prompt treatment without need to remove device
Nulligravid Adolescent Case: Practice Tips (continued)

- Os finder
- Uterine dilators
- Timing of insertion

Nulligravid Adolescent Case: Counseling Points

- Follow-up and side-effect monitoring important
- Counsel regarding signs of expulsion
- Encourage use of condoms with new partners
- Make sure patients can get through to you or staff


Case Presentation: Uterine Fibroids

- "Barbara," 42-year-old G3P3
- Medical history:
  - Uterine fibroids
  - Obesity (BMI = 35)
  - Heavy menstrual bleeding, dysmenorrhea
- Has completed childbearing, does not desire sterilization
- Seeks nonsurgical treatment for fibroids

Consider: LNG IUS

Case Presentation: Heavy Menstrual Bleeding

> “Diane,” 24-year-old nulligravida
> Medical history:
> • Heavy menstrual bleeding, dysmenorrhea
> Presents for relief of heavy bleeding and cramping
> Has tried OCs in the past, dislikes having to take a daily pill

Consider: LNG IUS

Heavy Menstrual Bleeding Case: Clinical Considerations & Practice Tips

> Evaluate cause:
  • Review menstrual history
  • History of other types of bleeding suggesting coagulopathy
  • Endometrial biopsy to detect lesion or polyp
  • Consider vaginal ultrasound or sonohysterogram
  • Anovulation

Heavy Menstrual Bleeding Case: Counseling Points

> To be expected:
  • Lower volume of menstrual bleeding
  • Dysmenorrhea may improve
  • Breakthrough spotting
  • Unpredictable bleeding is common
  • 3–6 months for LNG IUS to have full effect on endometrium
Case Presentation: Post-Abortion IUD Insertion

> “Ellen,” 28-year-old nullipara
> Presents for 1-week follow-up after medical abortion
> Wants highly effective, long-term, “forgettable” contraceptive method

**Consider:** Copper T or LNG IUS

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Post-Abortion IUD Insertion Case: Clinical Considerations

- IUC may be safely inserted immediately after spontaneous or induced abortion
- **Advantages:**
  - Patient is known not to be pregnant
  - Motivation may be high because patient may be thinking about birth control
  - Studies in U.S. and Finland document significant reduction in repeat abortion


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We're Far From The Ideal, But We Are Making Progress...."Doggus Interruptus".

> Highly effective
> Safe
> Convenient
> Inexpensive
> Easily reversed
> Predictable bleed
> Noncontraceptive health benefits

*Doggus Interruptus*
Summary
> Three forms of LARC methods approved in U.S.:
  • Single Rod Hormonal Implant (Implanon/Nexplanon)
  • T380A copper T
  • LNG-releasing IUS
  • These are the most effective & reversible methods available with efficacy equivalent to sterilization

Summary (continued)
> IUC can be appropriate choice in properly selected patients including adolescents and nulliparous women
> Improved counseling, training and promotion of LARC methods are essential to reducing our high unintended pregnancy rates.

Resources
> WHO/CDC Medical Eligibility Criteria (www.reproductiveaccess.org gives summary of 1-4 evidence based criteria scale)
> Association of Reproductive Health Professionals (www.arhp.org)
> Family Pact (www.familypact.org …go to providers section) good clinical practice alerts and good summary guides