NEW OPTIONS IN CONTRACEPTIVE CHOICES

Kristina Tocce, MD, MPH
Assistant Professor of Obstetrics and Gynecology
Division of Family Planning
University of Colorado Anschutz Medical Campus
Disclosures

- No potential conflicts of interest
Learning objectives

- Utilize the US MEC in daily practice
- Appropriately counsel patients regarding long-acting contraceptives
- Offer minimally invasive sterilization for appropriate candidates
- Incorporate the most effective emergency contraceptive methods into practice
>1,800 recommendations for safety of contraceptive methods among men and women with certain characteristics or medical conditions
Categories for Medical Eligibility Criteria for Contraceptive Use

- **1** = A condition for which there is no restriction for the use of the contraceptive method.
- **2** = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- **3** = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- **4** = A condition that represents an unacceptable health risk if the contraceptive method is used.
What is LARC?

- **Long-acting**
  - Provides passive contraception after single initiation event

- **Reversible**
  - Discontinuation is followed by return to fertility

- **Current methods available**
  - **Hormonal**
    - Levonorgestrel IUS (Mirena & Skyla)
    - Subdermal etonogestrel implant (Implanon/Nexplanon)
  - **Non-hormonal**
    - Copper T 380A IUD (Paragard)
Why an Update on LARC?

- Misinformation among providers and patients is common
- Selection of candidates is unduly restrictive
- The US has an unacceptably high rate of unintended pregnancy leading to abortion and unplanned birth compared to similar societies
Unintended Pregnancies in the United States

6.6 million pregnancies

Data from 2006-2008 National Survey of Family Growth

- Intended: 51%
- Abortion: 21%
- Unintended birth and Fetal Loss: 28%

Unintended: 49%

U.S. Contraceptive Use 2006-2008

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

- IUC-LNG: 0.1
- IUD-Copper T: 0.8
- Injectable (DMPA): 3
- Pill-Combined: 8
- Condom-Male: 15
- Spermicides: 29
- No Contraception: 85

Dispelling Common Myths About IUCs

In fact, IUCs:

- *Are not* abortifacients
- *Do not* cause ectopic pregnancies
- *Do not* cause pelvic infection
- *Do not* decrease the likelihood of future pregnancies

*more...*

Dispelling Common Myths About IUCs (continued)

In fact, IUCs:

- *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

Copper T labeling change was approved in 2005.

LNG-IUS labeling:
- “women with at least one child”
- “in a stable, mutually monogamous relationship”
- “no history of pelvic infection”

IUCs Available in the United States

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

- **Copper T 380A IUD**
  - Copper ions
  - Approved for 10 years’ use
Skyla™
levonorgestrel-releasing intrauterine system 13.5 mg
### LNG-releasing IUSs

<table>
<thead>
<tr>
<th>Mirena</th>
<th>Skyla</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 52 mg in reservoir</td>
<td>□ 13.5 mg in reservoir</td>
</tr>
<tr>
<td>□ 20 mcg/day</td>
<td>□ 14 mcg/day</td>
</tr>
<tr>
<td>□ 10 mcg/d @ 5 yrs</td>
<td>□ 5 mcg/d @ 3 yrs</td>
</tr>
<tr>
<td>□ 99.8% effective @ 1 yr; 99.3% effective @ 5 yrs</td>
<td>□ 99.1% effective @ 3 years</td>
</tr>
<tr>
<td>□ 32x32mm device</td>
<td>□ 28x30mm device</td>
</tr>
<tr>
<td>□ 4.75 mm inserter</td>
<td>□ 3.8 mm inserter</td>
</tr>
<tr>
<td>□ 20% amenorrhea</td>
<td>□ 12% amenorrhea</td>
</tr>
<tr>
<td>□ $850 for 5 years</td>
<td>□ $650 for 3 years</td>
</tr>
</tbody>
</table>
Mechanism of Action: Copper T IUD

- Primary mechanism is prevention of fertilization
  - Reduce motility and viability of sperm
  - Inhibit development of ova?
- Inhibition of implantation is a possible secondary mechanism

What really happens to bleeding with the Copper T?

<table>
<thead>
<tr>
<th></th>
<th>Pre-IUD</th>
<th>12 months</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of bleeding</td>
<td>4.8 ± 0.2</td>
<td>6.1 ± 0.3</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Mean blood loss</td>
<td>59 ± 8 ml</td>
<td>92 ± 13 ml</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Ferritin, Hgb</td>
<td>22, 13.1</td>
<td>20, 13.0</td>
<td>NS</td>
</tr>
<tr>
<td>Painful menses</td>
<td>4/18</td>
<td>5/18</td>
<td>NS</td>
</tr>
</tbody>
</table>

Milsom, I et al Contraception 1995
Mechanism of Action: LNG IUC

- Primary mechanism is fertilization inhibition
  - Cause cervical mucus to thicken
  - Inhibit sperm motility and function

US data: LNG-IUS bleeding

- Gets better predictably, rapidly
- At 1 year, 20% amenorrhea, 10% monthly cycles
- Limited data yrs 4-5
Safety: IUCs Do Not Cause PID

- PID incidence for IUC users is similar to that of the general population
- Risk is increased only during the first month after insertion
- Preexisting STI at time of insertion, not the IUC itself, increases risk

Rate of PID by Duration of IUC Use

n=∼20,000 women

Rate per 1,000 woman years

9.25

<21 days of use

1.6

21 days - 8 years of use

IUD insertion and STI screening

- Follow CDC guidelines for STI screening
- Screen women at high risk of STIs
  - aged 25 years or younger
  - multiple sex partners
- Screen for STIs and place IUD on the same day
- Administer treatment if test results are positive
- Leave IUD in place

Safety: IUC Does Not Cause Infertility

- IUC is not related to infertility
- Chlamydia is related to infertility

Tubal infertility by previous copper T IUD use and presence of chlamydia antibodies, nulligravid women

Fertility Rates in Parous Women After Discontinuation of Contraceptive

Screening: Poor Candidates for Intrauterine Contraception

- Known or suspected pregnancy
- Puerperal sepsis
- Immediate post septic abortion
- Unexplained vaginal bleeding
- Cervical or endometrial cancer

Screening: Poor Candidates for Intrauterine Contraception (Continued)

- Uterine fibroids that interfere with placement
- Uterine distortion (congenital or acquired)
- Current PID
- Current purulent cervicitis, chlamydia, or gonorrhea
- Known pelvic tuberculosis

WHO. Medical Eligibility Criteria for Contraceptive Use. 2010.
Immediate start for LARC?

- Insert IUD or implant at any time during menstrual cycle
- Reasonably exclude pregnancy
- No advantage to inserting during menses
- No backup method needed for copper IUD
- Backup contraception x 7 days e.g. condoms with levonorgestrel intrauterine system
IUC for Postpartum Use

- May be safely inserted in postpartum women
  - Immediate postplacental insertion
  - After complete uterine involution

IUC Use During Lactation

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

IUC Use and Follow-up

- Schedule follow-up visits at:
  - Around 3–6 weeks, at clinician’s discretion
  - Routine well-woman care

- Advise return visit if there is:
  - Possible expulsion or displacement
  - Severe cramping or bleeding

- No data on routine thread checks by patient

IUC Use for “Older Women”

- LNG IUC can be an appropriate choice for perimenopausal women, especially those with dysfunctional uterine bleeding

- LNG IUC can be used off-label as an adjunct to estrogen therapy for postmenopausal women

Safety: IUCs May Be Used by HIV-Positive Women

- No increased risk of complications compared with HIV-negative women
- No increased cervical viral shedding
- WHO Category 2 rating
  - Uncomplicated solid organ transplantation

Use of long-acting contraceptives in young adults

- Are the patch or ring better than the pill?
  - Harder to forget to use
  - No difference if motivation wanes

- Make “non-pregnant” the default state
  - Levonorgestrel IUS (<20 yoa MEC= cat 1; >20 yoa = cat 1)
  - Copper-T IUD (<20 yoa MEC= cat 1; >20 yoa = cat 1)
  - Etonogestrel implant (MEC= category 1)
Use in Adolescents: Official guidance

- **ACOG**
  - “…top tier methods of contraception, including IUDs and implants, should be considered first-line choices for nulliparous and parous adolescents.”

- **CDC**
  - The U.S. *Medical Eligibility Criteria for Contraceptive Use*
    - IUD and nulliparity: Category 1
    - IUD and adolescent: Category 1
Contraceptive Implant: Implanon/Nexplanon

- Single implant rod (4 cm in length and 2 mm in diameter) made of EVA
- Contains 68 mg of etonogestrel
- Effective for 3 years
- Inhibits ovulation during the entire treatment period
- No impact on BMD

www.contraceptiononline.org
% women experiencing unintended pregnancy during the first year of use

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<tr>
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<th>Perfect Use</th>
<th>Continuation</th>
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<td></td>
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<tr>
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<td>Male Sterilization</td>
<td>0.15</td>
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</table>
Estradiol Levels During Treatment

Weight Changes

<table>
<thead>
<tr>
<th></th>
<th>Implanon Package insert</th>
<th>Depo-Provera Package insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Year</td>
<td>2.8 lbs</td>
<td>5.4 lbs</td>
</tr>
<tr>
<td>2 Years</td>
<td>3.7 lbs</td>
<td>8.1 lbs</td>
</tr>
<tr>
<td>5 Years</td>
<td>?</td>
<td>13.8 lbs</td>
</tr>
</tbody>
</table>
Implant Drug Interactions

- NOT RECOMMENDED with chronic use of potent hepatic enzymes inducers
  - Potential decreased efficacy
  - Could result in unintended pregnancy
- Examples:
  - Anti-HIV protease inhibitors
    - Barbiturates
    - Griseofulvin
    - Rifampin
    - Phenytoin
    - Carbamazepine
    - Felbamate
    - Oxcarbazepine
    - Topiramate
Review of Implanon bleeding

- Data from 11 clinical trials ($N = 923$)
  - bleeding-spotting records
  - dysmenorrhea
  - discontinuation

- Bleeding patterns analyzed via reference period
  - amenorrhea (22.2%)
  - infrequent (33.6%)
  - frequent (6.7%)
  - prolonged bleeding (17.7%).

- bleeding-spotting days $\leq$ natural cycle in 75% of RPs,
  - occurred at unpredictable intervals

Truly unpredictable?

- The bleeding pattern experienced during the initial phase predicted future patterns for the majority of women.

- Pattern in first 3 months:
  - Favorable bleeding patterns tended to continue.
  - Bad patterns ≥ 50% chance of improvement.
  - 11.3% discontinued due to bleeding irregularities.
  - 77% with dysmenorrhea: complete resolution.

Prolonged, frequent, and/or heavy bleeding with etonogestrel implant

Estrogen contraindicated

Doxy 100 mg bid x 5 days

NSAIDs: ibuprofen 800 mg or mefenamic acid 500 mg tid x 5 days

Estrogen not contraindicated

Low dose estrogen or COCs (x14-28 days)

Adolescent mothers: immediate post-partum implants

- Etonogestrel implant offered to be placed before discharge home after delivery

- N=396
  - 43% chose immediate PP implant (IPI)
  - 57% ANY other contraceptive strategy

- Followed for 2 years

Tocce et al. AJOG 2012
Implant Continuation

Reasons for discontinuation (n=46)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Count</th>
<th>Percentage</th>
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<tr>
<td>Irregular bleeding</td>
<td>19</td>
<td>41.6%</td>
</tr>
<tr>
<td>Headache</td>
<td>5</td>
<td>10.9%</td>
</tr>
<tr>
<td>Moodiness</td>
<td>4</td>
<td>8.7%</td>
</tr>
<tr>
<td>Weight gain</td>
<td>4</td>
<td>8.7%</td>
</tr>
</tbody>
</table>
Repeat Pregnancy

- 2.6% at 12 months
- 18.6% at 24 months
- 41.2% at 24 months

Significance:
- p ≤ 0.001 for 24 months
Annual costs per 1000 women

- $-17,283
- $520,823
- $2,257,270

-6 months
- one year
- two years

IPI
Control
Net savings/loss for Medicaid

$0
$500,000
$1,000,000
$1,500,000
$2,000,000
$2,500,000
$3,000,000
$3,500,000
$4,000,000

$2,257,270

$-17,283
$520,823
2013 CDC Report: Colorado

- 2008-2012 teen births decreased 34%

- 2008: 6,079 babies born to teen moms
  - 37.3 births/1,000 teens

- 2012: 4,144 babies born to teen moms
  - 23.9/1,000 teens

- 2008-2012 repeat teen births decreased 45%
  - >50% of postpartum adolescents using LARC in CO
  - 22.4% nationwide
Colorado teen birth rate plunges, far fewer second children

April 3, 2013
Clinical pearls: the younger patient

- Make it easy to stay non-pregnant
  - Don’t hold patients hostage to cervical screening, STI prevention, smoking cessation........

- Implants and IUDs are
  - Desired by patients IF OFFERED
  - Safe
  - Easy to insert
  - Easy to remove
  - Highly acceptable
  - Have few true contraindications
% women experiencing unintended pregnancy during the first year of use

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The “older” patient
When and how to stop contraception?

Patient in late 40's taking COCs

- IUD, DMPA, barriers
- Continue COCs until 50
- Use barrier methods until no periods x 12 months
- Check FSH on placebo week
- Could stay suppressed longer

- Continue COCs until 55
- May be more hormones than she needs
- Could have occasional ovulation
Transcervical sterilization has moved female sterilization from a minimally invasive laparoscopic technique to a less invasive hysteroscopic procedure.

**Essure® Office Setting**

Only 12% of patients are aware of this option for sterilization!
Hysteroscopic Sterilization
Hysteroscopic Sterilization
Hysteroscopic Sterilization

- HSG at 3 months to document occlusion; repeat at 6 mo if not occluded.
- Continue birth control until HSG shows bilateral occlusion.
- Outside the US: pelvic x-ray at 12 weeks to document placement.

Emergency Contraception (EC)

IF YOU'VE BEEN SWEPT OFF YOUR FEET
YOU'VE GOT 3 DAYS TO GET THEM BACK ON THE GROUND

EMERGENCY CONTRACEPTION
USE WITHIN 3 DAYS OF OPENING
Emergency contraceptives

- Prevent pregnancy when used after intercourse
- Inhibit ovulation, sperm motility/capacitation, fertilization, or implantation
- Will not interrupt an implanted pregnancy
- Do not protect against STIs
General Safety of EC

- No deaths or serious complications
- MEC: No situations where risk of combined or progestin-only ECPs outweigh the benefits
- No need for office visit, pelvic exam, labs
- Repeated use ECPs is safer than pregnancy

US Medical Eligibility Criteria for Contraceptive Use (US MEC) 2010
Percentage of women who have ever used EC has increased over time

Figure 1. Percentage of sexually experienced women aged 15–44 who have ever used emergency contraception: United States, 1995, 2002, and 2006–2010, and frequency of use among women who have ever used emergency contraception, 2006–2010

1 Significant linear trend.
NOTES: Percentages are rounded to the nearest whole number. Access data table for Figure 1 at: http://www.cdc.gov/nchs/data/databriefs/db112_tables.pdf#1.
EC in the 1920s

“DON’T TAKE CHANCES WITH MARRIAGE HYGIENE, MY DEAR, ‘Lysol’ is Safe”

SAYS DR. CLOTILDE DELAUNAY, LEADING GYNECOLOGIST OF PARIS
History of EC Methods

Mid-1960s: High-dose estrogens

Early 1970s: Yuzpe regimen

Late 1970s: Copper-T IUD

Mid-1990s: Levonorgestrel-only pills

2010: Ulipristal Acetate

Progestin-Only

MEC= category 2 for women with medical conditions
## LNG EC efficacy

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>#</th>
<th>% preg</th>
<th>% averted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1-72 hours</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LNG 1.5 mg</td>
<td>1,198</td>
<td>16</td>
<td>1.3%</td>
<td>84%</td>
</tr>
<tr>
<td>LNG 0.75 mg x 2</td>
<td>1,183</td>
<td>20</td>
<td>1.7%</td>
<td>79%</td>
</tr>
<tr>
<td><strong>72-120 hours</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LNG 1.5 mg</td>
<td>150</td>
<td>4</td>
<td>2.7%</td>
<td>63%</td>
</tr>
<tr>
<td>LNG 0.75 mg x 2</td>
<td>164</td>
<td>4</td>
<td>2.4%</td>
<td>60%</td>
</tr>
</tbody>
</table>

Ulipristal Acetate (UA)

FDA approved 8/2010; not included in the MEC 2010
SPRM: Ulipristal acetate

- Selective Progesterone Receptor Modulator
  - Agonist & Antagonist Effects
  - Low vs. high dose
  - Long term use → suppresses hormonal stimulation of reproductive organs

- Potential Implications:
  - Treatment of leiomyomas
  - Treatment of endometriosis
  - Daily contraception
  - Suppression of endometrium
Ulipristal acetate for EC

- **Primary Mechanism:**
  - Blocks or delays LH surge and follicular rupture when taken prior to ovulation
    - Delays follicular rupture by 4-10 days
  - May also delay maturation of endometrium?
  - May interfere with implantation?

UA is superior to LNG for EC

<table>
<thead>
<tr>
<th>time</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;24 hrs</td>
<td>0.35 (0.11-0.93)</td>
</tr>
<tr>
<td>&lt;72 hrs</td>
<td>0.58 (0.33-0.99)</td>
</tr>
<tr>
<td>&lt;120 hrs</td>
<td>0.55 (0.32-0.93)</td>
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Emergency Contraception: IUD Insertion

- Copper-T IUD (ParaGard)
  - MEC for interval Cu-IUD insertion applies to insertion for EC
- First described as EC in 1976
- Insertion within 5 days after unprotected sex
- No decrease in efficacy
- Provides 10 additional years of highly effective contraception
- Much more effective than ECPs

Trussell J, Raymond EG. 2007.
Copper IUD for EC

- Failure rate ~0.1%
  - >7,000 insertions with only 10 failures
- Reduces risk by >99%
- Requires office visit and procedure
- Does not protect against STIs

- Effectiveness of LNG IUS has not been studied & is not recommended
Mechanism of Action

- **Spermicidal**
  - Increased # of leukocytes in the EM cavity
  - Tissue breakdown products are toxic to all cells (sperm and blastocysts)

- High effectiveness implies IUD must prevent pregnancy after fertilization.

http://ec.princeton.edu/questions/ec-review.pdf
FAQs
Advanced Rx Provision of EC?

- Contraception is not 100% effective

- Provision before the time of need prevents exceeding the time limit for that product

- Advanced provision does not affect frequency of unprotected intercourse or use of contraception

Jackson et al. Obstet Gynecol 2003
Glasier et al. Lancet 2010
BMI & EC: 2 RCTs

- Compared to non-obese women taking EC

- LNG:
  - Decreasing efficacy with increasing BMI
  - Equal to women not using EC at BMI 26

- Ulipristal Acetate:
  - Did not have a significantly higher risk of pregnancy
  - Equal to women not using EC at BMI 35

Conclusions

- Incorporate US MEC in daily practice
- Utilize LARC as 1st line contraception!
- Offer minimally invasive sterilization for appropriate candidates
- Effectively use EC
Questions?
Thank You!