

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

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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

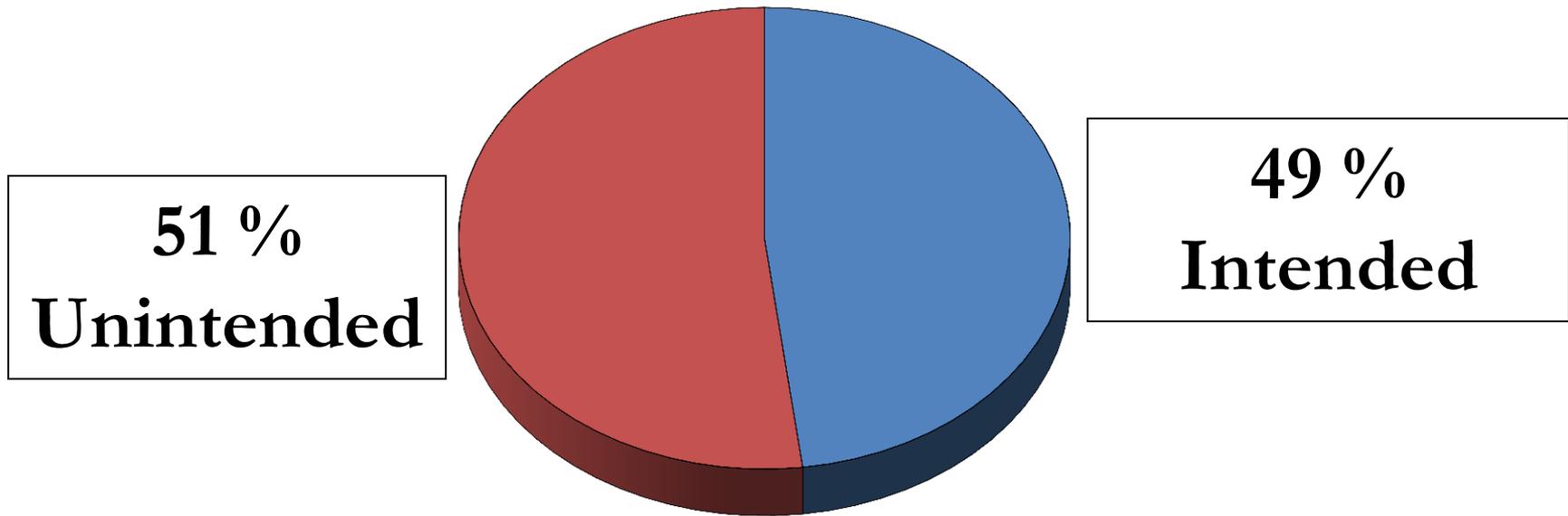


# Learning Objectives

- 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



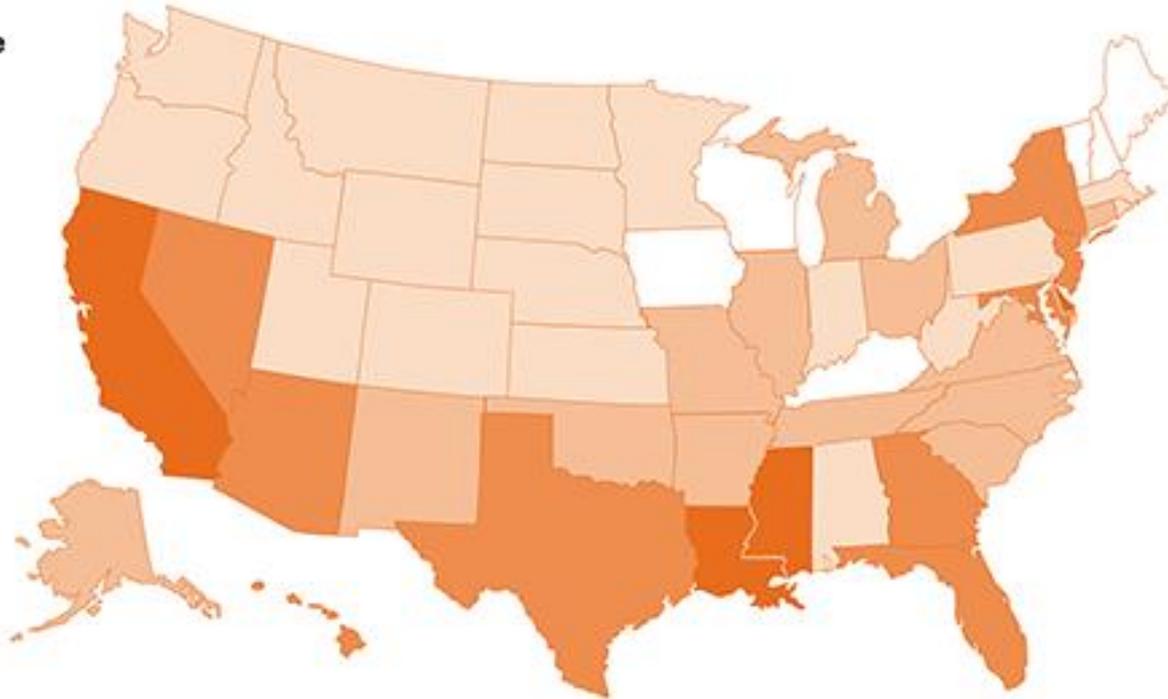
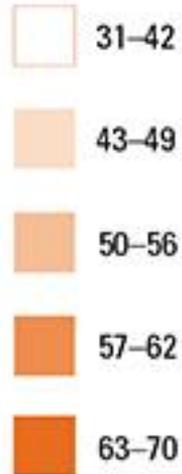
# 6.6 Million Pregnancies Annually



# How is New Mexico doing?

## Unintended Pregnancy Rates, by State, in 2008

Unintended pregnancy rate

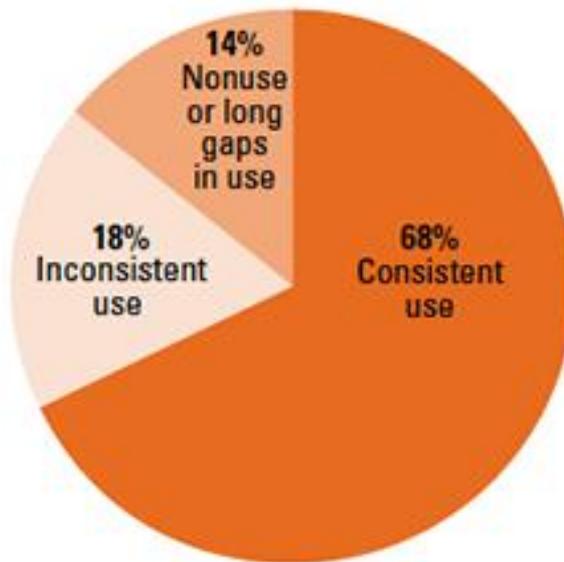


\*Rates for Arizona, Indiana, Kansas, Montana, Nevada, New Hampshire, North Dakota and South Dakota estimated by multiple regression.

## Modern Contraception Works

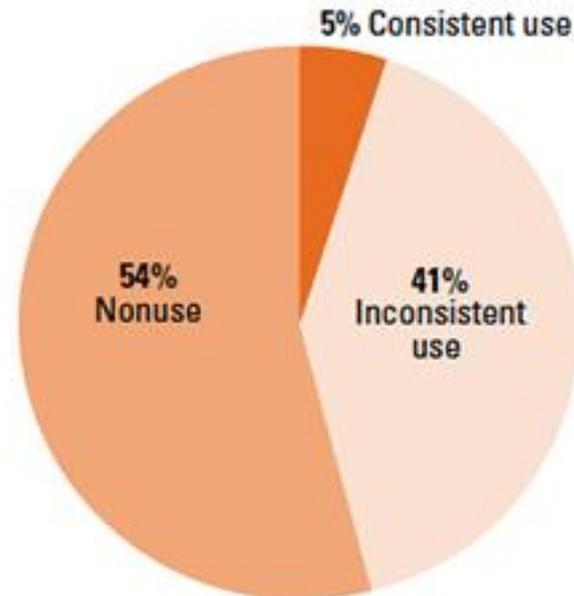
The two-thirds of U.S. women at risk of unintended pregnancy who practice contraception consistently and correctly account for only 5% of unintended pregnancies.

Women at Risk  
(43 Million in 2008)



By consistency of method use all year

Unintended Pregnancies  
(3.1 Million)



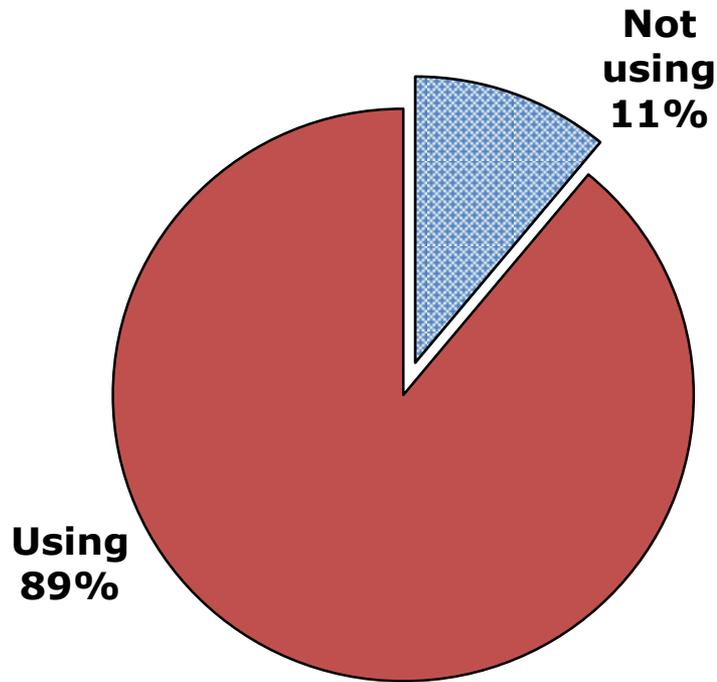
By consistency of method use during month of conception

Sonfield et al., 2014

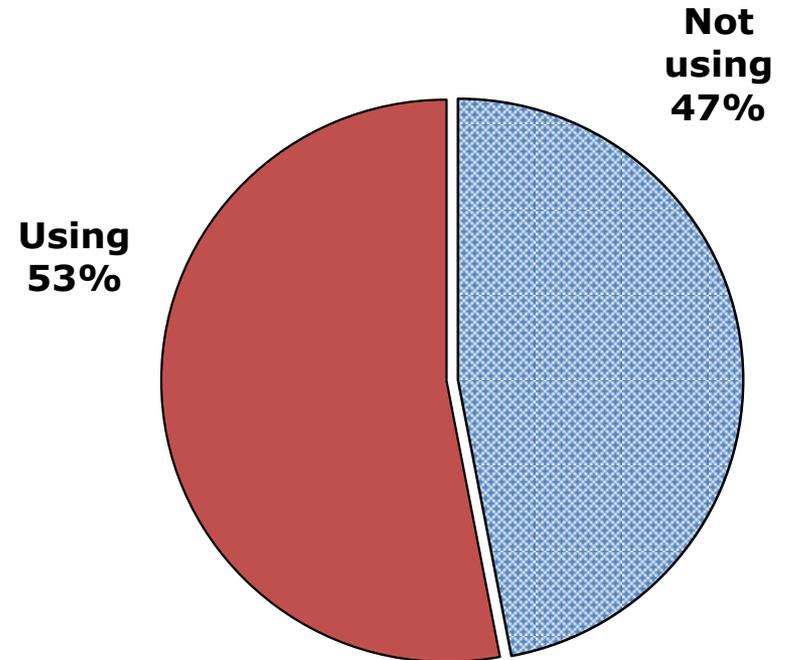


**The small proportion of women who do not use contraceptives**

**... account for roughly half of all unintended pregnancies**

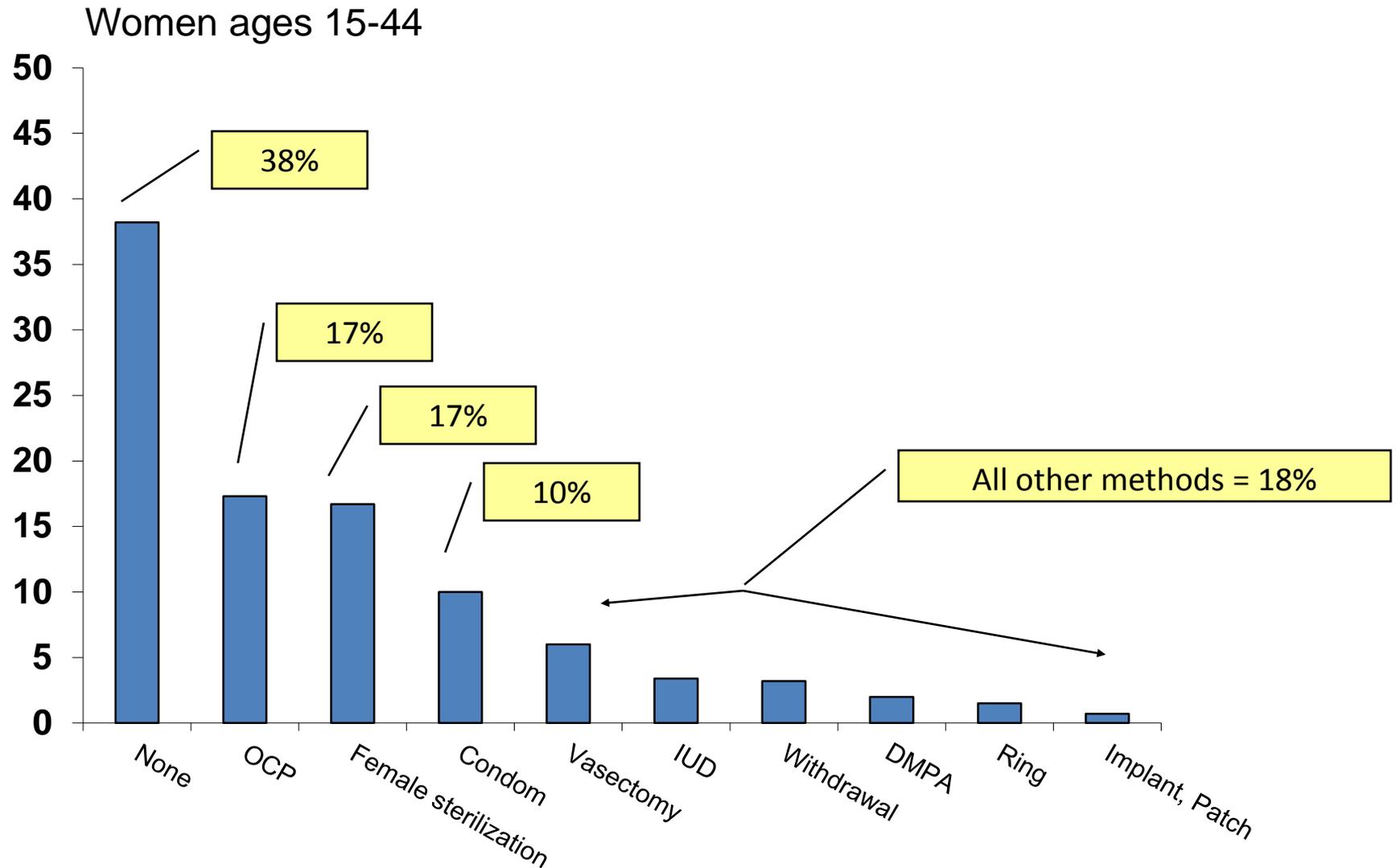


**Women at risk of unintended pregnancy,**



**Women experiencing unintended pregnancies,**

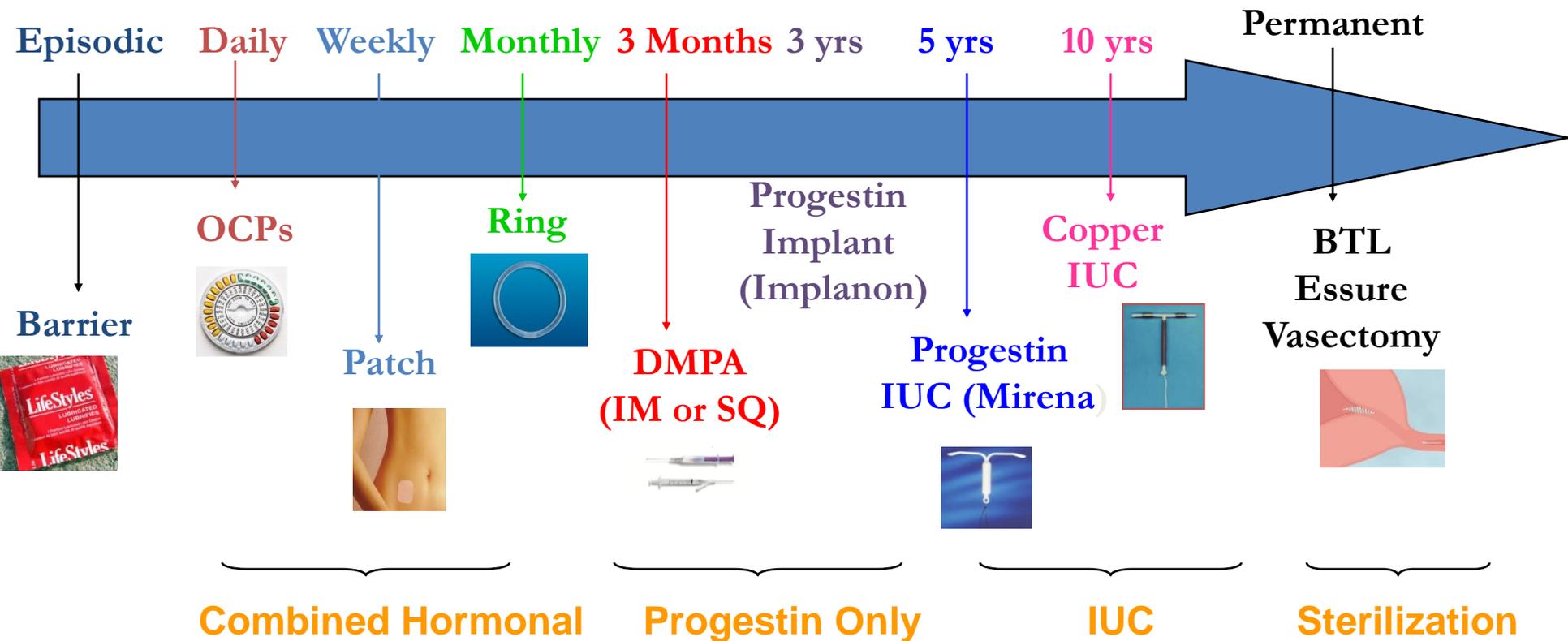
# Contraceptive use & non-use in the US, 2006-2010 NSFG



# Contraception Methods

Least effective

Most effective



# Contraceptive Efficacy

Perfect Use

≠

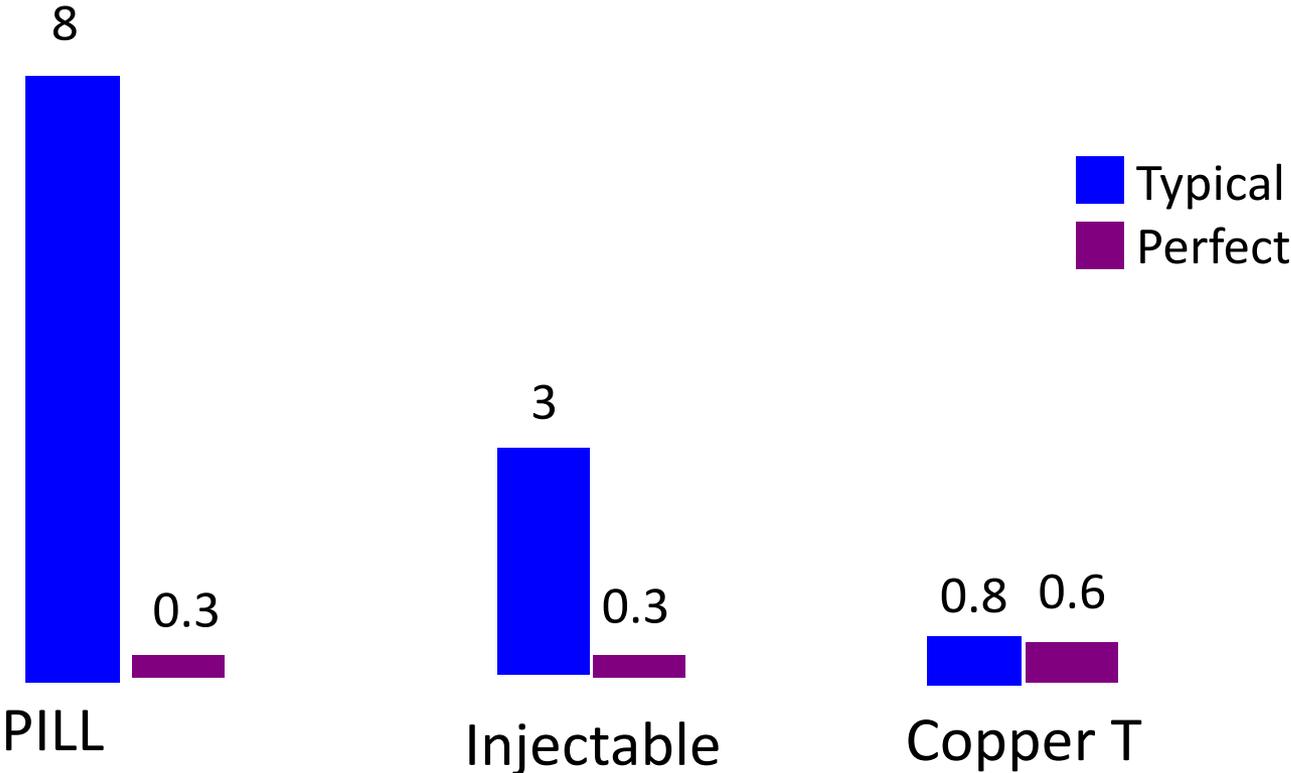
Typical Use

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



Hatcher R, et al. Contraceptive Technology. 2004.

# Continuation rates

| <b>% Continuation at one year</b> |     |
|-----------------------------------|-----|
| Pills, patch, ring                | 68% |
| Condoms                           | 60% |
| Depo-provera                      | 56% |
| ParaGard (copper T)               | 78% |
| Mirena (LNG)                      | 81% |
| Nexplanon                         | 82% |

# 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!**



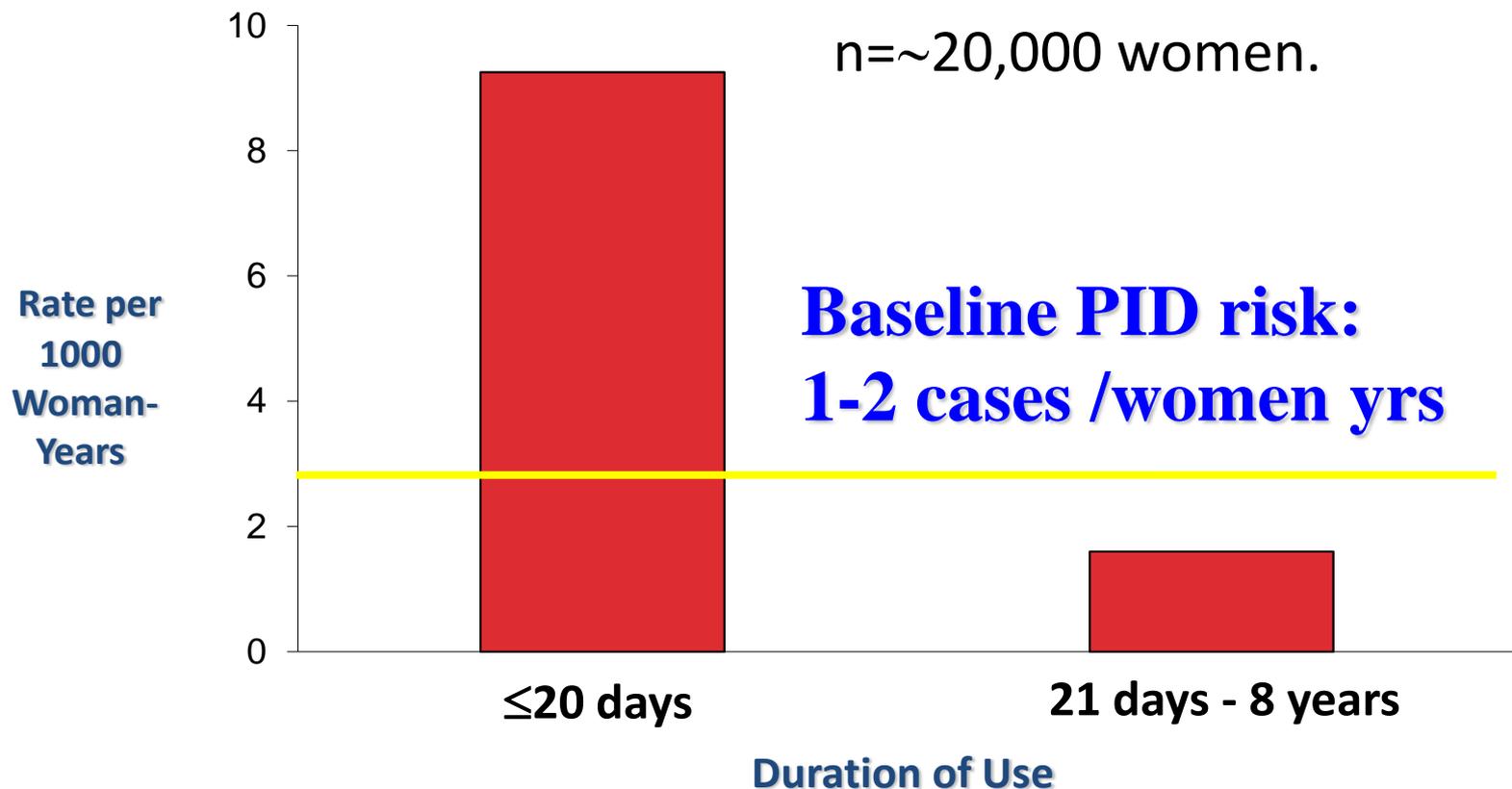
# Who is a candidate for an IUD?

- ✓ 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



# 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

Svensson L, et al. *JAMA*. 1984.  
Sivin I, et al. *Contraception*. 1991.  
Farley T, et al. *Lancet*. 1992.  
Grimes, DA, *Lancet*, 2000



# STI screening before insertion?

*Routine* screening NOT necessary!

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

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

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

- No cases of PID when PP switched to same day screening<sup>2</sup>
- No benefit to prophylactic antibiotics<sup>3</sup>
- ACOG: no routine screen<sup>4</sup>

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

| OLD LABEL   | NEW LABEL   |
|---|---|
| Acute PID or history of PID                                 | Acute PID or current behavior suggesting high risk of PID |
| Postpartum or postabortal endometritis in past 3 months     | Postpartum or postabortal endometritis in past 3 months   |
| Uterine or cervical cancer or unresolved Pap smear          | Known or suspected uterine or cervical malignancy         |
| Untreated acute cervicitis/<br>vaginitis                    | Mucopurulent cervicitis                                   |
| Patient or partner w/multiple partners                      | REMOVED   |
| Increased susceptibility to infection (AIDS, leukemia, etc) | REMOVED   |

# Old vs. new package insert

| <b>OLD LABEL</b>                    | <b>NEW LABEL</b> |
|-------------------------------------|------------------|
| Pregnancy or suspicion of pregnancy | No change        |
| Distorted uterine cavity            | No change        |
| Current IUD in place                | No change        |
| Genital bleeding of unknown source  | No change        |
| Wilson's disease (Paragard only)    | No change        |

# Key messages: FDA-approved new ParaGard label

## OLD LABEL

ParaGard recommended for women who have had at least one child

ParaGard recommended for women in a stable, mutually monogamous relationship

## NEW LABEL

***ParaGard appropriate for nulliparous women***

***ParaGard appropriate for women without a relationship requirement***



# IUDs and ectopic pregnancy

| Ectopic pregnancy rates per 1,000 Woman Years |           |
|---|-----------|
| Non contraceptive users                       | 2.00-4.50 |
| Levonorgestrel IUD                            | 0.20      |
| Tcu-380A IUD                                  | 0.20      |

- 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

Speroff L, Darney P. Clinical Guide to Contraception. 2005.



# Will abdominal sterilization become obsolete?

| We thought...                              | Now we know...                                |
|--|---|
| Hormones dangerous > 35                    | OK to use till menopause                      |
| IUDs dangerous                             | IUDs safe till menopause                      |
| Tubal the most effective method            | IUDs, Implanon as effective as tubal          |
| Laparoscopy safer than laparotomy          | IUD, hysteroscopy safer than either           |
| Regret is rare                             | 40% young women request info about reversal   |
| Tubal most cost-effective method over time | IUD most cost effective method over 2-5 years |

# 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



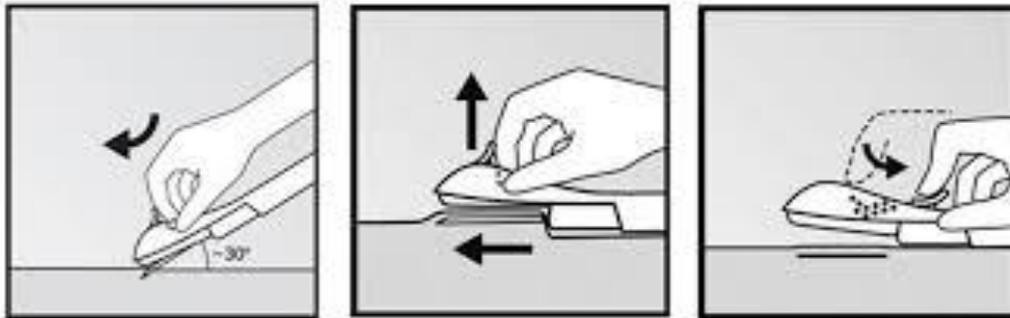
# Contraindications

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



# Nexplanon™

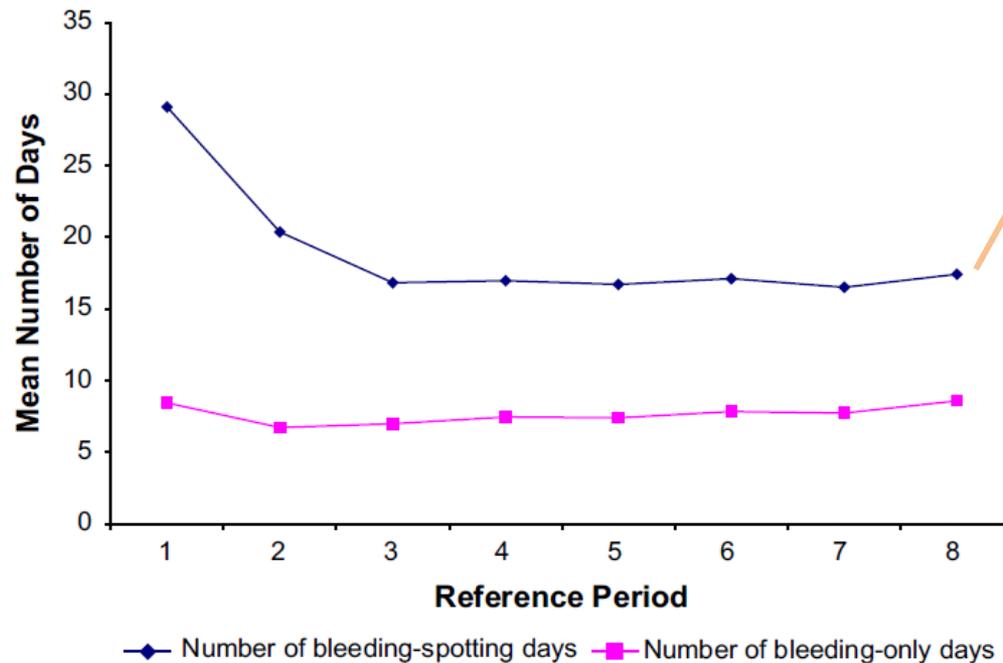
- Training required to insert/remove
- Easier than Implanon!
- Unlike Implanon, can be visualized on XRay





# ETG Implant & Bleeding

Bleeding parameters for the reference period analysis group.



17 bleeding-spotting days/90d

Infrequent: 34%

Amenorrhea 22%

Prolonged bleeding 18%

Frequent bleeding 7%

Darney. *ENG implant clinical experience. Fertil Steril* 2009.

**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. . .

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



## 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

# LNG-IUS Update

Skyla is a small T-body made of soft, flexible plastic.

Actual measurements



**99.95% pure silver ring differentiates Skyla on ultrasound**

Patients should tell their provider if they have Skyla if getting an MRI

**Removal threads**

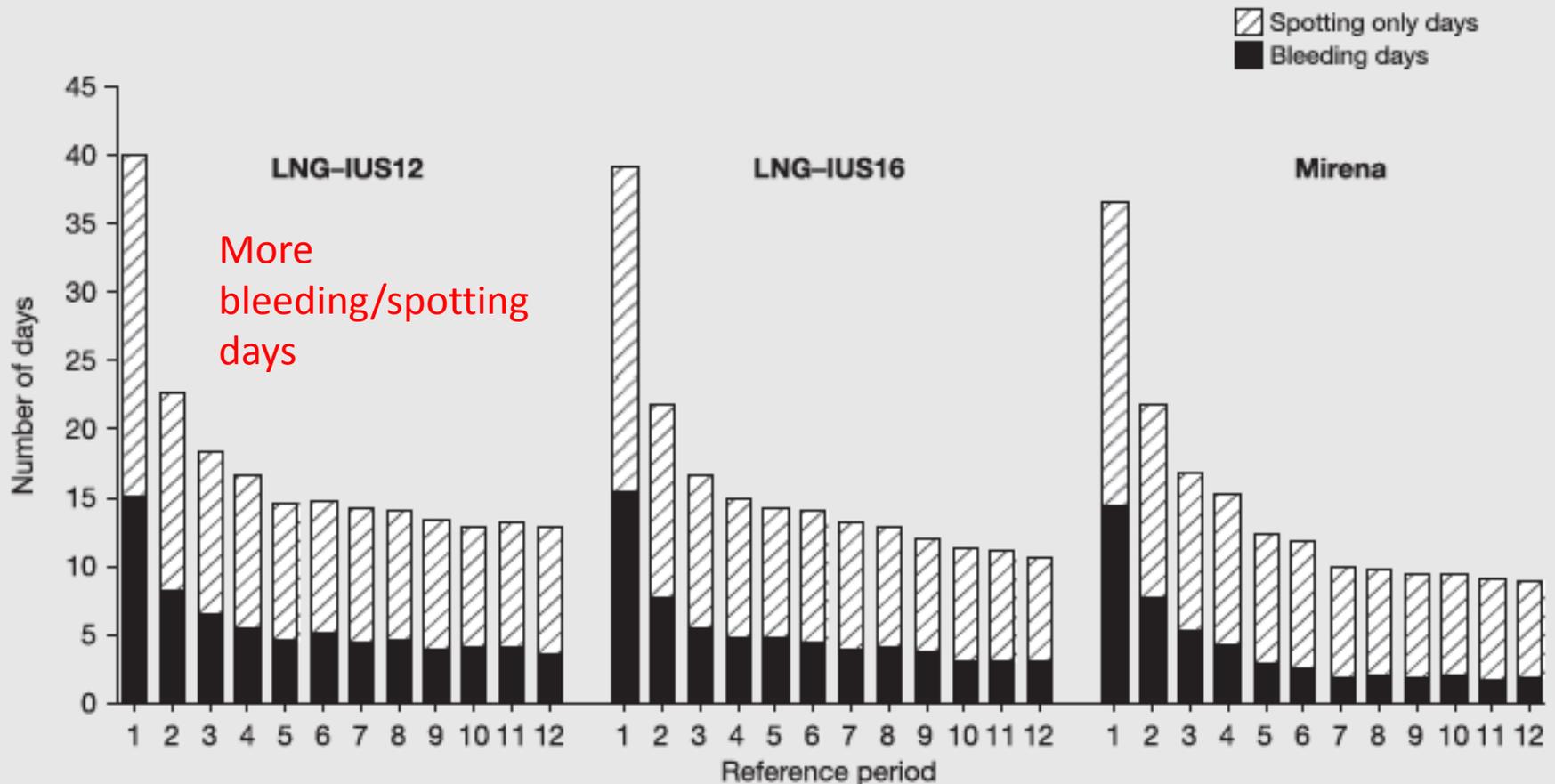


The Skyla inserter is designed for single-handed loading into the insertion tube.

# 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)**

| Skyla                            | First 90 days<br>N=1,531 | Second 90 days<br>N=1,475 | End of year 1<br>N=1,329 | End of year 3<br>N=903 |
|----------------------------------|--------------------------|---------------------------|--------------------------|------------------------|
| Amenorrhea <sup>1</sup>          | <1%                      | 3%                        | 6%                       | 12%                    |
| Infrequent bleeding <sup>2</sup> | 8%                       | 19%                       | 20%                      | 22%                    |
| Frequent bleeding <sup>3</sup>   | 31%                      | 12%                       | 8%                       | 4%                     |
| Prolonged bleeding <sup>4</sup>  | 59%                      | 17%                       | 9%                       | 3%                     |
| Irregular bleeding <sup>5</sup>  | 42%                      | 28%                       | 23%                      | – <sup>6</sup>         |

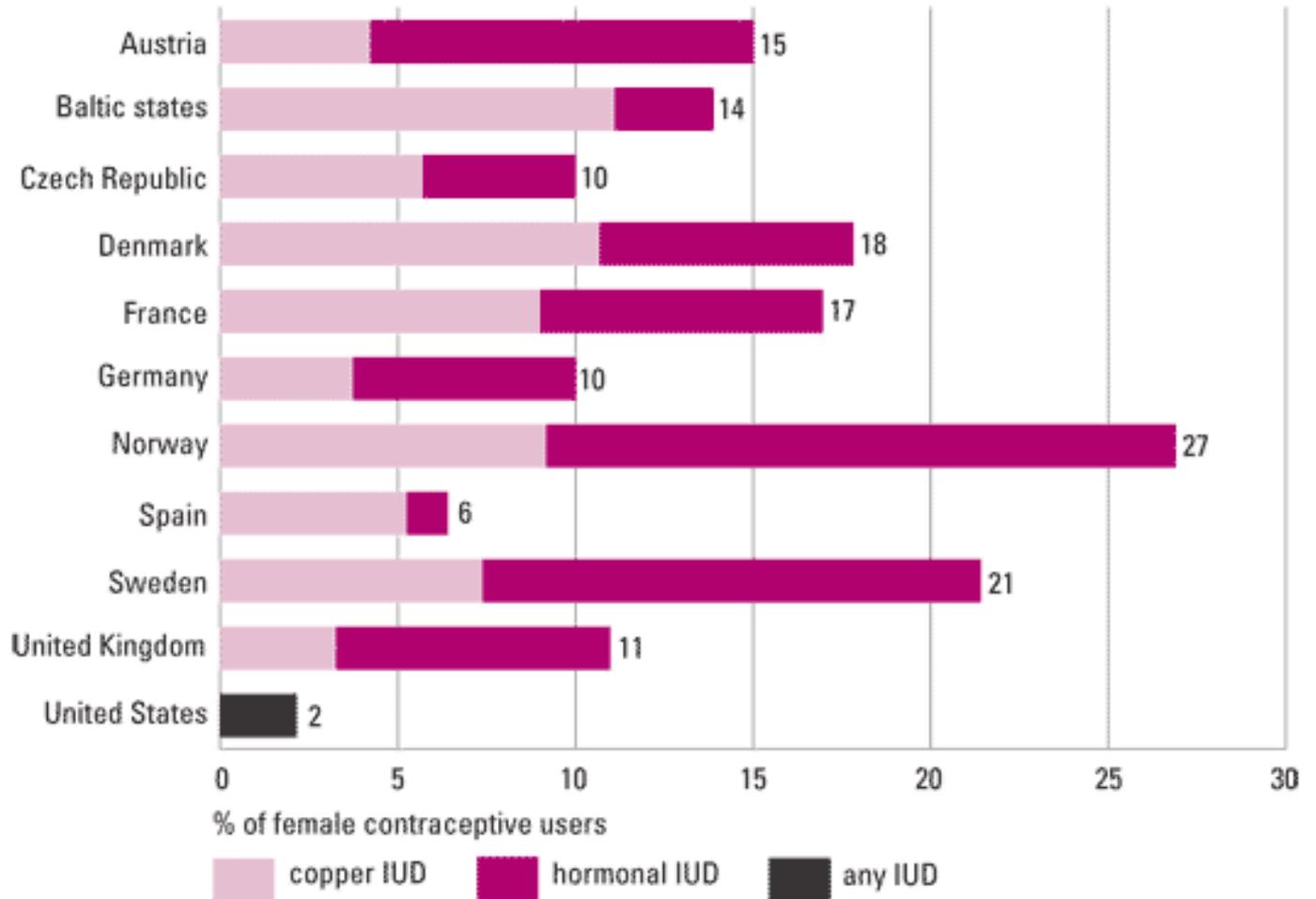
- Compared to Mirena:
  - 50% amenorrhea by 12 mo
  - 25% oligomenorrhea throughout 2 y
  - Spotting 25% @ 6mo -> 8% @ 18 mo-> 11% @ 24 mo.

# 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



# 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  
Harper CC et al. 2013. Prev Med

# 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



Kavanaugh et al. 2013. J Ped Adolesc Gynecol  
Rubin et al. 2010. J Womens Health  
Asker C et al. 2006. J Fam Plann Repro Health Care



# What are we missing?

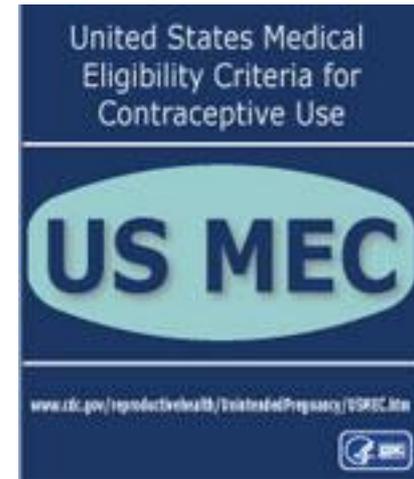
- Training
- Us (providers) . . . Wait, what?
- Access
  - Lack of counseling about LARC
- Patient concerns/myths
  - Overly restrictive provision of LARC
  - Misconceptions about risk of infection, infertility, nullips
  - We ALL do it!
    - Pediatricians
    - Family medicine
    - Ob/Gyns

Swanson KJ et al. 2013. J Ped Adolesc Gynecol  
Callegari et al. 2014 J Am Board Fam Med  
Stanwood N et al. 2002. Obstet Gynecol  
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.)

| Condition                   | Sub-condition                                       | Combined pill, patch, ring |   | Progestin-only pill |   | Injection |   | Implant |   | LNG-IUD |    | Copper-IUD |    |
|-----------------------------|---|----------------------------|---|---------------------|---|-----------|---|---------|---|---------|----|------------|----|
|                             |   | I                          | C | I                   | C | I         | C | I       | C | I       | C  | I          | C  |
| Pelvic inflammatory disease | a) Past, (assuming no current risk factors of STIs) |                            |   |                     |   |           |   |         |   |         |    |            |    |
|                             | (i) with subsequent pregnancy                       | 1                          |   | 1                   |   | 1         |   | 1       |   | 1       | 1  | 1          | 1  |
|                             | (ii) without subsequent pregnancy                   | 1                          |   | 1                   |   | 1         |   | 1       |   | 2       | 2  | 2          | 2  |
|                             | b) Current  | 1                          |   | 1                   |   | 1         |   | 1       |   | 4       | 2* | 4          | 2* |



# 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

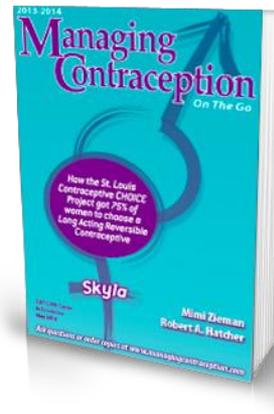
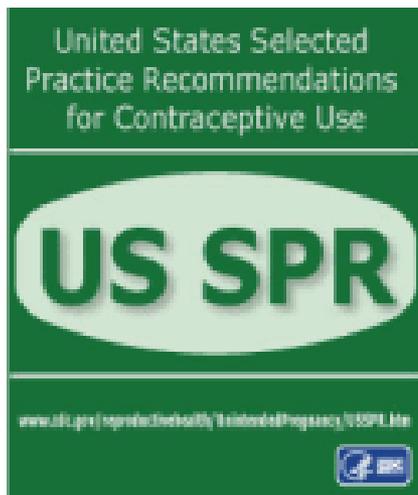
# Conclusions

- 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.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](http://www.who.int/reproductivehealth/topics/family_planning/en/index.html)