What’s New in Contraception

Anne Burke, MD, MPH

Baltimore, MD

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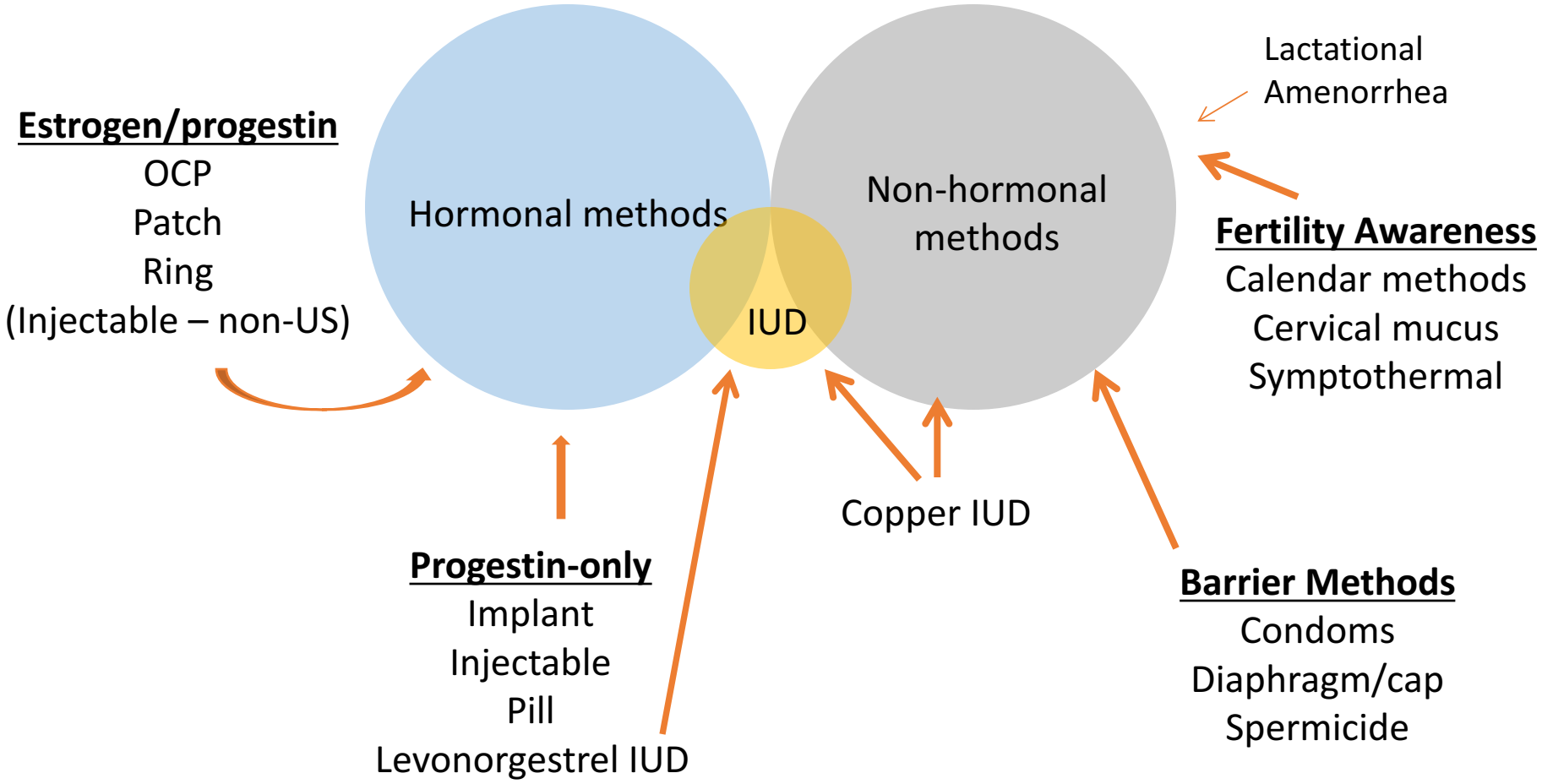
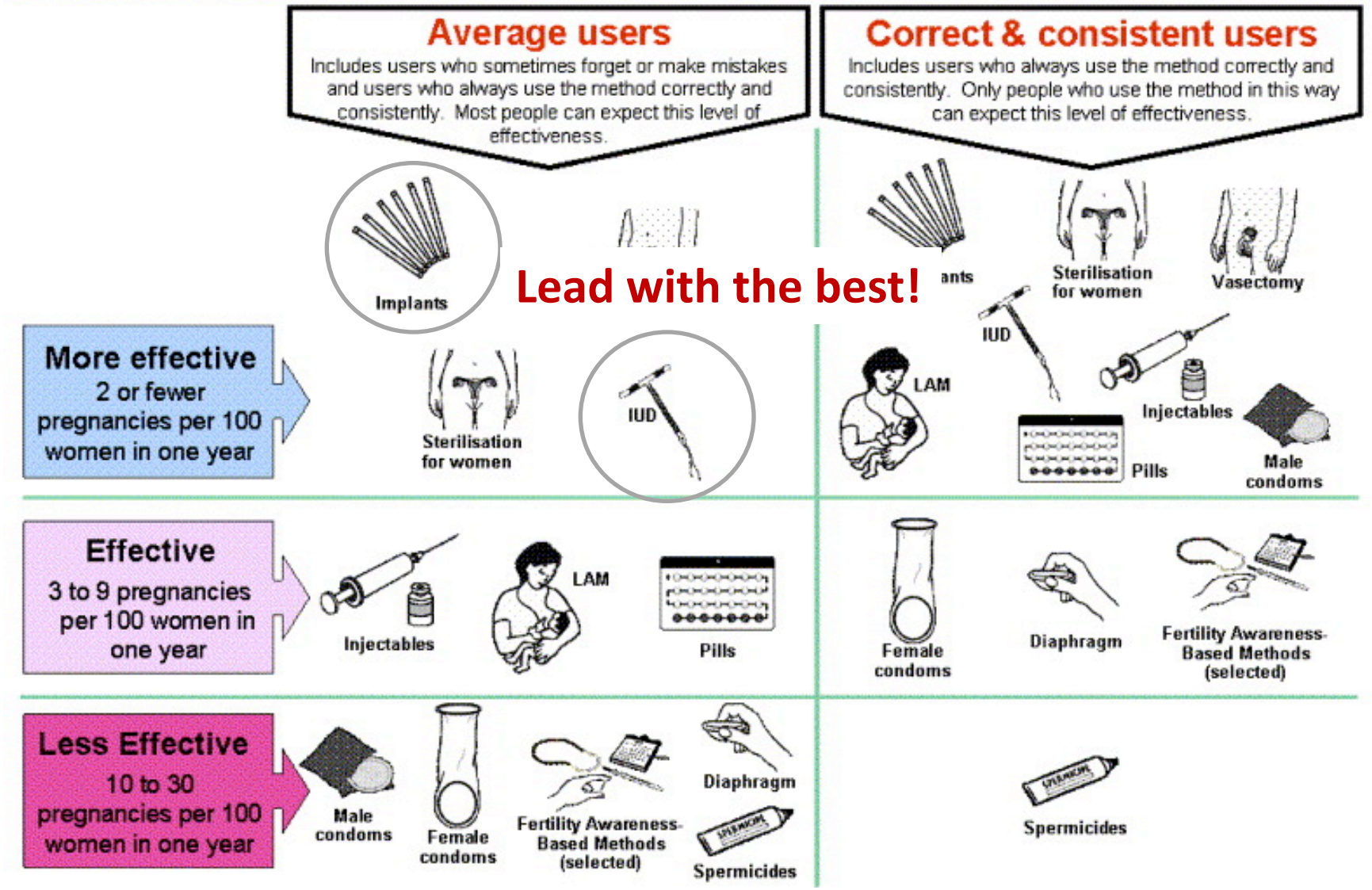
Types of Contraception



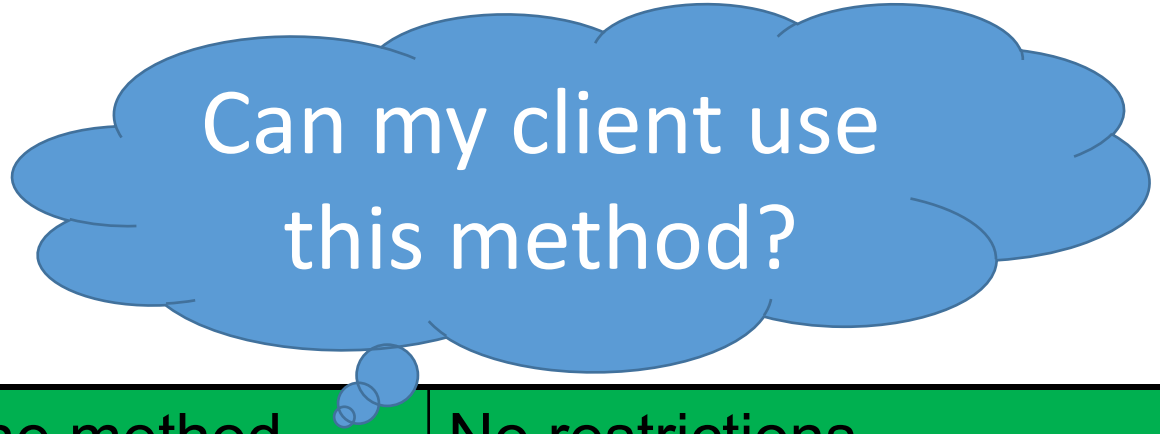
Objectives

- Update on long-acting reversible methods
- Counseling
- Adolescents
- Postpartum
- Vaginal rings
- WHO Injectable update

Comparing effectiveness of contraceptive methods



WHO Medical Eligibility Criteria



1	Can use the method	No restrictions
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

Update on Long-Acting Methods

Long Acting Reversible Contraception (LARC)

Pregnancy rates in first year of use (per 1000 women)

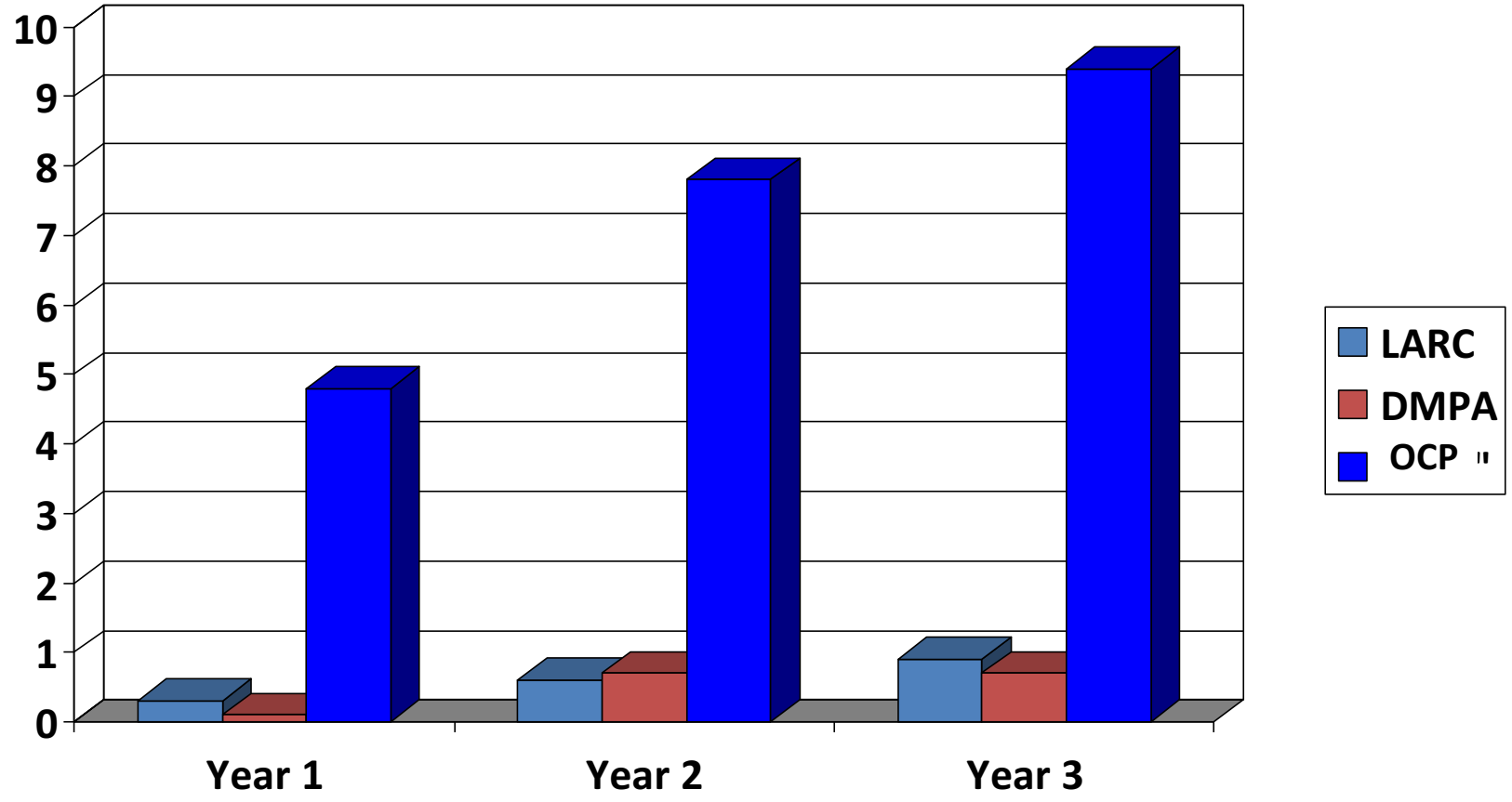
6

1-2

~1

Trussell, Contraception, 2011

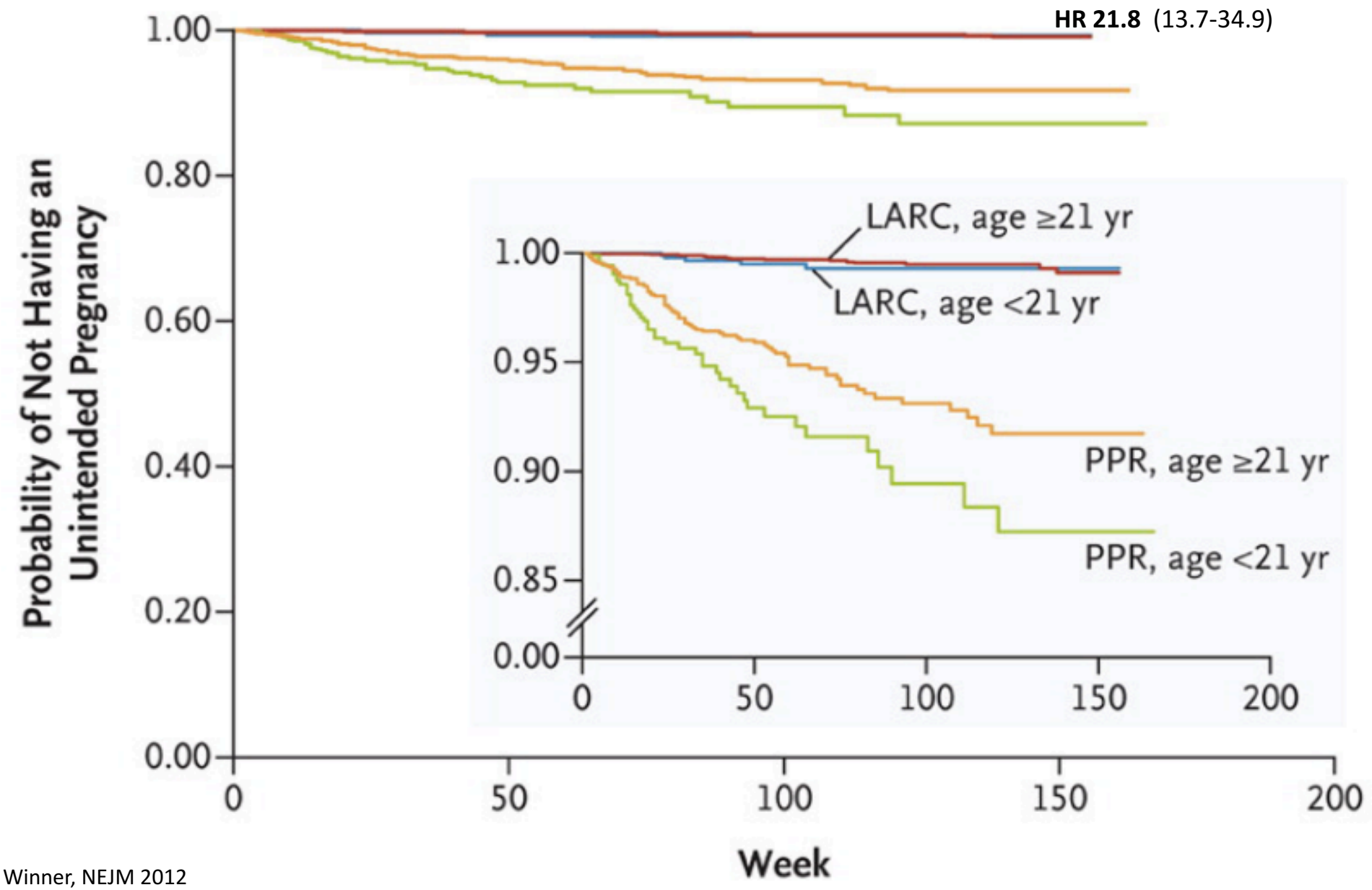
Contraceptive Failure: LARC vs. the rest



Cumulative % of women with contraceptive failure

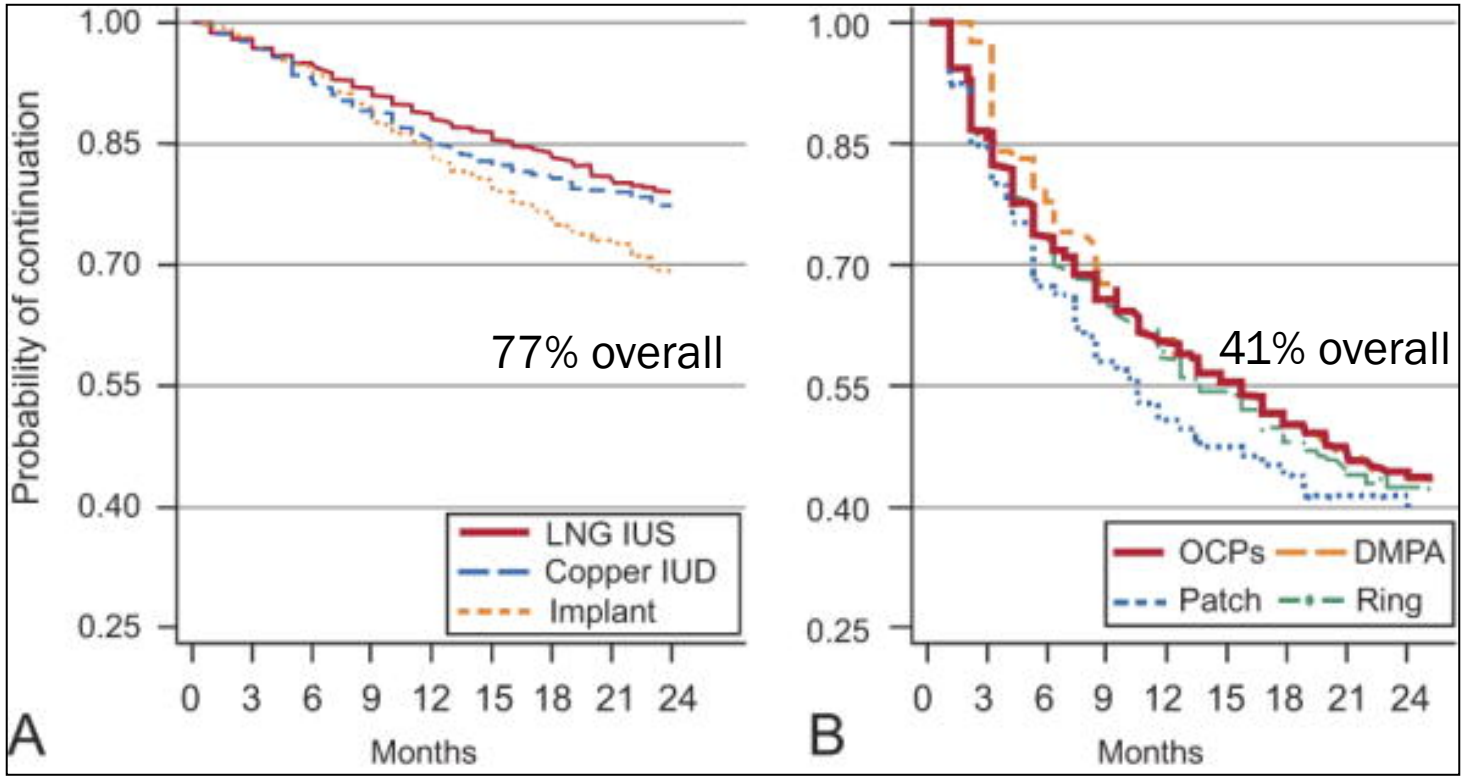
Winner B, et al, NEJM 2012

Pregnancy prevention – highly effective



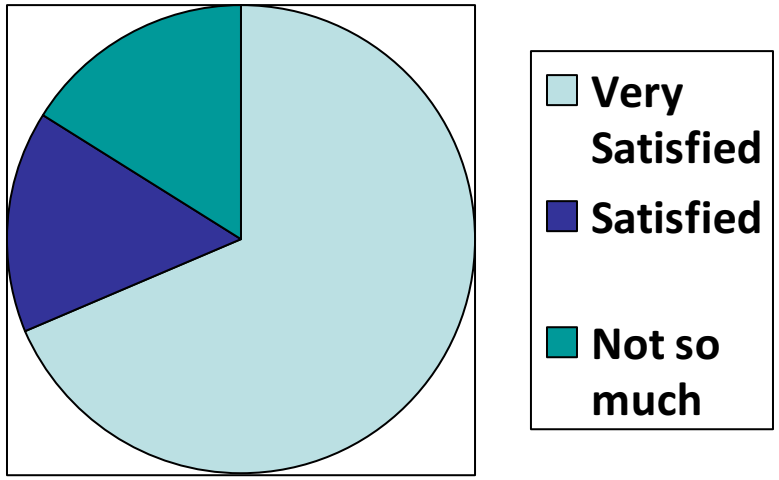
Winner, NEJM 2012

Continuation over 24 months

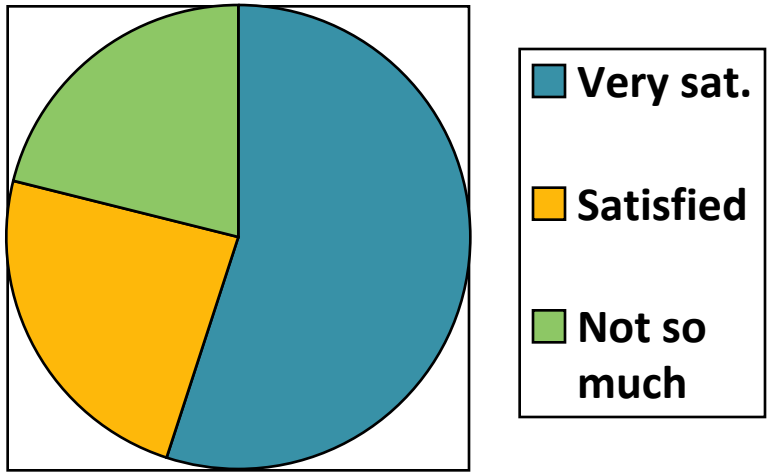


Twenty-Four-Month Continuation of Reversible Contraception. ONeil-Callahan, Micaela; Peipert, Jeffrey; MD, PhD; Zhao, Qiuhong; Madden, Tessa; MD, MPH; Secura, Gina; PhD, MPH
Obstetrics & Gynecology. 122(5):1083-1091, November 2013. DOI: 10.1097/AOG.0b013e3182a91f45

Satisfaction with long-acting methods is high



IUD (N= 2,324)



Implant (N=522)

Twenty-Four-Month Continuation of Reversible Contraception. ONeil-Callahan, Micaela; Peipert, Jeffrey; MD, PhD; Zhao, Qiuhong; Madden, Tessa; MD, MPH; Secura, Gina; PhD, MPH
Obstetrics & Gynecology. 122(5):1083-1091, November 2013. DOI: 10.1097/AOG.0b013e3182a91f45

Most women, most of the time, are candidates for LARC methods

- Almost all women can use implant
- Category 4:
  - Breast cancer
  - Allergy

IUD Category 4 conditions
Pregnancy
Cervix, breast, endometrial cancer
Distorted uterine cavity
Current PID
Current purulent CT/GC

Do not unnecessarily restrict insertion of LARC Methods

Table 2. Selected Practice Recommendations for the Initiation of LARC Methods.*

Contraceptive Method	Timing of Initiation†	Additional Contraception Needed as Back-up‡	Examinations or Tests Needed before Initiation
Copper-containing IUD	Any time	Not needed	Bimanual examination and cervical inspection§
Levonorgestrel-releasing IUD	Any time	If more than 7 days after menses started, use back-up method or abstain from sexual intercourse for 7 days.	Bimanual examination and cervical inspection§
Hormonal implant	Any time	If more than 5 days after menses started, use back-up method or abstain from sexual intercourse for 7 days.	None

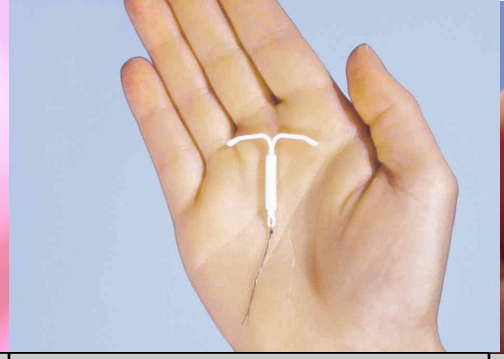
* This table is adapted from Curtis et al.[19]
† LARC methods can be initiated if the provider is reasonably certain that the woman is not pregnant.
‡ The recommendations for the use and duration of a back-up method were determined on the basis of the mechanism of action of the contraceptive method and on the basis of data on the minimum duration of use necessary for contraceptive effectiveness.
§ Most women do not require additional screening for sexually transmitted diseases (STDs) at the time of insertion of an IUD. If a woman with risk factors for STDs has not been screened for gonococcal infection and chlamydial infection according to the STD Treatment Guidelines of the Centers for Disease Control and Prevention (CDC) (www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion.

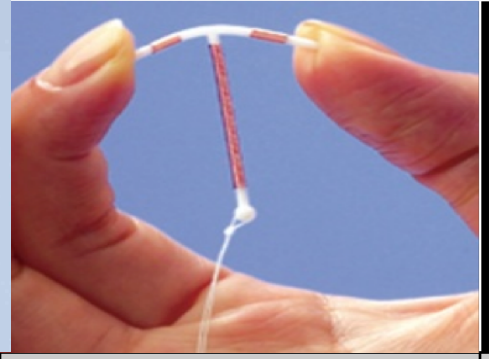
Curtis KM, Peipert JF. N Engl J Med 2017;376:461-468.

How to be reasonably sure a woman is not pregnant

If all answers are	PREGNANCY CHECKLIST	If any answer is
NO …then cannot rule out pregnancy	Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	**YES** …then can be reasonably sure she is not pregnant
	Have you abstained from sexual intercourse since your last menstrual period or delivery?	
	Have you had a baby in the last 4 weeks?	
	Did your last menstrual period start within the past 7 days (or within the past 12 days if you are planning to use an IUD)?	
	Have you had a miscarriage or abortion in the past 7 days (or within the past 12 days if you are planning to use an IUD)?	
	Have you been using a reliable contraceptive method consistently and correctly?	

Source: USAID, FHI 2008

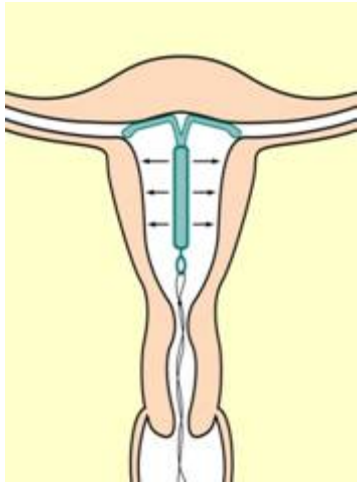




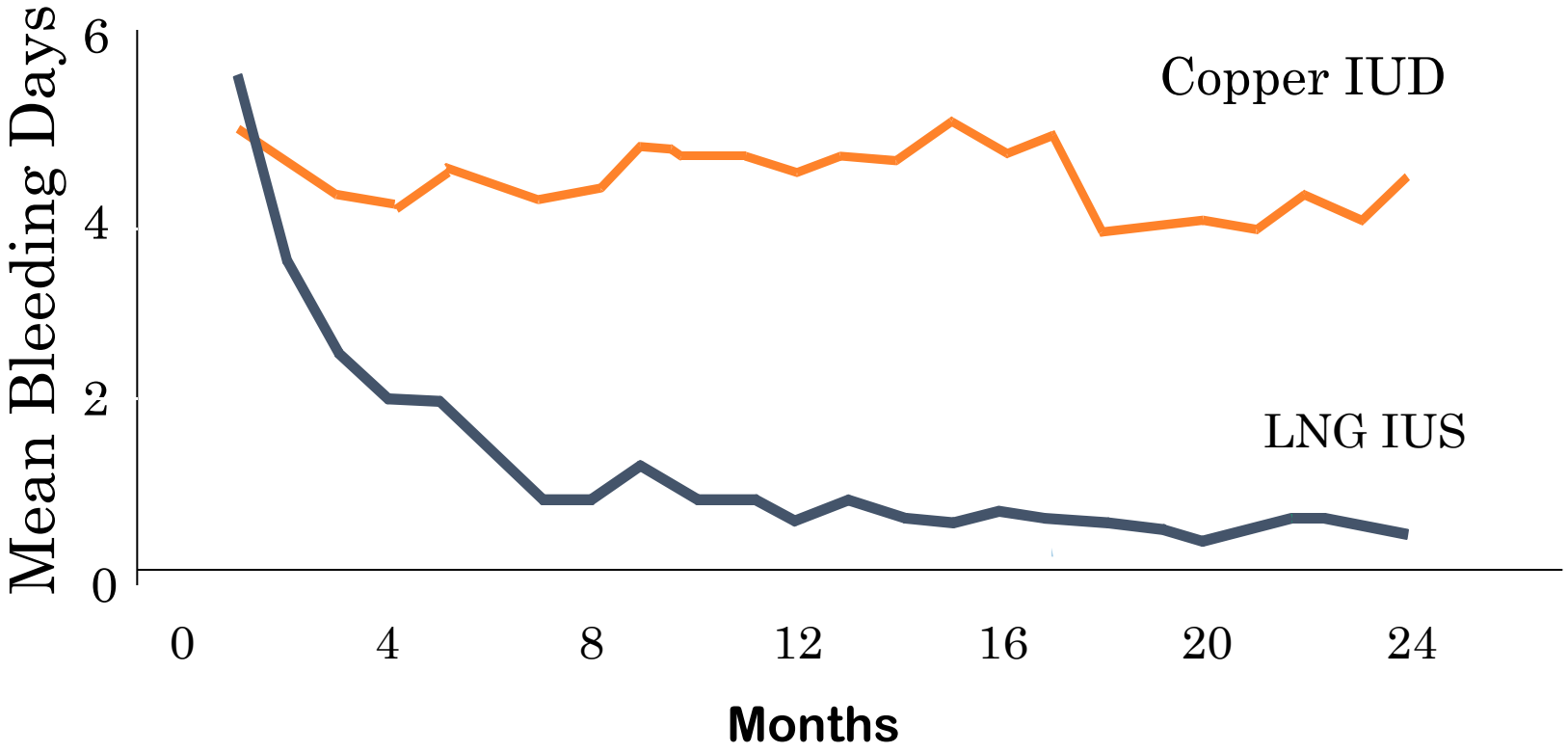
(LNG-IUS)	(LNG-IUS)	(Copper T IUD)	(Copper T IUD)
28x30mm	32x32mm	32x36mm	24x30mm
3 years	5 years	12 years	5 years
0.4% failure	0.2% failure	0.6% failure	0.6% failure
Initially releases 14mcg/day levonorgestrel → 5mcg/day (3 yrs)	Initially releases 20mcg/day levonorgestrel → 10mcg/day (5 yrs)	No hormone Copper ions	No hormone Copper ions
-Thickens cervical mucus -Thins endometrial lining -Spermicidal -Incomplete ovulation suppression		-Spermicidal -Change in ovum transport speed	-Spermicidal -Change in ovum transport speed

IUDs: Mechanism

- Mechanism: primarily by preventing fertilization
  - Copper has direct effects on uterus, sperm and ova
  - Levonorgestrel:
    - THICKENS cervical mucus
    - THINS endometrial lining

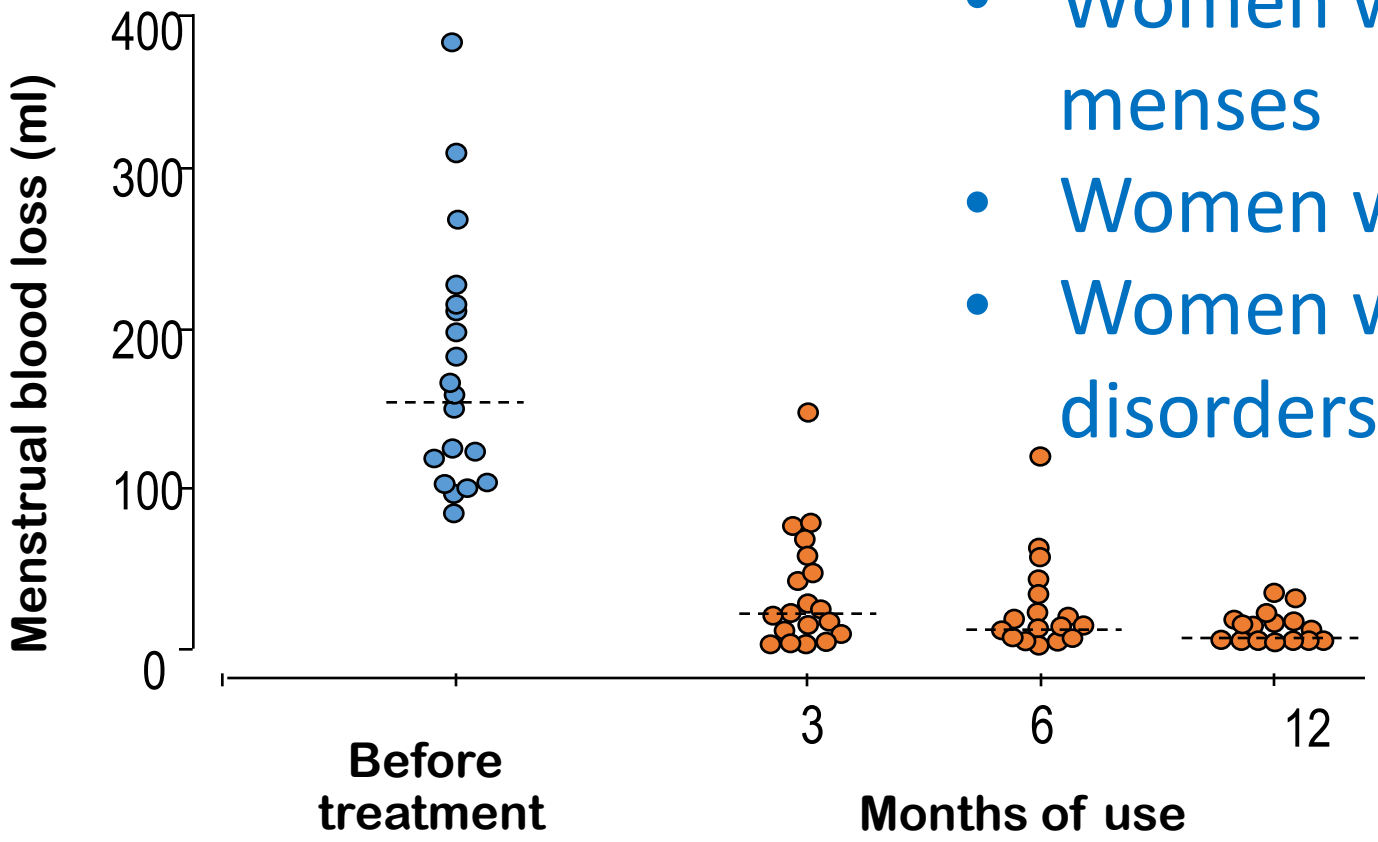


IUDs and bleeding patterns



Luukkainen and Toivonen. 1992;90

LNG IUD: Treatment Heavy Bleeding



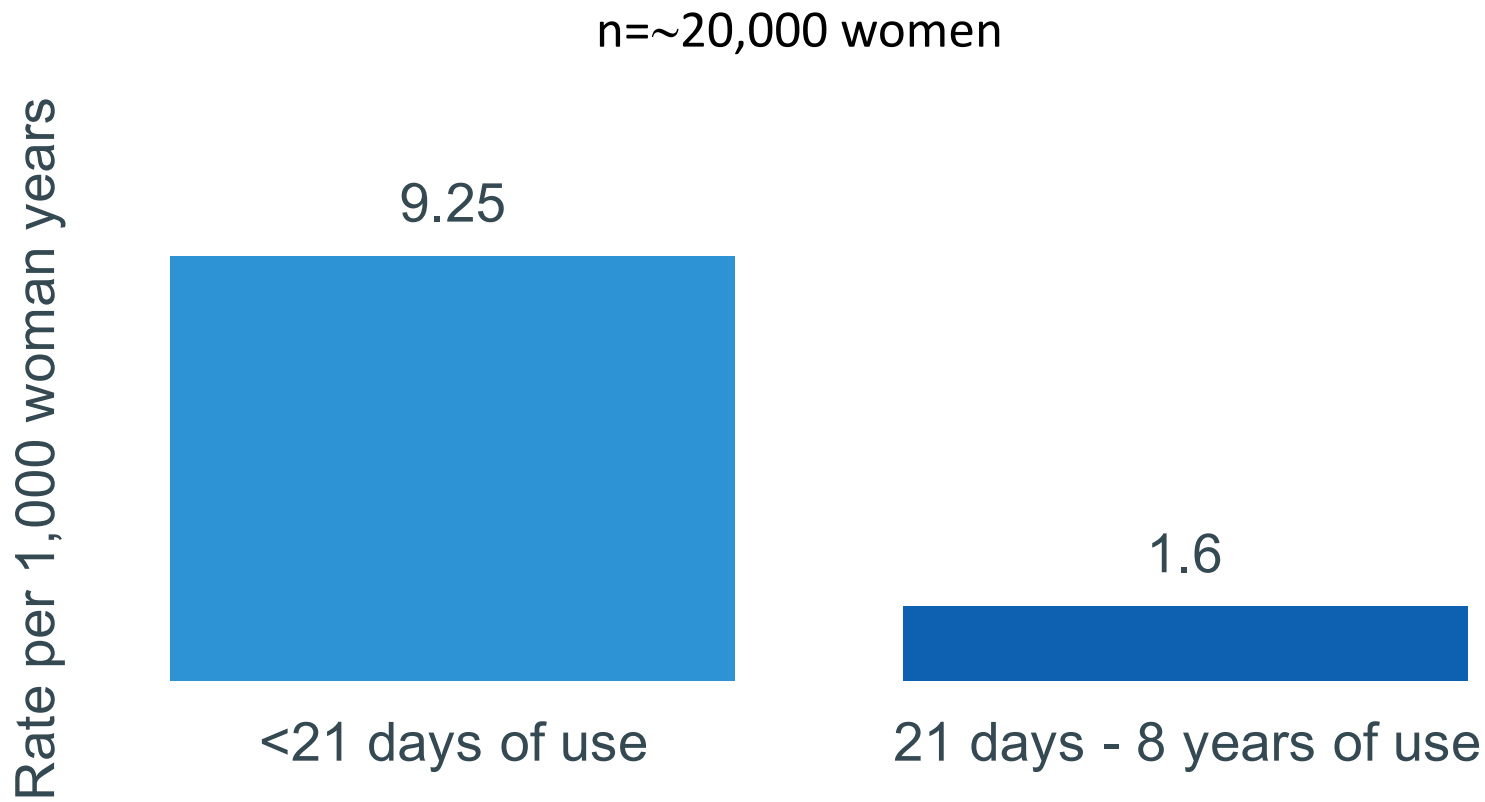
- Women with heavy menses
- Women with anemia
- Women with bleeding disorders

Andersson BJOG 1990

IUDs for nulliparous women?

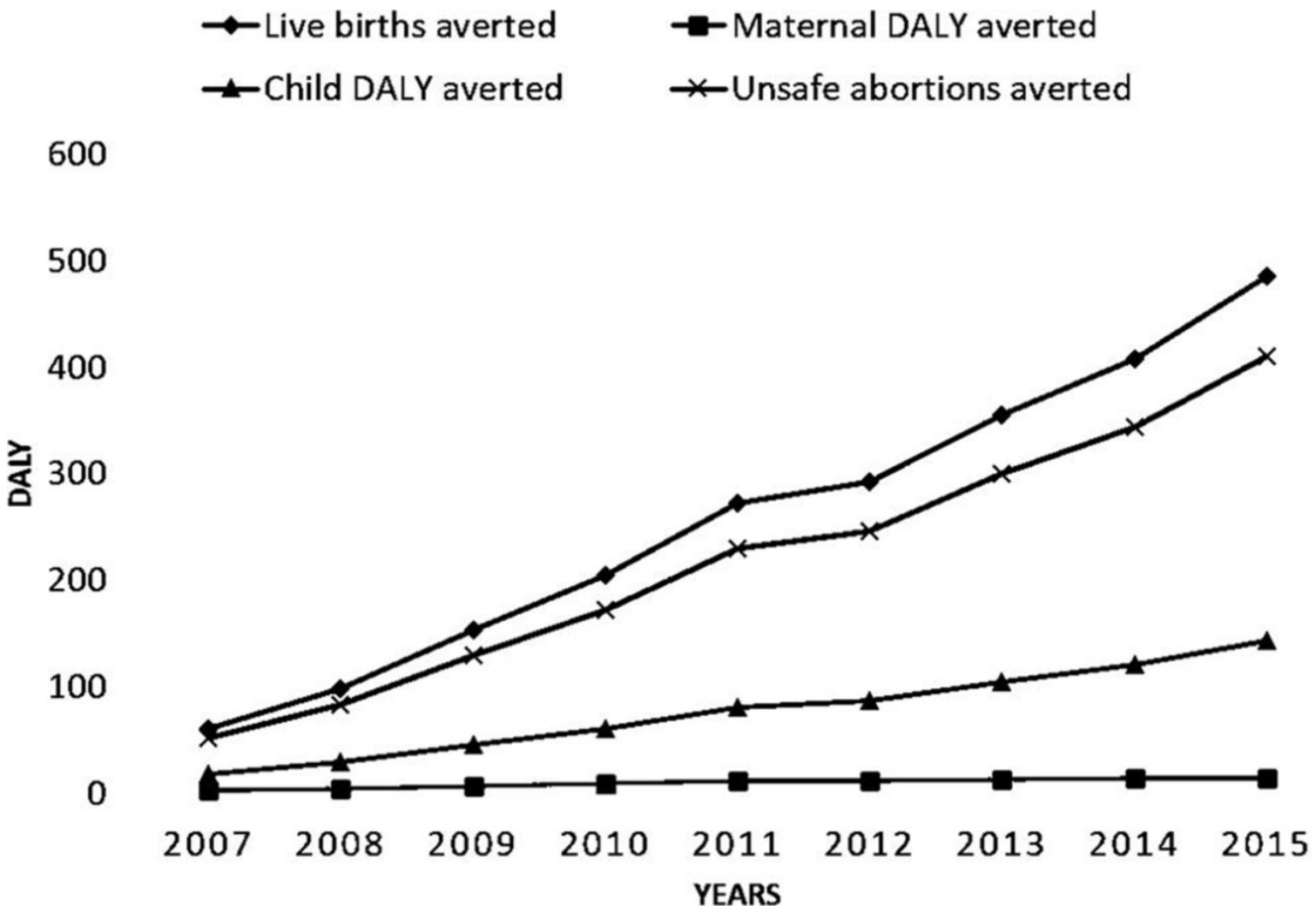
- **Yes!**
- Women who've not had children can still get IUD
- Sometimes the uterus is smaller
- Newer, smaller IUD may be recommended
- Today's IUDs do NOT cause infertility
- Complication rates are LOW

Rate of PID by Duration of IUD Use



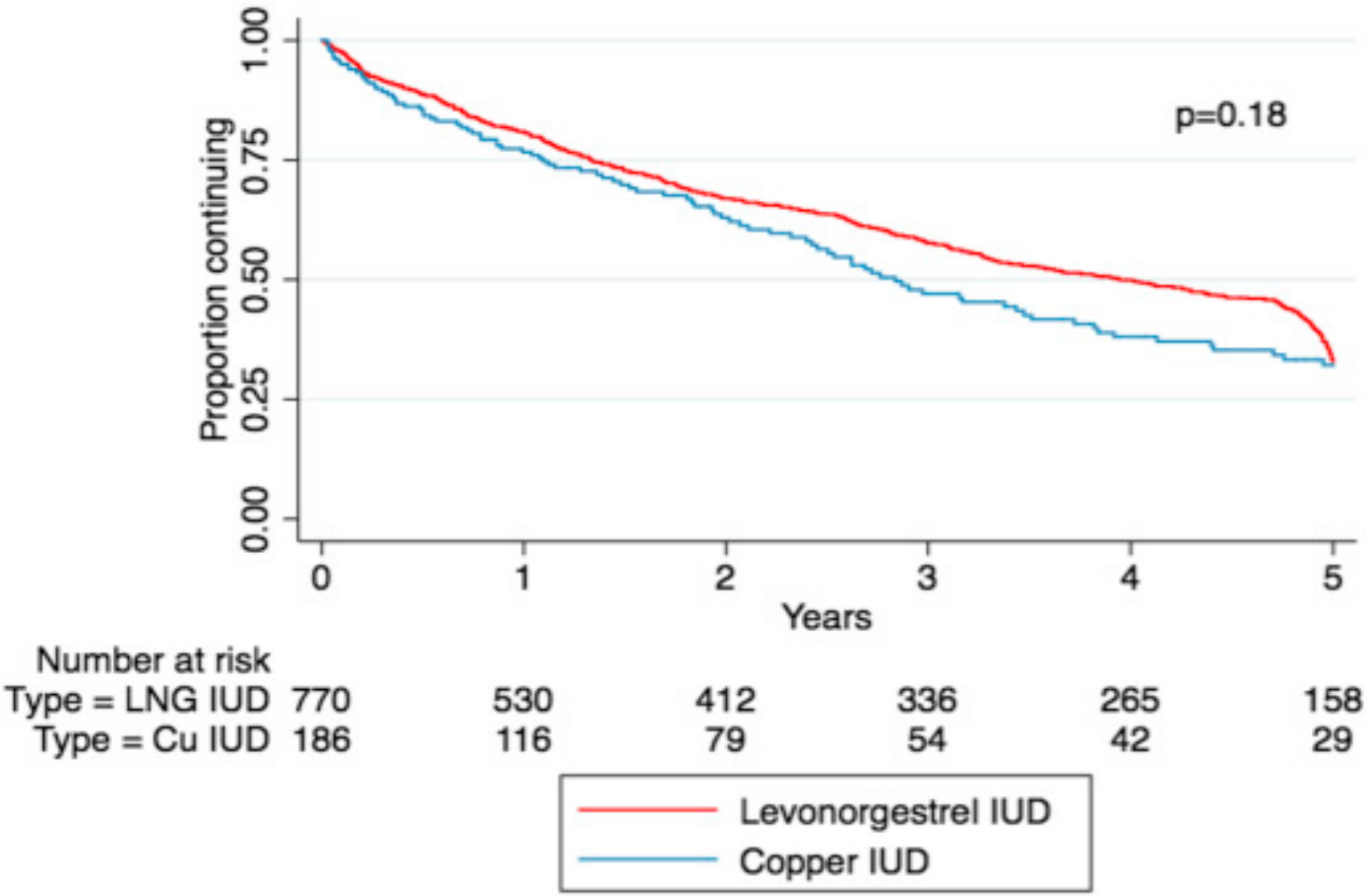
Adapted from Farley T, et al. *Lancet*. 1992.

Provision of no-cost LNG IUS over 9 years in Brazil (N=15,000): Health effects of preventing unplanned pregnancy



Jessica M Ferreira et al. J Fam Plann Reprod Health Care
doi:10.1136/jfprhc-2016-101569

Continuation: Does IUD type make a difference?

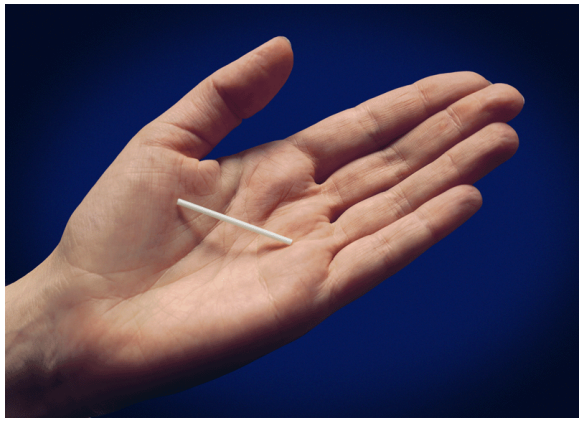


Phillips et al. Intrauterine device continuation. Am J Obstet Gynecol 2017.

Comparison of Hormonal Implants

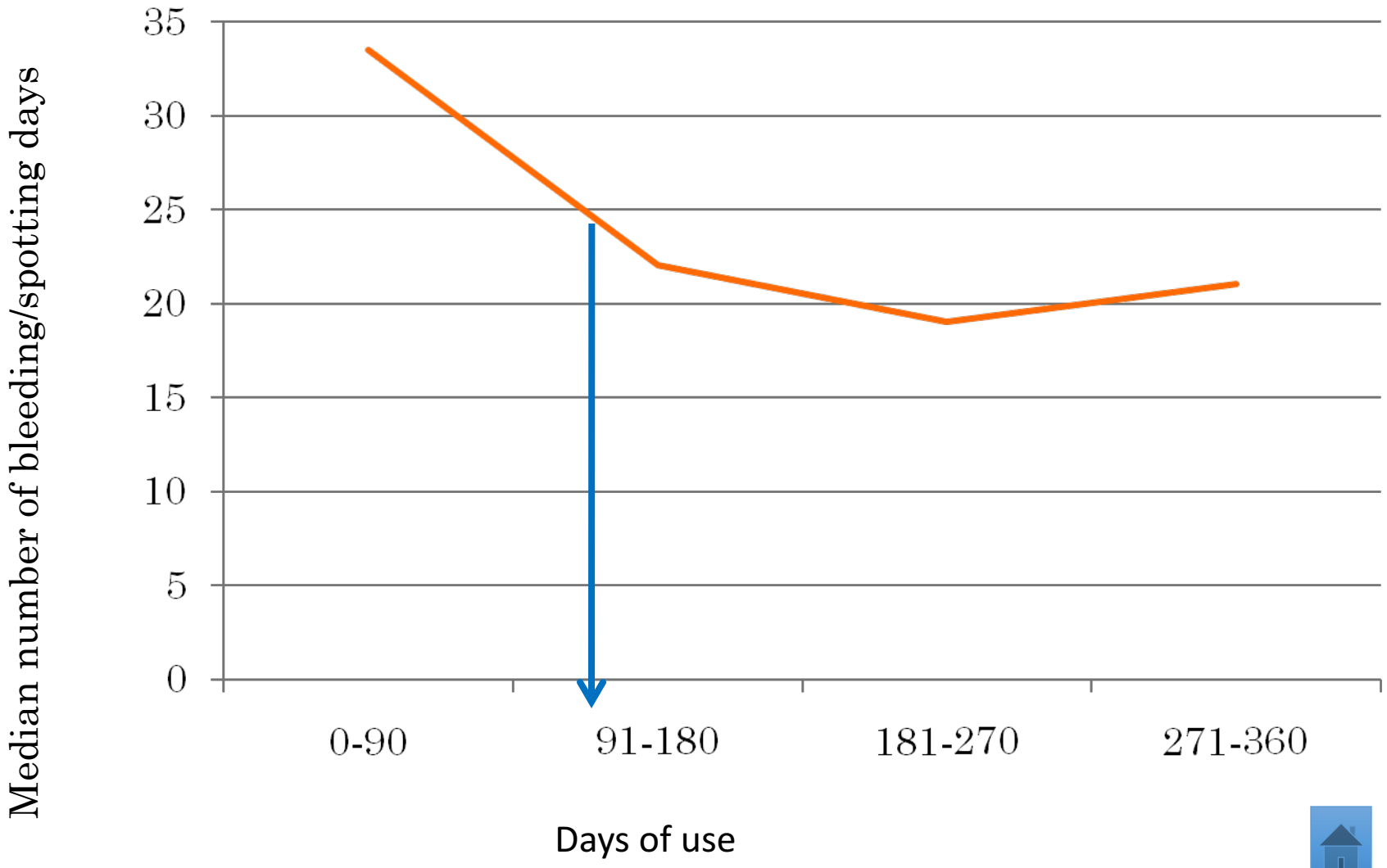
	Jadelle	ImplanonNXT	Sino-implant (II)/Zarin
Manufacturer	Bayer Healthcare	Merck/MSD	Shanghai Dahua Pharmaceutical Ltd.
Formulation	150 mg levonorgestrel in 2 rods	68 mg etonogestrel in 1 rod	150 mg levonorgestrel in 2 rods
Mean Insertion & Removal time	Insertion: 2 min Removal: 5 min	Insertion: 1 min Removal: 2-3 min	Insertion: 2 min Removal: 5 min
Labeled duration	5 years	3 years	4 years
Trocars	Autoclavable and Disposable	Pre-loaded disposable	Disposable

Implanon/Nexplanon™ Etonogestrel Implants



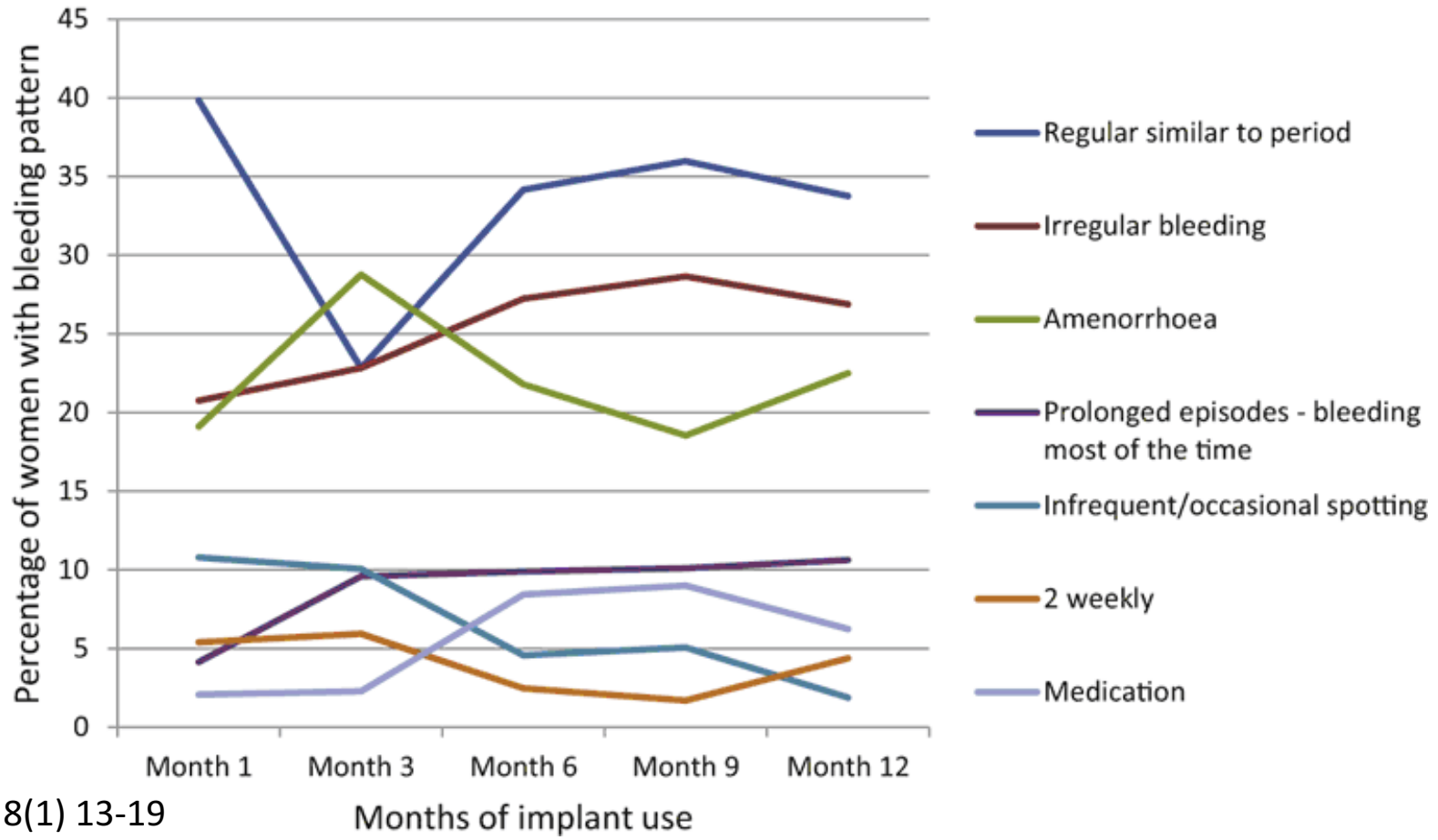
- Progestin-only method
- Prevents ovulation
- Long-acting (3 years)
- Main side-effect is unpredictable menstrual cycles
- Fertility returns within a few days of removal

Single-rod IMPLANT: bleeding



Zheng 1999 Contraception

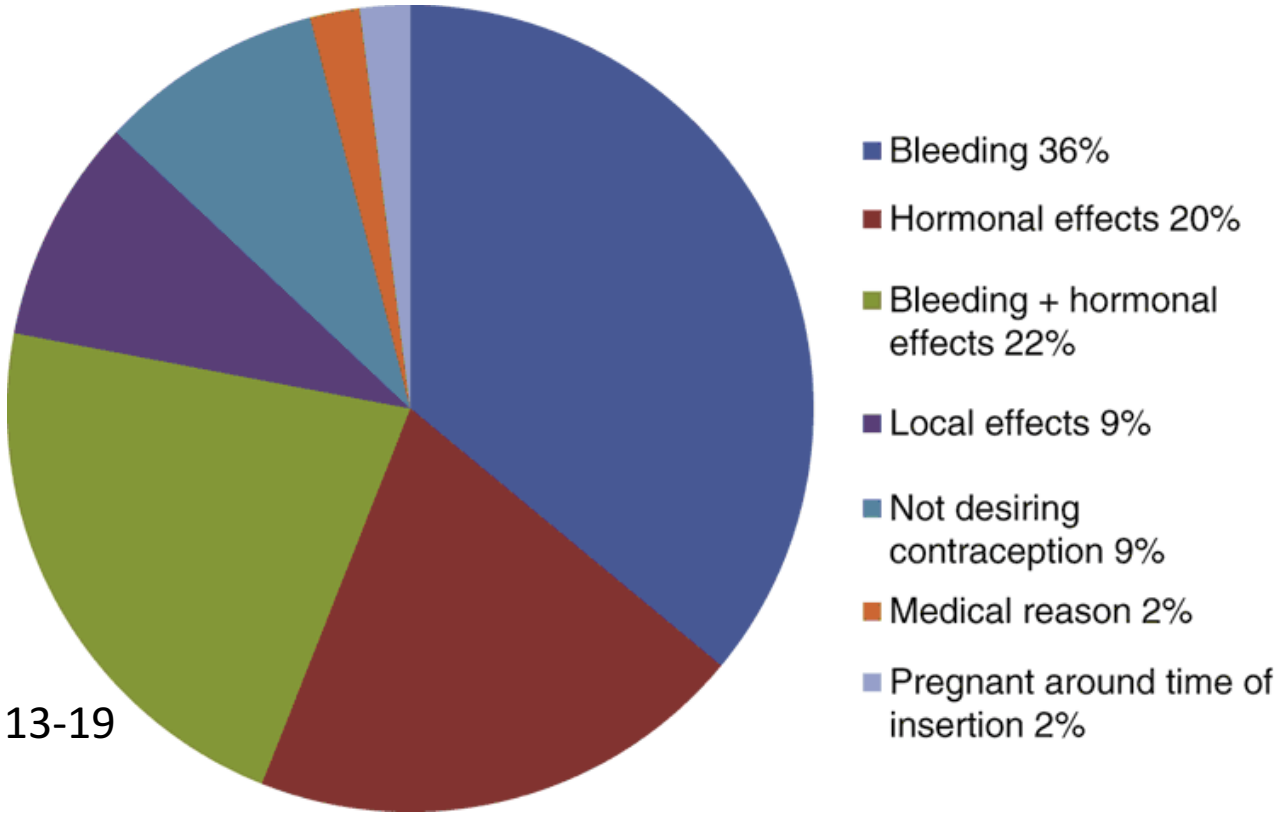
Levonorgestrel implant: Bleeding patterns



Roke et al, Journal of Primary Health Care 8(1) 13-19
http://dx.doi.org/10.1071/HC15040; 2016

Implant satisfaction

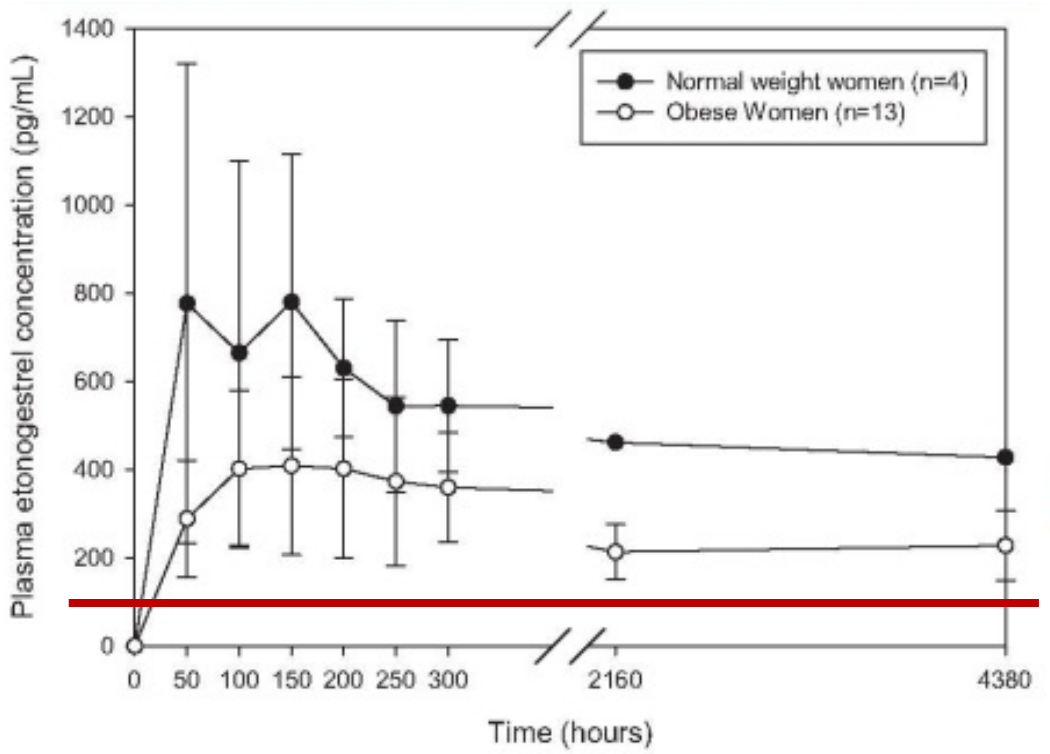
- Most women (70-80%) satisfied
- “Fit and forget”
- Reasons for removal:



Roke et al, Journal of Primary Health Care 8(1) 13-19
http://dx.doi.org/10.1071/HC15040

Longer than 3 years?

- Study comparing ENG and LNG implants showed continued efficacy up to 5 years of use



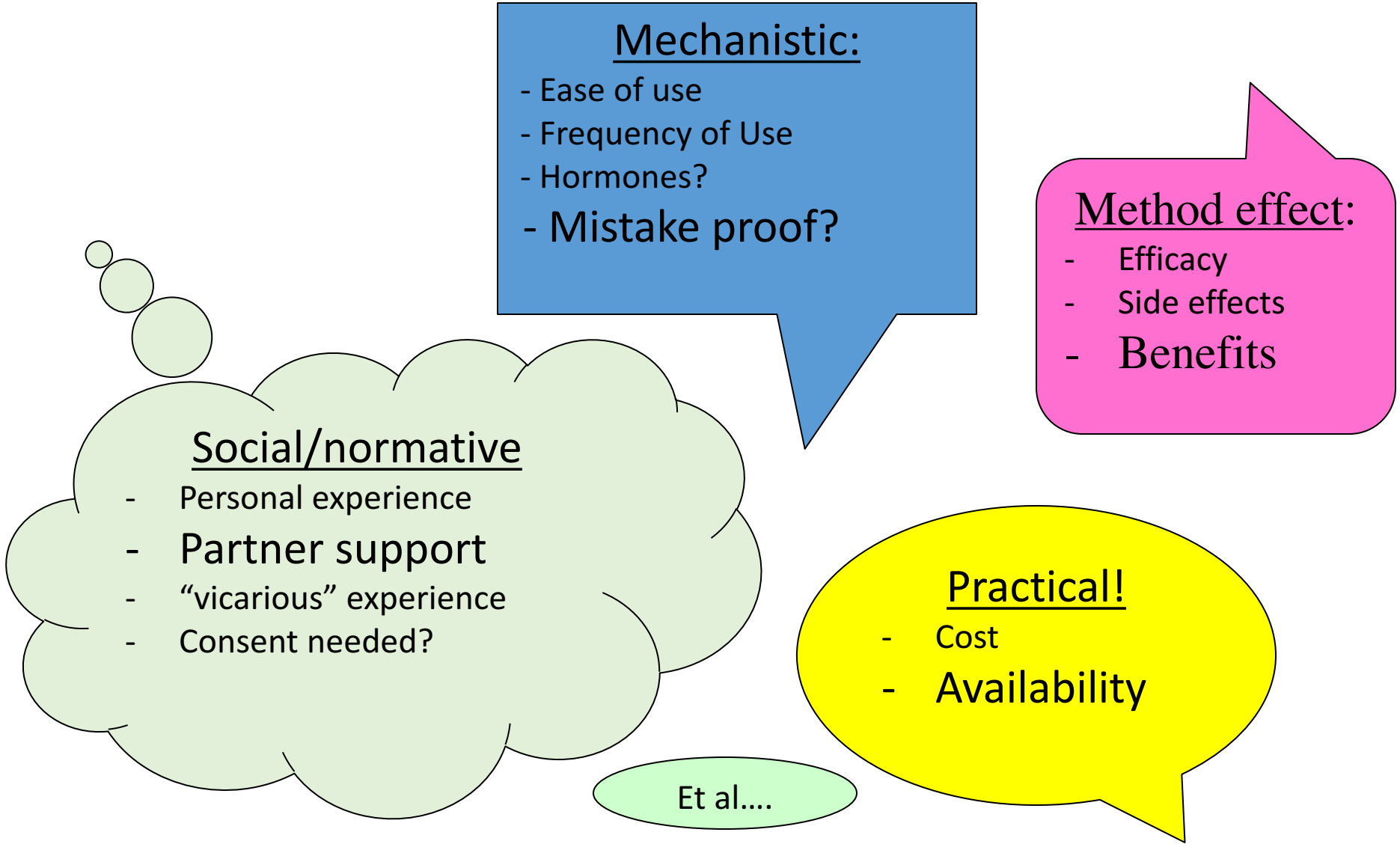
McNicholas, et al, 2017; Ali et al 2016

Reproductive Justice Considerations

- Is Efficacy everything?
- Not magic solution to unintended pregnancy (UIP)
  - Access is important but…
  - Research indicates this is not always the reason for UIP
  - UIP as a cause or consequence of social inequality?
- What WE want or what Clients want?

Higgins JA,Contraception April 2014
doi:10.1016/j.contraception.2014.01.027

Factors influencing contraceptive choice



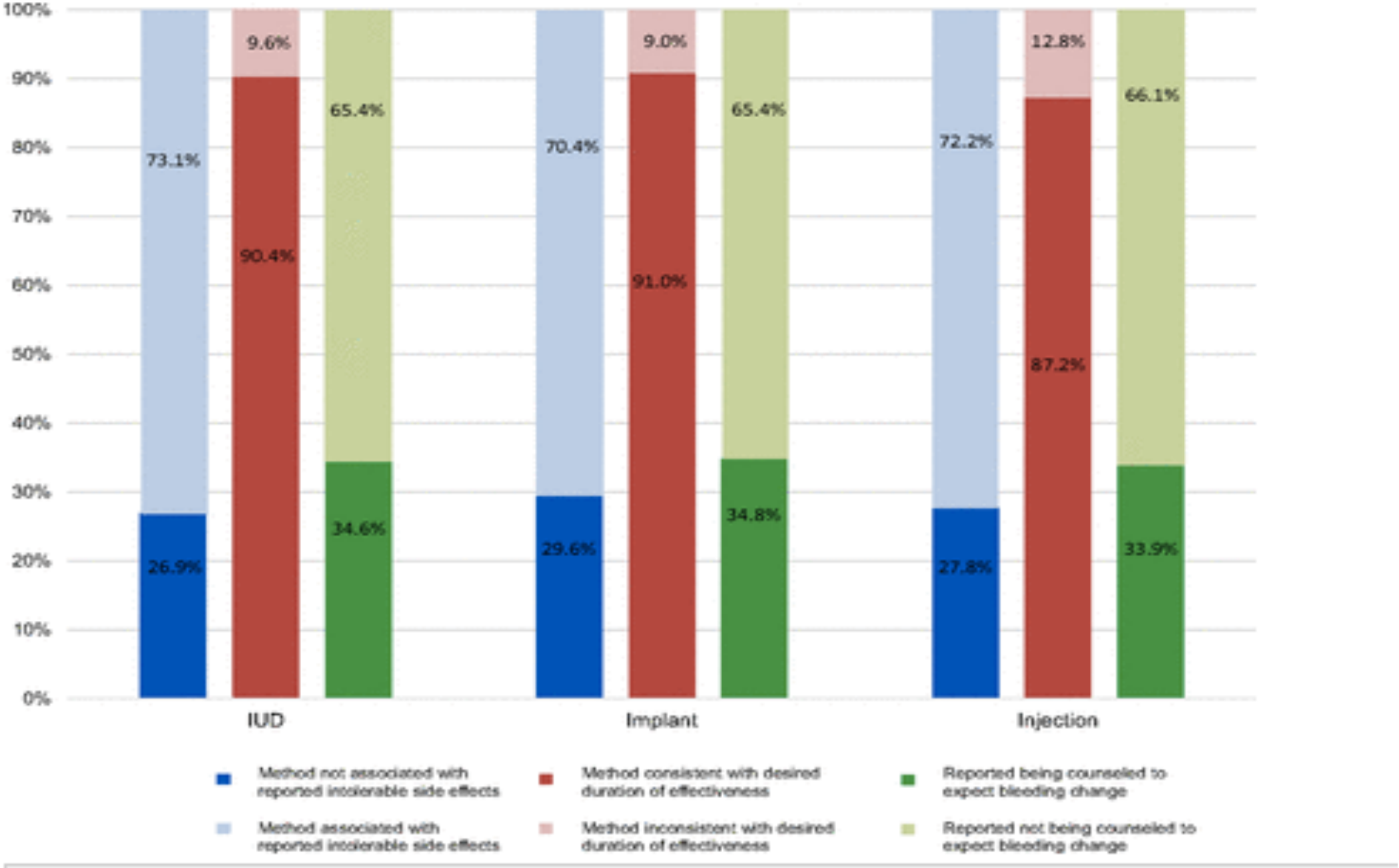
Wyatt, et al. BMC Womens Health. 2014; 14: 28.

Importance of Counseling

Percentage of Women Who Reported Being Counseled to Expect Commonly Occurring Side Effects by Method Adopted

Method and Side Effect Counseled to Expect	No. (%)
Implant (N=135)	
Irregular bleeding	28 (20.7)
Decreased bleeding	14 (10.4)
No menses	37 (27.4)
Not counseled on any of these side effects	39 (28.9)
Injectables (N=109)	
Decreased bleeding	12 (11.0)
No menses	46 (42.2)
Weight gain	13 (11.9)
Not counseled on any of these side effects	34 (31.2)
IUD (N=52)	
Irregular bleeding	6 (11.5)
Increased bleeding	16 (30.8)
Not counseled on any of these side effects	26 (50.0)

Romisnki, et al, **Comparing Women's Contraceptive Preferences With Their Choices in 5 Urban Family Planning Clinics in Ghana.** GHSP 2017



Romisnki, et al, **Comparing Women's Contraceptive Preferences With Their Choices in 5 Urban Family Planning Clinics in Ghana.** GHSP 2017

Diversity and Disparities

- Clinician counseling can be biased
  - Often unconscious, but it's there
- Providers may communicate differently depending on patient's race/ethnicity
- Providers may treat patients differently based on socio-economic status (SES), race/ethnicity, age

Dehlendorf, 2014; Dehlendorf, 2010; Burgess, 2007

Diversity and Disparities

- Recognition of differences and biases can help to improve quality, equity

Dehlendorf, 2014; Dehlendorf, 2010; Burgess, 2007

Adolescents and contraception

- A 16-year-old student who has never been pregnant presents to the clinic requesting birth control.
- She is healthy.
- She plans to become sexually active with her boyfriend in the near future.
- She is worried about getting pregnant.
- How would you counsel her?

WHO Guidance

- In general, adolescents are eligible to use any method of contraception and must have access to a variety of contraceptive choices.
- Age alone does not constitute a medical reason for denying any method to adolescents.
- While some concerns have been expressed regarding the use of certain contraceptive methods in adolescents these concerns must be balanced against the advantages of avoiding pregnancy.

WHO MEC 2009

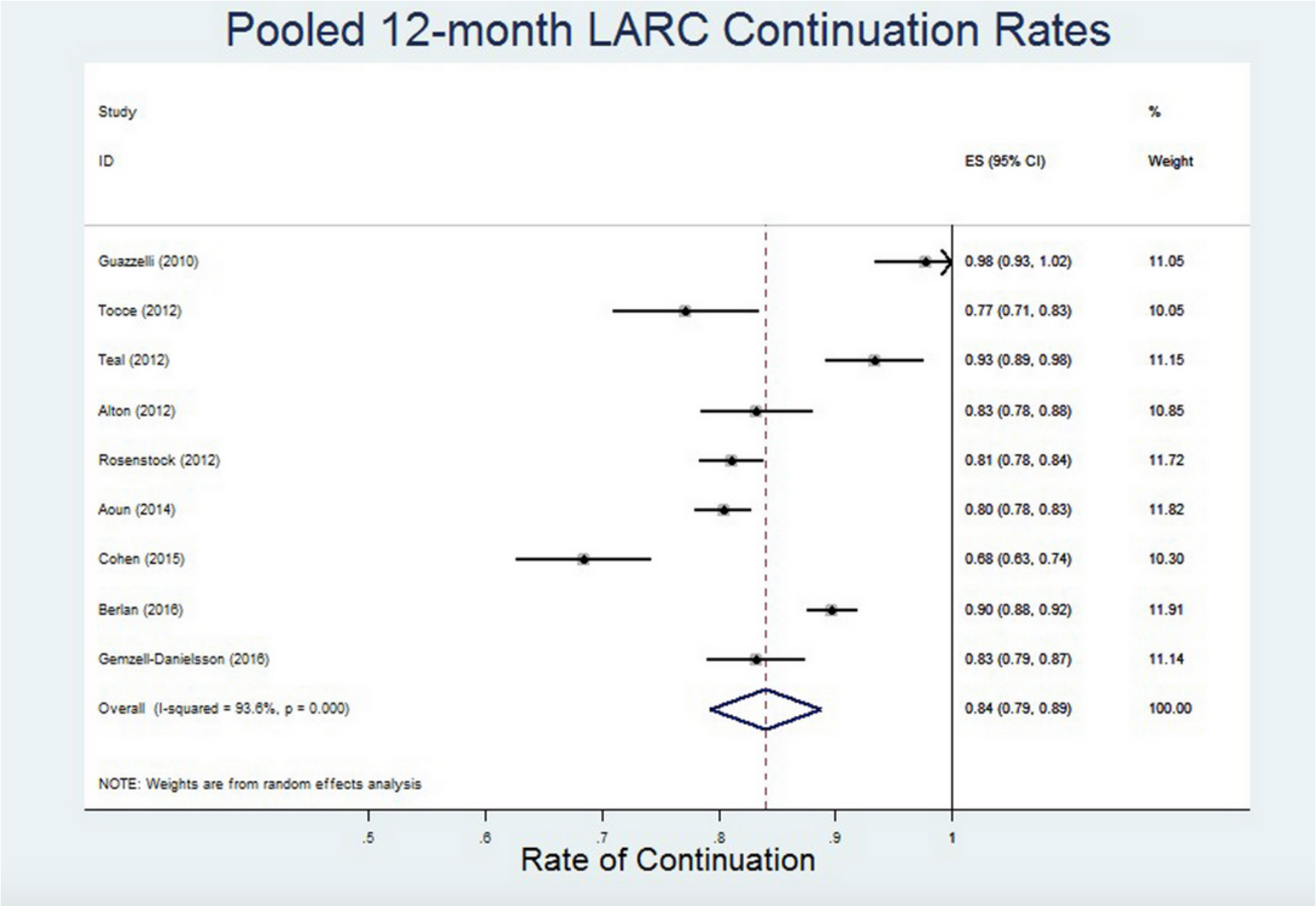
WHO Guidance

- Consider:
  - Social and behavioral context (example: STI risk)
  - Daily regimens more challenging than for adults
  - Sporadic patterns of sexual intercourse
  - Need to conceal (married vs. unmarried)
- Counseling is very important

WHO MEC Recommendations

Contraceptive Method	MEC Category
Combined hormonal methods	1
Injectable	2
Progestin-only pill	1
Implant	1
IUD	2
Barrier	2
Emergency Contraceptive Pills	OK

LARC Continuation among adolescents



Diedrich. LARCs and adolescents. Am J Obstet Gynecol 2017.

Adolescents, side effects, and the implant: "Wear dark underpants, mainly"

- In a study of adolescents discontinuing by 6 months, most experienced **significant and prolonged negative side effects**, which they were often unprepared for.
- Reported knowing side effects were possible, but they hoped they would not be affected.
- Wanted more specific examples of side effects rather than general descriptions
- Offered examples of how to counsel for irregular bleeding:
- "wear dark underwear, buy pads, think about how irregular bleeding will affect your relationship with your parents or others."

Lunde, et al, 2017

Postpartum contraception

Postpartum Contraception: Individual Considerations

Benefits
Immediate initiation

Risks
Immediate initiation

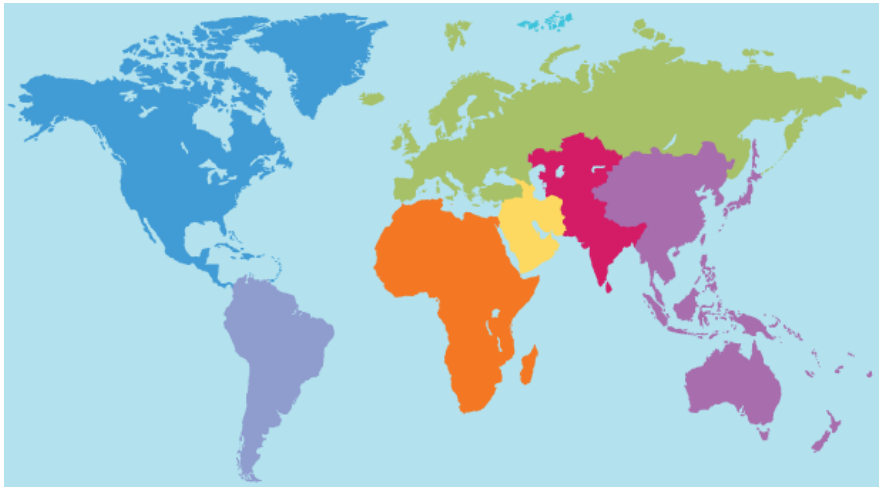
Patient preference

35% of women do not return for follow-up visit.

Ogburn et al. *Contraception* 2005

Importance of Birth Spacing

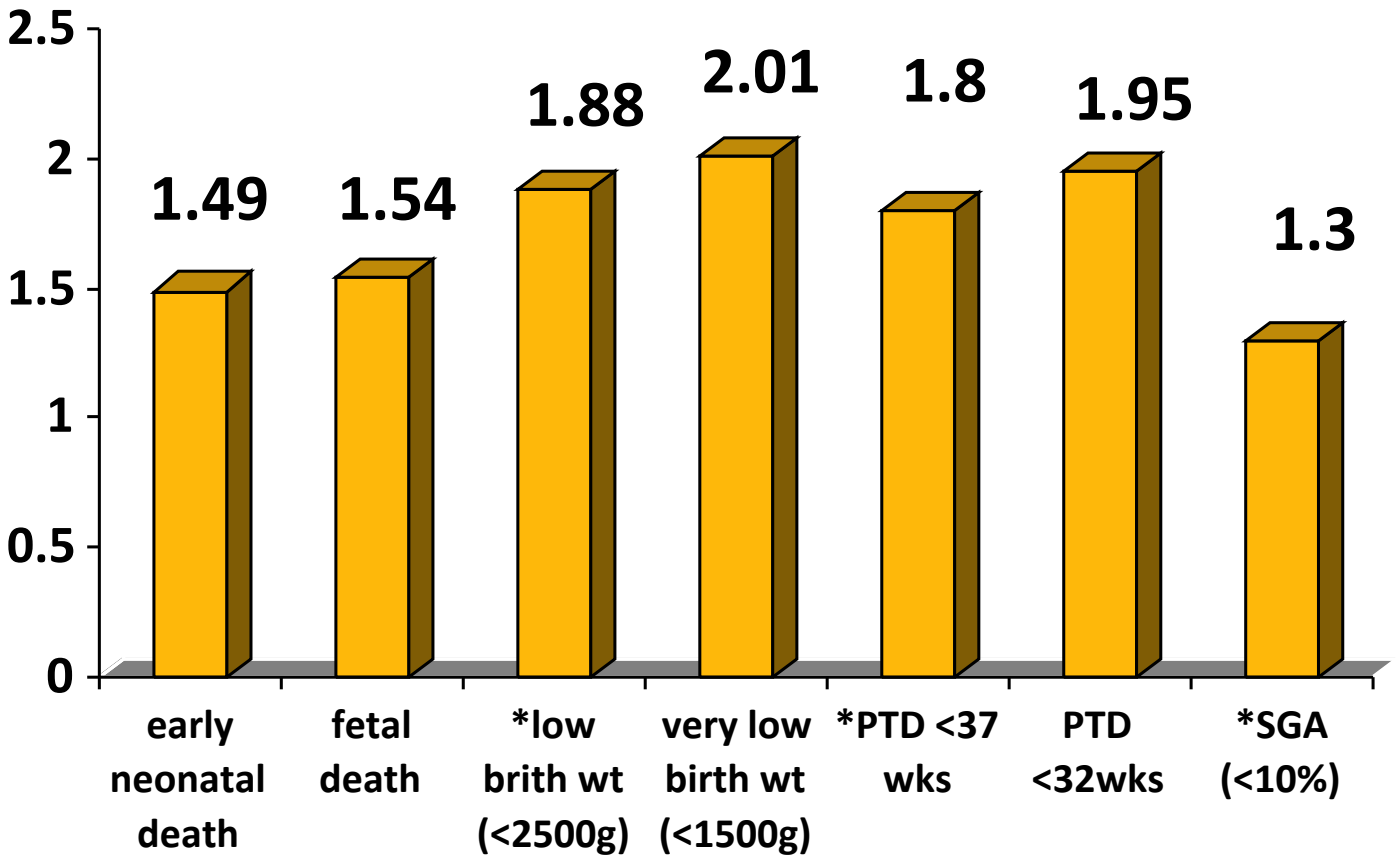
- Developing countries:
  - 40% do not obtain contraception within 1 yr.
- United States:
  - 12% are using no method and 7% low-efficacy method in 9 mos.



Ross & Winfrey 2001 IFPP
Conde-Agudelo et al 2000 BMJ
http://www.cdc.gov
MMWR Morb Mortal Wkly Rep, 2009
Fanello et al 2007 J Gynecol Ostet

Effect of Short Inter-pregnancy Intervals

Neonatal Outcomes



Odds Ratio at pregnancy intervals of <6 months vs. 18-23 months

N=1.2 million

Conde-Agudelo et al. *Ob/Gyne* 2005

Same evidence, different conclusions? (example: injectables)

WHO MEC: **Clarification**: There is **theoretical** concern about the potential exposure of the neonate to DMPA/NET-EN during the first 6 weeks postpartum. In many settings, however, pregnancy-related morbidity and mortality risks are high, and access to services is limited. **In such settings, DMPA/NET-EN may be among the few methods widely available and accessible to breastfeeding women immediately postpartum**.

US CDC MEC: Evidence: Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that **initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum**.

Similar (or maybe lower quality) of evidence for combined methods and breastfeeding

Source: WHO MEC2015, CDC MEC 2016

Contraception and Breastfeeding: Implants

- Observational studies mostly found no difference in outcomes in the first 6 weeks postpartum.
- Two studies found no difference in supplementation comparing LNG implant with IUD users; one of these also found no difference in breastfeeding duration.
- Breastfeeding duration similar between users of an etonogestrel (ETG) implant compared with Cu-IUD.

Phillips, et al, Contraception 2016

Contraception and Breastfeeding: Injectables

- No effect or improved outcomes
- DMPA vs. nonhormonal method postpartum: no difference in breastfeeding frequency or continuation up to 6 months.
- One study found no differences in exclusive breastfeeding up to 6 months for those who did not initiate DMPA compared with those who initiated by 3 or 6 months.
- DMPA vs. other contraceptive methods
  - DMPA: more likely to be fully breastfeeding at 3 and 6 months postpartum
  - more likely to continue breastfeeding through 12 and 18 months. (67% vs 35%)

Phillips, et al, Contraception 2016

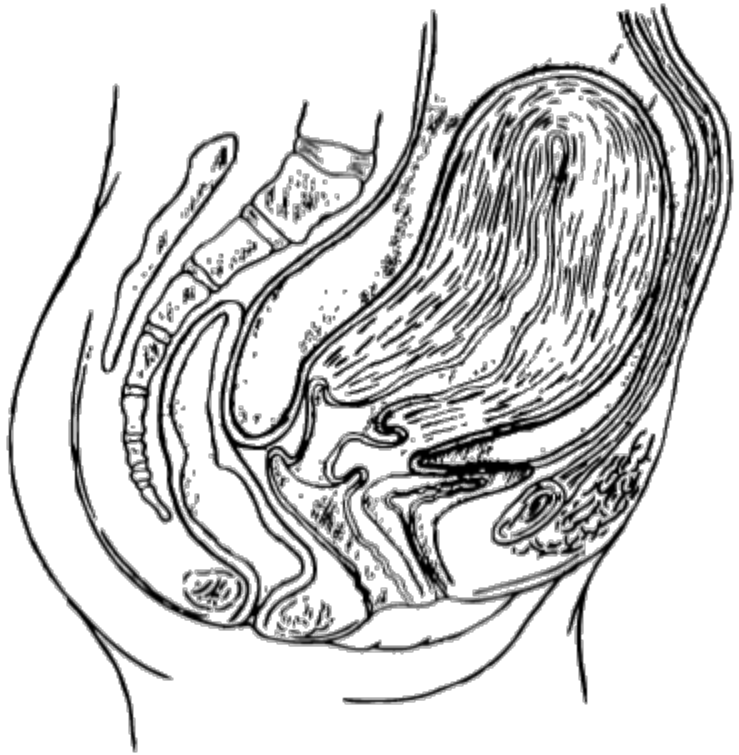
Postpartum IUD: Definitions

- Immediate post-placental/postpartum (IPP) IUD insertion: IUD insertion within 10 minutes of delivery of the placenta

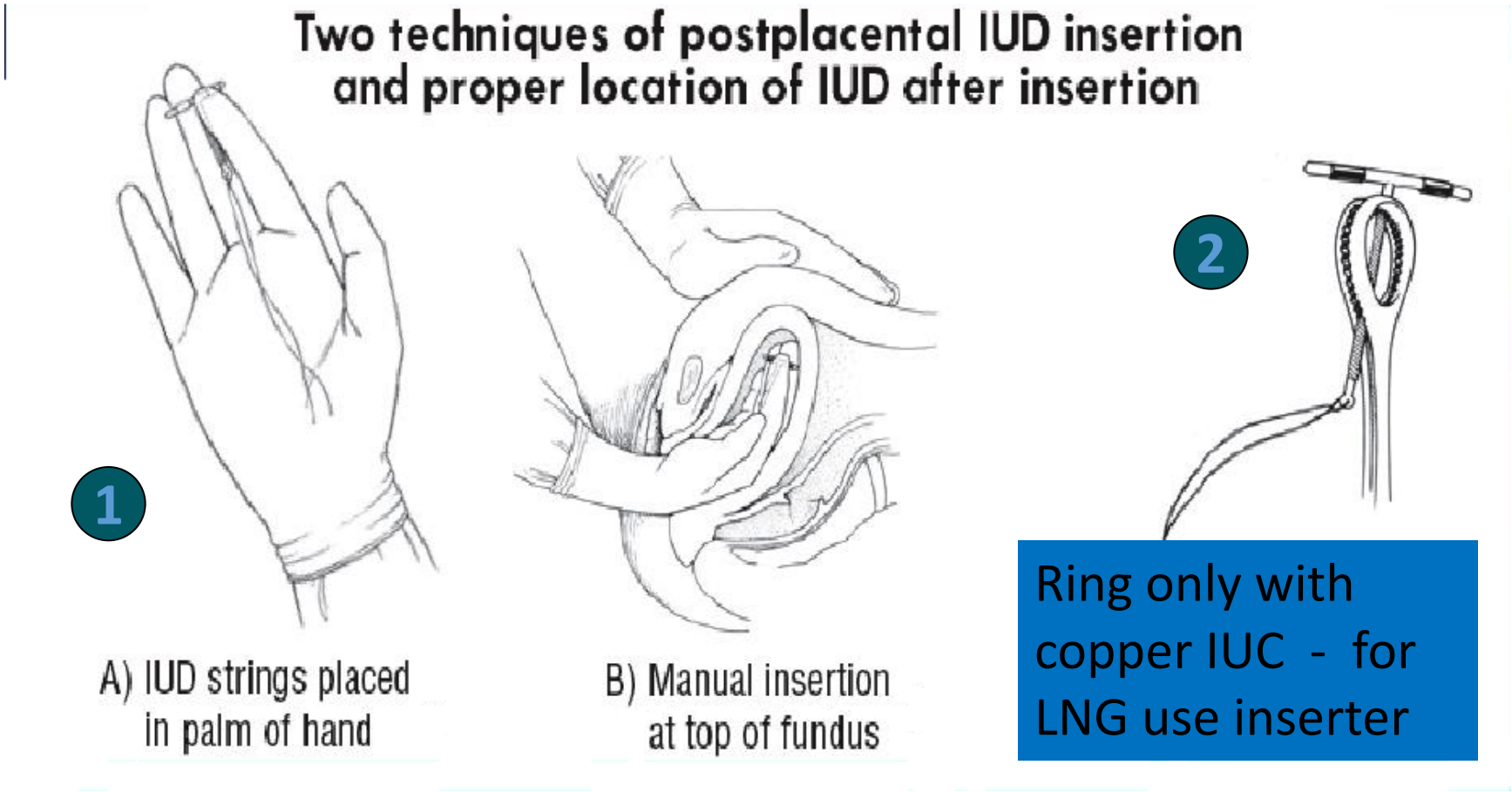
- Early postpartum (EP) period: 10 minutes to 48 hours after delivery

- Interval (INT) IUD insertion: 4-8 weeks postpartum

Uterus, Immediately Postpartum



PP IUC: Techniques



Ring only with copper IUC - for LNG use inserter

WHO Medical Eligibility for Contraceptive Use

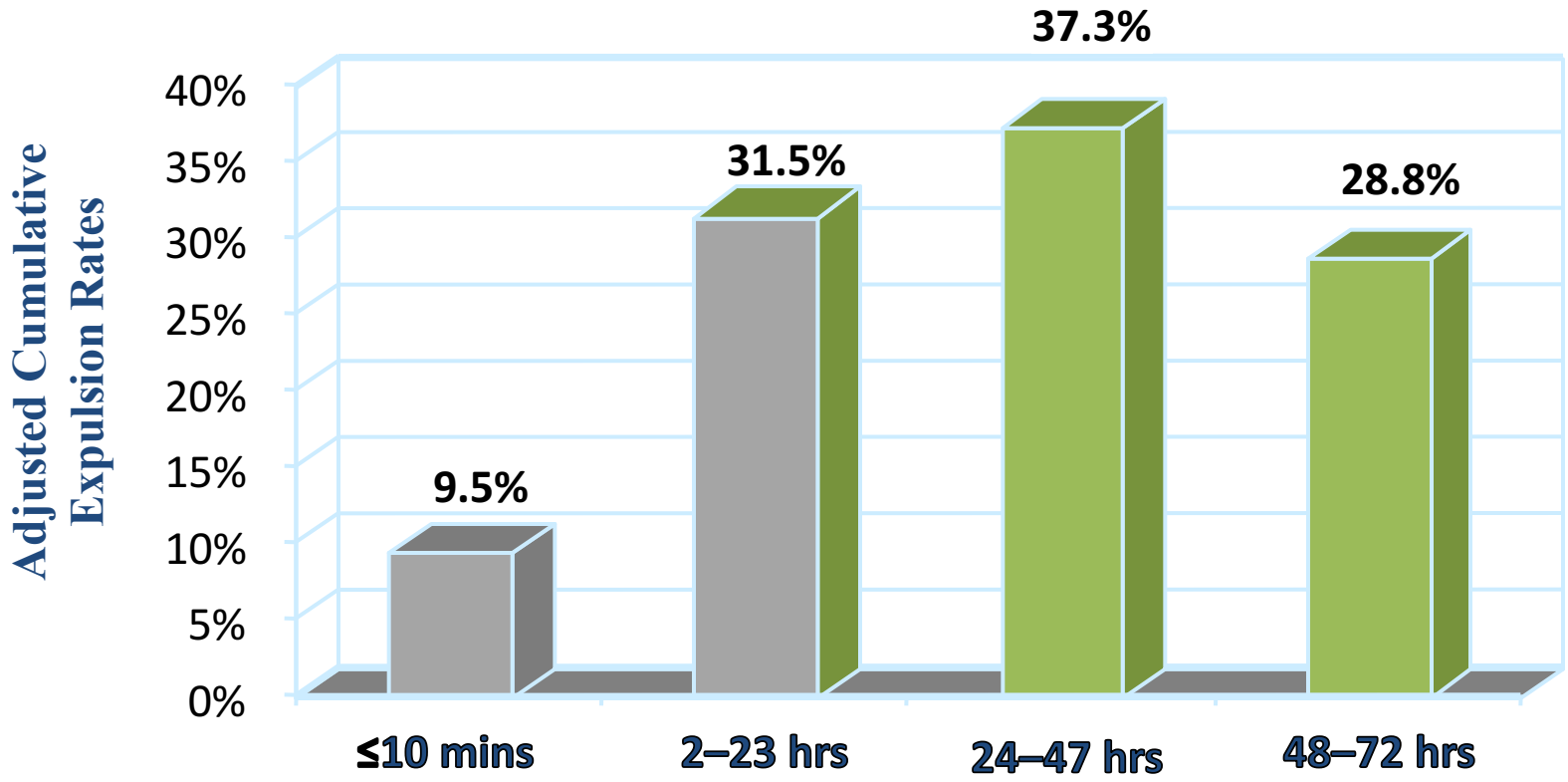
Postpartum*	LNG IUS	Copper IUD
<10 minutes after delivery of the placenta	1/2 Difference for BF	1
10 minutes after delivery of the placenta to <4 weeks	3	3
≥4 weeks	1	1
Puerperal sepsis	4	4

*including post-Cesarean section

Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. MMWR May 2010;59:1-86.

Why 10 minutes? Does timing matter?

Postpartum IUD Insertion



p<0.001 (≤10 minutes compared to all other groups)

Chi I-C, et al. Contraception 1985.

CDC Medical Eligibility for Contraceptive Use

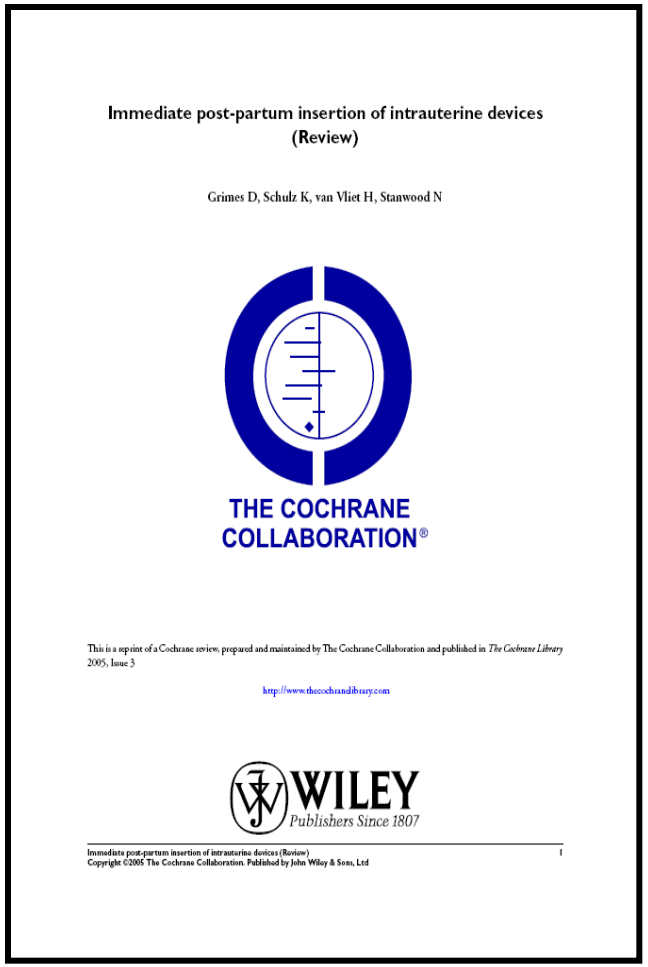
Postpartum*	LNG IUS	Copper IUD
<10 minutes after delivery of the placenta	2	1
10 minutes after delivery of the placenta to <4 weeks	2	2
≥4 weeks	1	1
Puerperal sepsis	4	4

*Breastfeeding or non-breastfeeding women, including post-Cesarean section

Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. MMWR May 2010;59:1-86.

Cochrane Review 2010

- Nine trials
- No increase in infection, bleeding, or perforation
- Expulsion rates are higher for immediate versus delayed insertion



Immediate post-partum insertion of intrauterine devices (Review)

Grimes D, Schulz K, van Vliet H, Stanwood N

THE COCHRANE COLLABORATION®

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Immediate post-partum insertion of intrauterine devices (Review) 1

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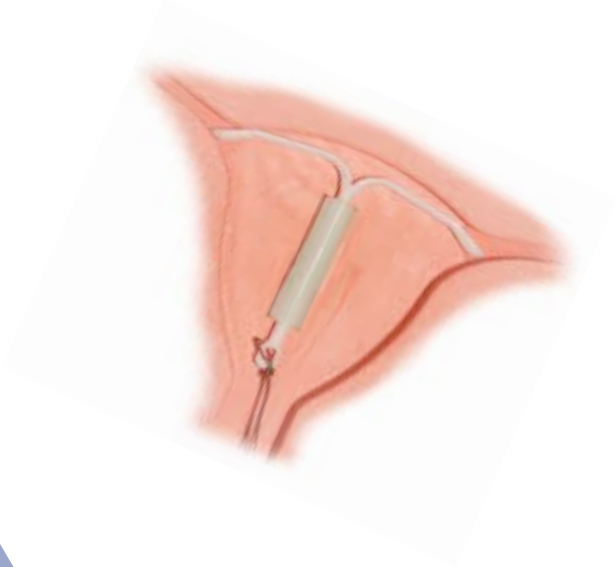
Immediate postpartum IUD and implant program outcomes: hot off the press

- Prospective study, 2013-16
- Copper IUD, LNG-IUS, Single-rod implant
- 6-month continuation rate >80% for all methods

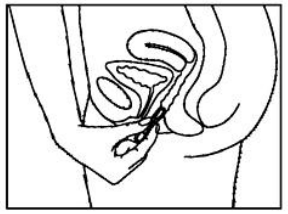
- Of 211 IUD -→ 21 expelled
  - LNG-IUS: 17% expulsion
  - Copper IUD: 4% expulsion
  - Why the difference?
  - Does it matter?

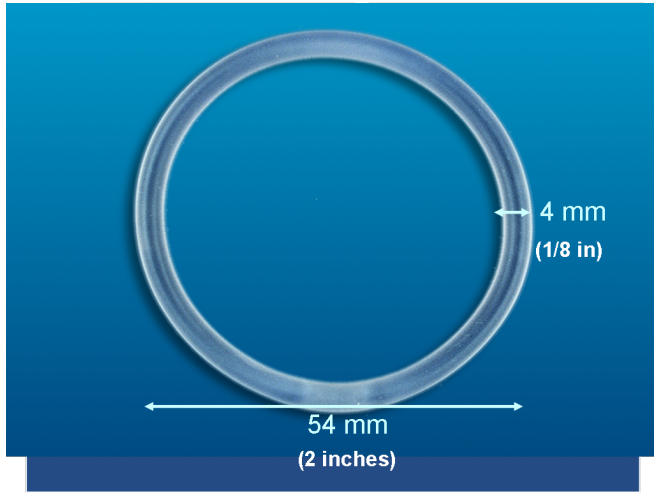


Eggebroten, et al, AJOG, 2017

Vaginal rings: a longer-acting, short-acting method?

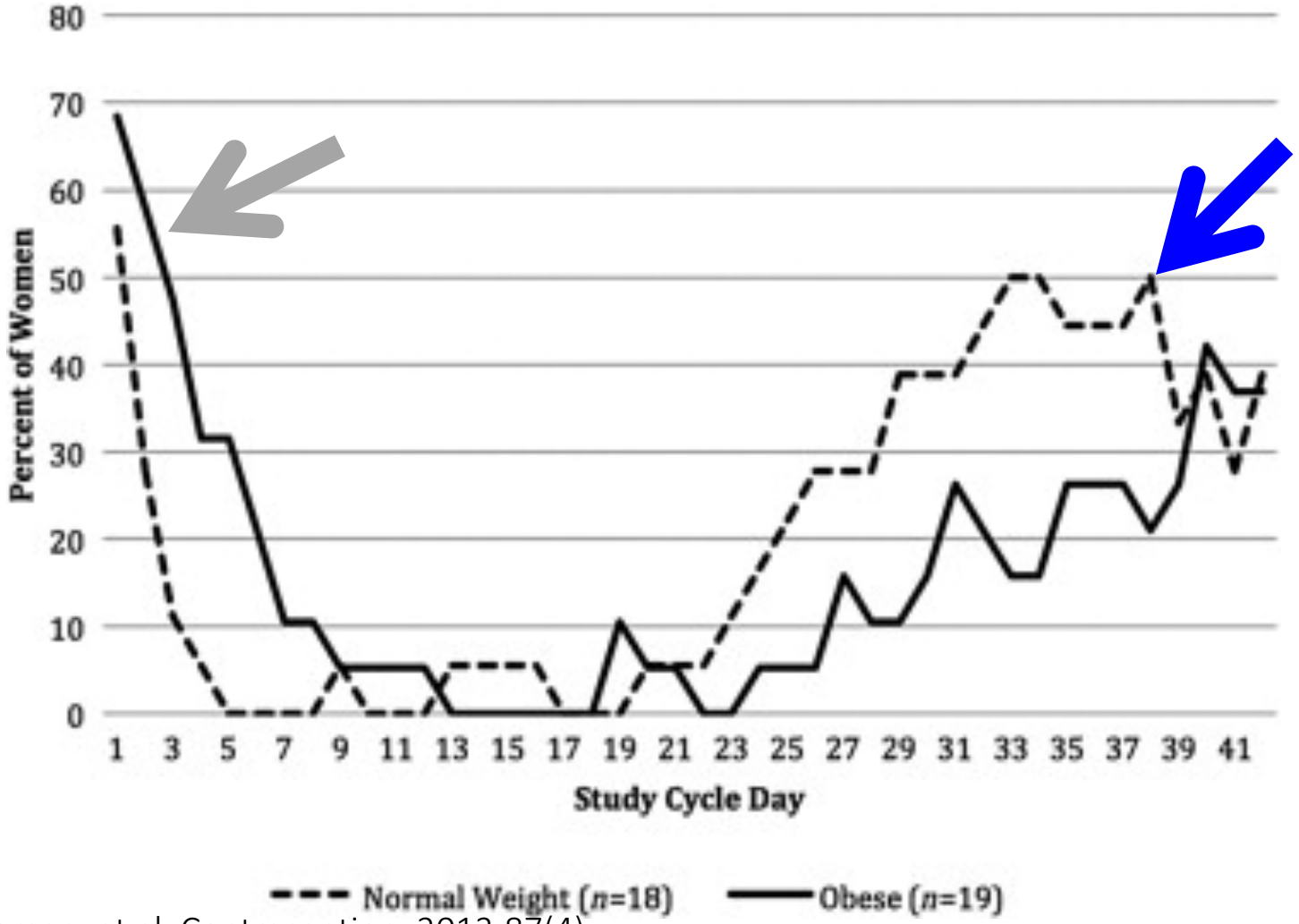
- Can be left in place for 3 weeks (or longer)
- Recent analysis suggests well tolerated, possibly with better bleeding profile than oral contraceptive pills
- Opportunities for better compliance →
  - Potential to be more effective in preventing pregnancy
  - In recent study, ring users about half as likely as pill users to have unintended pregnancy
  - 20% more likely to use consistently/correctly





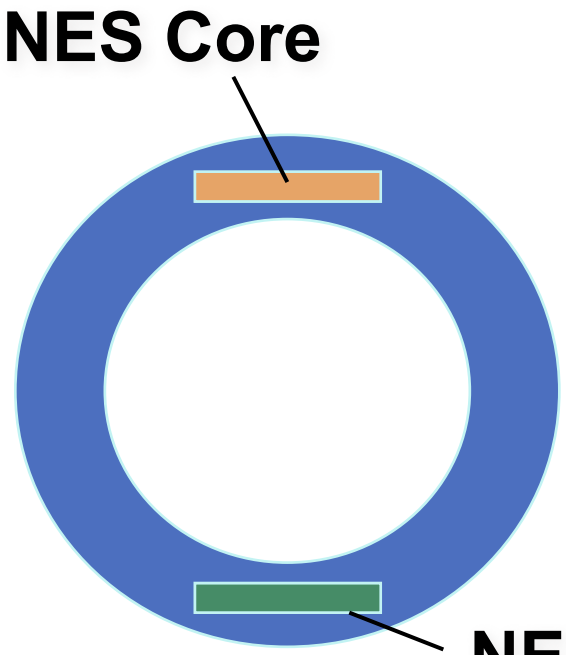
Lopez-Picado, Eur J Contra Health Care, 2017

Bleeding/Spotting on Ring



Dragoman, et al. Contraception. 2013;87(4)

Nestorone® / Ethinyl Estradiol CVR



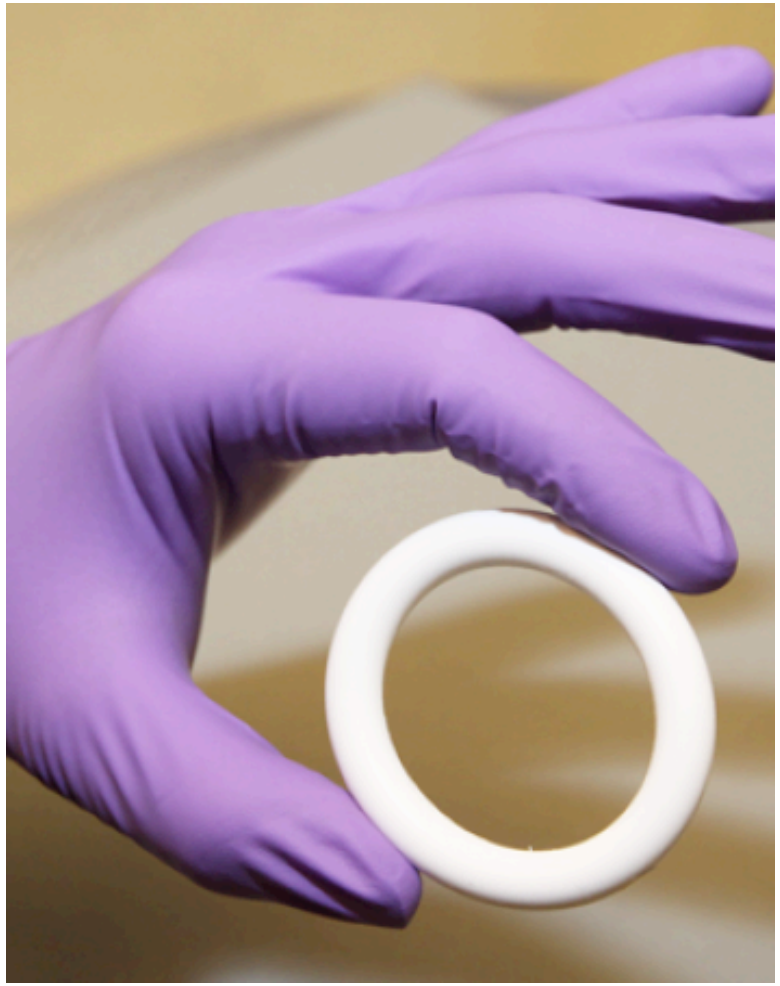
*Delivers NES, 13 cycles 3 weeks on followed
by 1 week off

Developed by the Population Council
Sponsored by USAID, NICHD, WHO

8.4 mm (3/8”) in cross section
58 mm (2 1/4”) in diameter

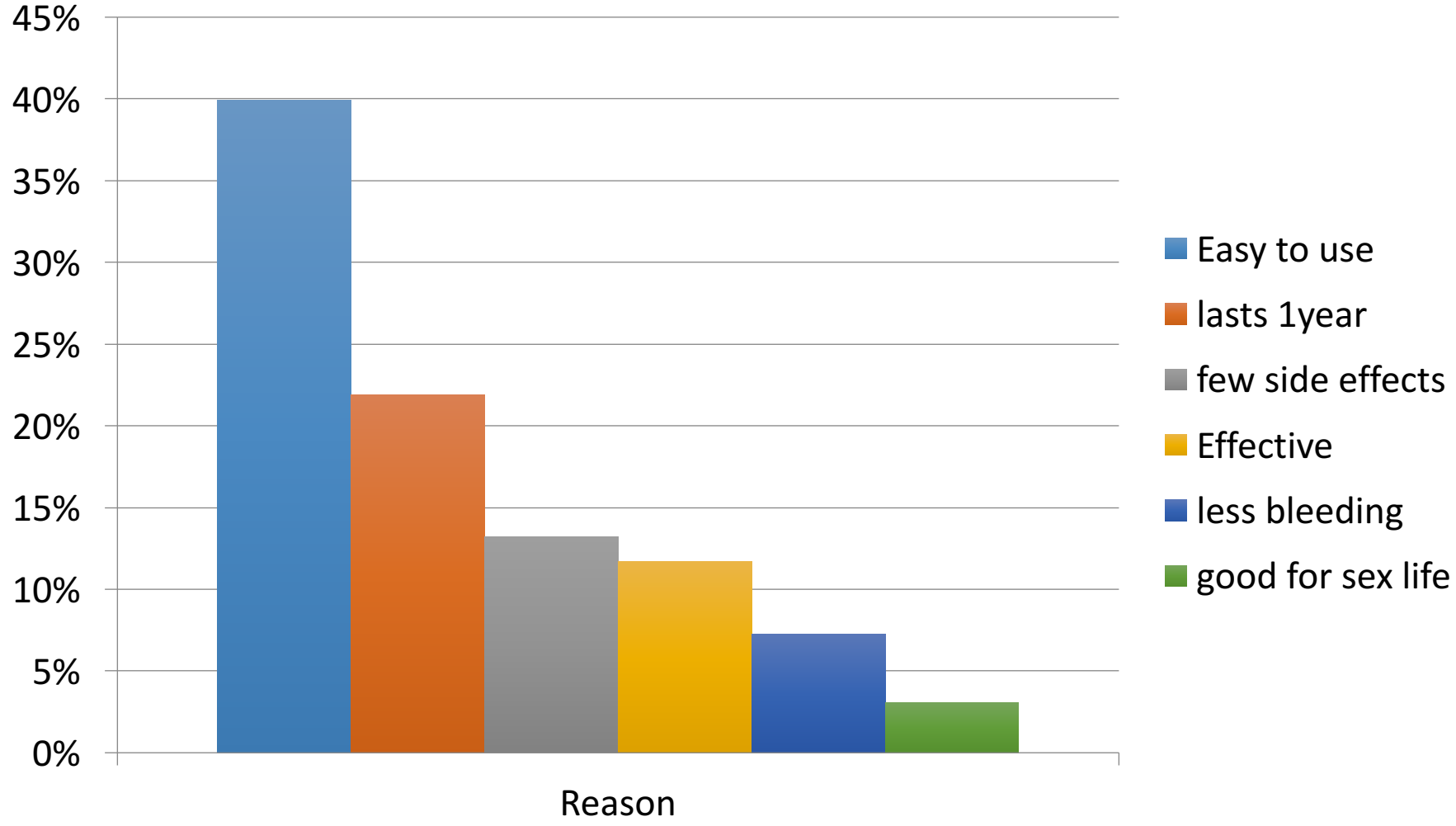
NICHD National Institute of Child Health & Human Development
World Health Organization
Population Council

Nestorone/Ethinyl Estradiol CVR (Contraceptive Vaginal Ring)



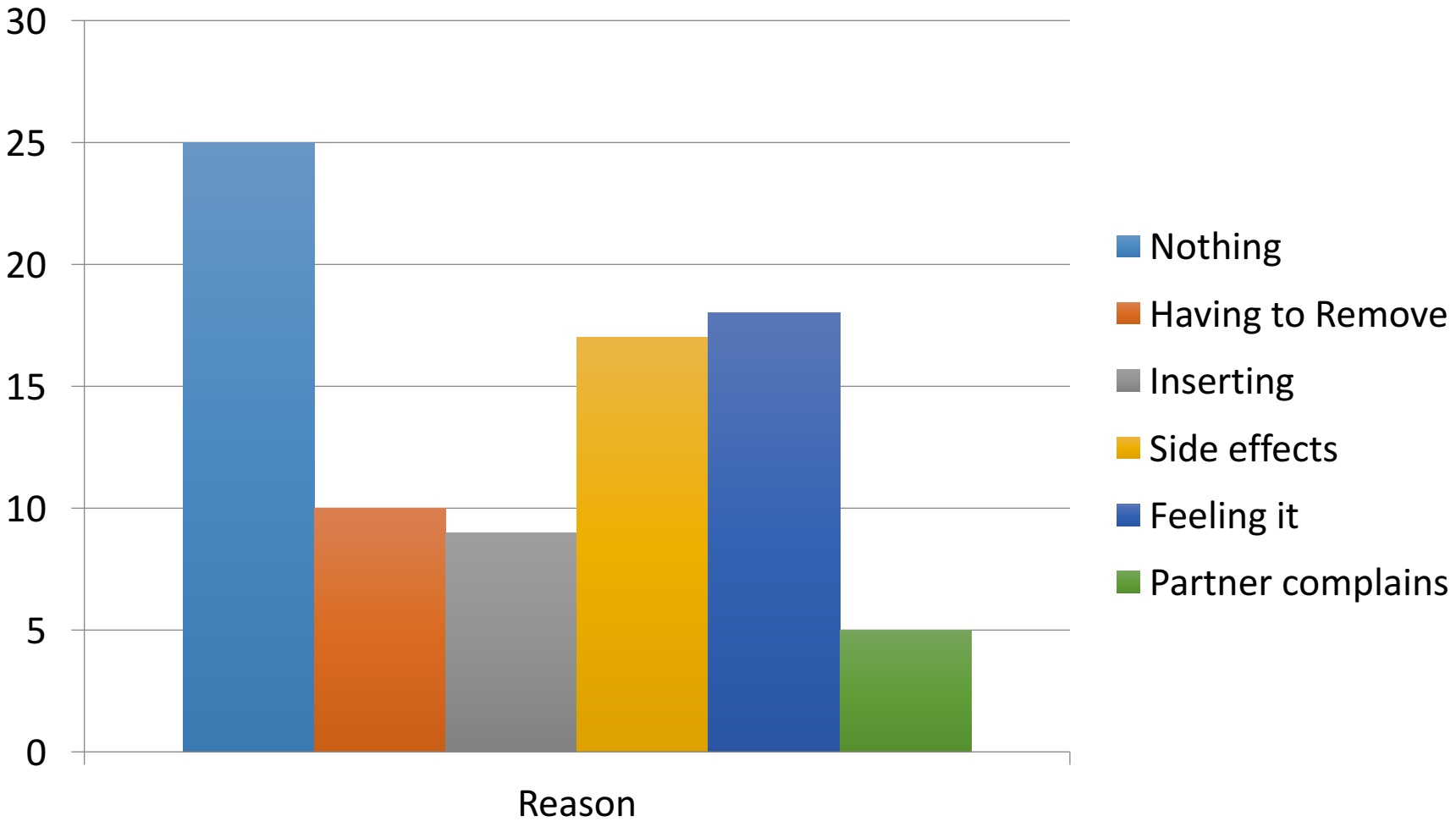
- Use for 1 year
  - In for 21 days, remove for 7
  - 13 Cycles of use
- Effective, safe
- 2 ¼ inches (~6cm) in diameter
- No refrigeration
- Woman-controlled
- 3-month ring under study

CVR: What did you like the most?



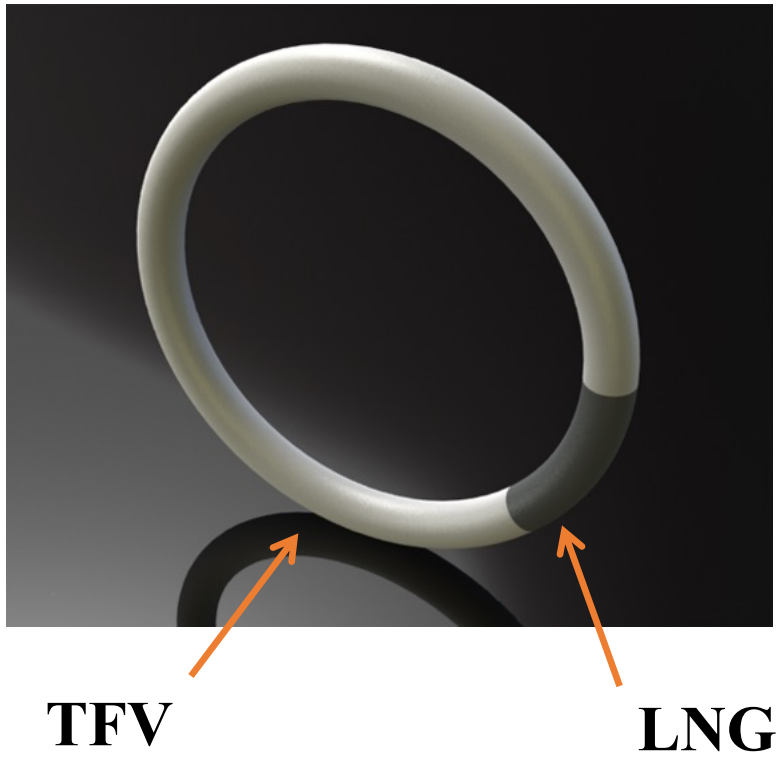
Merkatz, et al. Contraception Nov 2014; 90(5):514

CVR: What did you dislike the most?



Merkatz, et al. Contraception Nov 2014; 90(5):514

TFV/Levonorgestrel (LNG) IVR: Segmented Reservoir Design



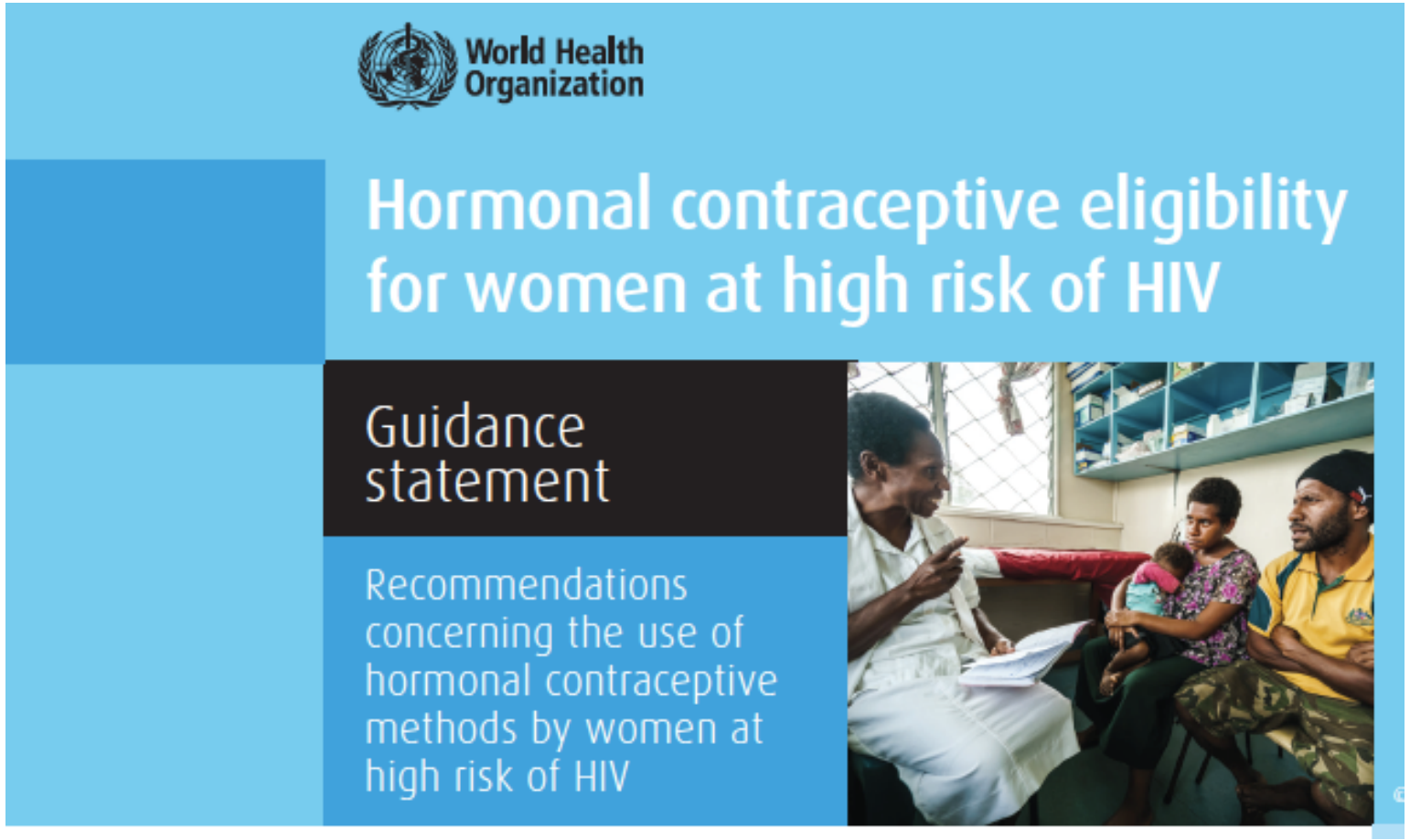
- Builds on the TFV-only reservoir IVR design
- Segmented approach allows for independent optimization of each drug's delivery needs
- LNG release rate is controlled by:
  - Rate-controlling membrane (thickness and diffusivity)
  - Length of the LNG segment

Most Contraceptives Not Linked to HIV Infection, but Depo-Provera May Raise Risk

Details Category: HIV Prevention Published on Wednesday, 10 August 2016 00:00 Written by Liz Highleyman

Birth control pills and some types of injectable and implanted contraceptives were not associated with an increased risk of HIV acquisition in an updated meta-analysis that included several recent studies, researchers reported in the August 5 online edition of *AIDS*. However, evidence continues to suggest that use of depot medroxyprogesterone acetate (DMPA or Depo-Provera) raises the likelihood of HIV infection. The World Health Organization (WHO) plans to meet soon to assess whether guidance needs to change in the light of the new findings.

Who Guidance Statement 2017



Background: rights-based approach

- Informed and free decision making
- Importance of contraceptive choice
- Risks of unintended pregnancy and HIV infection may be weighed differently by individual women
  - The woman should have a significant voice in the conversation

- **“Based on current evidence, FP Programmes delivering services to women at high risk of HIV infection can continue to offer all methods of contraception.”**

Hormonal contraception and HIV acquisition: WHO Guidance statement

- “The preponderance of data for oral contraceptive pills, injectable NET-EN, and levonorgestrel implants do not suggest an association with HIV acquisition, though data for implants are limited.
- “The new, higher quality studies on DMPA (or mixed injectables) had hazard ratios between 1.2 and 1.7,
- Although confounding cannot be excluded, new information increases concerns about DMPA and HIV acquisition risk in women.
  - But - If the association is causal, the magnitude of effect is likely hazard ratio 1.5 or less.
- Data for other hormonal contraceptive methods, including NET-EN, are largely reassuring.
  - Why DMPA?

The bottom line: women at high risk of HIV acquisition

Progestogen-only contraceptives (POCs)				
Condition	**CATEGORY I = initiation, C = continuation**			**Clarifications/evidence**
	POP	DMPA/ NET-EN	LNG/ETG	
High risk of HIV	1	2	1	CLARIFICATION: There continues to be evidence of a possible increased risk of acquiring HIV among progestogen-only injectable users. Uncertainty exists about whether this is due to methodological issues with the evidence or a real biological effect. In many settings, unintended pregnancies and/or pregnancy-related morbidity and mortality are common, and progestogen-only injectables are among the few types of methods widely available. Women should not be denied the use of progestogen-only injectables because of concerns about the possible increased risk. Women considering progestogen-only injectables should be advised about these concerns, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV. EVIDENCE: Evidence from 13 observational studies of DMPA, NET-EN or non-specified progestogen-only injectables, which were considered to be "informative but with important limitations" *(4)*, continues to show some association between use of progestogen-only injectables and risk of HIV acquisition, but it remains unclear whether this results from a causal relationship or methodological limitations. Two small studies assessing levonorgestrel implants, which were considered to be "informative but with important limitations" *(4)*, did not suggest an elevated risk, although the risk estimates were imprecise. One study reported no association between use of progestogen-only pills and HIV acquisition *(4)*.

POP = progestogen-only pill; DMPA = depot medroxyprogesterone acetate (injectable), NET-EN = norethisterone enanthate (injectable); LNG/ETG = levonorgestrel and etonogestrel (implants).

Why Category 2?

- “Advantages generally outweigh theoretical or proven risks.”
- 13 observational studies are “informative but with important limitations”:
  - Low-to-moderate quality
- Incorporate women’s preferences and values
- Support informed consent and a wide range of available options

Thank you!.... & discussion