
A Clinical Update on Intrauterine Contraception for HIV-Positive Women

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Parallel Paths Project

- A series of training sessions on topics of reproductive health for HIV/AIDS social and medical service providers
 - Find more and updated information at: http://mcrh-tn.org/outreach_parallel_paths.asp
 - Funding for this project provided by the MAC AIDS Fund.
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Learning Objectives

- Name the two forms of intrauterine contraception available in the United States
- Rank efficacy associated with intrauterine contraceptives compared with other contraceptive methods
- List three selection criteria for appropriate candidates for intrauterine contraception

more...


Learning Objectives (continued)

- Identify two possible side effects of each type of intrauterine contraceptive
 - Develop skills required for proper insertion techniques for the two methods of intrauterine contraception
 - Discuss strategies for follow-up of intrauterine contraceptive users
-

History of Intrauterine Contraception

1909:
Grafenberg develops
ring-shaped IUC device

1967:
"T" shaped device
developed



1962:
1st international conference on
IUCs; designs for plastic spiral
and plastic loop presented

Richter R. *Deutsche Med Wochenschr.* 1909.; Grafenberg E. 1929.; Ishihama A. *Yokohama Med Bull.* 1959.; Oppenheimer W. *Am J Obstet Gynecol.* 1959.; Berelson B. 1964; Marguiles LC. 1962.; Lippes J. 1962.; Hubacher D, Cheng D. *Contraception.* 2004.

History of Intrauterine Contraception

1968:
Contraceptive action
of intrauterine copper
reported

1980:
Levonorgestrel IUC
tested in randomized
clinical trials



1976:
Copper T 200 becomes
first copper IUD

History of Intrauterine Contraception

1988:
Copper T 380 IUD
available in the
United States

Only 2% of US
women use IUCs
today



2001:
LNG IUC available in
the United States

Why an Update on Intrauterine Contraception?

1 in 5

pregnancies ends
in abortion

Why an Update on Intrauterine Contraception?

20%

of women selecting
sterilization at age 30
years or younger later
express regret

Why an Update on Intrauterine Contraception?

There is a need for effective
contraceptive methods that are

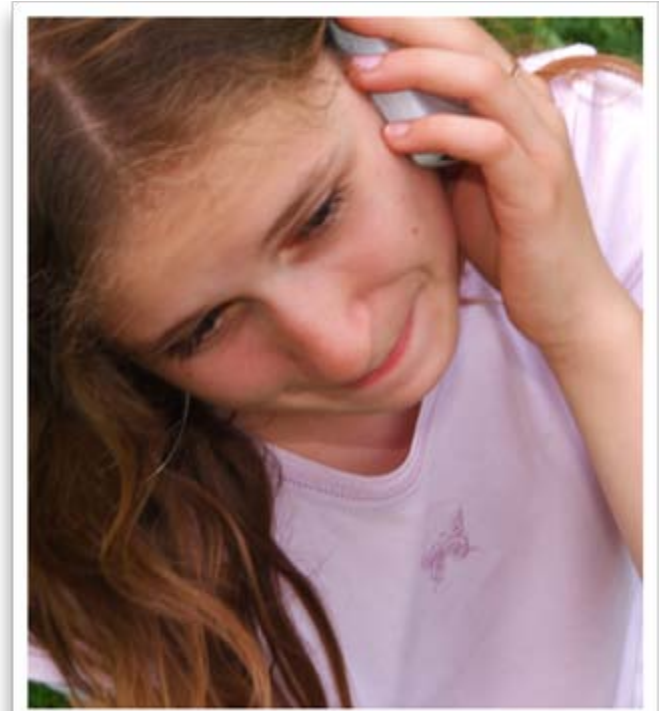
forgettable

more...

Finer LB, et al. *Perspect Sexual Reprod Health*. 2003.; Hillis SD, et al. *Obstet Gynecol*. 1999.; Stanwood NL, et al. *Obstet Gynecol*. 2002.

Why an Update on Intrauterine Contraception? (Continued)

- Myths exist about intrauterine contraception
- Selection of candidates is unduly restrictive
- Misinformation about intrauterine contraception among providers and patients is common

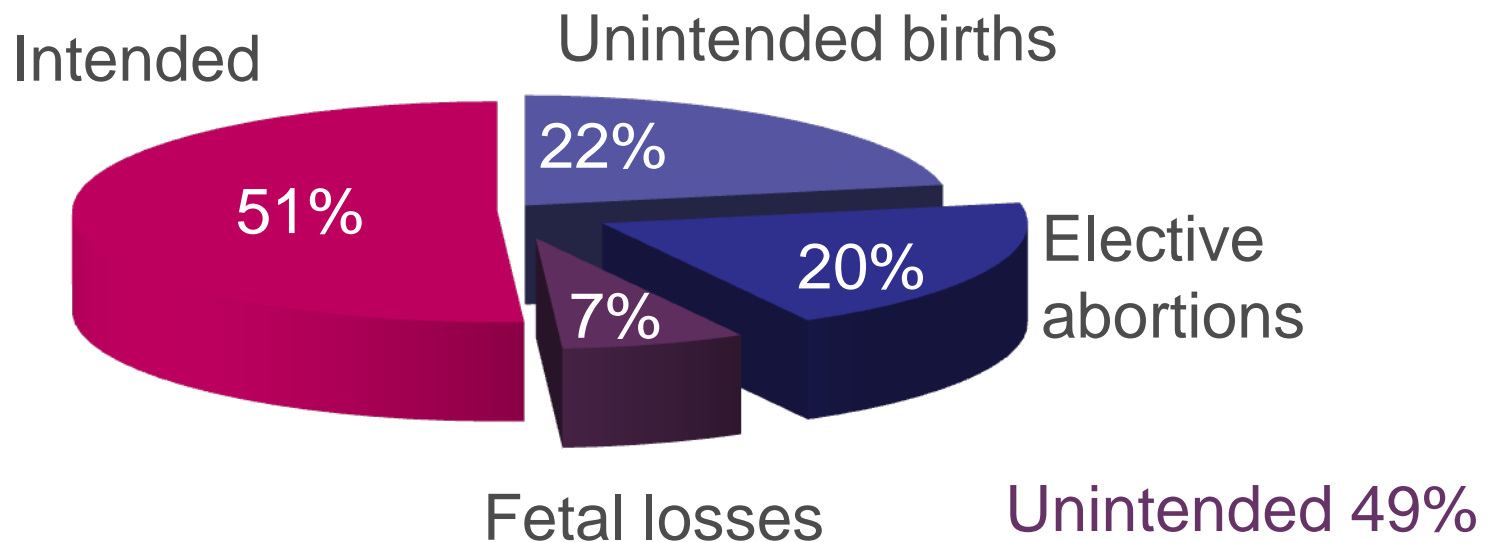


Presentation Outline

- Contraceptive Use
 - Overview of Intrauterine Contraception
 - Patient Screening and Counseling for IUCs
 - IUC Insertion and Management
-

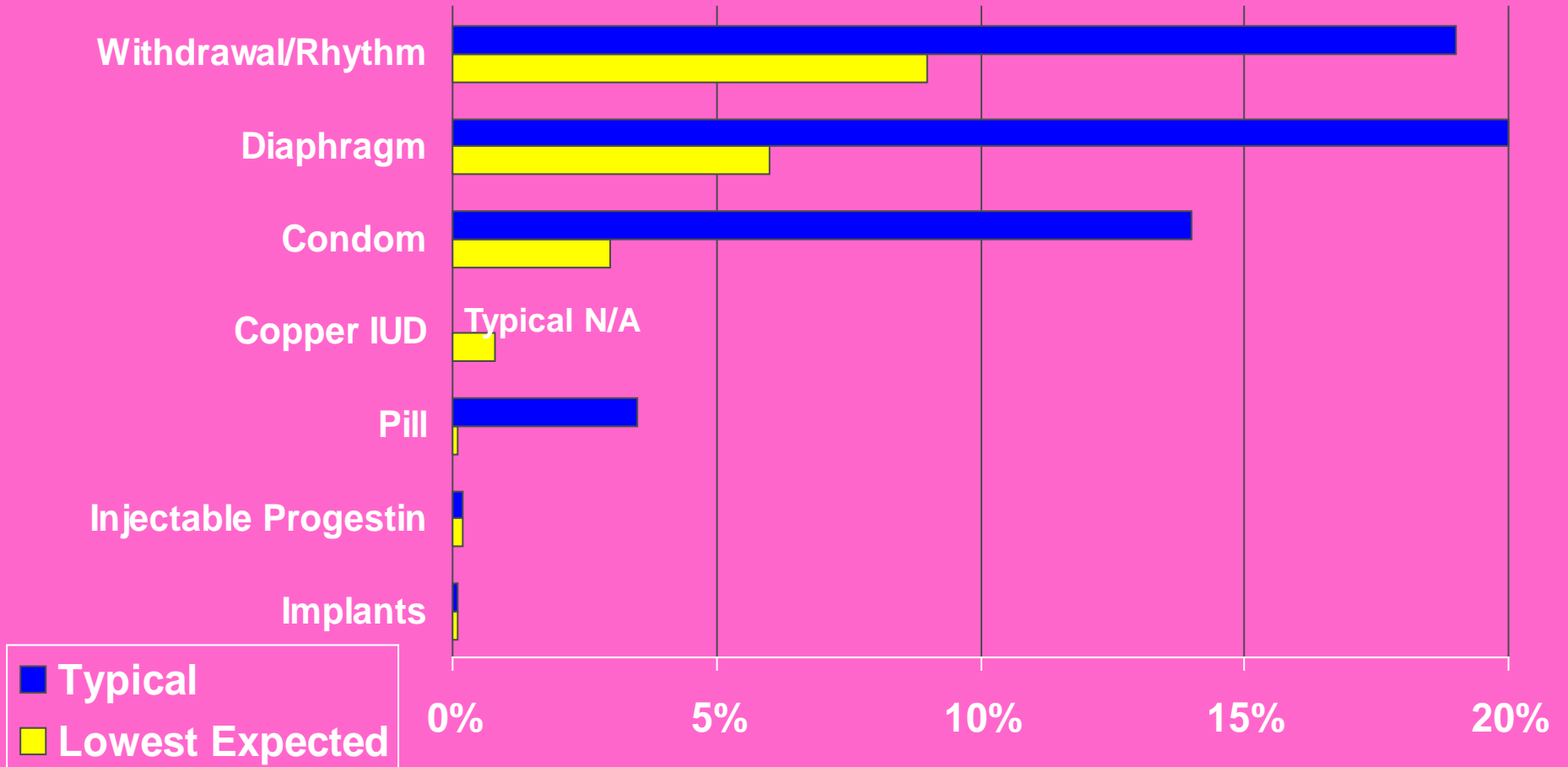
Unintended Pregnancies in the United States

Data from 2002 National Survey of Family Growth



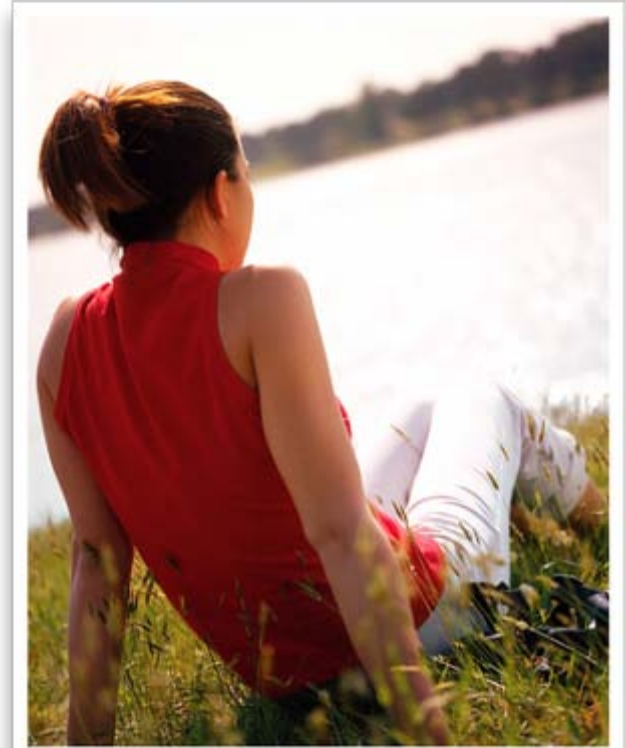
6.4 Million Pregnancies

Contraception Failure Rates (1st Year) Reversible Methods



Question

Why are there so many unintended pregnancies in the United States?



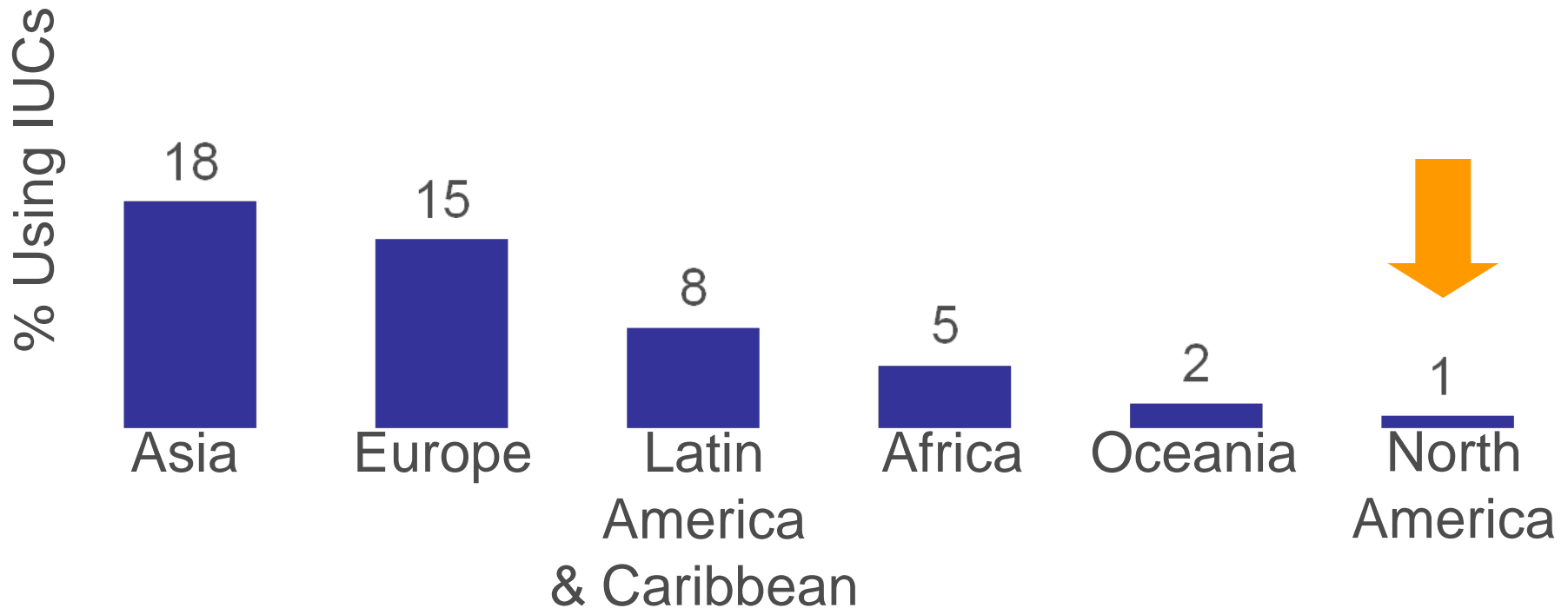
Case Study

- 31 yo, G2P2, postpartum 12 weeks
- Breastfeeding
- Doesn't want more children
- Considering sterilization—
not sure
- Makes appointment for IUC
- Doesn't return for insertion
- Why not?



Worldwide Use of IUCs

Use for Married Women of Reproductive Age

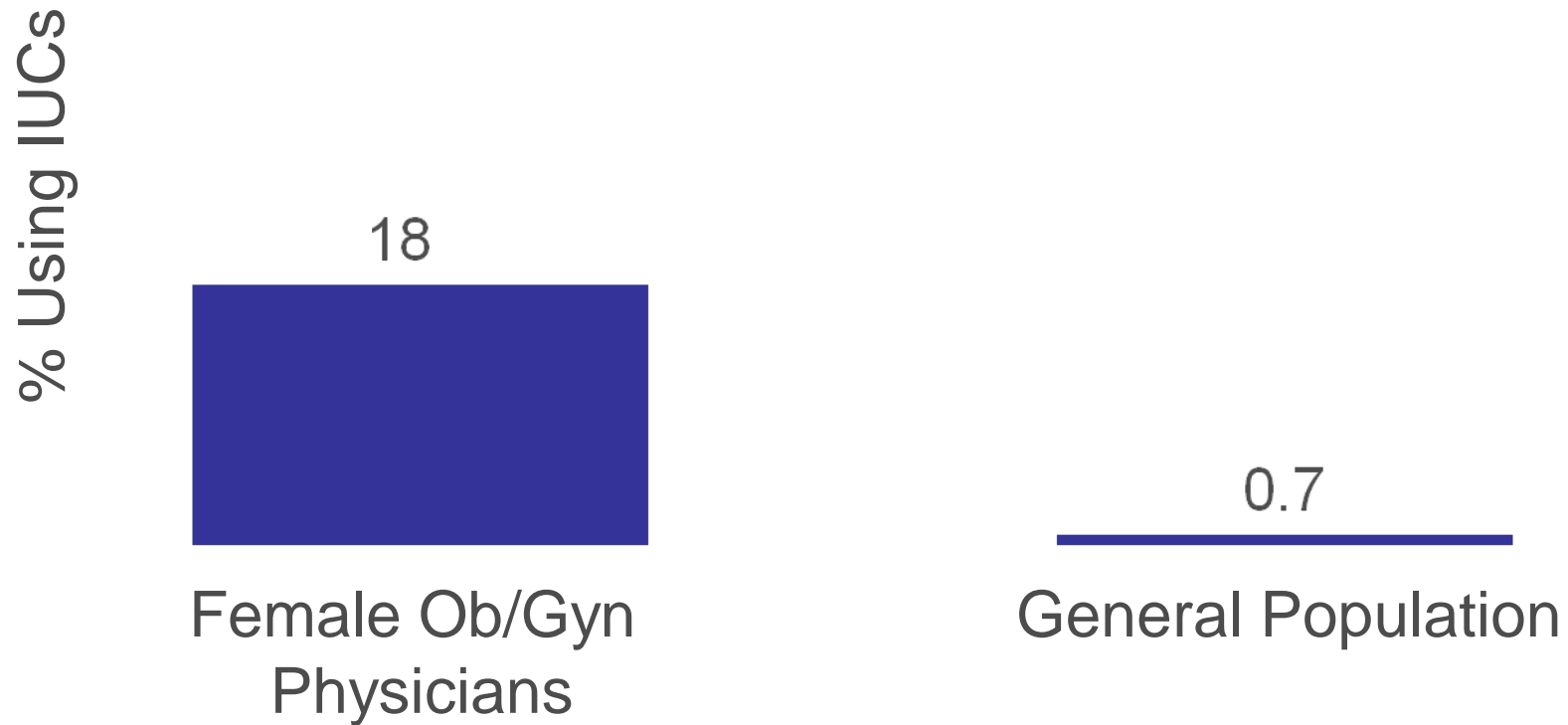


Question

Why is contraceptive use different in other parts of the world?



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



Question

What do female ob/gyns know about intrauterine contraception that the average American woman doesn't?



Why IUCs 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



What Do Women Find Unacceptable About IUCs?

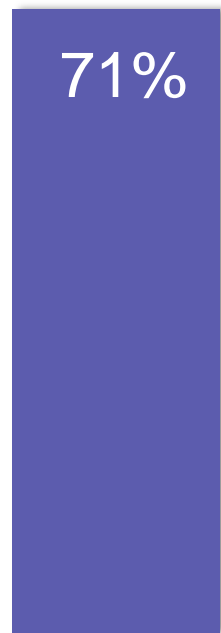
- Lack of objective information
- Reported side effects
- Anxiety about IUC insertion
- Infection risk
- Lack of personal control of IUC after insertion



Most Young Pregnant Women Unsure about IUC Characteristics

How safe/effective are IUCs compared to pills, injections, or tubal sterilization?

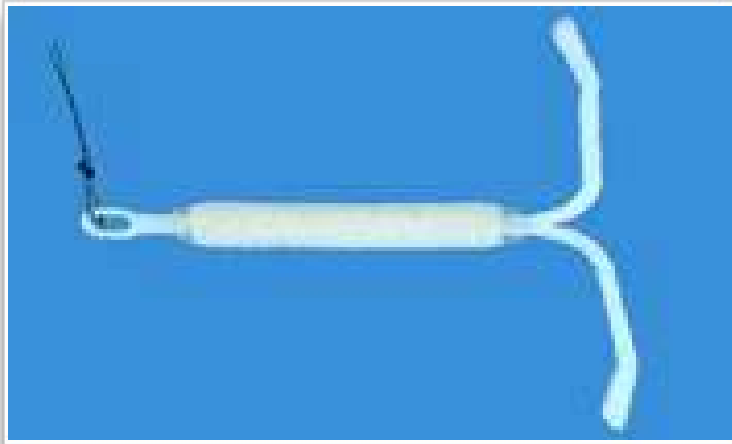
Unsure of safety



Unsure of efficacy



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



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
- *Are not* large in size

more...

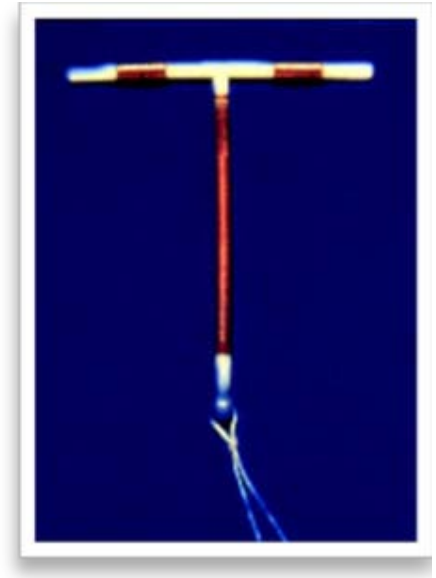
Dispelling Common Myths About IUCs (continued)

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

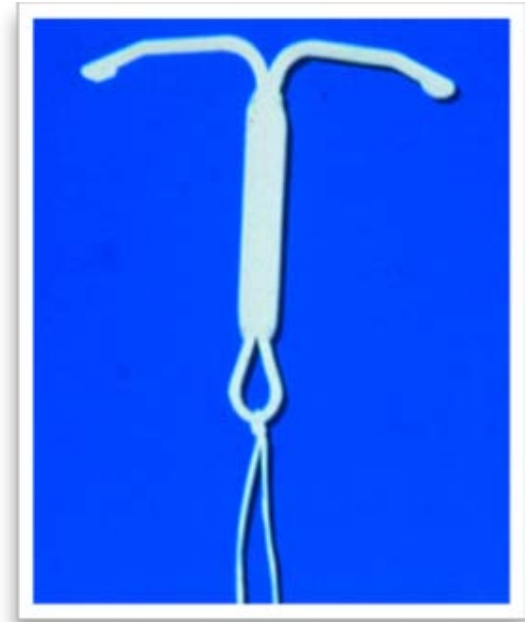
Mechanism of Action: Copper T IUD

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



Mechanism of Action: LNG IUC

- Primary mechanism is fertilization inhibition
- Cause cervical mucus to thicken
- Inhibit sperm motility and function
- Inhibition of implantation is a secondary mechanism



Percentage of Women with Fertilized Eggs in Oviducts After Midcycle Coitus

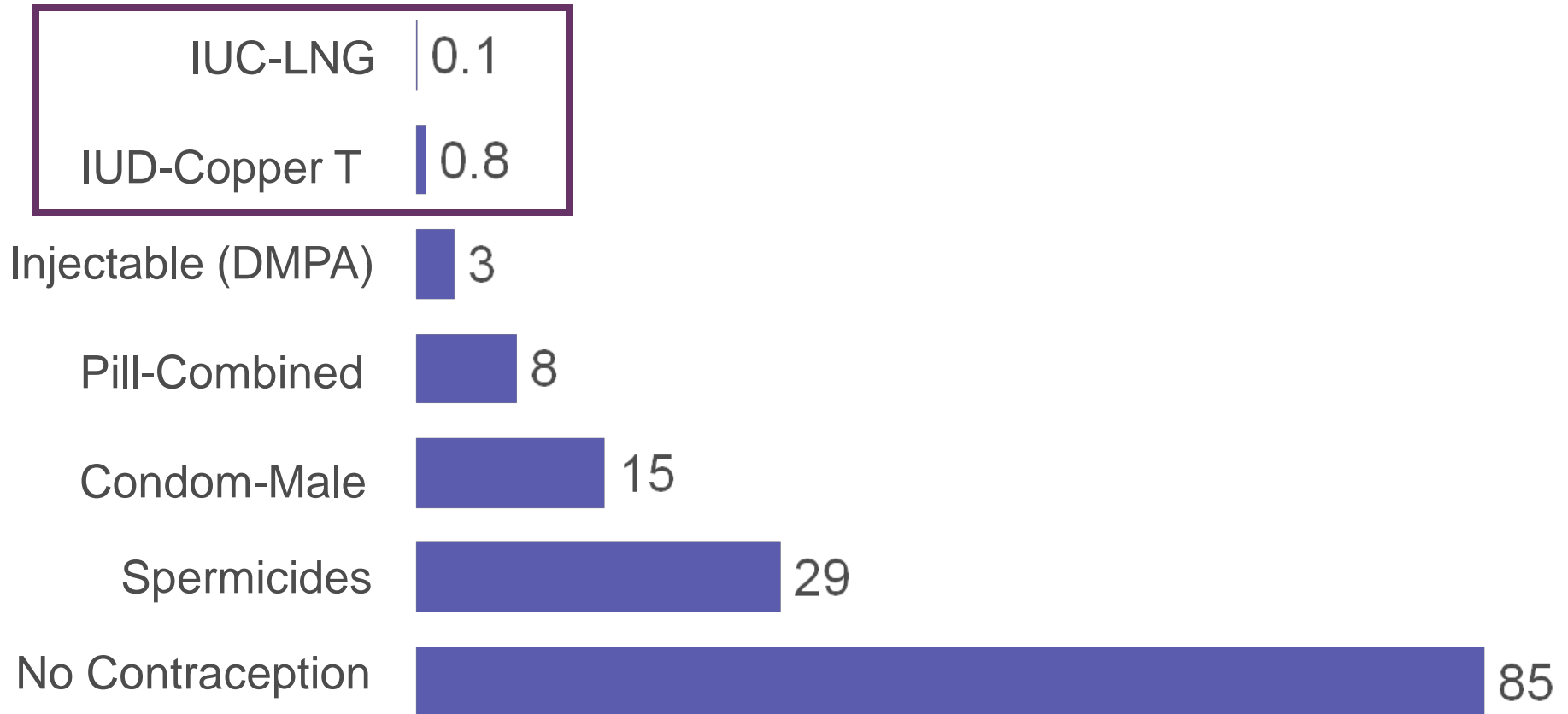
	Normal development (%)	No development (%)	Abnormal development (%)
Control (n=20)	50	15	35
IUC (n=14)	0	64	36

IUC Efficacy Comparable to Sterilization

5-year gross cumulative failure rate



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



Adapted from Trussell J. In Hatcher RA, et al. *Contraceptive Technology: 18th revised ed*, 2004.

Safety: Overview

Recent data continue to demonstrate the safety of the current IUCs



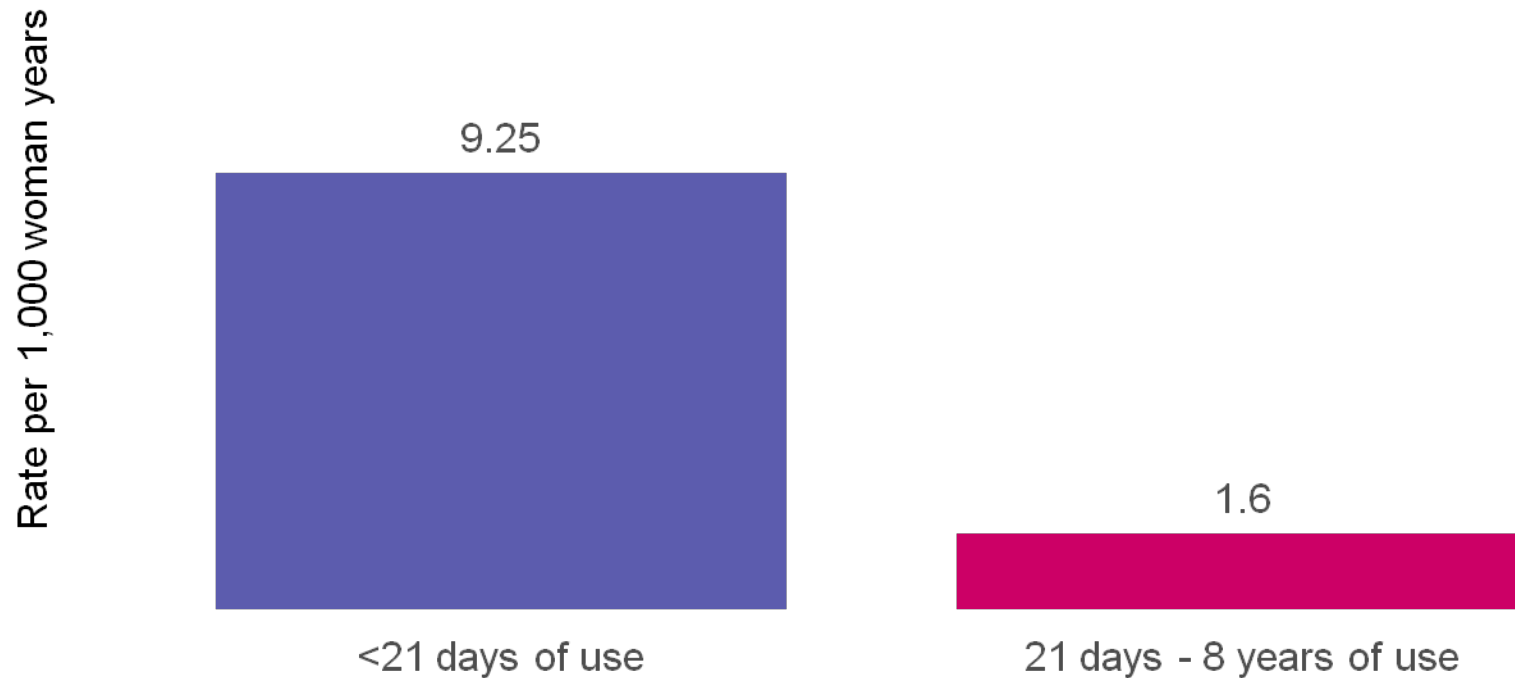
Hubacher D, et al. *NEJM*. 2001; Nelson AL. *Obstet Gynecol N Am*. 2000; Meirik O, et al. *Obstet Gynecol*. 2001.

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

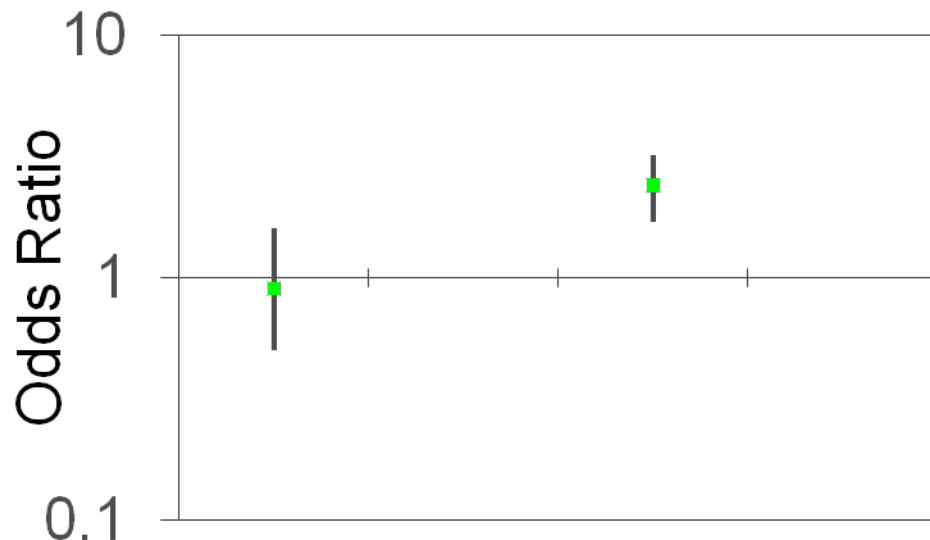
n=~20,000 women



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

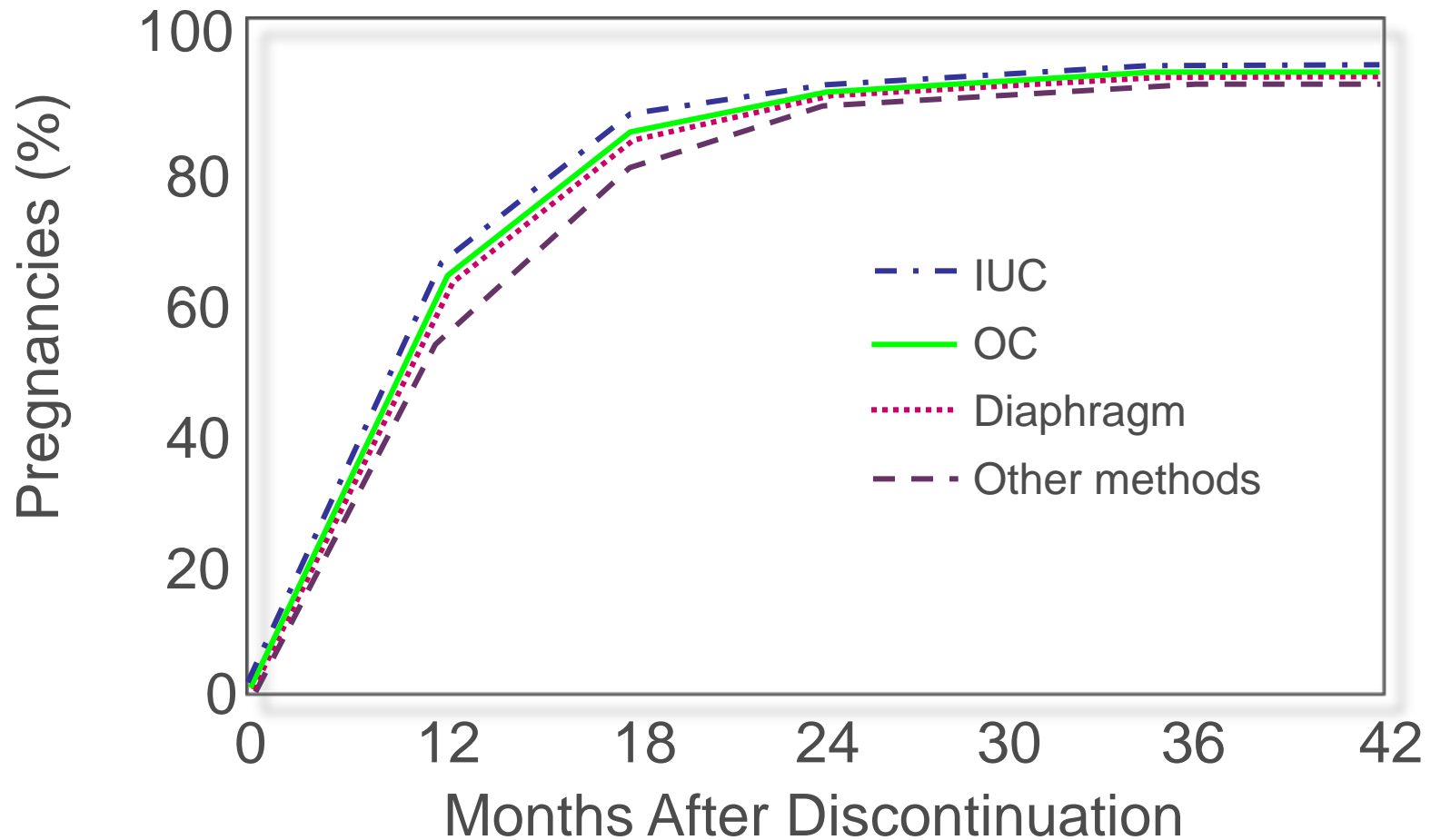
Safety: IUC Does Not Cause Infertility

- 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



Based on data from Vessey MP, et al. *Br Med J*. 1983.

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



Intrauterine Device (IUD)

- **Few studies on IUD and HIV-infected women**
 - **IUD results in inflammatory response in the endometrium and can alter the microenvironment of the uterus, cervix, and tubes**
 - **Recruitment of inflammatory cells and increased blood lymphocytes and macrophages may provide targets for HIV replication**
-

Effect of IUD on cervical shedding of HIV-1 DNA

- A prospective study of 98 HIV(+) women undergoing IUD insertion, Nairobi, Kenya
- Cervical swabs were collected before IUD (Copper T 380A) insertion and 4 months thereafter for detection on HIV-1 DNA
- HIV-1 DNA shedding was 50% at baseline and 43% at follow-up (OR 0.8, 95%CI 0.5-1.2)
- No difference, in multivariate model controlling for previous hormonal contraceptive use, condom use, ectopy, friable cervix, cervical infections, CD4

Complications of use of IUD among HIV-1 infected women

- 649 (156 HIV-infected and 493 HIV uninfected) women in Nairobi, Kenya who met local eligibility criteria for IUD insertion were enrolled in 1994-1995
 - No evidence of: history of ectopic pregnancy, pregnancy within previous 42 days, fibroids, active PID, malignancy in reproductive tract, abnormality of the vagina, cervix, or endometrial cavity, known copper allergy, mucopurulent cervicitis, unexplained abnormal vaginal bleeding, or high risk for STD
 - Sinie SK, Morrison CS, Sekadde-Kigonda et al. *The Lancet* 1998 351:1238-1241
-

Complications of use of IUD among HIV-1 infected women

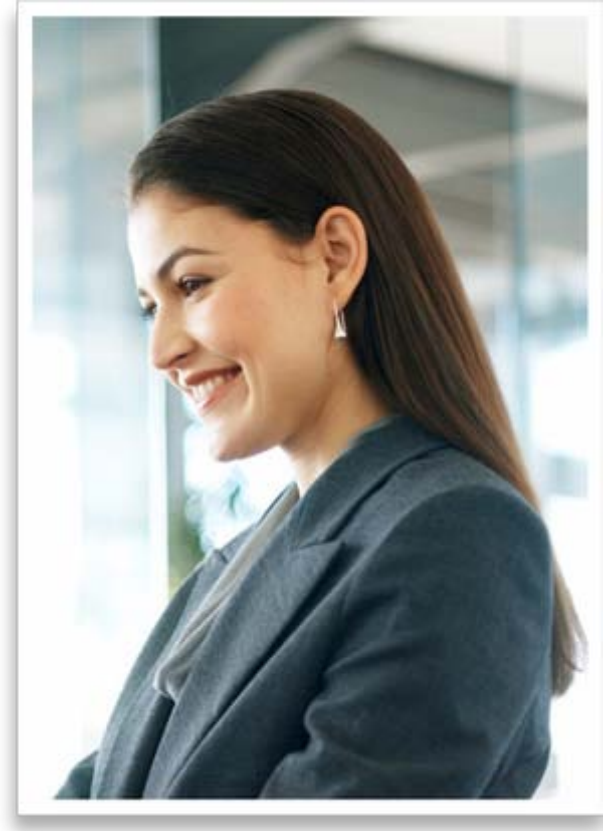
Outcome type	HIV(+)	HIV(-)	CRR	AOR
Complications				
Overall	11 (7.6%)	37 (7.9%)	0.97	0.80
PID	2 (1.4%)	1 (0.25)		
IUD removals	6 (2.1%)	18 (3.8%)		
IUD expulsions	3 (2.1%)	17 (3.6%)		
Pregnancies	0	1 (0.2%)		
Infection related comp.	10 (6.9%)	27 (5.7%)	1.21	1.02
IUD complaints	37 (25.7%)	90 (19.1%)	1.34	1.41

Safety: LNG IUC Does Not Increase Breast Cancer Risk

Age group(y)	LNG users: Incidence rate per 100,000 woman-years	Average Finnish population: Incidence rate per 100,000 woman-years
30–34	27.2	25.5
35–39	74.0	49.2
40–44	120.3	122.4
45–49	203.6	232.5
50–54	258.5	272.6

Safety: IUCs May Be Used in Nulligravid Women

- No evidence of increased infertility in nulliparous users of IUCs
- Risk of PID and subsequent infertility is dependent on non-IUC factors



LNG IUC vs. OCs in Nulligravid Women: Termination Rates, Reasons

Reason	LNG IUC termination rate per 100	OC termination rate per 100
Pain*	6.66	0
Hormonal	4.95	9.75
Bleeding	2.52	0
Spotting	0	1.25
Expulsion	1.20	NA
Other medical	2.13	1.09

*Statistically significant difference

Copper T IUD Labeling Does Not Exclude Nulliparous Women

Copper T labeling change was approved in 2005 to include more potential candidates beyond women who have had one child and are in a mutually monogamous relationship



Potential Side Effects

During insertion	First few days	First few months	Type
Variable pain and/or cramping	Light bleeding	Inter-menstrual bleeding	<i>Copper T:</i> Heavier or prolonged menses
Vaso-vagal reactions	Mild cramping	Cramping	<i>LNG:</i> Gradual decrease in menstrual flow

Sivin I, et al. *Contraception*. 1991.

Silverberg SG, et al. *Int J Gynecol Pathol*. 1986.

IUC Non-contraceptive Benefits

Protection
against
endometrial
cancer

Alternative to
hysterectomy
or endometrial
ablation

Treatment of
heavy
bleeding/
dysmenorrhea

Copper T IUD	✓		
LNG IUC	✓	✓	✓

Hill DA, et al. *Int J Cancer*. 1997; Rosenblatt KA, et al. *Contraception*. 1996;
Hurskainen R, et al. *Lancet*. 2001; Andersson JK, et al. *Br J Obstet Gynaecol*. 1990.

LNG IUC Non-contraceptive Uses

Good evidence

- Heavy bleeding
- Dysmenorrhea and pain
- Endometrial protection during hormone or tamoxifen therapy in perimenopausal and postmenopausal women

more...

LNG IUC Non-contraceptive Uses

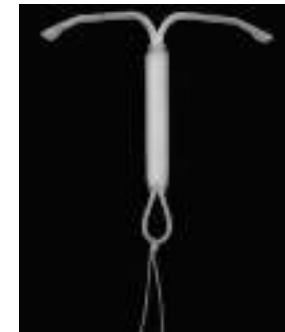
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Limited evidence

- Uterine fibroids
- Endometriosis
- Adenomyosis
- Endometrial hyperplasia or cancer

IUC Is Cost Effective

- Higher one-time startup, but incurs substantially lower cost over time
- Both IUC manufacturers offer patient payment plan options
- Bulk discounts are available to clinicians



Costs for Patients

- Patient costs are a factor in choosing contraceptive method
 - Up-front costs concern some women
 - Costs of side effects associated with some contraceptives are high compared with those for an IUC
 - Public clinics and pharmaceutical company patient assistance programs can be explored for low-income or uninsured patients
-

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

more...

Screening & Counseling Goals for Providers (Continued)

4

Allow time for questions

5

Provide written materials in the appropriate language and literacy level

Considerations in Choice of Contraceptive Methods

- Effectiveness
 - Side effects
 - Convenience
 - Duration of action and childbearing plans
 - Patient choice
 - Reversibility
 - Non-contraceptive benefits
 - Cost
 - Privacy
-

Women Referred for Sterilization

15% did
not
attend
clinic

54% had
sterilization

29%
chose
alternative
method

N=100 women

Screening: Appropriate Candidates for Intrauterine Contraception

Women of any reproductive age seeking long-term, highly effective contraception



more...

Screening: Appropriate Candidates for Intrauterine Contraception (Continued)

Copper T IUD

Good method for women who don't want hormonal contraception or want contraception for more than 5 years

LNG IUC

Good method for women who request less menstrual flow and/or who experience dysmenorrhea, dysfunctional uterine bleeding

Screening: Poor Candidates for Intrauterine Contraception

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

more...

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

IUC Insertion After Spontaneous or Induced Abortion

- IUCs may be safely inserted immediately after spontaneous or induced abortions
- IUC insertion is not recommended after septic abortion

IUC for Postpartum Use

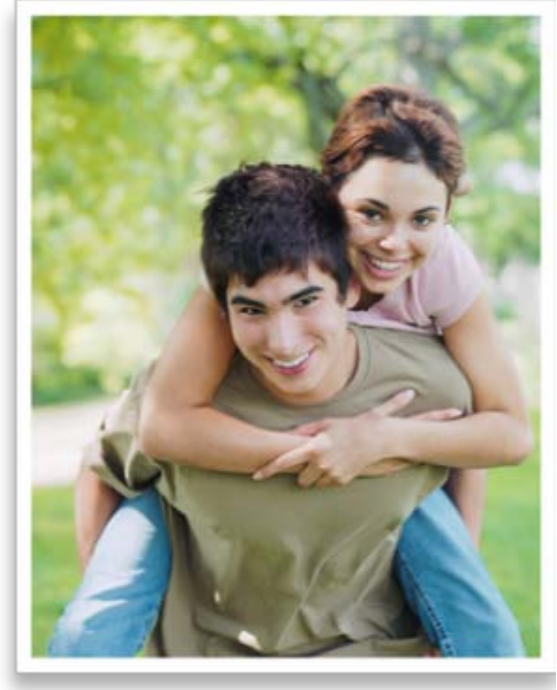
- May be safely inserted in postpartum women
- Copper T within 48 hours of delivery or after 4 weeks postpartum once the uterus is involuted
- LNG at 6 weeks postpartum

IUC 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

IUC Use for Adolescents

- Appropriate for properly selected and counseled adolescents
- Follow-up and side-effect monitoring important
- Encourage use of condoms with new partners



Checklist for STI Risk Assessment

Circle appropriate answer	Yes	No
Is the client < 25 years old?	1	0
Is she currently living apart from her husband or partner?	1	0
During the last year, has she had bleeding between periods <u>or</u> bleeding or spotting within 24 hours after sex?	1	0
Is her school education < secondary level?	1	0

Checklist for STI Risk Assessment

(Continued)

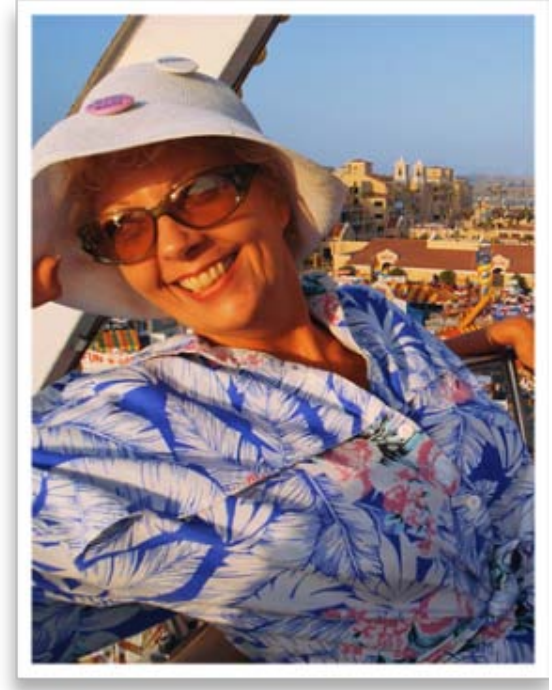
How many different sexual partners has she had during the last 3 months?	None 0	One	> One
If she has had one or more partners, how often has she used a condom in the last 3 months?		↓	↓
Never used condoms		0	1
Sometimes used condoms		1	1
Always used condoms		0	0

Scoring STI Risk Assessment

Recommended action	Low cervical infection population (<10%)	High cervical infection population (=10%)
Counsel/refer for IUC insertion without any reservations	If score is 0–2	If score is 0
Consider presumptive treatment for chlamydia/gonorrhea (if available) <u>or</u> counsel/refer to use another contraceptive	If score is 3+	If score is 1+

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



IUC Counseling Topics

- Effectiveness
- Mechanism of action
- Characteristics of method, including changes to menstrual flow
- Insertion and removal procedures

more...

IUC Counseling Topics (Continued)

- Side effects and possible complications
 - Instructions on follow-up
 - Non-contraceptive benefits
 - Use of condoms with new partners
-

IUC Side Effects & Complications

Side Effects

Menstrual
effects



Complications

Infection
Perforation
Pregnancy
Expulsion
Missing threads

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

LNG IUC: Management of Late Abnormal Bleeding

Matched-pair, case-control study

- 15 users with unacceptable bleeding after > 6 months of use vs. 15 control users with no abnormal bleeding
- Device displacement or leiomyomas detected more commonly in cases than controls

more...

LNG IUC: Management of Late Abnormal Bleeding (Continued)

Conclusion:

- Consider ultrasonography and hysteroscopy to evaluate bleeding complaints in long-term users of LNG device
- Replace device if it is displaced

Timing of Insertion of Intrauterine Contraception

Timing	Pros	Cons
With menses	Ensures patient not pregnant	Scheduling; interim pregnancy
Midcycle anytime	Convenience; low rate of expulsion	Must rule out pregnancy
Emergency contraception (copper IUD)	Convenience; pregnancy prevention	Pregnancy

more...

Timing of Insertion of Intrauterine Contraception (Continued)

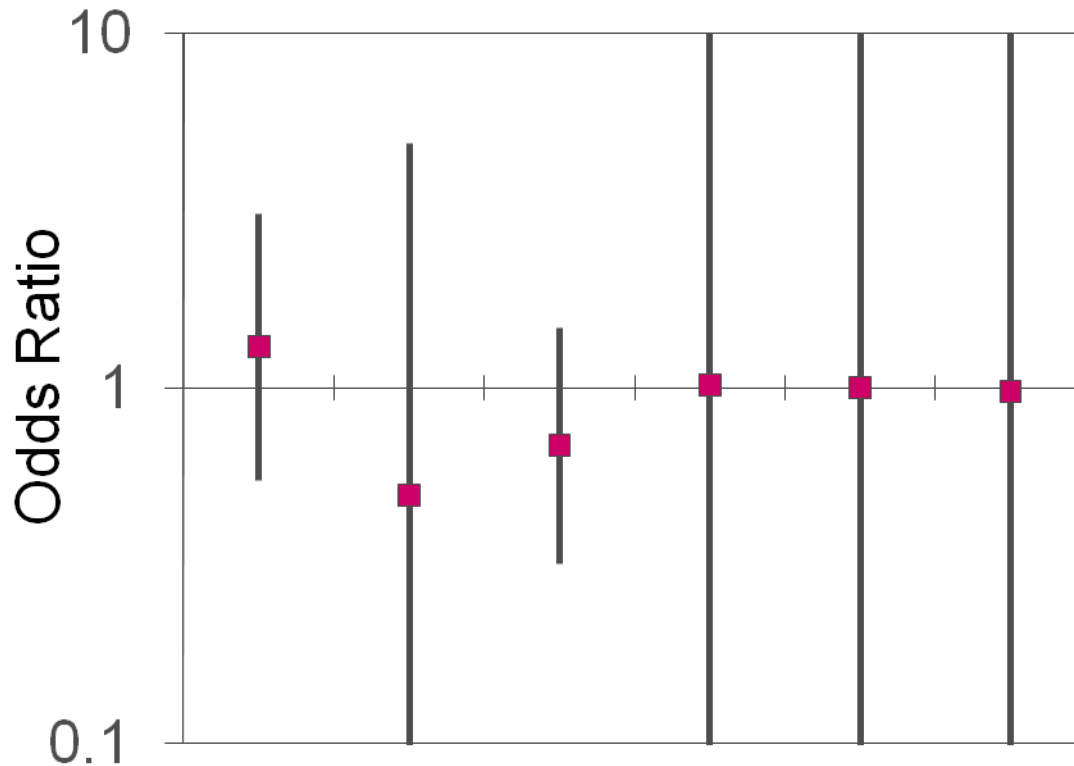
Timing	Pros	Cons
Cesarean delivery	Convenience; low rate of expulsion	Strings may not be visible or palpable at cervix
Postplacental	Convenience	Increased rate of expulsion (7%–15%)

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



Prophylactic Antibiotics Before Insertion



Have not been shown to reduce risk of PID when given prophylactically

Steps for Insertion: Technique Varies According to Product

1

Perform pelvic exam to assess size and position of uterus

2

Apply tenaculum

3

Sound the uterus

more...

Steps for Insertion: Technique Varies According to Product (Continued)

4

Load the device

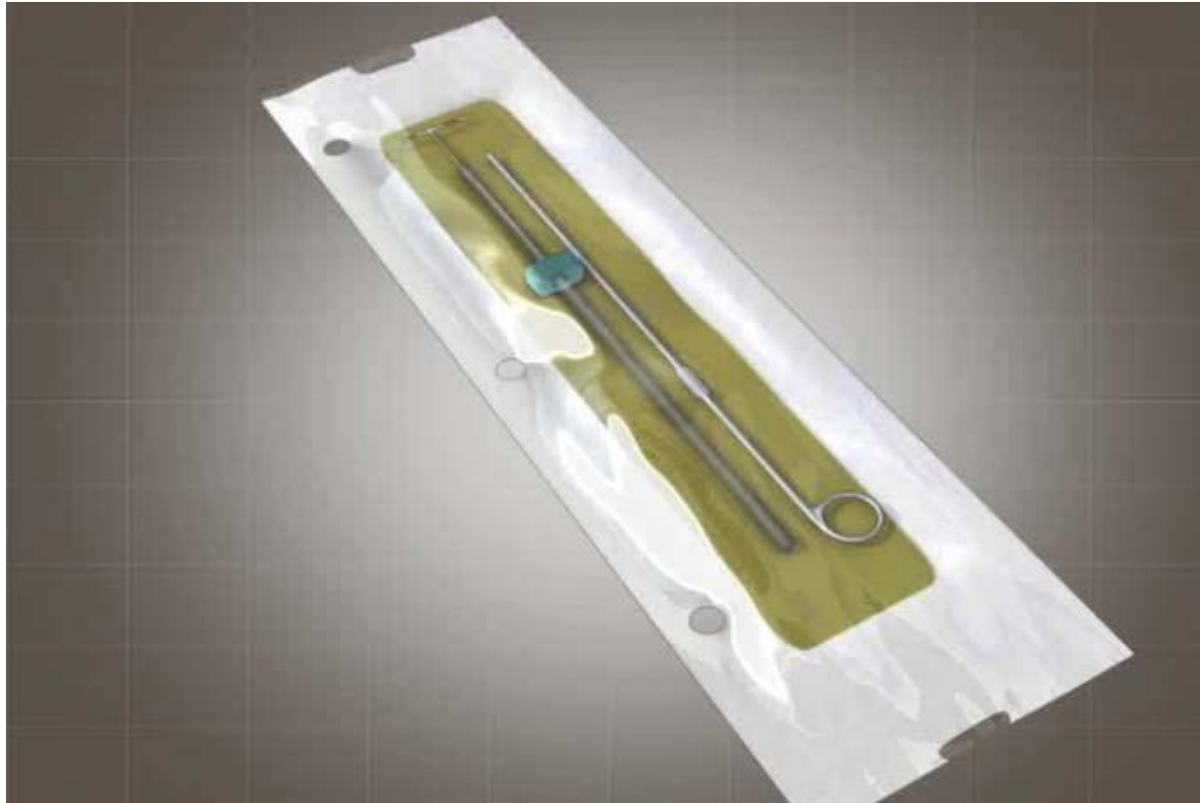
5

Place the device

6

Cut the threads

Animated Insertion: Copper T IUD



<http://www.youtube.com/watch?v=FuPFbgSm0QQ>

Animated Insertion: LNG IUS



<http://www.youtube.com/watch?v=hlfV8tKgw6E>

IUC Insertion Tricks of the Trade

- For women with narrow cervical canal
 - Prime cervix with misoprostol 400 mcg a few hours before insertion
- For pain management
 - Oral NSAID 400 mg PO and/or
 - Instill lidocaine in uterine cavity with an endometrial sampler
 - The sampler can be used instead of sound to measure depth of uterus

more...

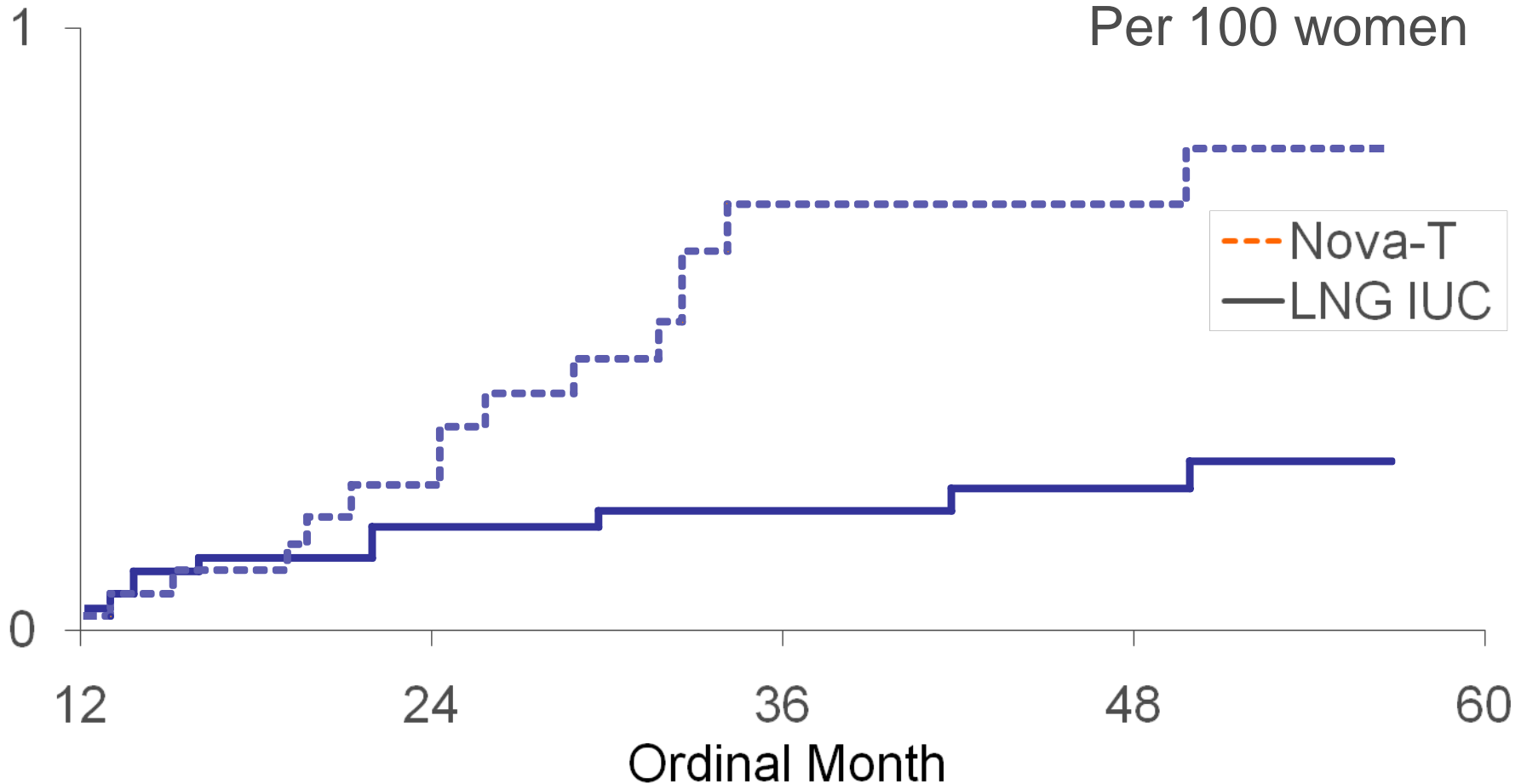
IUC Insertion Tricks of the Trade

(Continued)

To visualize cervix

- Use large speculum
 - If vaginal walls obscure cervix, cut off end of condom and slip over metal speculum
 - Get better light
-

IUC 5-Year Cumulative Gross Removal Rate for PID



IUC Net Termination & Continuation Rates per 100 at 1 and 5 Years

Event	Nova T 1 year	LNG IUC 1 year	Nova T 5 years	LNG IUC 5 years
Pregnancy	0.9	0.1	4.2	0.3
Expulsion	3.4	3.4	5.5	4.9
Bleeding	5.7	5.8	16.2	10.9
Pain	1.6	1.6	4.2	4.2
Hormonal	0.1	2.3	1.1	8.4
PID	0.4	0.3	1.6	0.6
Other	4.9	6.7	22.7	23.8
Continuation	83.0	79.9	44.5	46.9

Signs of Possible Complications

Symptom	Possible Explanation
Severe bleeding or abdominal cramping 3–5 days after insertion	Perforation, infection
Irregular bleeding and/or pain every cycle	Dislocation or perforation
Fever, chills, unusual vaginal discharge	Infection

more...

Signs of Possible Complications

(Continued)

Symptom	Possible Explanation
Pain during intercourse	Infection, perforation, partial expulsion
Missed period, other signs of pregnancy, expulsion	Pregnancy (uterine or ectopic)
Shorter, longer, or missing threads	Partial or complete expulsion, perforation

Management of Cramping

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



Expulsions

- Partial or unnoticed expulsion may present as irregular bleeding and/or pregnancy
 - Risk of expulsion related to:
 - Provider's skill at fundal placement
 - Age and parity of woman
 - Time since insertion
 - Timing of insertion
-

Copper T: Management of Heavy Bleeding Lasting > 3 Months

1

Examine for infection or fibroids

2

Check for signs of anemia and treat, if needed

3

Prescribe NSAIDs

4

Remove device if medically indicated or unacceptable to patient

Management of Missing Threads

- Rule out pregnancy
 - Probe for threads in cervical canal
 - Prescribe back-up contraceptive method
 - Obtain ultrasound or x-ray, as needed
 - Remove a copper T IUD in abdomen promptly
-

Management of STIs

If STI diagnosed:

- IUC removal not necessary if symptoms improve within 72 hours of treatment
- Treat infection
- Counsel patient about prevention of STI transmission

Management of PID

If PID diagnosed:

- IUC removal may not be necessary
- Treat infection
- Recommendations to remove IUC 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 IUC In Situ

- Determine site of pregnancy
 - Intrauterine or ectopic
- Remove IUD if threads available
- Removal decreases risk of:
 - Spontaneous abortion
 - Premature delivery

IUC Summary

- Two options available in United States
 - Efficacy equivalent to sterilization
 - Broader options for insertion timing
 - Can be inserted in nulligravid women
 - Can be inserted after abortion or delivery
 - Cost effective
-