Clinical Update in Intrauterine Contraception

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Training in Reproductive Health Research WHO 2007

Learning Objectives

- State the efficacy associated with intrauterine contraception as compared to other contraceptive methods.
- List the different categories of IUCs available.
- List selection criteria for appropriate candidates for intrauterine contraception.
- List non-contraceptive uses and benefits of IUC.
- Identify possible side effects of intrauterine contraception.

Why an Update on Intrauterine Contraception?

- Study of 10,683 women having abortions
- 46% not using contraception
- 54 % using contraception
 - Method failure
 - Incorrect or inconsistent use: Condoms, OCPs,
 Withdrawal, Periodic Abstinence

RK Jones et al. Perspectives on Sexual and Reproductive Health, 2002, 34(6):294

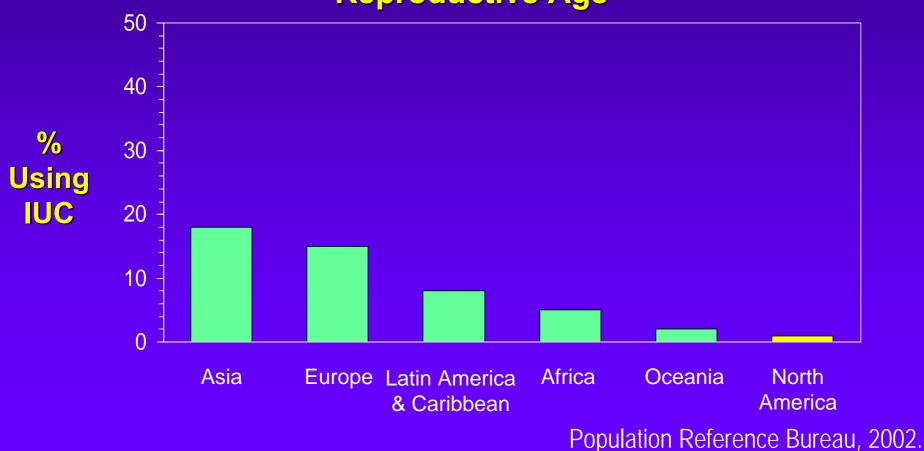
Why an Update on Intrauterine Contraception? (continued)

- Myths exist about intrauterine contraception and selection of candidates is unduly restrictive
- Misinformation about intrauterine contraception is common

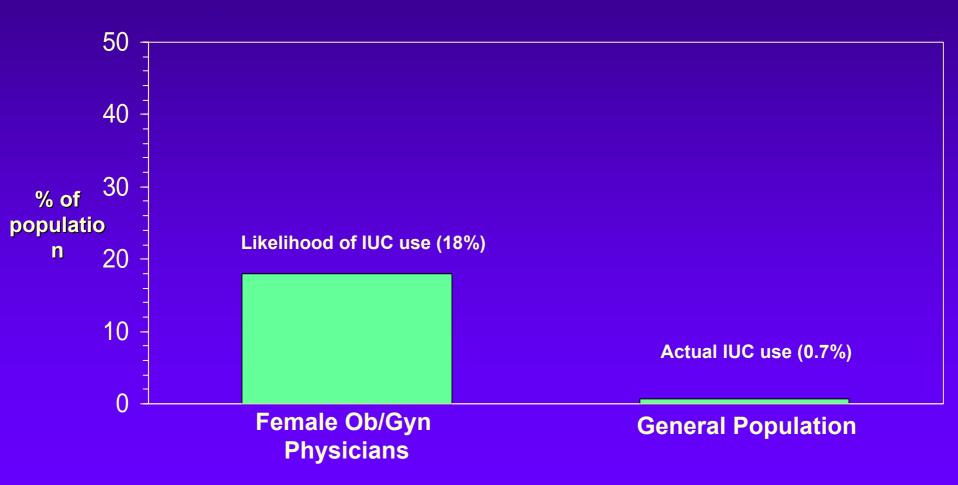
Contraceptive Use

Worldwide Use of IUC

Estimated Use Among Married Women of Reproductive Age



IUC use by Female Ob/Gyns and IUC use by All Women in the United States



Population Reference Bureau, 2002.; The Gallup Organization, 2004.

Why IUC is Underutilized

- Dearth of trained and willing professionals to insert devices
- Negative publicity about method
- Misconceptions by health care providers and the public
- Access issues in some countries; litigation worries in others

Weir. *CMAJ* 2003. Stanwood, NL. *Obstet Gynecol* 2002. Steinauer JE. *Family Planning Perspectives* 1997.

Overview of Intrauterine Contraception

Characteristics of IUC

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

Belhadj H, et al. *Contraception.* 1986. Skjeldestad F, Bratt H. *Advances in Contraception.* 1988. Arumugam K, et al. *Med Sci Res.* 1991. Tadesse E. *Easr Afr Med J.* 1996.

Former Methods of IUC Worldwide



Examples of Available Methods of IUC



Copper T 380A IUD

- Copper ions
- Approved for 10 years use
- Failure 0.8% first year of use
- Ten year failure <3%



LNG IUS

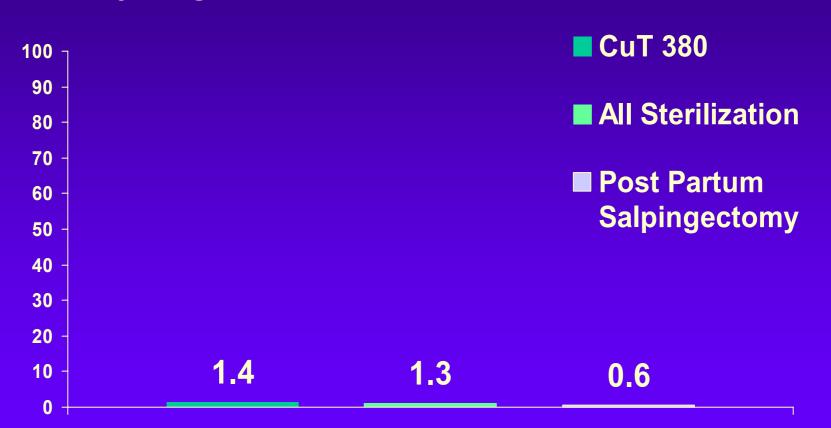
- 20 mcg levonorgestrel/day
- Approved for 5 years use
- Failure 0.1% first year
- 5 year failure 0.7%

Which copper-containing device?

- Effectiveness varies by amount of copper
 - Cumulative pregnancy 5.8 for TCu220 versus 2.2
 TCu380 over 12 years
 - Copper-loading on arms increases efficacy
- Expulsion rates lower for T-shaped devices
- Performance unchanged by age or parity
- TCu380A overall performed better than other devices, and easier to insert than TCu380S

Efficacy: IUC is Comparable to Sterilization

5-year gross cumulative failure rate

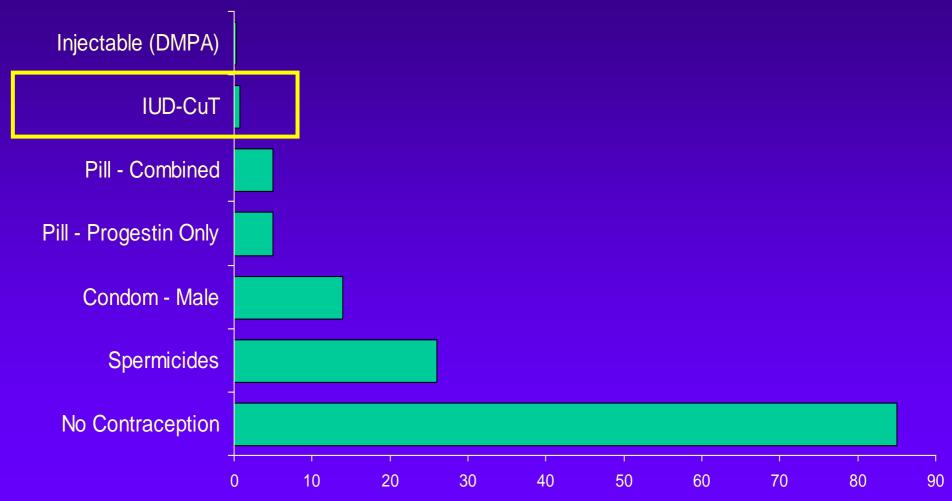


WHO. Mechanism of Action, Safety, and Efficacy of Intrauterine Devices.

1987.

Peterson, et al. Am J Obstet Gynecol . 1996.

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



Adapted from Trussell J, Vaughan B. Fam Plann Perspect. 1999.

Dispelling Common Myths About IUC

- In fact:
 - -ARE NOT abortifacients
 - -DO NOT cause ectopic pregnancies
 - -DO NOT cause pelvic infection
 - DO NOT decrease the likelihood of future pregnancies

Mechanism of Action

Copper IUC:

- Contraceptive effectiveness is enhanced by continuous copper release
- Intense copper and foreign-body reaction which is spermicidal
- Effect occurs before ova reaches uterus
- Few, if any, sperm reach the fallopian tubes
- Endometrial inflammation prevents implantation (secondary action)

• LNG IUS:

- Thickened cervical mucus
- Sperm motility inhibited
- Endometrium suppressed
- Weak foreign body reaction

IUCs are Not Abortifacients

- Following insemination sperm are not present in the tubes of IUD users
- Absence of hCG in the serum of 30 IUD users over 30 months
- Absence of normal, fertilized ova in flushed fallopian tubes of IUD users
- Reduced ectopic pregnancy rate

- Tredway, AmJOG 1975
- Segal, Fertil Steril 1985
- Alvarez , Fertil Steril 1988

Recovery of Tubal Sperm after Salpingectomy 2-36 Hours After Midcycle Coitus

	Control	Loop IUD
	(n=30)	(n=30)
Cervical mucus sperm	30	30
Tubal sperm	14	0

Rate of Ectopic Pregnancy:

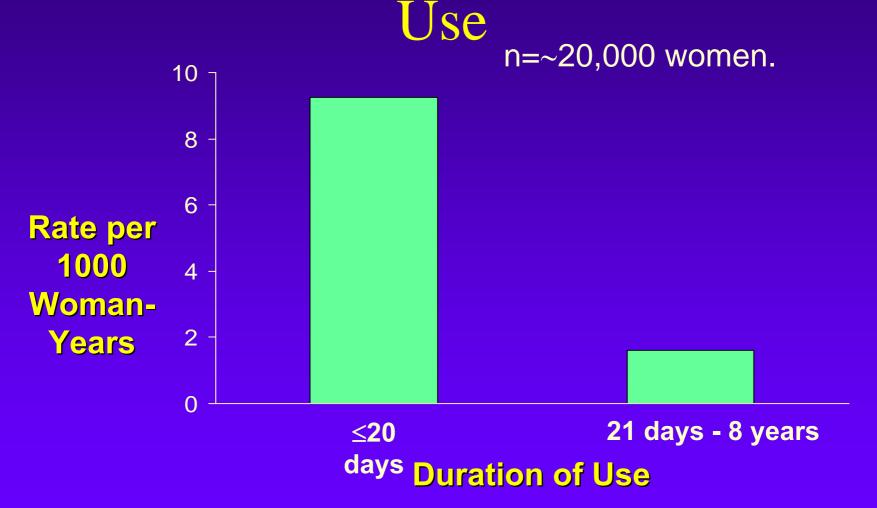
Rate Per 1000 Woman-Years

Method	Rate of Ectopic Pregnancy
Intrauterine Copper Contraceptives (380 mm ² of copper surface)	0.2
Levonorgestrel-releasing intrauterine contraceptive (20 mcg)	0.2
Cohabiting, non- contraceptors	3.25-4.50

Safety: IUCs Do Not Cause PID

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

Rate of PID by Duration of IUC



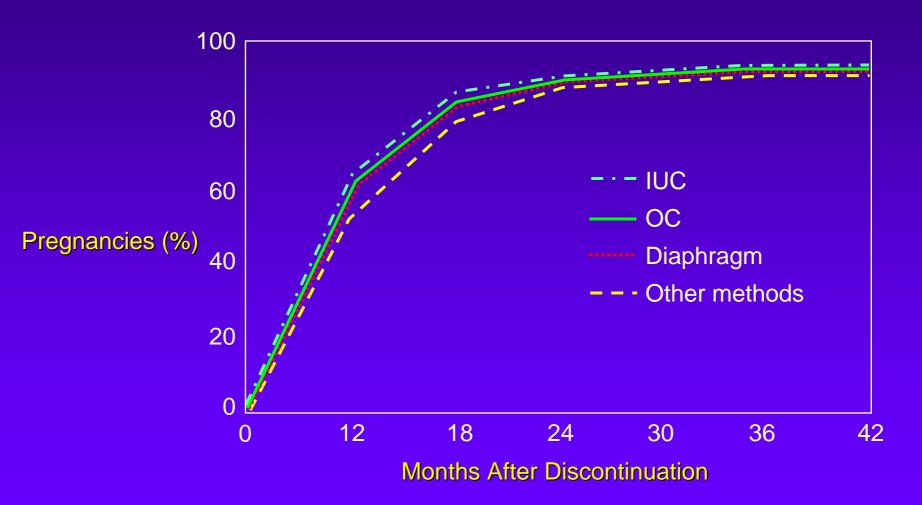
Adapted from Farley T, et al. *Lancet*. 1992;339:785-788.

Safety: IUC Use Compared with Pregnancy and Abortion

Event	Chance of Death in a year
Risk for women preventing pregnancy using IUC	1 in 10,000,000
Risk per pregnancy from continuing pregnancy beyond 20 weeks	1 in 10,000
Risk from terminating pregnancy with legal abortion before 12 weeks	1 in 181,000

Koonin LM, et al. *MMWR CDC Surveill Summ.* 1997. Lawson, et al. *Am J Obstet Gynecol.* 1994.

Safety: Fertility in Parous Women After Discontinuation of Contraceptive



Based on data from Vessey MP, et al. Br Med J. 1983;286:106.

Potential Side Effects

- During insertion
 - Variable pain and/or cramping
 - Vasovagal reactions
- First few days:
 - Light bleeding and mild cramping
- First few months
 - Intermenstrual bleeding, cramping
- CuT IUD: Heavier or prolonged menses
- LNG IUS: spotting, lighter menses
 - 20% amenorrhea at one year

Side Effects and Complications

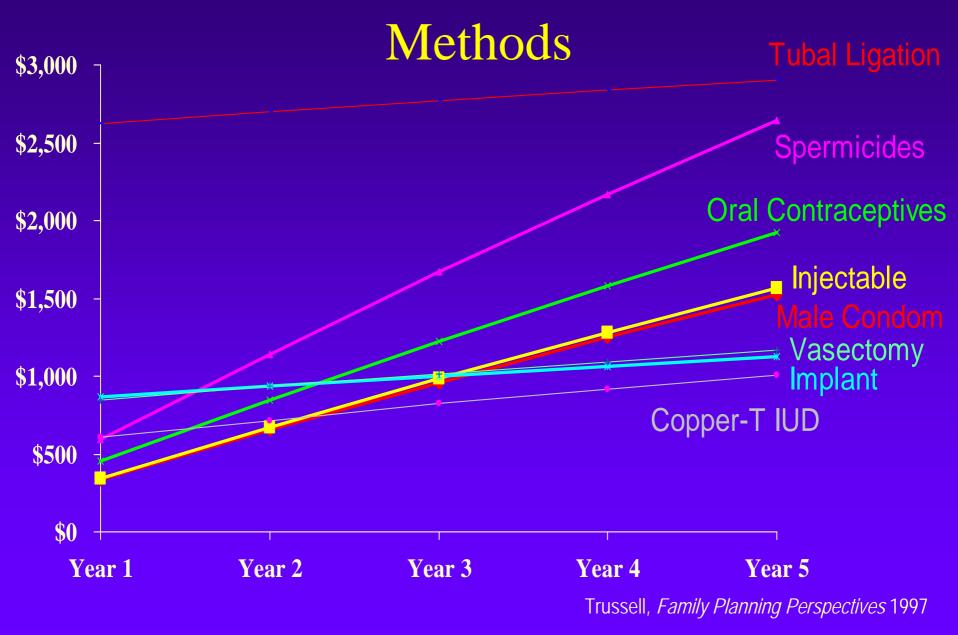
- Side effects
 - Menstrual effects
 - LNG IUS may have hormonal side effects
- Possible complications
 - Infection
 - Perforation
 - Pregnancy
 - Expulsion
 - Missing String

Comparison: Number of Bleeding Days



Cost-Effectiveness

Cumulative Costs of Selected



Non- Contraceptive Uses

Non-contraceptive uses: Endometriosis

- After primary surgery for endometriosis
 - Significant reduction symptoms for the LNG-IUS group compared with GnRH agonist (OR 0.14, 95% CI = 0.02 to 0.75)
 - More patients were satisfied with their treatment results in the LNG-IUS group (75%, 15/20) than in the control group (50%, 10/20)
 - Another study demonstrated efficacy starting LNG-IUD
 2 years after surgery
 - Benefit of intervention every 5 years, normal estrogen levels, compared to those on GnRH treatment

<u>Vercellini, 2003</u> <u>Petta, 2005</u>

Non-contraceptive use: Menorrhagia

- LNG IUS more effective than cyclical norethisterone
 - Women with an LNG IUS are more satisfied
 - Experience more side effects; intermenstrual bleeding and breast tenderness.
- Compared to endometrial ablation, the LNG IUS
 - Results in a smaller mean reduction in menstrual blood loss
 - Satisfaction is the same in both groups
- Compared to immediate hysterectomy
 - The LNG-IUS treatment costs less than hysterectomy
 - 20% of LNG-IUS users had undergone hysterectomy at one year, and 40% at 5 years
 - No difference in measured quality of life

Non-contraceptive Benefits of Intrauterine Contraception

	Protection against endometrial cancer	Alternative to hysterectomy or endometrial ablation	Treatment of menorrhagia/dysmenorrhea
Copper T IUD	$\sqrt{}$		
LNG IUS	√	√	√

Hubacher D, et al. *Obstet Gynecol Surv* 2002. Hurskainen, et al. *Lancet*. 2001. Andersson JK, et al.. *Br J Obstet Gynaecol*. 1990. Crosignani et al. *Obstet Gynecol* 1997

Patient Screening and Counseling for Intrauterine Contraception

Screening: Appropriate Candidates for Intrauterine Contraception

'Women of any reproductive age seeking longterm, highly effective contraceptive'

-Stephanie Teal, MD, MPH ARHP September 2004

IUC Candidates

• Refrain:

- Active, recent (3 months), or recurrent infection: PP endometritis, post septic abortion, active STIs, purulent cervicitis or pelvic TB
- Pregnancy
- Distorted uterine cavity
- Untreated cervical cancer, uterine cancer or malignant GTD or undiagnosed pathologic vaginal bleeding
- Wilson's disease (copper T)
- For LNG IUD: breast cancer

• Exercise caution:

- High risk for PID/STD (condoms recommended)
- Impaired response to infection
- For LNG IUD: migraine with aura, current DVT, heart disease, liver tumour/cirrhosis, past breast cancer

IUC Candidates

- Advantages outweigh disadvantages:
 - Valvular heart disease
 - Uterine fibroids without cavity distortion
 - Prolonged menses
 - Nulliparous women
- Not restricted:
 - Prior PID
 - Past ectopic
 - Irregular menses
 - Expulsion and patient would like to try again

Insertion Following Spontaneous or Induced Abortion

- May be safely inserted immediately following spontaneous or induced abortions
 - No increase in PID or perforation rates
 - Expulsion rates higher in immediate placement (1.9% in 3 months) versus interval, <13 wks
 - 43% of women didn't return for interval placement
 - Higher rates after second trimester abortion (19%)
 - T-shaped devices had half the rate of pregnancy and expulsion
- Do not use after septic abortion

IUC for Postpartum Women

May be safely inserted in postpartum women, without increasing bleeding or infection rates

- Immediately postpartum
 - After vaginal delivery, within 48 hours of placental expulsion
 - Lower expulsion rates if within 10 minutes (9% vs 16-30%)
 - Immediately after placental removal in caesarean section (4-10% at 6 months)
- Or starting at 4 weeks postpartum once uterus is involuted

Zhou, et al *Intl J Gynecol Obstet*, 1991 Treiman K, et al. *Population Reports*. 1995. Mishell DR Jr, Roy S. *Am J Obstet Gynecol*.1982;143:29.

IUC Use During Lactation

- For Copper IUDs:
 - Effectiveness not decreased
 - Uterine perforation unchanged
 - Expulsion rates unchanged
 - Decreased insertional pain
 - Reduced rate of removal for bleeding and pain
- Do not have similar data for LNG-IUS

IUD Candidates: HIV Positive Women

- No increased risk of complications compared with HIV negative women
 - No increase in PID
- No increased cervical viral shedding
- In AIDS
 - If clinically well, on ARVs, IUDs may be used

WHO. Medical Eligibility Criteria for Contraceptive Use.

Morrison. BJOG 2001.

Richardson et al. AIDS 1999.

Sinei et al. Lancet 1998.

European Study Group on Heterosexual Transmission of HIV. BMJ 1992.

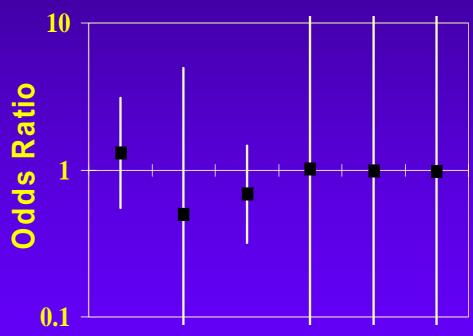
IUD Insertion and Management

Timing of Insertion

Timing	Pros	Cons
With menses	Ensures patient not pregnant	Scheduling; interim pregnancy
Mid-cycle/ Anytime	Convenience; low expulsion rate	Must rule out pregnancy

Prophylactic Antibiotics Before Insertion

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



Cu 380A Gross Removal and Continuation Rates

Event Ra	te (per 100 parous users at 1 yr)	
Infection	0.3	
Pregnancy	0.5	
Other medical	0.5	
Planning pregnancy	0.6	
Other personal	0.7	
Expulsion	2.3	
Bleeding/pain	3.4	
Continuation	92.1	

Manufacturer's prescribing information.

Signs of Possible Complications

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

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 strings	Partial or complete expulsion, perforation

Management of Cramping

- Mild:
 - Consider NSAIDs
- Severe or prolonged:
 - Examine for partial expulsion, perforation, or
 PID
 - Remove IUD 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

Management of Heavy Bleeding Lasting More Than 3 Months

- Examine for infection or fibroids
- Check for signs of anemia and treat, if needed
- Consider NSAIDs
- Remove device if medical indication or unacceptable to patient

Management of Missing String

- Rule out pregnancy
- Probe for strings in cervical canal
- Prescribe back-up contraceptive method
- Obtain ultrasound or x-ray, as needed
- IUD in abdomen should be removed promptly

Risk of Uterine Perforation

- Rare: 1/1000 insertions
- Linked to:
 - Uterine position and consistency
 - Skill/experience of provider with technique required
 - Time of insertion after childbirth
- Reduced through directed training and observation

Caliskan E, et al. *Eur J Contracept Reprod Health Care.* 2003.

Grimes, et al. Cochrane Library, 2001, Issue 2.

Markovitch O, et al. *Contraception* 2002.

Harrison-Woolrych M, et al. *Contraception* 2003.

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 in intrauterine pregnancy if strings available
- Removal decreases risk of
 - Spontaneous abortion
 - Premature delivery

Summary

- Efficacy equivalent to sterilization
- Proven safety
- Broader options for insertion timing
- Can be inserted after abortion or delivery
- Cost effective