



# Contraceptive Technology Update (CTU)

**MAQ Exchange**



## CTU: Objective

To present  
updated information on  
important current issues  
in contraceptive technology



# How the Information Was Selected

- ◆ **Programmatic relevance**
  - Improve programs
  - Change practices
- ◆ **Correct outdated and incorrect information**
- ◆ **Recently obtained**
- ◆ **Evidence-based**



# The Process for Selecting the Information

- ◆ Lead agency(ies)
- ◆ Multi-disciplinary review
- ◆ MAQ planning group
- ◆ Local needs assessment



# Eligibility Criteria: WHO 1996 Classifications (known conditions)

Classification of Known Conditions	Definition
1	no restriction on use
2	benefits generally outweigh risks
3	risks generally outweigh benefits
4	unacceptable health risk



# Classification of Selected Clinical Procedures to Be Done Before Providing a Method of Contraception

- ◆ **Class A:** *essential and mandatory* in all circumstances for safe and effective use of the contraceptive method
- ◆ **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context. The risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available
- ◆ **Class C:** does not contribute substantially to safe and effective *use* of the contraceptive method

**Source:** WHO. *Selected Practice Recommendations for Contraceptive Use*. 2002.



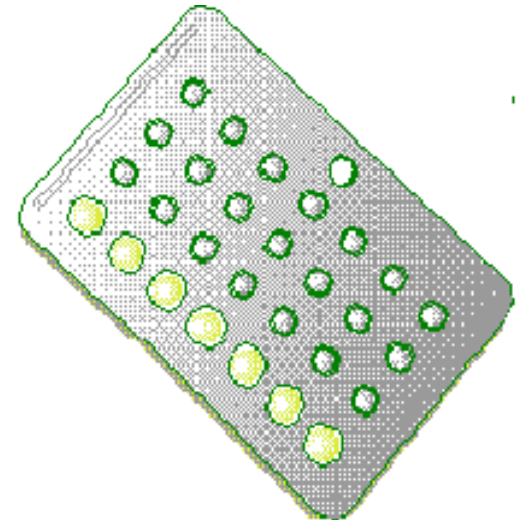
# Pills Have Changed Over Time

- ◆ **New pills are safer due to reduced hormonal dose**
- ◆ **Typical dosages by year (approximate)**
  - 1960s: 1970s: 50 mcg of ethinyl estradiol
  - 1980s: 1990s: 30 mcg of ethinyl estradiol
  - Present: 20 mcg of ethinyl estradiol (becoming available)



# COCs Have Non-Contraceptive Benefits

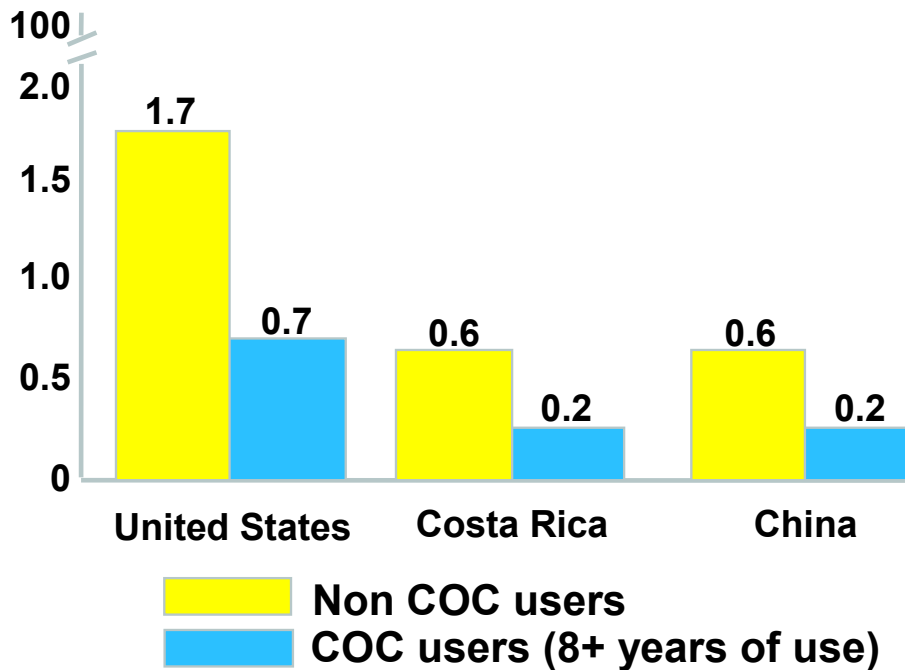
- ◆ Reduce the risk of:
  - benign breast disease
  - ovarian and endometrial cancer
  - functional ovarian cysts
  - ectopic pregnancy
  - symptomatic PID
- ◆ Menstrual improvements





# COCs Provide Ovarian Cancer Protection

Lifetime risk of acquiring ovarian cancer  
Number per 100 women



COCs reduce risk by more than 50%

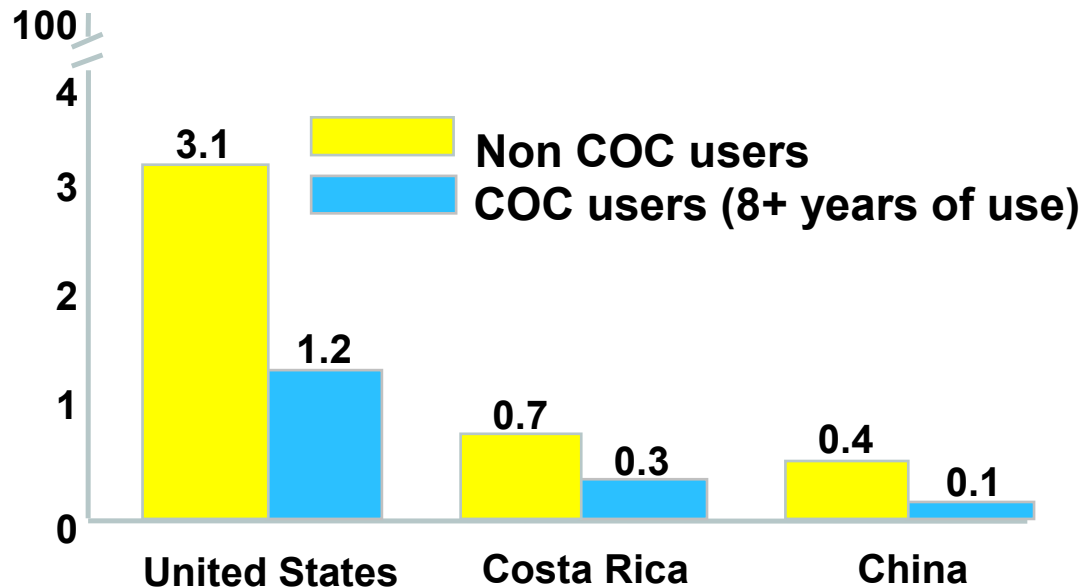
Protection develops after 12 months of use and lasts for at least 15 years

Source: Petitti and Porterfield, 1992.



# COCs Provide Endometrial Cancer Protection

Lifetime risk of acquiring endometrial cancer  
Number per 100 women



COCs reduce risk by more than 50%

Protection develops after 12 months of use and lasts for at least 15 years

Source: Petitti and Porterfield, 1992; CASH Study, 1987.



# Women Who Can Use COCs Without Restriction

*(Selected examples)*

- ◆ Adolescents
- ◆ Nulliparous women
- ◆ Postpartum (3 weeks, if not breastfeeding)
- ◆ Immediately postabortion
- ◆ Women with varicose veins
- ◆ Any weight (including obese)

*Source: WHO, Medical Eligibility Criteria for Contraceptive Use.  
Second Edition, 2000.*



# Women Who Should Not Use COCs

*(Selected examples)*

- ◆ **Breastfeeding (<6 weeks postpartum)**
- ◆ **Smoke heavily AND are over age 35**
- ◆ **At increased risk of cardiovascular disease**
- ◆ **Have certain pre-existing conditions (breast cancer, liver tumors or cancer, etc.)**
- ◆ **Pregnant\***

\*NA, no proven effects on the fetus, if taken accidentally during pregnancy

**Source: WHO, *Medical Eligibility Criteria for Contraceptive Use*.  
Second Edition, 2000.**



# When to Initiate COCs

- ◆ Anytime provider is reasonably sure woman is not pregnant
- ◆ Preferably during first 5 days of cycle
- ◆ If after day 5, use back-up for 7 days
- ◆ Postpartum:
  - not breastfeeding: delay 3 weeks
  - breastfeeding: delay 6 months or until discontinue breastfeeding
- ◆ Immediately after abortion



# How Can You Be Reasonably Sure a Woman is Not Pregnant

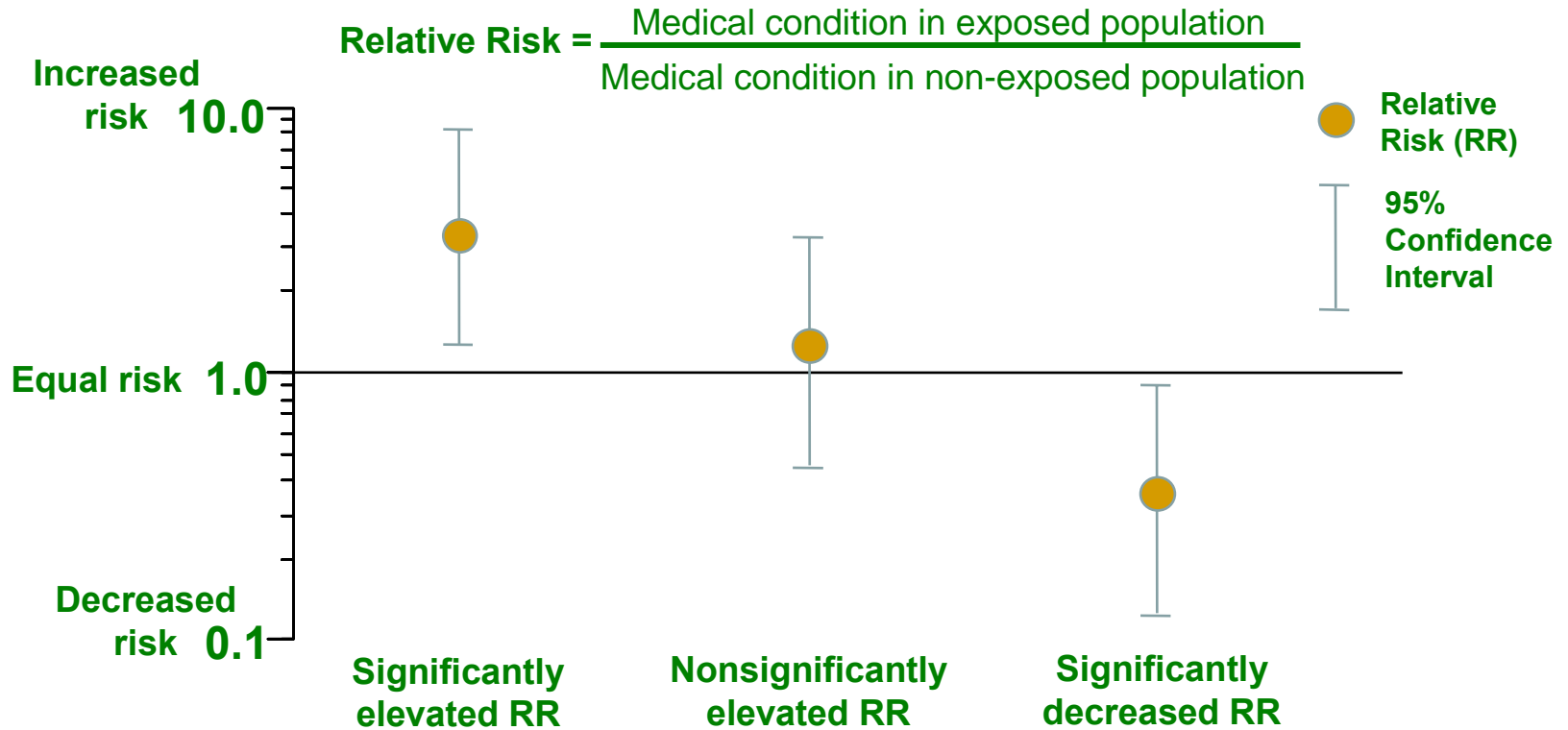
You can be reasonably sure if she has no symptoms or signs of pregnancy, and:

- ◆ has had no intercourse since last normal menses, **or**
- ◆ is correctly and consistently using another reliable method, **or**
- ◆ is within first 7 days after onset of normal menses, **or**
- ◆ is within 4 weeks postpartum (non-lactating women), **or**
- ◆ is within first 7 days postabortion, **or**
- ◆ is amenorrheic, fully breastfeeding and less than 6 months postpartum

**Source: TGWG: Recommendations for Updating Selected Practices in Contraceptive Use, 1994.**

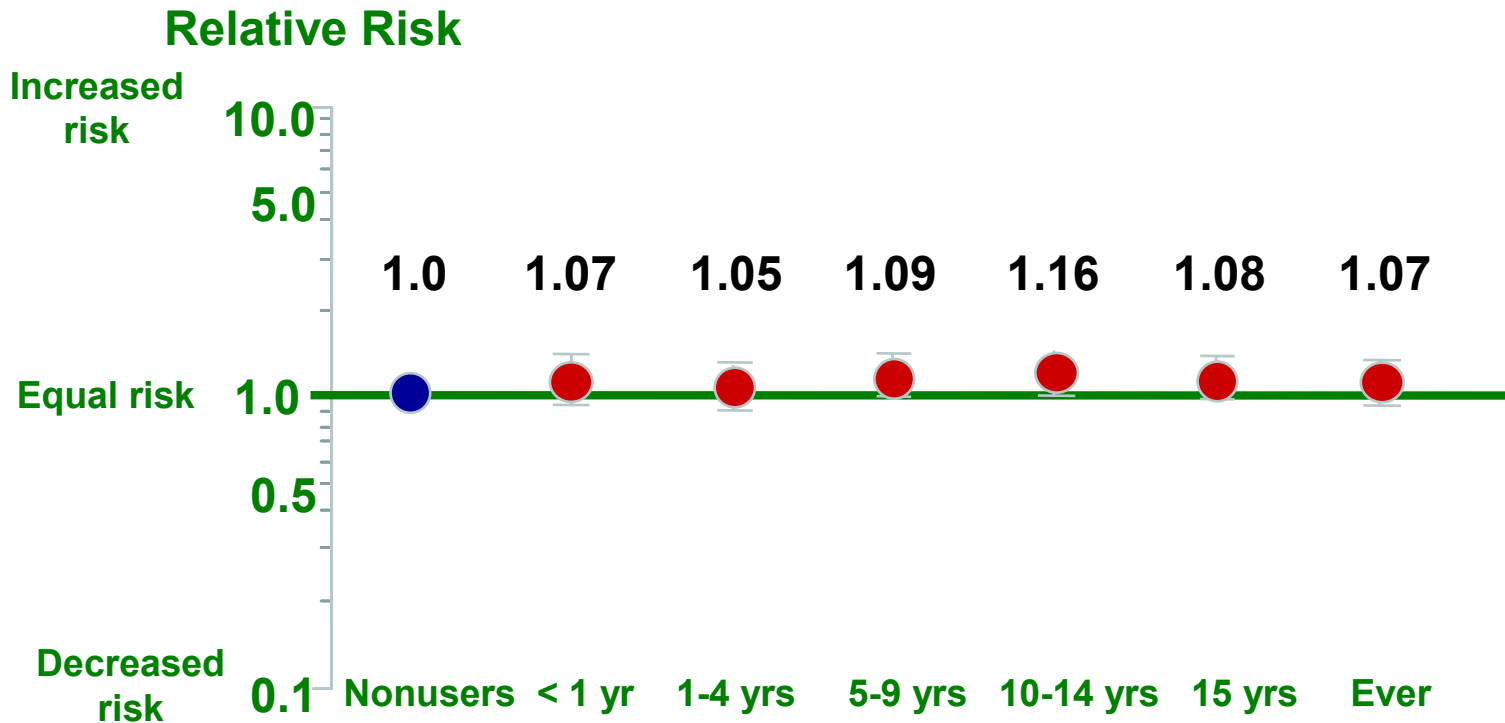


# Relative Risk with 95% Confidence Intervals





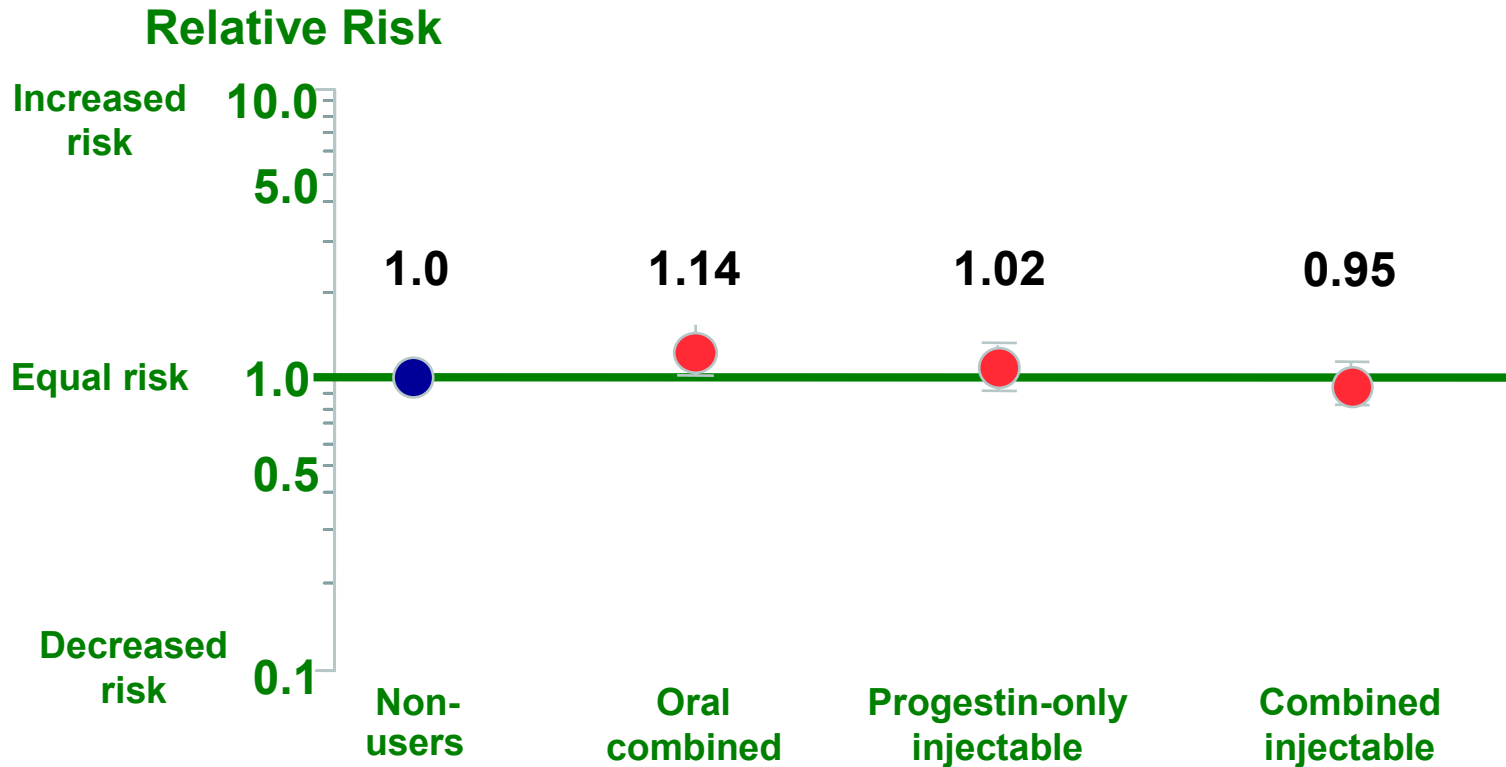
# Risk of Breast Cancer, by Duration of COC Use



Source: Collaborative Group on Hormonal Factors in Breast Cancer, *Lancet* 1996.



# Risk of CVD and Use of Hormonal Contraceptives



Source: WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, *Contraception* 1998; 57: 315-324.



# Characteristics of Progestin-Only Pills (POPs)

**Especially suitable for breastfeeding women and others who should not use estrogen**

- ◆ **Contain no estrogen**
- ◆ **Less progestin than COCs**
- ◆ **All pills in pack are active**
- ◆ **Progestin amount same throughout**
- ◆ **Continuous use**
- ◆ **Must be taken at same time every day**



# Client Access and Availability to Oral Contraceptives

- ◆ Use many types of trained providers
- ◆ Use less formal approaches such as community-based services:
  - health structure linkage desirable
  - initial screening checklists useful
  - training and supervision necessary
  - educational materials recommended
  - operational re-supply system needed



# No Age and Parity Restrictions for DMPA Use

**Women of any age and parity  
can use DMPA\***

**\* women under age 18 can “generally use”  
(WHO category 2)**

*Source: TGWG: Recommendations for Updating Selected Practices in Contraceptive Use, 1994 and WHO, Medical Eligibility Criteria for Contraceptive Use. Second Edition, 2000.*



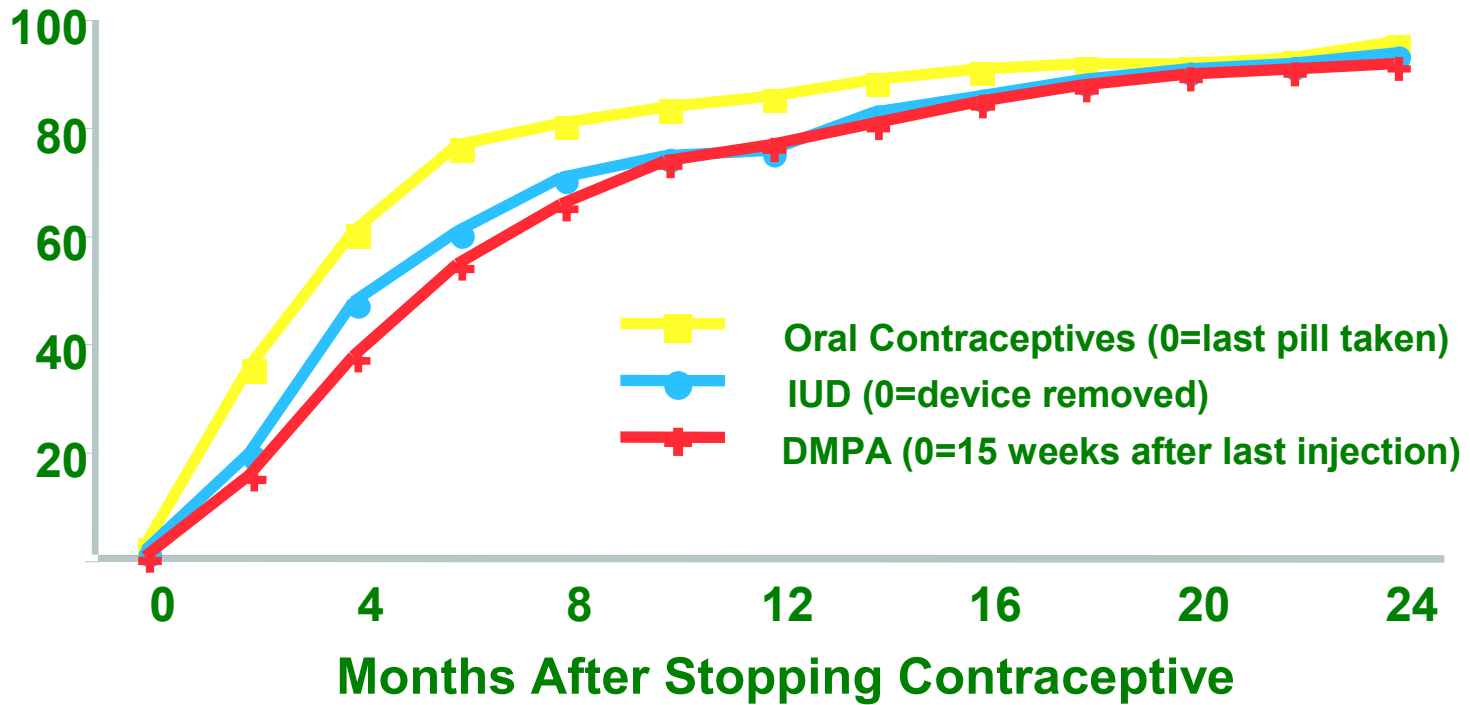
# Comparative Characteristics of DMPA and NET-EN

	DMPA	NET-EN
<b>Effectiveness</b>	<b>(no significant difference)</b>	
<b>Bleeding</b>	<b>More amenorrhea</b>	<b>More irregular</b>
<b>Needle/pain</b>	<b>Smaller/less</b>	<b>Larger/more</b>
<b>Reinjection window</b>	<b>2 - 4 weeks early or late</b>	<b>1 - 2 weeks early or late</b>
<b>Duration</b>	<b>3 months</b>	<b>2 months</b>
<b>Cost</b>	<b>Less expensive</b>	<b>More expensive</b>



# Return to Fertility After Stopping DMPA Use

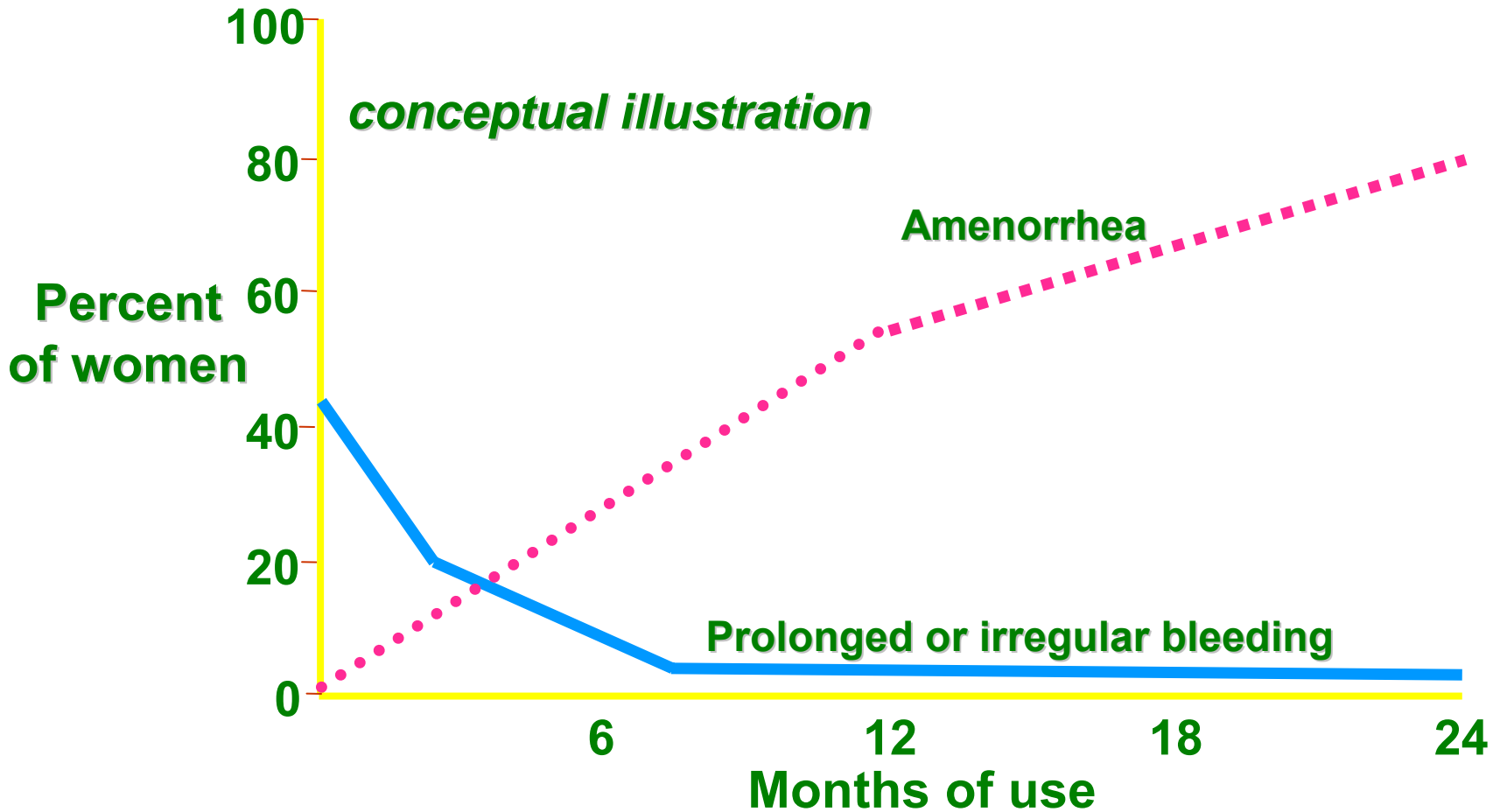
Percent of Women Having Conceived



Source: Tieng, 1982.



# Menstrual Changes During DMPA Use





# Types of Monthly Combined Injectables

Cyclofem  
(Cyclo-Provera):  
25 mg DMPA  
5 mg estradiol cypionate

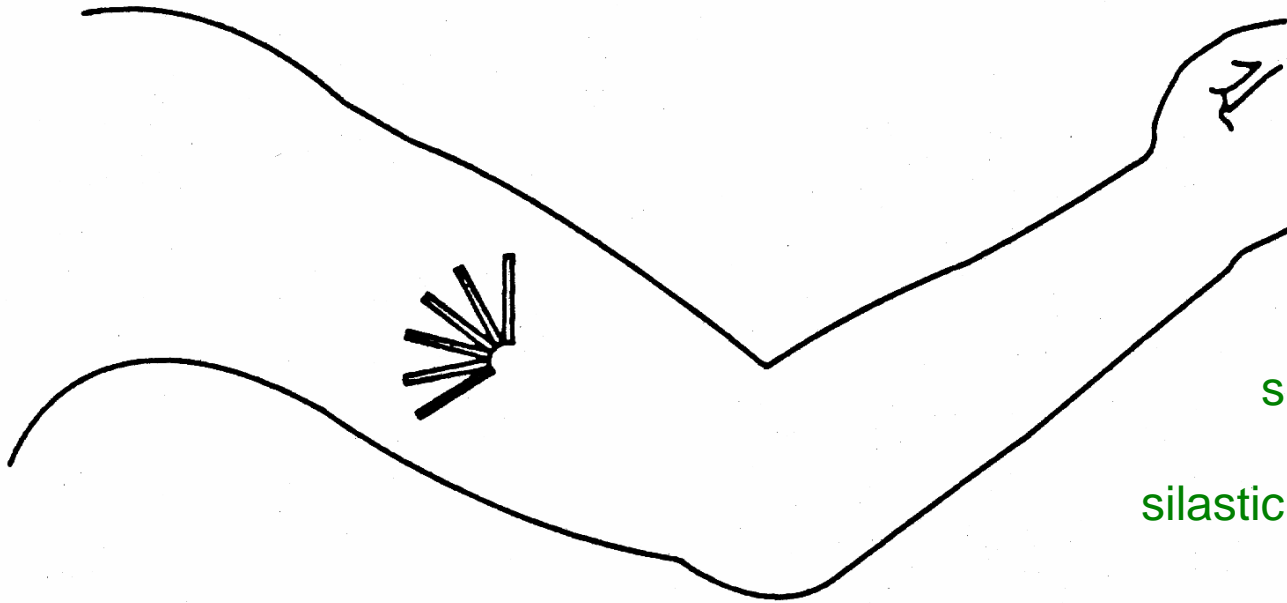
Mesigyna  
(Norigynon):  
50 mg NET-EN  
5 mg estradiol valerate



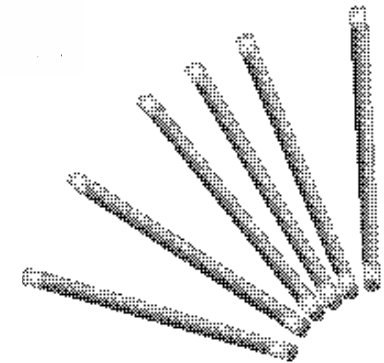
# Effectiveness of Injectable Contraceptives

Product	First Year Pregnancy Rate
DMPA	0.1
NET-EN	0.4
Cyclofem	0.2
Mesigyna	0.4

# Norplant



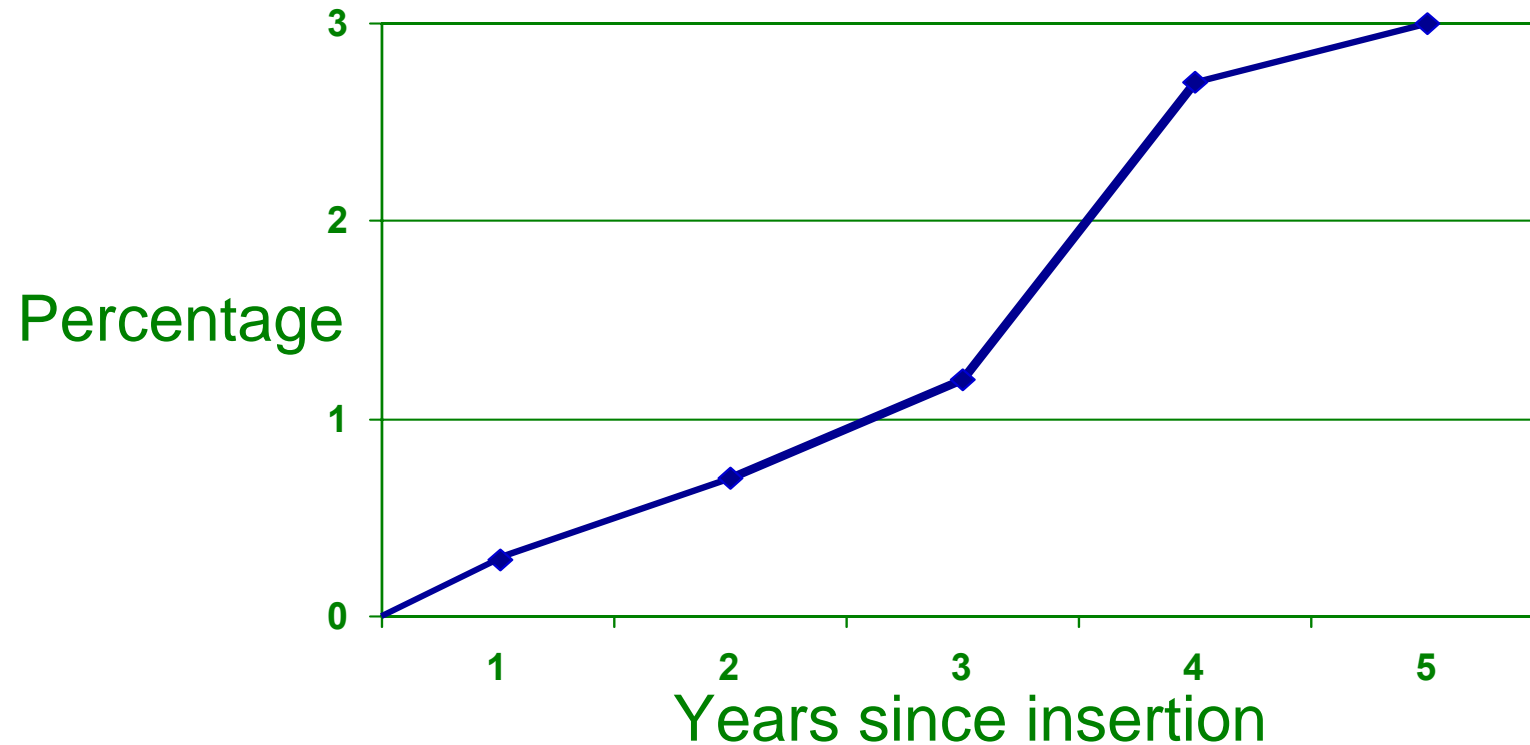
silastic tubing  
with  
silastic medical adhesive





# Efficacy of Norplant

## Cumulative gross rate of pregnancy

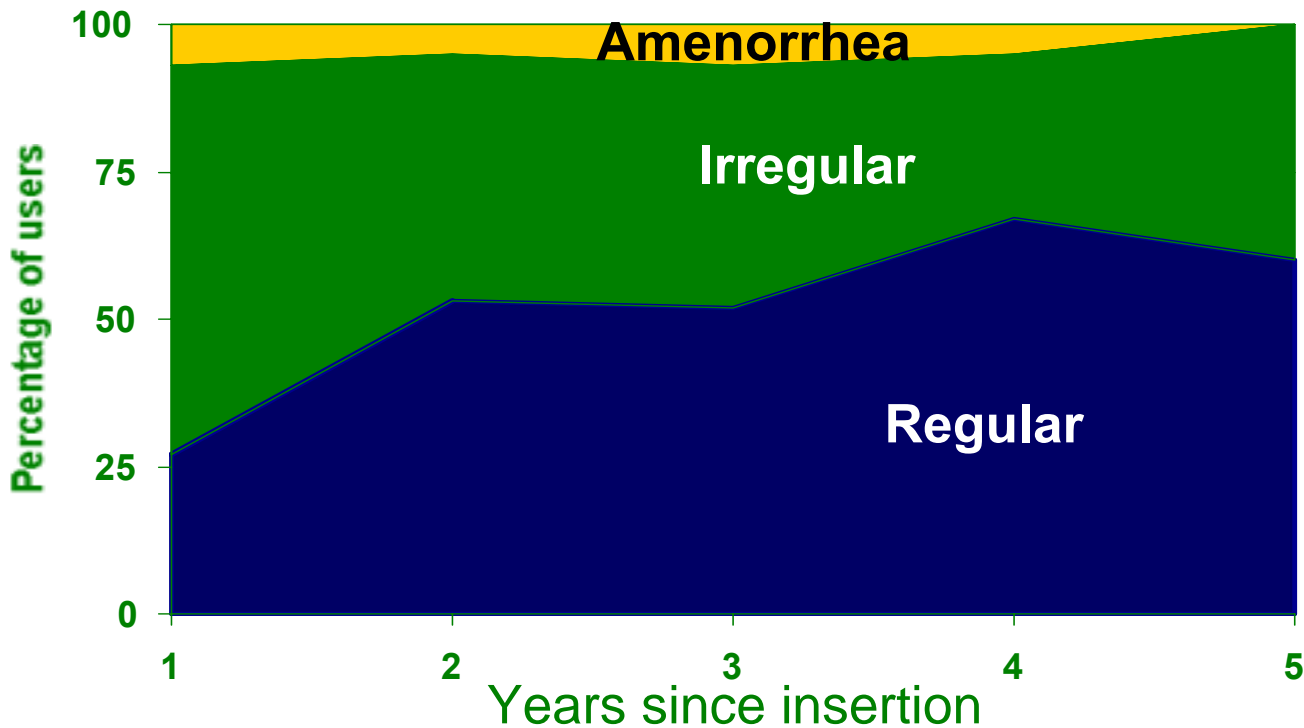


Source: Sivin et al, *Studies in Family Planning*, 1983; 14:184.



# Norplant Bleeding Patterns

Dominant patterns of bleeding



Source: Shoupe et al, *Obstetrics and Gynecology*, 1991.



# What are Emergency Contraceptive Pills (ECPs)?

Use of  
contraceptive pills

after unprotected intercourse  
to prevent pregnancy



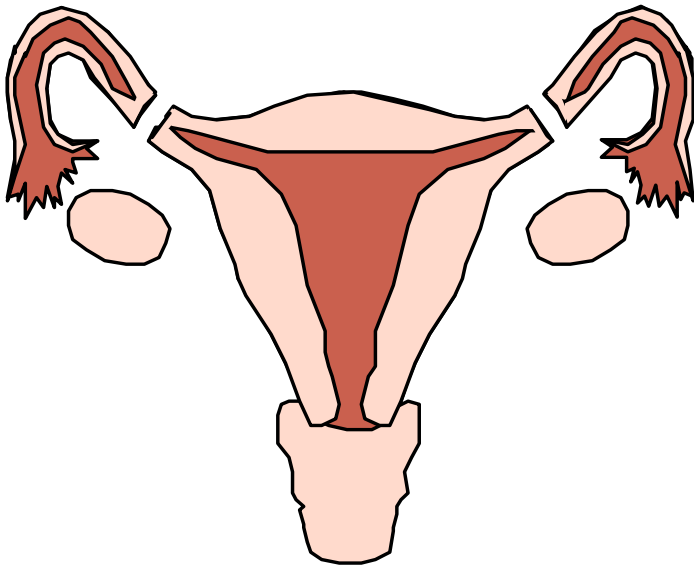
# Types of ECPs

- ◆ **Combined oral contraceptive pills**
  - containing ethinyl estradiol and levonorgestrel
  
- ◆ **Progestin-only oral contraceptive pills**
  - containing levonorgestrel

**Use only pill brands containing these hormones**

# Possible Mechanisms of Action of ECPs

Depending on when used during cycle, may:



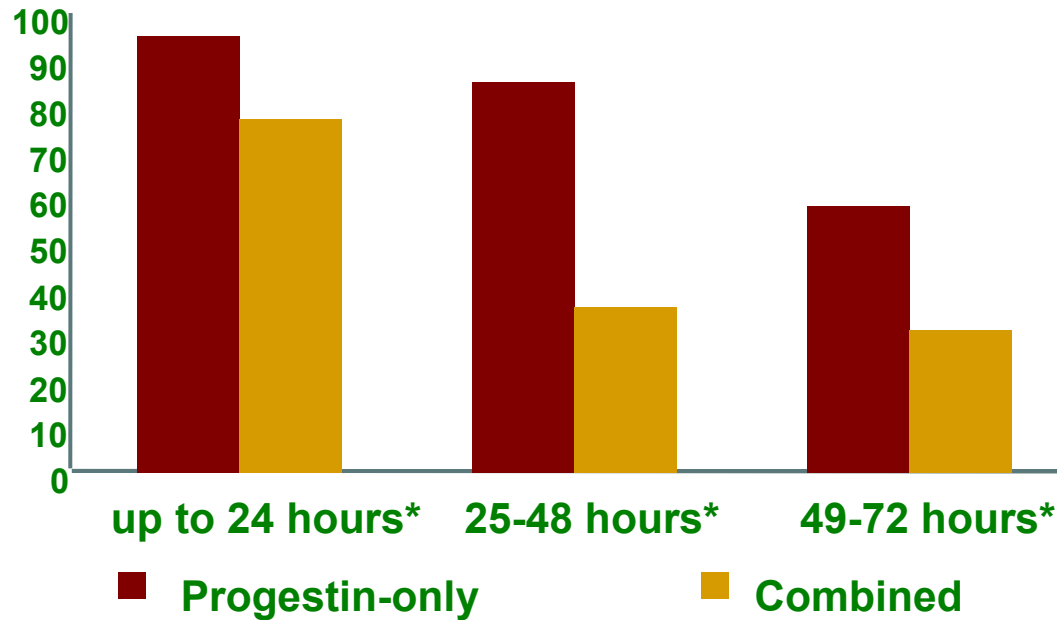
- ◆ inhibit or delay ovulation
- ◆ affect sperm and ovum function
- ◆ have possible effects after fertilization

EC pills do not interrupt an established pregnancy



# ECPs Are Most Effective When Taken Early

Percentage of pregnancies prevented



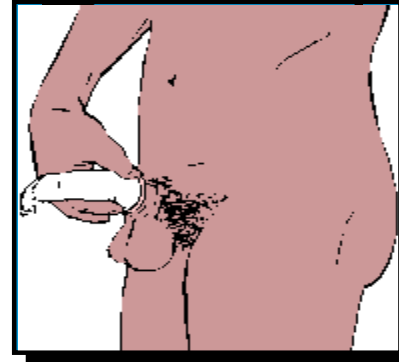
\* Timing refers to when regimen initiated

Source: WHO Task Force, *Lancet*, 1998; 352: 428-33.



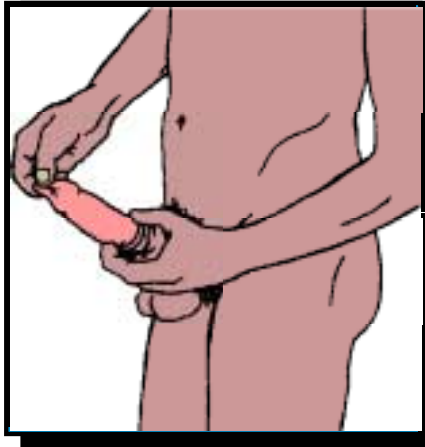
# Correct Use of the Male Condom

Open package carefully

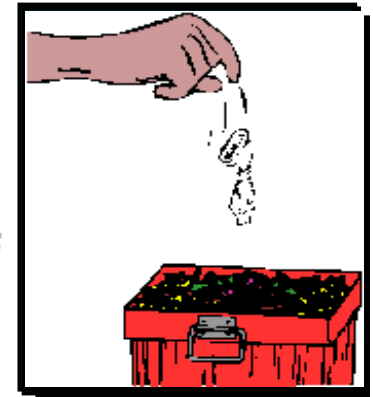


After intercourse, remove penis, while it is still erect, from vagina, holding onto condom

Unroll condom all the way to base of erect penis before genital contact

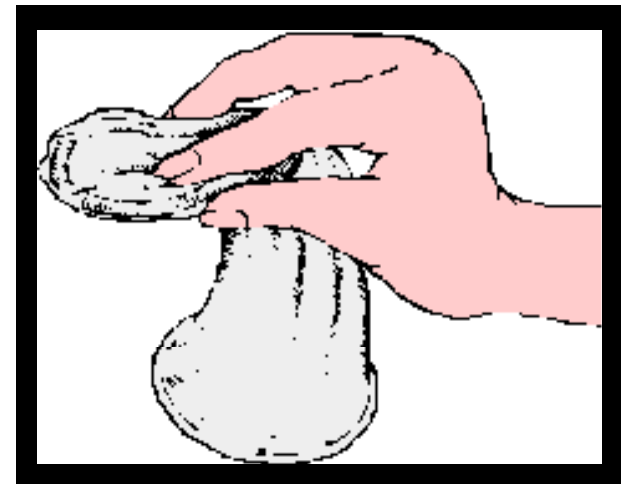
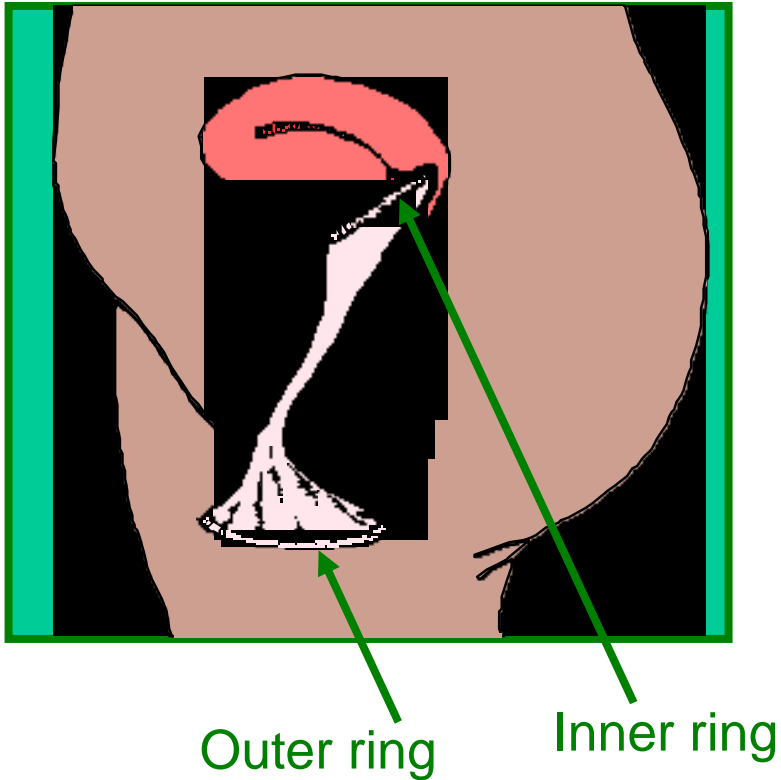


Dispose of condom properly



# Female Condom

Plastic sheath  
with ring  
at both ends

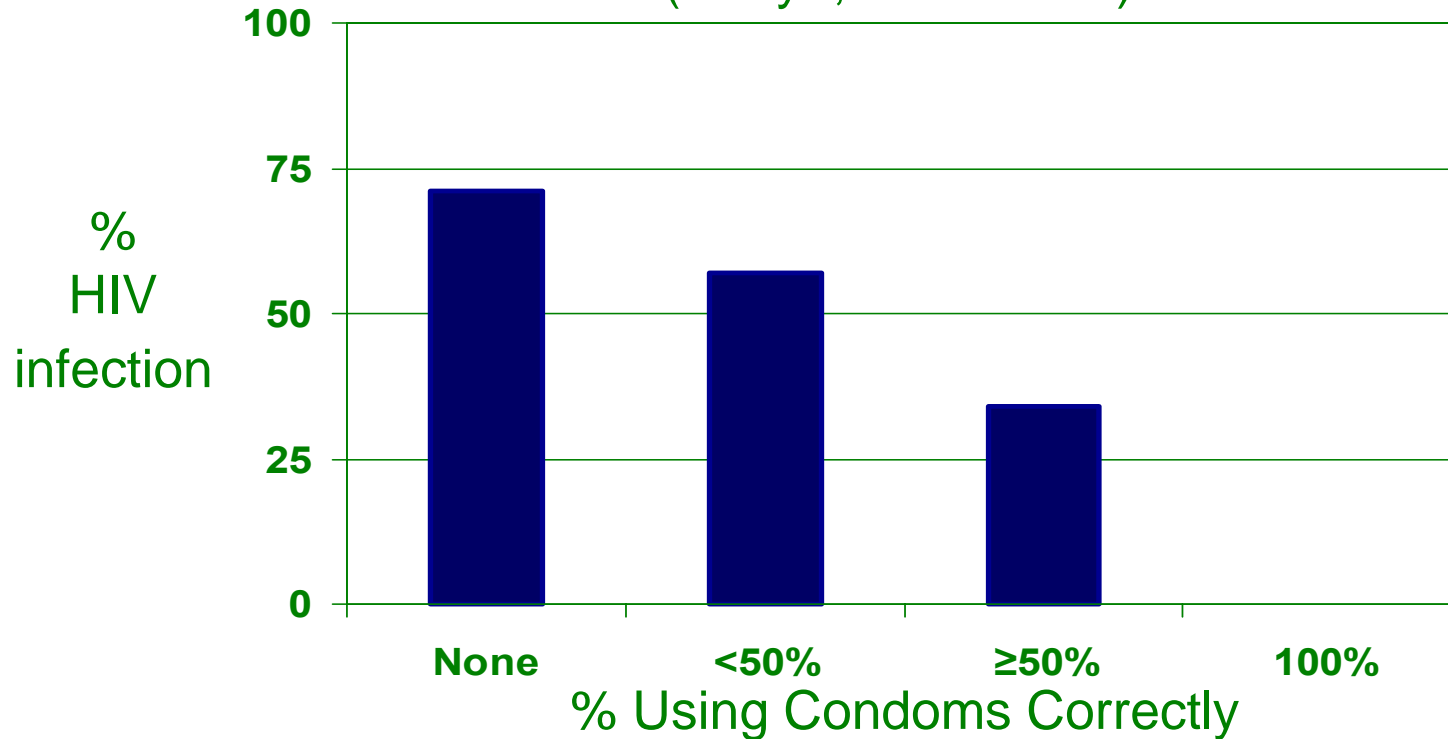


Grasping female condom  
for insertion



# Male Condom Protects Against HIV

Condom use among commercial sex workers  
(Kenya, 1985-1986)



Source: Ngugi et al, 1988.



# Dispelling Myths About IUDs

## IUDs...

- ◆ are not abortifacients
- ◆ do not cause infertility
- ◆ are unlikely to cause discomfort for male partner
- ◆ do not travel to distant parts of body
- ◆ are not too large for small women





# Main Mechanism of Action for Copper IUDs is Prevention of Fertilization

Precise mechanism of action not understood, but good evidence exists that copper IUDs work before fertilization

- ◆ **Few viable sperm found in fallopian tubes**
  - copper IUD inhibits sperm survival and transport
- ◆ **No detectable pregnancy even in first 10 days after ovulation**
  - copper IUD interferes with capacity of surviving sperm to fertilize egg

*Source:* Croxatto et al, Intl Conf on IUDs, 1994.

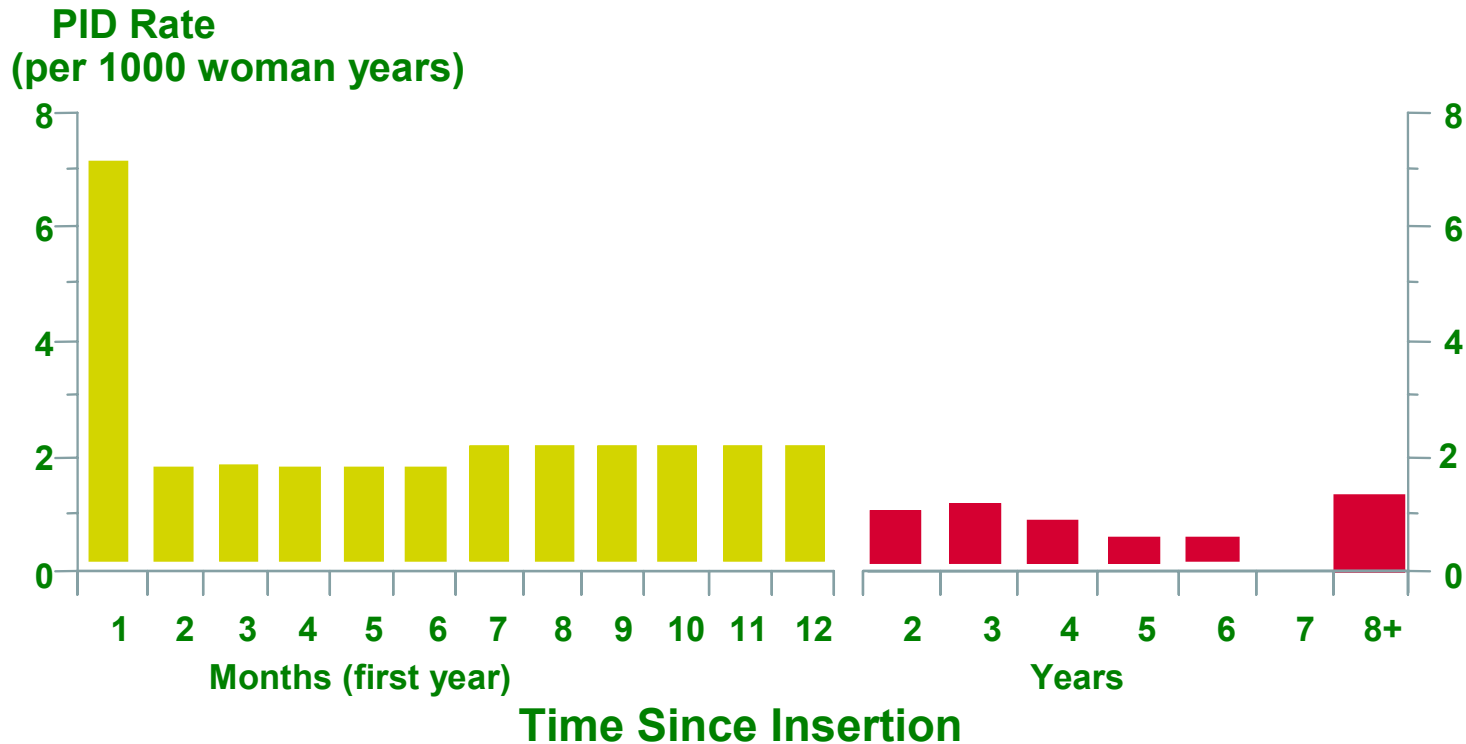


# Timing of IUD Insertion

- ◆ **Interval insertions:**
  - any time woman is not pregnant and has no signs of infection
- ◆ **Postpartum insertions:**
  - immediately after vaginal or caesarean delivery if no infection or hemorrhage (within 48 hours or delay 4 weeks)
- ◆ **Postabortion insertions (first trimester)**
  - immediately, if no infection



# Risk of PID is Highest in First Month After IUD Insertion



Source: Farley et al, 1992.



# Reducing Risk of PID in IUD Users

- ◆ **Screen clients for risk of STDs**
- ◆ **Counsel users about STD and PID risk factors**
- ◆ **Follow proper infection prevention insertion procedures**
- ◆ **Perform follow-up exam within 30 days of insertion**

**If these 4 steps taken, risk of PID is very low.**



# Women Who Can Use Copper IUDs

**Any woman who wants long-term, effective, reversible contraception**

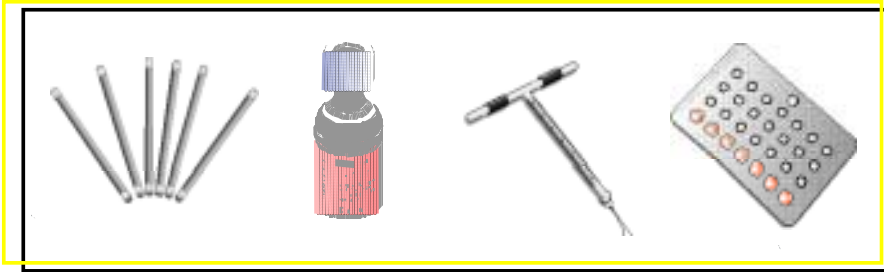
- ◆ **Especially suited for women who are**
  - at low risk of STDs
  - postpartum, postabortion, or breastfeeding
- ◆ **May be used by women who are:**
  - young
  - nulliparous

*Source: WHO, 1995.*

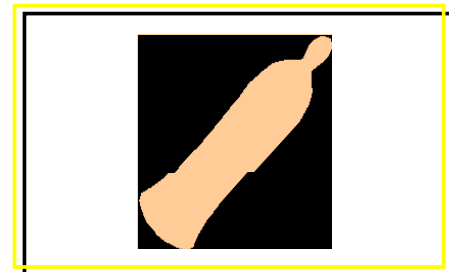


# Options for Dual Method Use

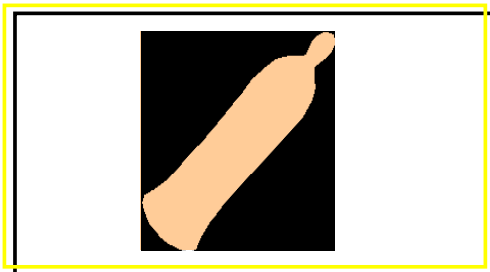
Primary method for pregnancy prevention



Condom added for STD prevention



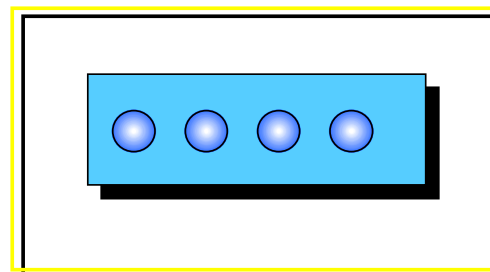
Primary method for STD and pregnancy prevention



Emergency contraceptive pills if condom not used, or if it breaks or slips



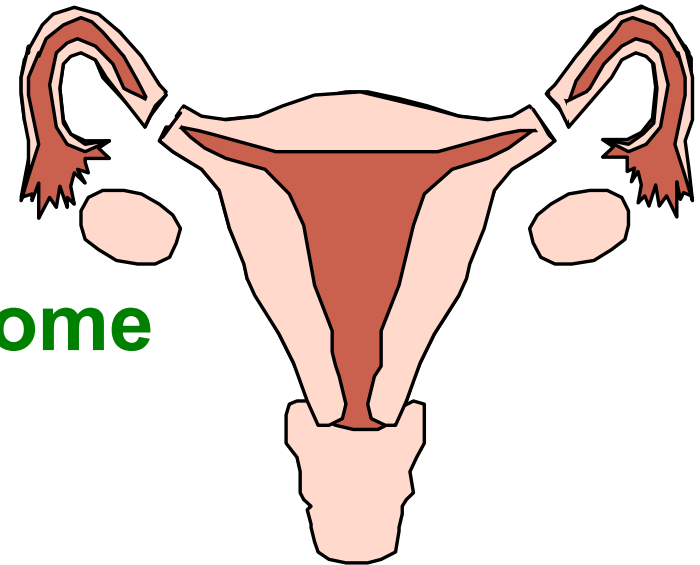
if needed





# Long-Term Health Impact of Female Sterilization

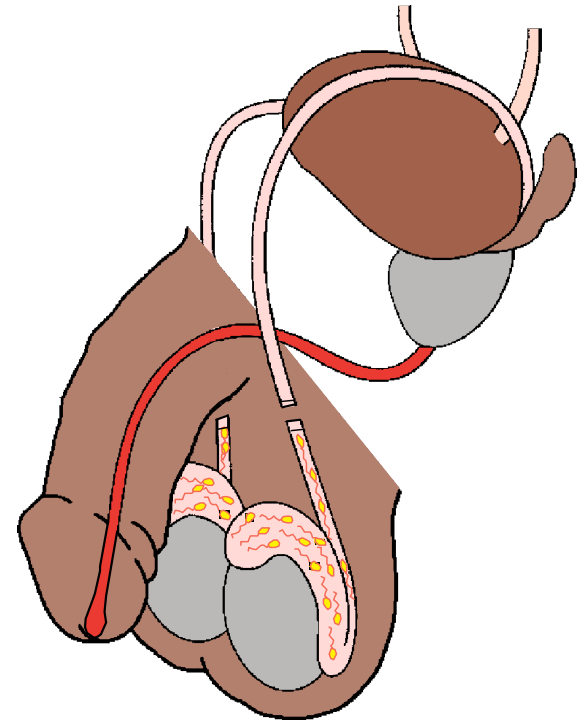
- ◆ Decreased ovarian cancer
- ◆ Decreased PID
- ◆ No post-sterilization syndrome
- ◆ Does not increase need for hysterectomy
- ◆ No HIV/STD protection





# Long-Term Health Impact of Vasectomy

- ◆ No association with testicular cancer
- ◆ No association with cardiovascular disease
- ◆ Probably no association with prostate cancer
- ◆ No HIV/STD protection





# Lactational Amenorrhea Method (LAM) is a Highly Effective Method

## LAM criteria:

- ◆ Menses not yet returned
- ◆ Infant less than six months
- ◆ Woman fully or nearly fully breastfeeding

*If any criteria change, start another method.*



# LAM Advantages

- ◆ **Universally available**
- ◆ **At least 98% effective**
- ◆ **No commodities/supplies required**
- ◆ **Bridge to other contraceptives**
- ◆ **Improves breastfeeding and weaning patterns**
- ◆ **Postpones use of hormones until infant more mature**



# LAM Efficacy Studies

	Chile	Ecuador	Pakistan	Philippines
# of women	422	330	391	485
Pregnancies	1	2	1	2
Effectiveness	99.55%	99.85%	99.42%	99.04%

Source: Perez et al, 1992; Sevilla et al, 1994; FHI, 1994.



# Natural Family Planning (NFP) Includes Various Methods

- ◆ **Withdrawal: removing penis before ejaculation**
- ◆ **Periodic abstinence: abstaining from intercourse during fertile time**
  - **calendar or rhythm**
  - **basal body temperature**
  - **cervical mucus**
  - **symptothermal**



# Characteristics of NFP

- ◆ **User-controlled**
- ◆ **Low cost**
- ◆ **Free from side effects and contraindications**
- ◆ **High pregnancy rates in typical use**
- ◆ **Requires training, motivation, and diligent monitoring**
- ◆ **Requires partner cooperation**



# Effectiveness of NFP

Percentage of women experiencing unintended pregnancy within first year of use

	Perfect use	Typical use
Calendar	9%	13%
Temperature	2%	20%
Mucus	3%	20%
Symptothermal	2-3%	13-20%

Source: Hatcher et al, *Contraceptive Technology*, 1998.



# Contraceptive Options for Youth

Age and Parity	Combined Hormonal Methods (Pills and Injectables), Condoms, Spermicides	Progestin-only Methods (Pills, Injectables and Implants)	IUDs	NFP, LAM
Under 18	No restriction	Can generally use	Can generally use	No restriction
18-20				
Over 20	No restriction	Can generally use	Can generally use	No restriction
Nulliparous				

Source: WHO, 2000.



# Contraceptive Pregnancy Rates

	Typical Use	Perfect Use
Norplant®	0.1	0.1
Vasectomy	0.15	0.1
DMPA/NET EN	0.3	0.3
Female sterilization	0.5	0.5
IUD (TCu-380A)	0.8	0.6
Progestin-only OCs during breastfeeding	1	0.5
LAM	2	0.5
COCs	6-8	0.1
Condom	14	3
Diaphragm w/spermicide	20	6
Fertility awareness-based methods	20	1-9
Female Condom	21	5
Spermicide	26	6
No method	85	85

**Very effective (0-1)**  
*Always very effective.*

**Effective (2-9)**  
*Effective as typically used.  
 Very effective when used perfectly.*

**Somewhat effective (10-30)**  
*Only somewhat effective as typically used.  
 Effective when used perfectly.*

*Adapted from: The Essentials of Contraceptive Technology, 1997.*



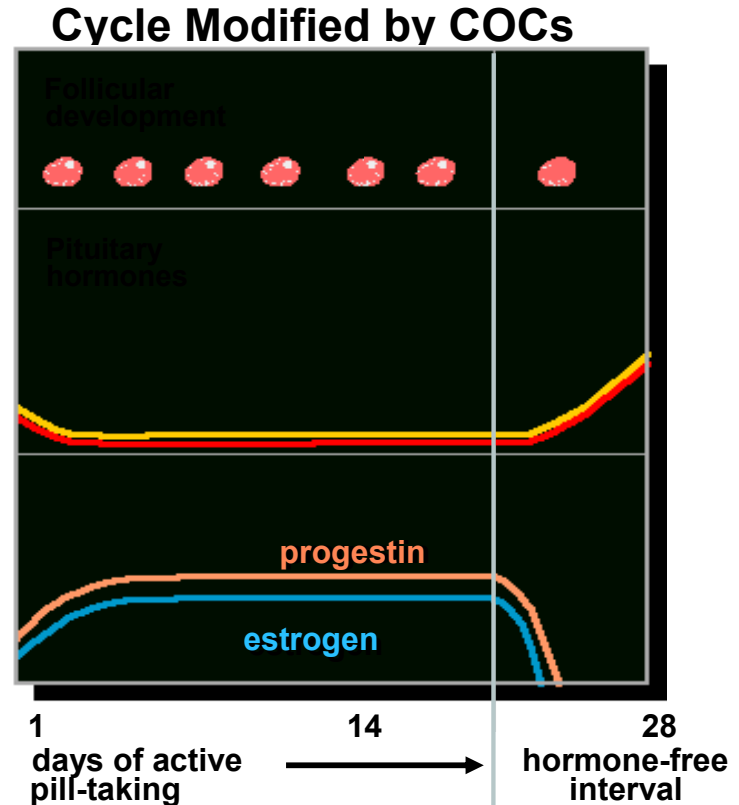
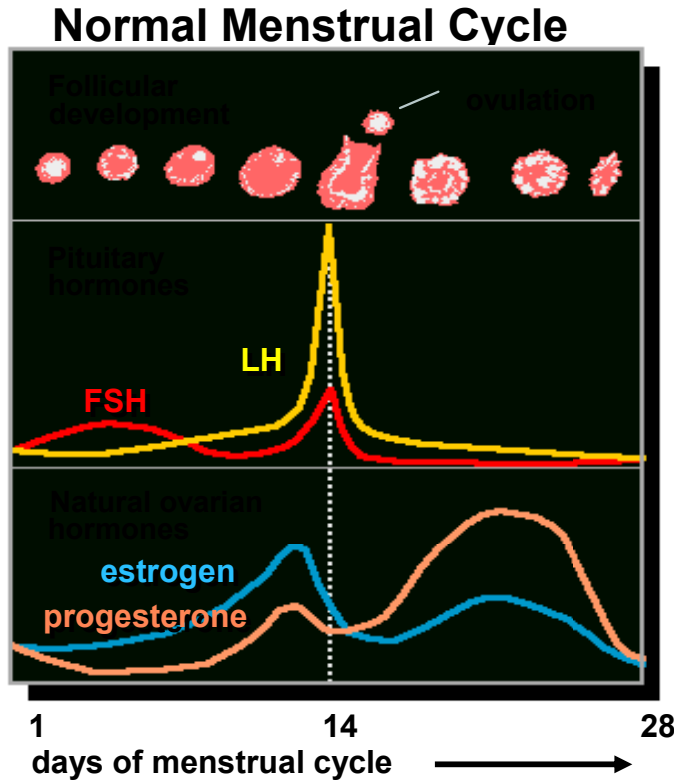
# CTU Summary

- ◆ Large variety of methods
- ◆ Minimal risks for clients
- ◆ Serious complications are rare
- ◆ New evidence-based eligibility criteria
- ◆ Many opportunities to initiate methods during the cycle
- ◆ When correctly used, all methods are more effective than no method
- ◆ Clients should be given their preferred (or desired) method whenever not medically contraindicated



# OPTIONAL SLIDES

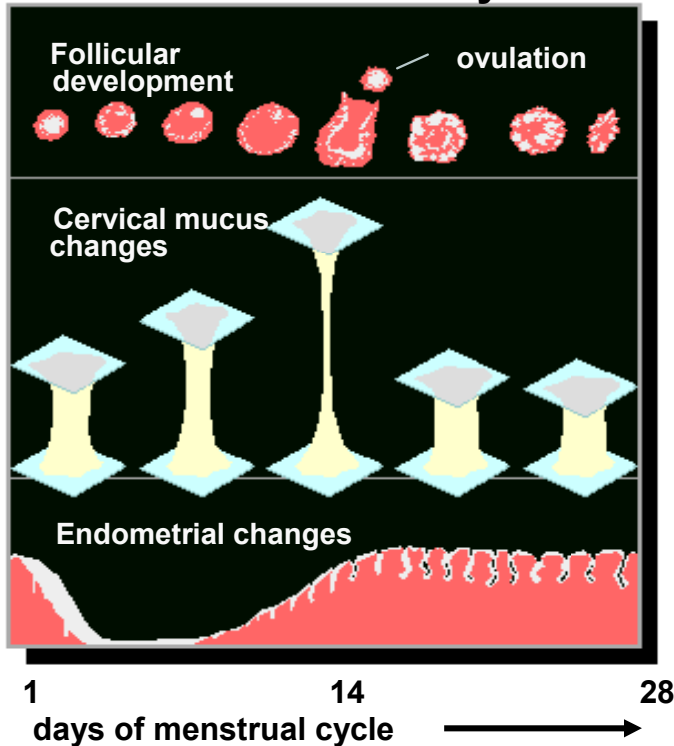
# COCs Mechanism of Action: Ovulation Suppression



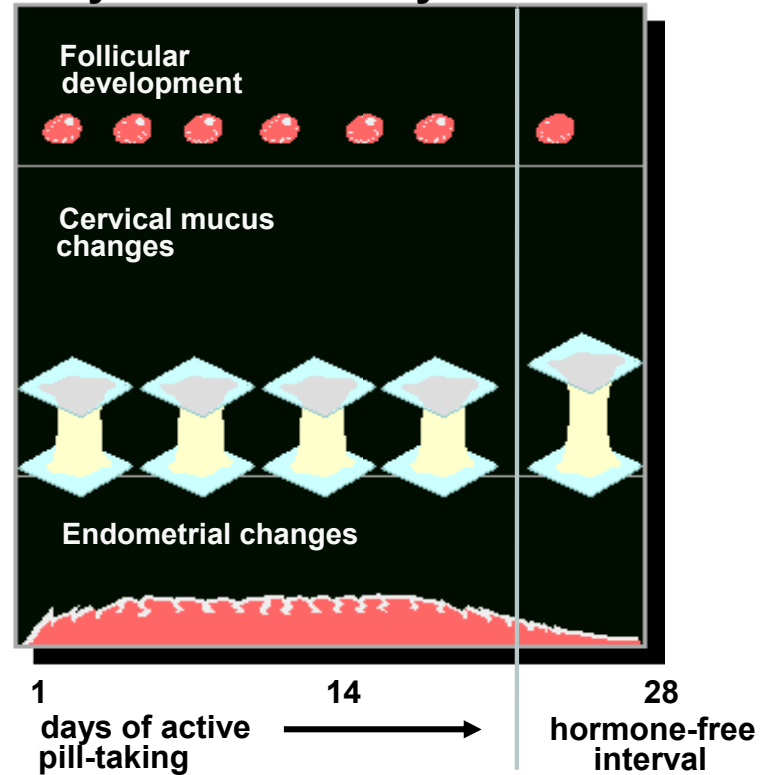
*Adapted from: Senanayake and Potts, 1995.*

# COCs Mechanism of Action: Mucus and Endometrial Changes

**Normal Menstrual Cycle**



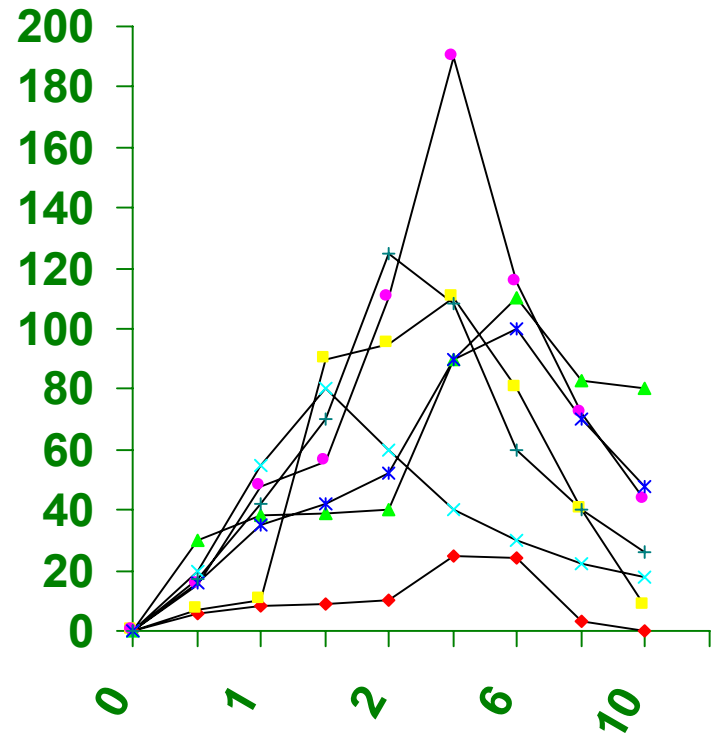
**Cycle Modified by COCs**





# Contraceptive Steroids Pharmacokinetics: Great Inter-Individual Variation

- ◆ Oral absorption
- ◆ Hepatic metabolism
- ◆ Enterohepatic recycling
- ◆ EE not bound by SHBG
- ◆ Progestins influence SHBG levels and are variably bound by SHBG



EE2 levels in seven women under constant conditions.

Source: Adapted from Goldzieher JW, *Am J Obstet & Gyn*, 1989.



# Hormonal Contraception in a Nutshell

	<b>Cervical Mucus</b>	<b>Inhibits Ovulation</b>	<b>Irregular Bleeding</b>	<b>Amenorrhea</b>
<b>Low P</b> without estrogen (Norplant, Minipill)	+++	+	++	+
<b>High P</b> without estrogen (DMPA)	++	+++	++	+++
<b>Low P</b> with estrogen (COCs)	+	++	+	-(+)

**P = Progestin**



# COCs Provide PID Protection

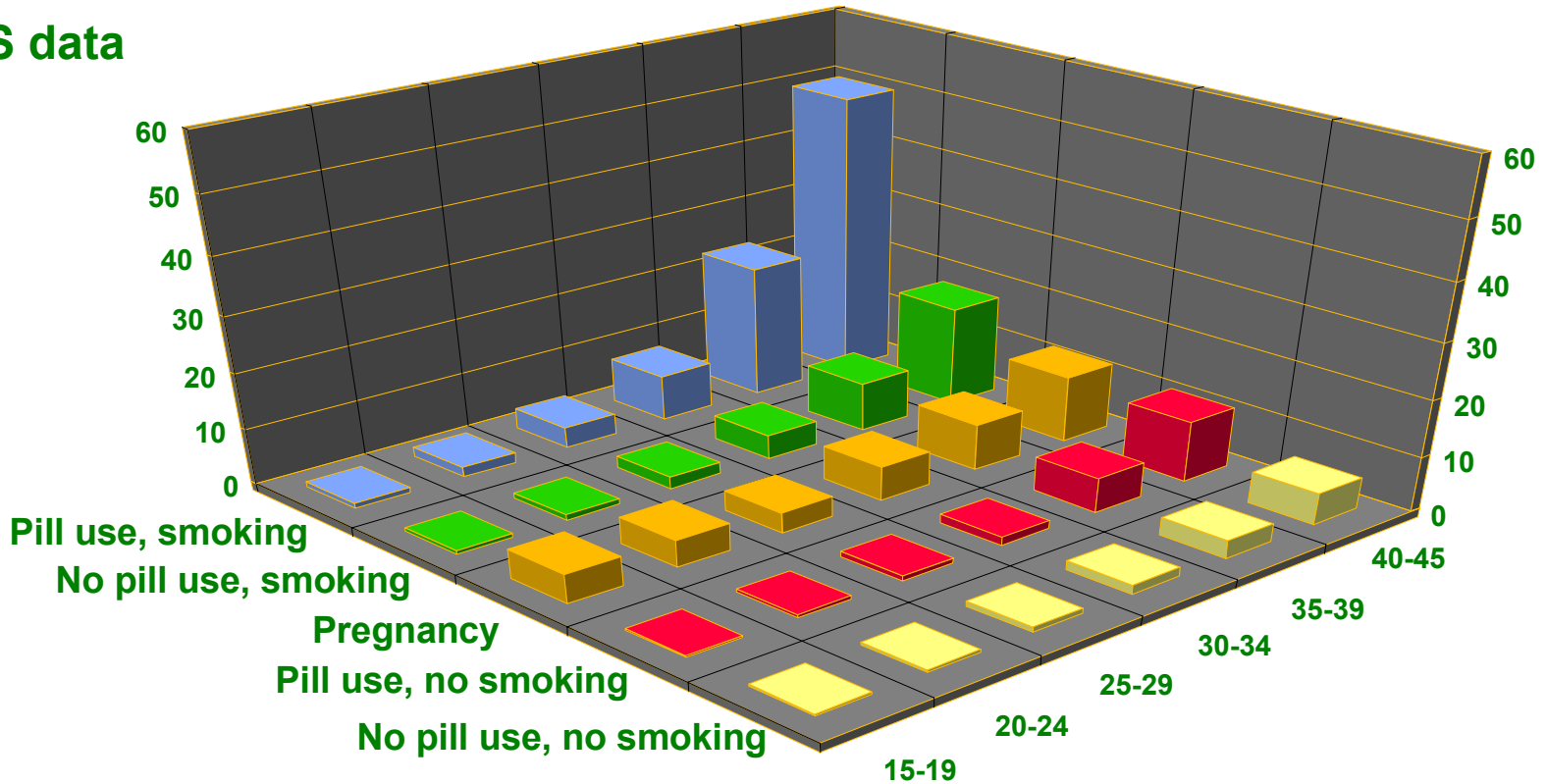
Methods	Relative Risk
None	1.0 (referent)
COCs	0.5 (0.4-0.6)
Short-term (1-12 mos.)	1.1 (0.8-1.5)
Long-term (13-24 mos.)	0.3 (0.2-0.4)

Source: Rubin et al, *Am J Obstet Gynecol*, 1982.



# COC Use and Estimated Annual Mortality Rates of CVD

US data



Source: Schwingl et al, 1997.



# Nonfatal Venous Thromboembolism May be More Common with Third Generation Pills

Situation	Rate (per 100,000 women/years)
No COC	5 - 11
COC with Desogestrel or Gestodene (3rd generation)	30
COC with Norethisterone or Levonorgestrel	15
Pregnant and postpartum women	60

Source: Vessey MP. *BJOG* 1997; 104:516.



# Meta-Analysis of Risk of Birth Defects with COC Ingestion During Pregnancy

	Number of Prospective Studies	Relative Risk	95% CI
Major congenital malformations	12	0.99	(0.93 - 1.19)
Congenital heart defects	8	1.06	(0.72 - 1.56)
Limb reduction defects	6	1.04	(0.30 - 3.55)

*Adapted from: Bracken MB, Obstet Gynecol, 76:552, 1990.*



# When to Initiate POPs

## ◆ Postpartum:

- breastfeeding: delay 6 weeks
- not breastfeeding: begin immediately

## ◆ Other women:

- anytime provider is reasonably sure that woman is not pregnant
- preferably within first 7 days of cycle
- after Day 7, use back-up for 7 days



# Advantages of POPs During Breastfeeding

- ◆ **Highly effective because of synergy with breastfeeding**
- ◆ **Bleeding irregularities are less common**
- ◆ **Less demanding schedule for correct use**



# Menstrual Bleeding Patterns During POP Use

Breastfeeding Women	Non-Breastfeeding Women
Irregular bleeding less common	Irregular bleeding, amenorrhea, or a combination are common
Amenorrhea more common	



# Switching and Discontinuing Use of POPs

- ◆ **Breastfeeding women:**
  - use POPs as long as desired
- ◆ **Non-breastfeeding women:**
  - may switch to another method any time
  - use back-up or abstain for 7 days after switching to other hormonal method
- ◆ **Discontinue pills any time; fertility returns rapidly**



# Provision of Pill Packs

- ◆ Can provide as many as possible, to guarantee continuous, ready access
- ◆ May be limited by programmatic, logistic or financial reasons
- ◆ Client should be able to obtain additional packs in the amount and at the time she requires

*Source: TGWG: Recommendations for Updating Selected Practices in Contraceptive Use, 1994.*

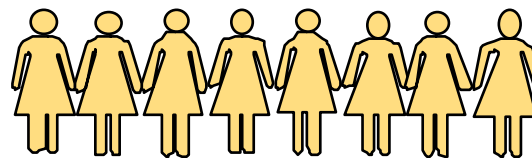


# Effectiveness of Combined Pills for Emergency Contraception

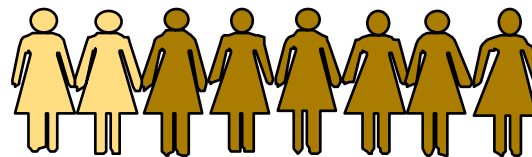
100 women have a single act of unprotected intercourse



*Emergency contraception not used*  
8 women would become pregnant



*Emergency contraception used:*  
2 women would become pregnant



Prevents 6 out of 8, or 75% of expected pregnancies

Source: Trussell et al. *Contraception*, 1998; 57: 363-69.

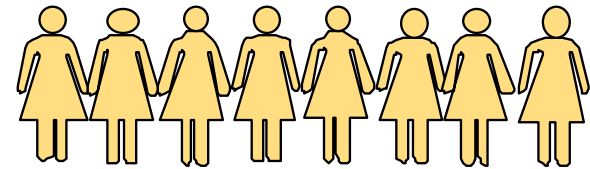


# Effectiveness of POPs for Emergency Contraception

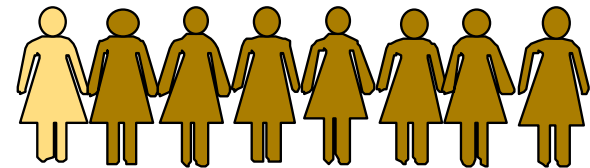
100 women have a single act of unprotected intercourse



*Emergency contraception not used:*  
8 women would become pregnant



*Emergency contraception used:*  
about 1 woman would become pregnant



Prevents 7 out of 8, or 85% of expected pregnancies

Source: WHO Task Force, *Lancet*, 1998; 352: 428-33.



# WHO Study: Comparison of Effectiveness of ECPs

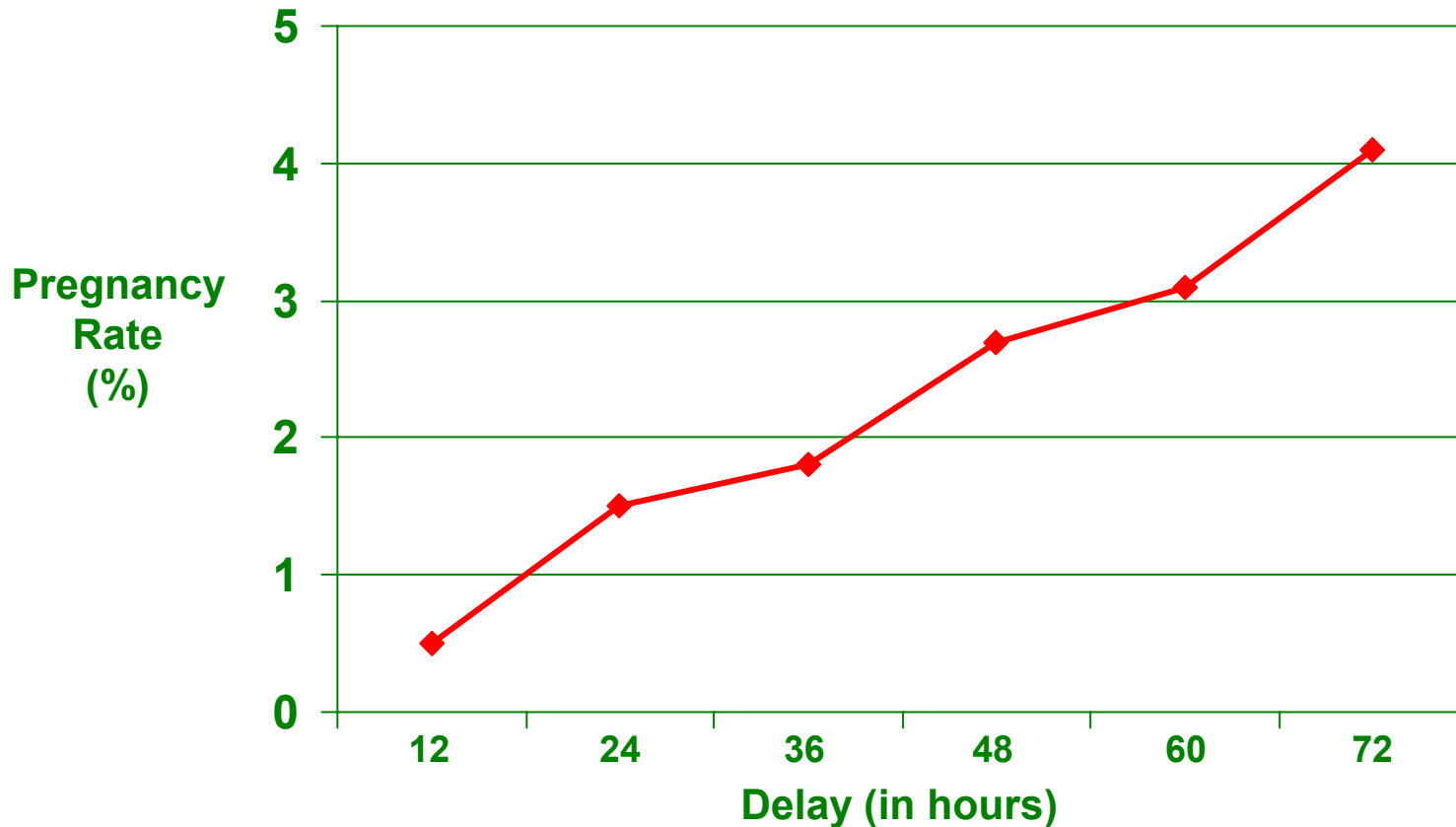
*Study shows progestin-only pills are more effective than combined pills*

Types of Pills	Percent of pregnancies prevented	
	Typical use	Correct use
Combined	57%	76%
Progestin-Only	85%	89%

Source: WHO Task Force, *Lancet*, 1998; 352: 428-33.



# Prompt Use of ECPs Increases Effectiveness



Source: G Piaggio, et al, *Lancet*. 1999.



## When to Initiate DMPA

- ◆ During first 7 days of cycle (with back-up for 7 days after Day 7)
- ◆ Anytime one is reasonably sure the woman is not pregnant
- ◆ Breastfeeding: 6th week postpartum
- ◆ Not breastfeeding: immediately postpartum
- ◆ Immediately following abortion

*Use as long as desired*



# DMPA Use in Breastfeeding Women

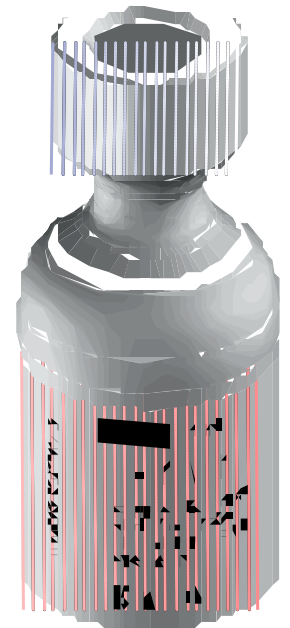
- ◆ **Studies show no effect on:**
  - **composition of breastmilk**
  - **initiation or duration of breastfeeding**
  - **growth and development of infant**
- ◆ **When to initiate:**
  - **after 6 weeks postpartum (preferred)**
  - **just before LAM expires, or whenever mother chooses**



# DMPA And Risk of Breast Cancer

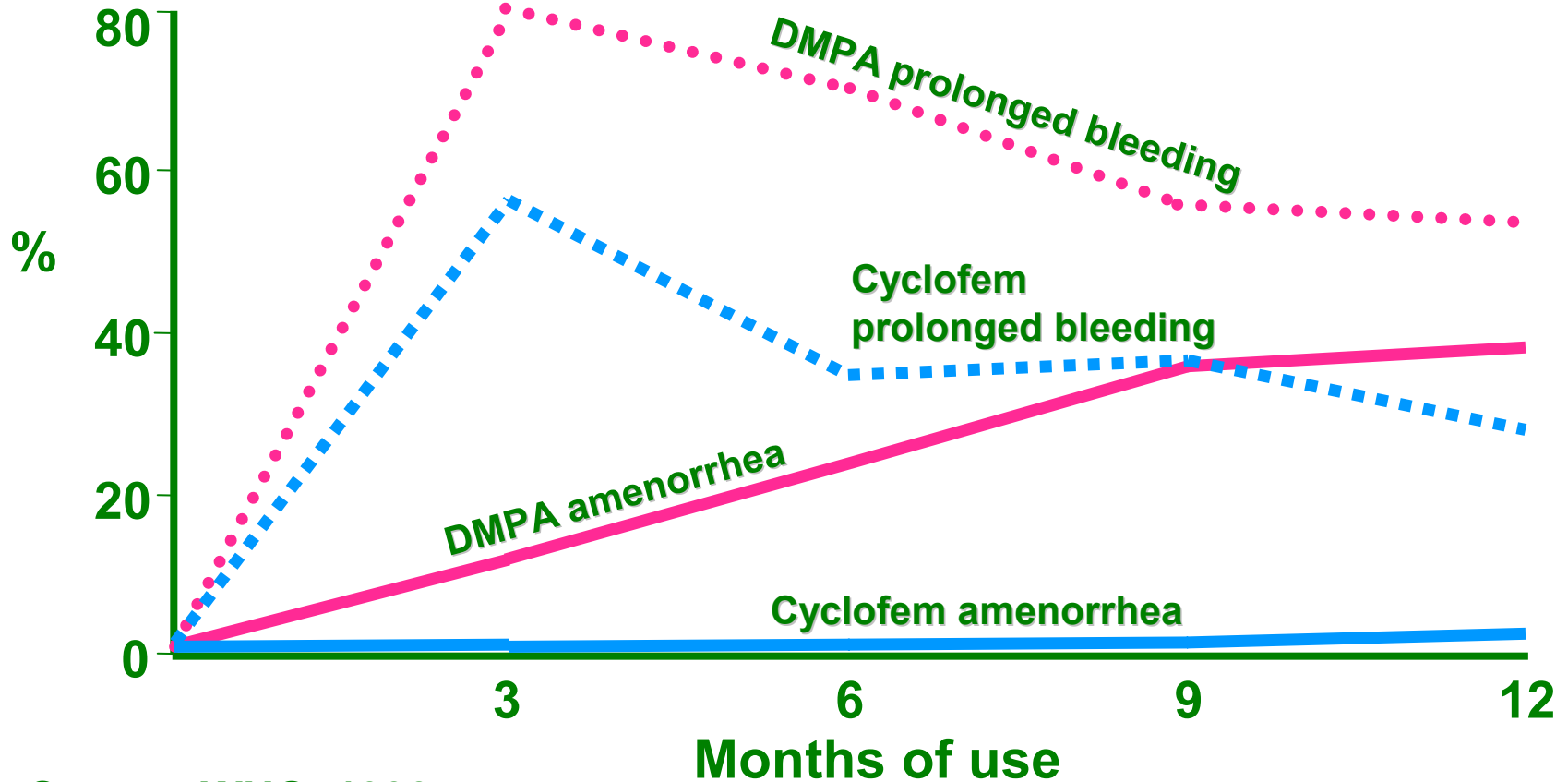
***No overall increase in cancer risk (WHO)***

- ◆ **Possibly slight increased risk in:**
  - women under 35
  - first 4 to 5 years of DMPA use
- ◆ **Probably due to accelerated growth of pre-existing tumors**





# Menstrual Changes During Injectables Use



Source: WHO, 1993.



# Lifetime of Copper TCu-380A IUD

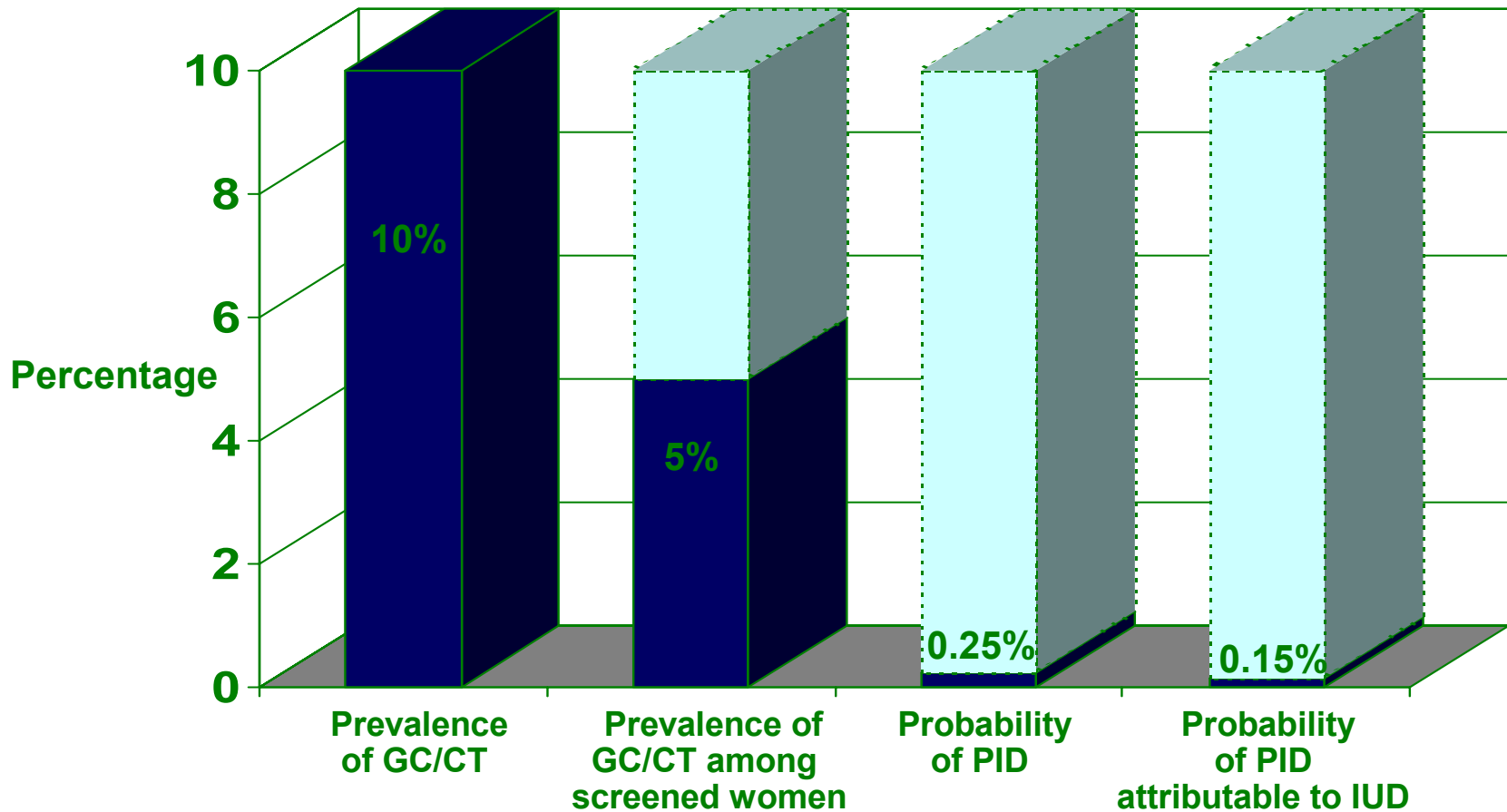
Intrauterine pregnancies, by year



Source: WHO, *Contraception*, 1997; 56: 341-52.



# Low Risk of PID to Individual IUD Users in Hypothetical High STD Setting



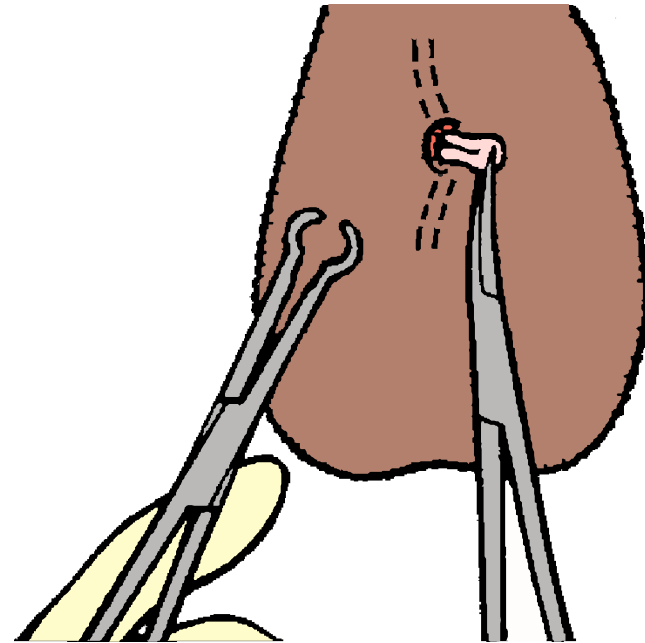


# Time-to-Effectiveness After Vasectomy

- ◆ Sperm count recommended
- ◆ Vasectomy not immediately effective
- ◆ Current recommendation:  
wait 12 weeks or 20 ejaculations
- ◆ Recent research suggests it could take  
even longer for *vas* to clear of sperm
- ◆ Back-up is recommended until  
vasectomy takes effect

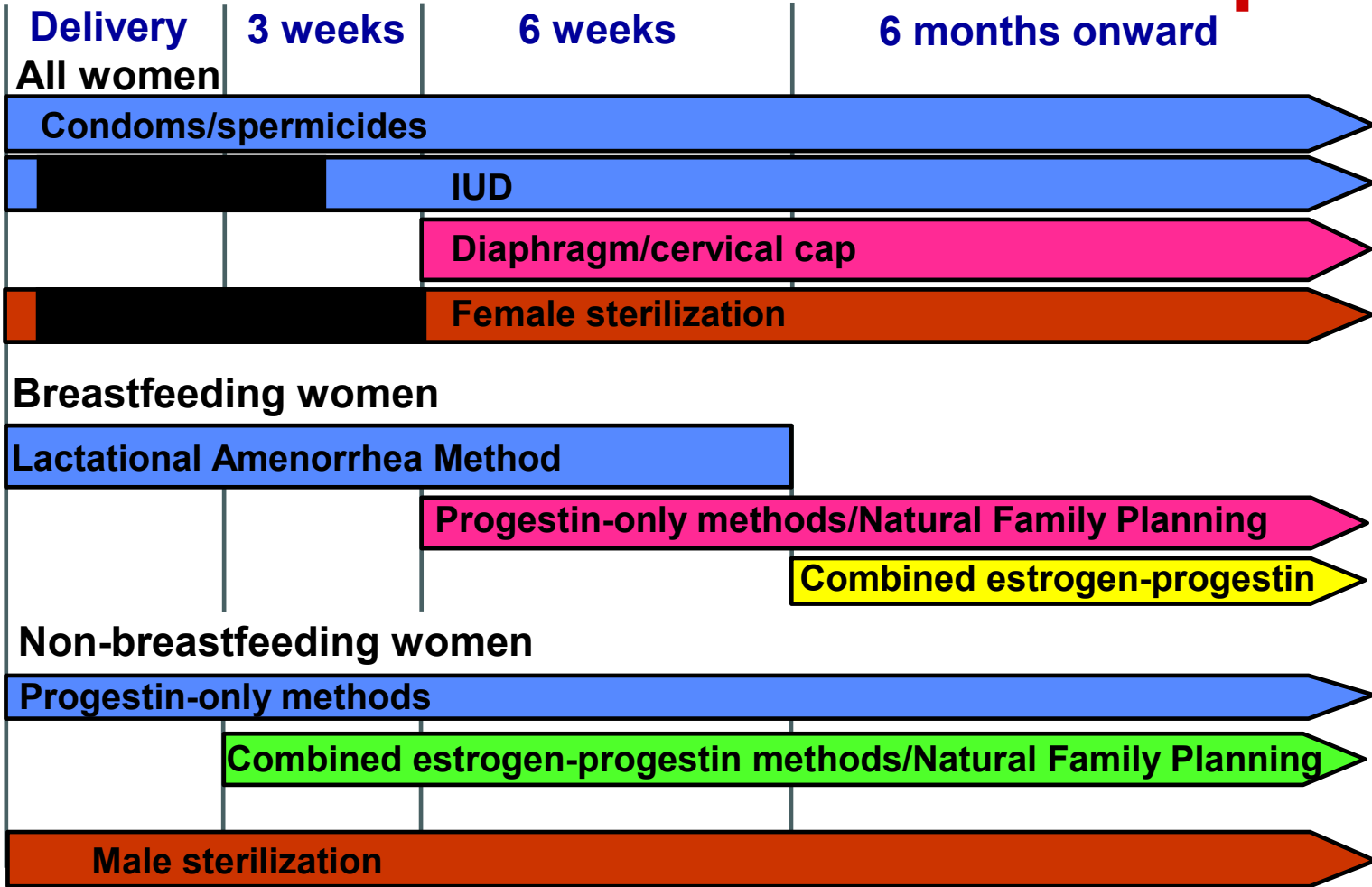
# Characteristics of No Scalpel Vasectomy (NSV)

- ◆ Small puncture
- ◆ Puncture stretched
- ◆ *Vas deferens* pulled through skin
- ◆ Less discomfort
- ◆ Lower infection and bleeding rates



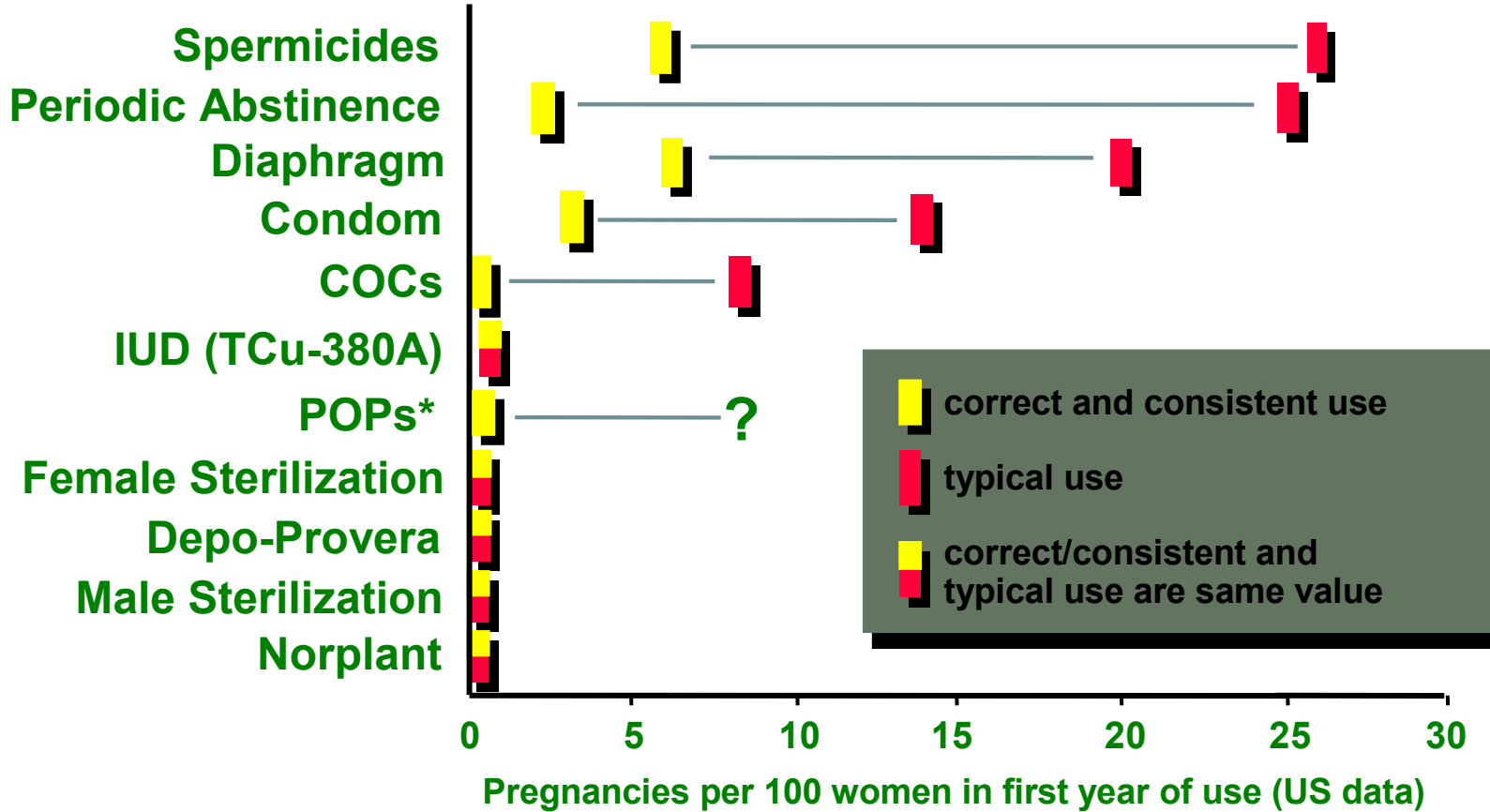


# Postpartum Contraceptive Options





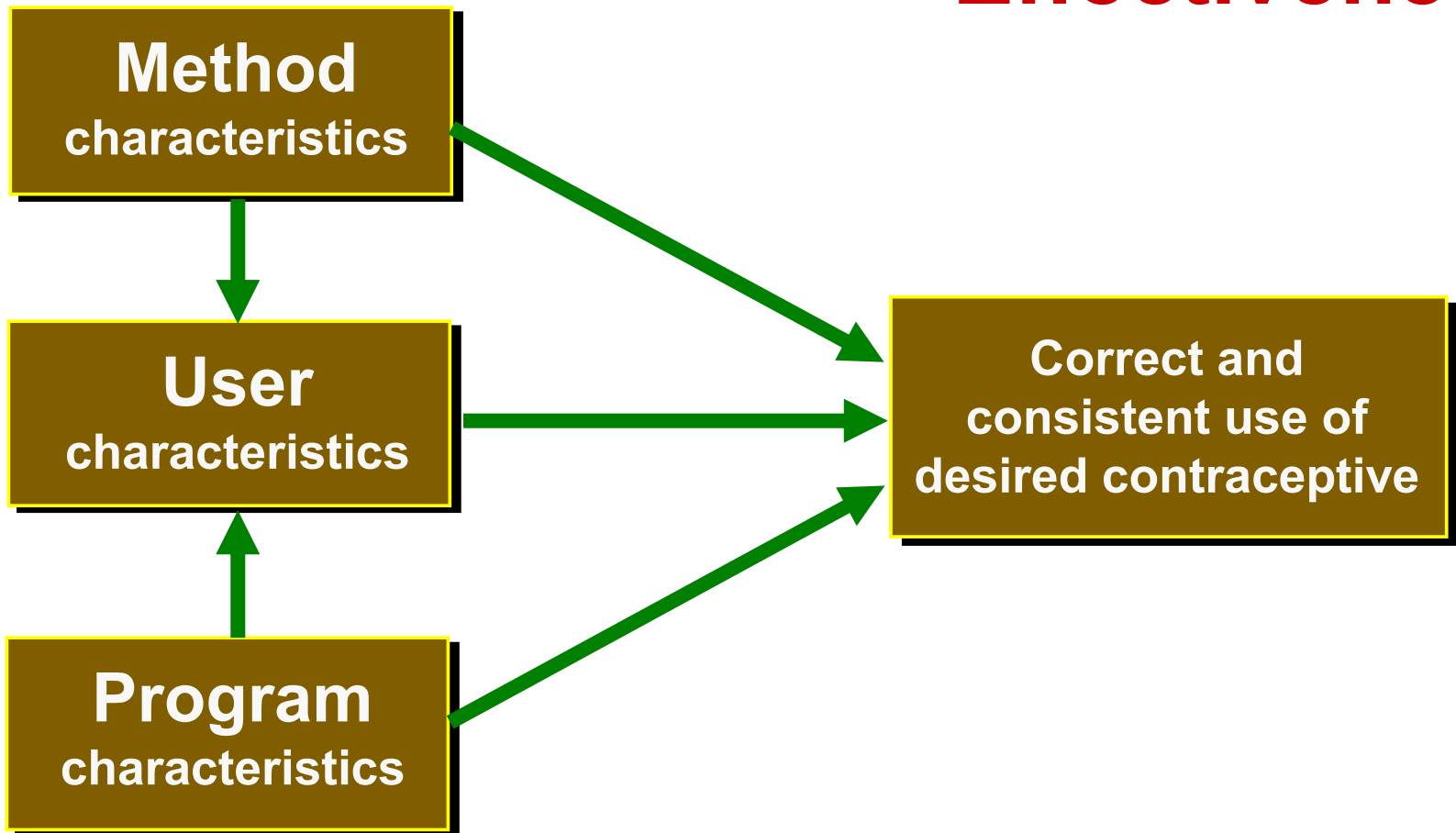
# Contraceptive Pregnancy Rates



\* Typical use data not available

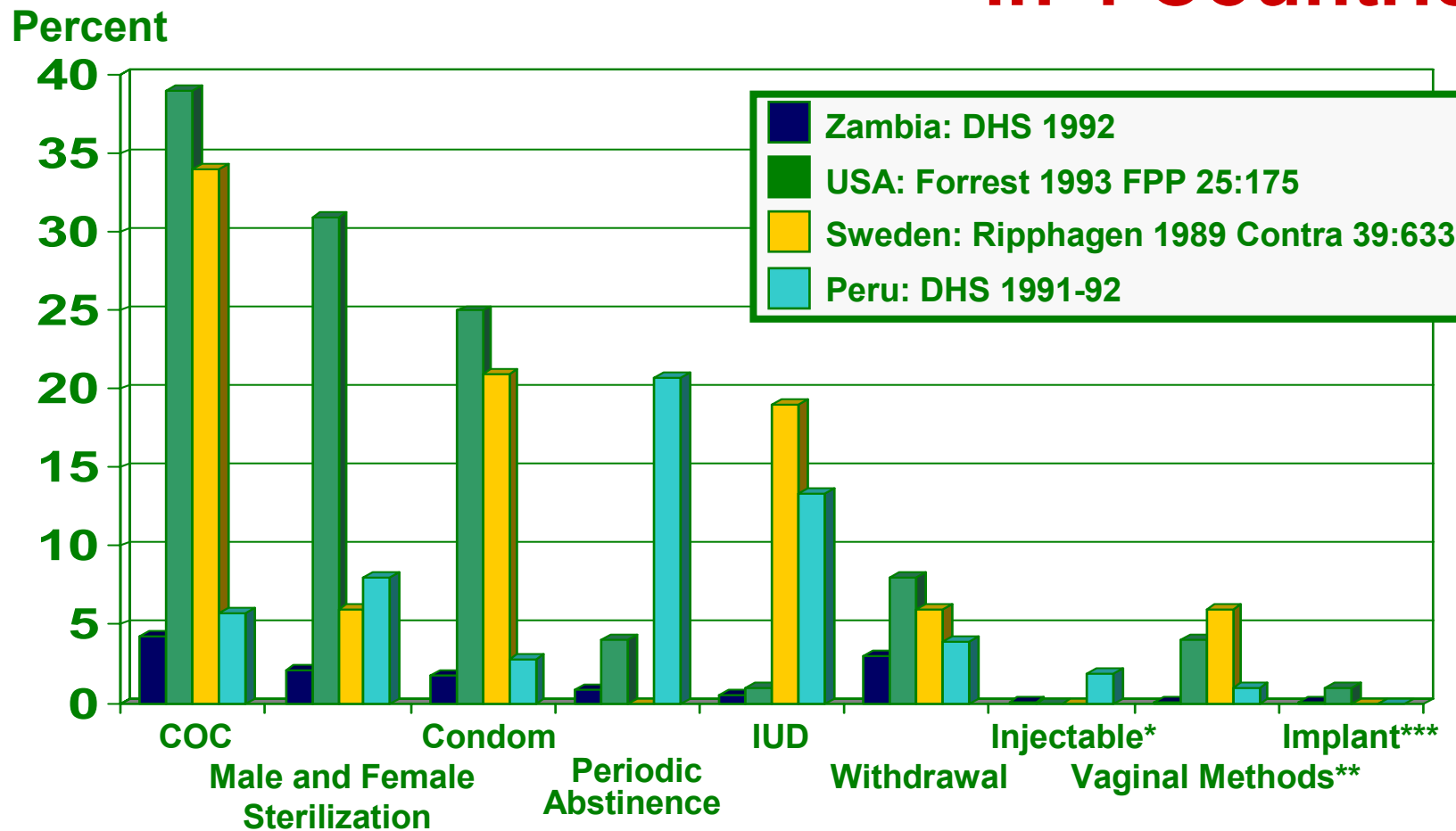


# Factors Affecting Method Effectiveness





# Contraceptive Prevalence in 4 Countries



\* data for USA not available  
 \*\* data for USA includes diaphragm only  
 \*\*\* data for Zambia, Peru not available



# Elements of Contraceptive Choice

**Effectiveness** - with correct and incorrect use

**Safety** - real and perceived

**Side Effects** - mood, nausea, menstrual disturbance, pain, weight gain, vaginal irritation, etc.

**Secondary Benefits** - prevent STDs, decrease blood loss, decrease menstrual cramps, protection from cancer

**Reversibility**

**Clinical Dependence/Consumer Control**

**Coital Independence**

**Cost**

**Other Acceptability** - convenience, sensation, messiness, abstinence, privacy, partner role, ethical, body image, fear of operation, obtrusiveness, etc.

**Programmatic** - logistics, delivery, cost, re-supply, deterioration, compliance, duration, service delivery intensiveness, accessibility, sustainability, quality assurance, local production, regulatory approval, etc.



## New Findings

- ◆ ECPs are also effective if the two doses are taken together (the woman doesn't have to wait 12 hours between doses).

- WHO, *Lancet*, 2002.

- ◆ The IUD is not contraindicated for nulliparous women.

- Hubacher et al, 2002.