FP: What's New, What's Hot, and What Does It Mean for LAC

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Managing Partner: EngenderHealth; Associated Partners: Cicatelli Associates Inc.; Family Health International; Futures Institute; Johns Hopkins Bloomberg School of Public Health Center for Communication Programs; Meridian Group International, Inc.; Population Council

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Part I. Context for FP in LAC: High CPR, but outliers

Subregion	All method CPR (%, married women)	Modern method CPR (%, married women)
North America	74	69
LAC	**72**	**63**
South America	75	66
Central America	67	59
Caribbean	62	58
Mexico / **Guatemala**	68 / 54	60 / **44**
D.R. / **Haiti**	73 / 32	70 / **25**
Colombia / **Peru**	78 / 71	68 / **48**
Brazil / **Bolivia**	77 / 61	70 / **35**

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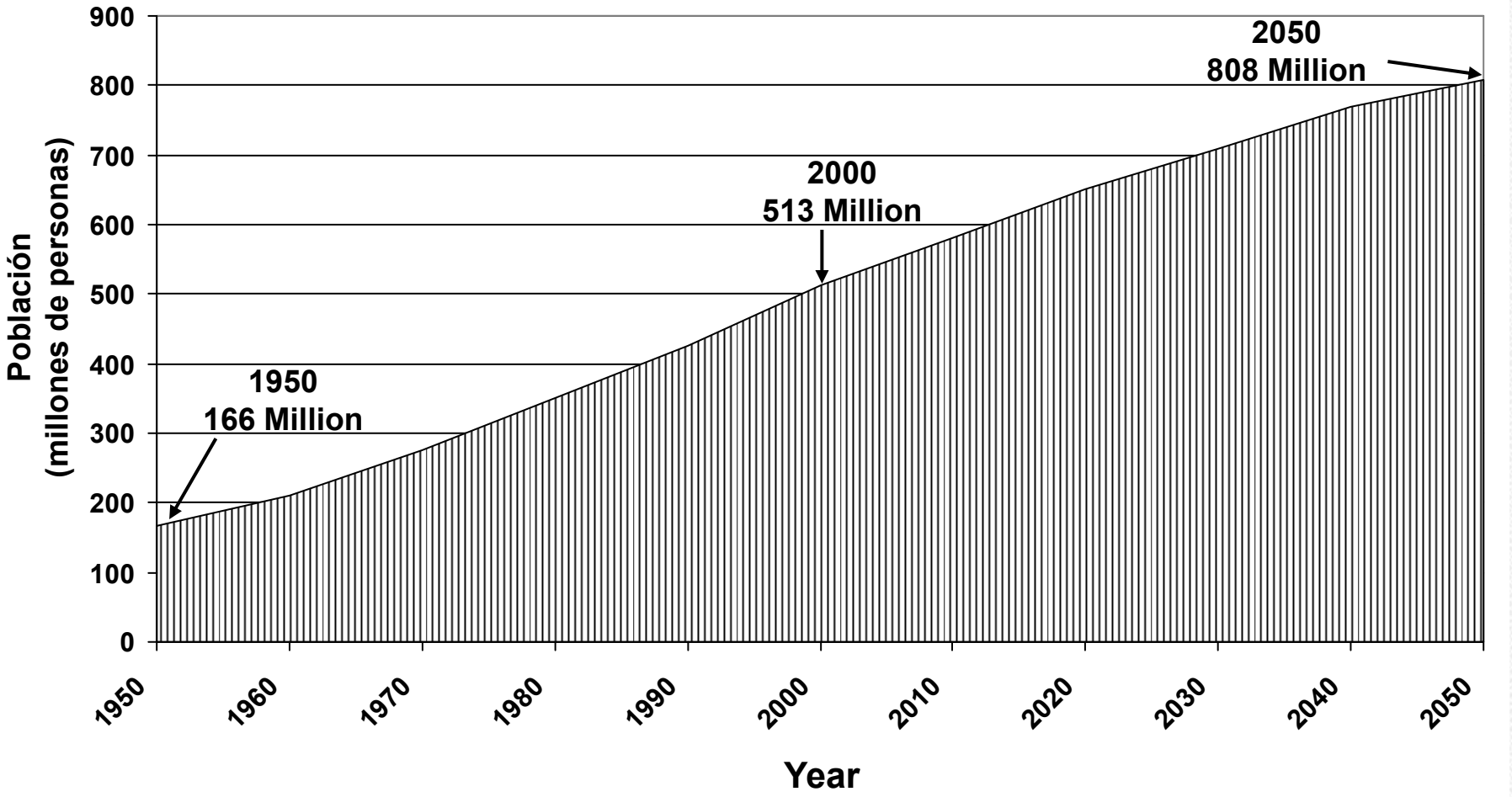
PRB, Family Planning Worldwide 2008 Data Sheet;
DHS, 2008-09 Preliminary information, Guatemala

Young, growing population in LAC: 30% < 15:
future need for more FP services is certain



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Rationales for FP still valid in LAC

- FP reduces maternal mortality and morbidity
  - MMR 15 times higher in LAC than in developed regions
  - One death per 770 births in LAC (vs. 1 per 11,000 births in developed regions)
  - MMR: 230 in Bolivia; 221 in rural Guatemala
- FP reduces abortion
  - LAC: 2nd highest abortion rate in world (after Eastern Europe)
  - Totals unchanging: 4.1 million abortions in 2003, 4.2 million in 1995
  - WHO & FIGO now define FP as part of PAC
- FP contributes to achievement of MDGs:
  - Poverty / equity / gender / national development
  - CPR and unmet need for FP now MDG 5 indicators

Seven Habits of Highly Successful Programs

- Following principles of fostering & sustaining behavior change
- Ensuring access to quality services, in all its dimensions
- Holistic programming (supply, demand, enabling environment)
- Focusing on meeting clients' reproductive intent
- Focusing also on the provider: "no provider, no program"
- Greater focus on method effectiveness: "Not all FP is the same"
- Ensuring contraceptive security [more than "commodity security," or "product"]

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Fostering change in medical settings:
Some key considerations

- Perceived **benefit**: most important variable influencing rate & extent of adoption of new provider or client behavior

  "What's in it for me?"

- Greater the perceived **relative advantage**, the more rapid the rate of adoption/change
- Other important variables:
  - **Compatibility** with medical system's norms, standards, practices
  - **Simplicity** of new behavior
- Technological change has "hardware" and "software"
- Fostering change requires repetition of effort & takes time

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It’s in the eye of the “changee”

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Slow pace of change in medical settings

- U.S. examples:
  - Unnecessary hysterectomies: 80,000 annually
  - 500,000 unnecessary C-sections, every year!
  - Correct treatment of heart attacks by experts: 11-year lag
  - Non-scalpel vasectomy (NSV):
    - *1972: invented in China*
    - *1980s: proven better / adopted as main approach in FP programs*
    - *2003: WHO still calling it a "new method"*
    - *2004: 51% (only) of vasectomies in U.S. via NSV*
    - *2010: ARHP CTU: despite evidence, no preference given to NSV*

Why is change slow in medical settings?

- Conservative and hierarchical
- Lack of perceived need for change

  "What's worked for me is working"
- Lack of provider motivation to change
- Lack of knowledge or understanding
  - of latest scientific findings
  - of benefits and risks of FP methods
- Fear of iatrogenic disease: *Primum non nocere!*
  - Great fear of "harm of doing" vs. "harm of not-doing"
  - FP perceived as a potential danger
  - Risks a woman faces from (unwanted) pregnancy not considered

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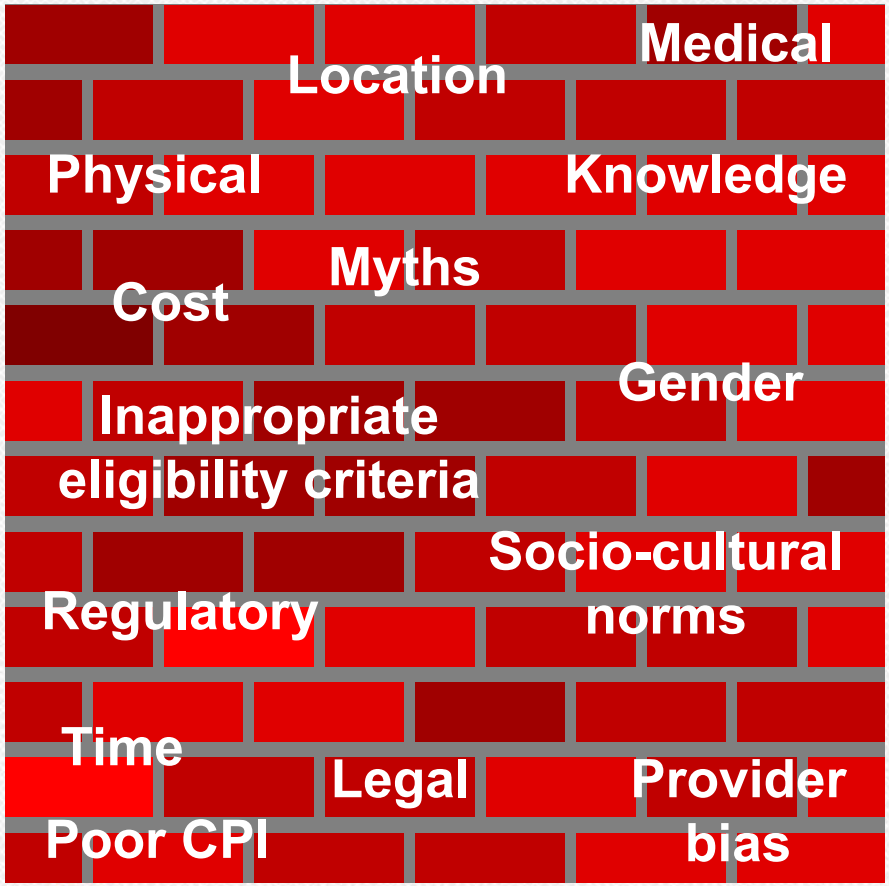
Medical barriers

- "… well-intentioned but inappropriate **policies or practices**, based … medical rationale, that result in scientifically unjustifiable impediment to, or denial of, contraception."
- Doctors are the "gatekeepers"
- Common medical barriers in LAC:
  - *Limitations on provider cadres*
  - *Provider bias* against (or for) a method
  - *Inappropriate eligibility restrictions*
  - *Unsubstantiated "contraindications"*
  - *Process hurdles (e.g., lab tests)*

Shelton, Angle, Jacobstein, *The Lancet*, # 340, 1992

Many barriers to FP access in LAC

Barriers to FP services



Categories of Barriers

- Cognitive
- Socio-cultural
- Geographic
- Financial / cost
- Health care system
  - Structure
  - Provider-level factors

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Not all FP is the same: Relative effectiveness of various FP methods in preventing pregnancy

Method	Number of unintended pregnancies among 1,000 women in 1st year of (typical) use
No method	850
Withdrawal	270
Female condom	210
Male condom	150
Pill	80
Injectable	30
IUD (CU-T 380A / LNG-IUS)	8 / 2
Female sterilization	5
Vasectomy	1.5
Implant	0.5

Source: Trussell J. Contraceptive efficacy. In Hatcher RA, et al. *Contraceptive Technology: Nineteenth Revised Edition*. New York NY: Ardent Media, 2007.

Continuation rates of various FP methods

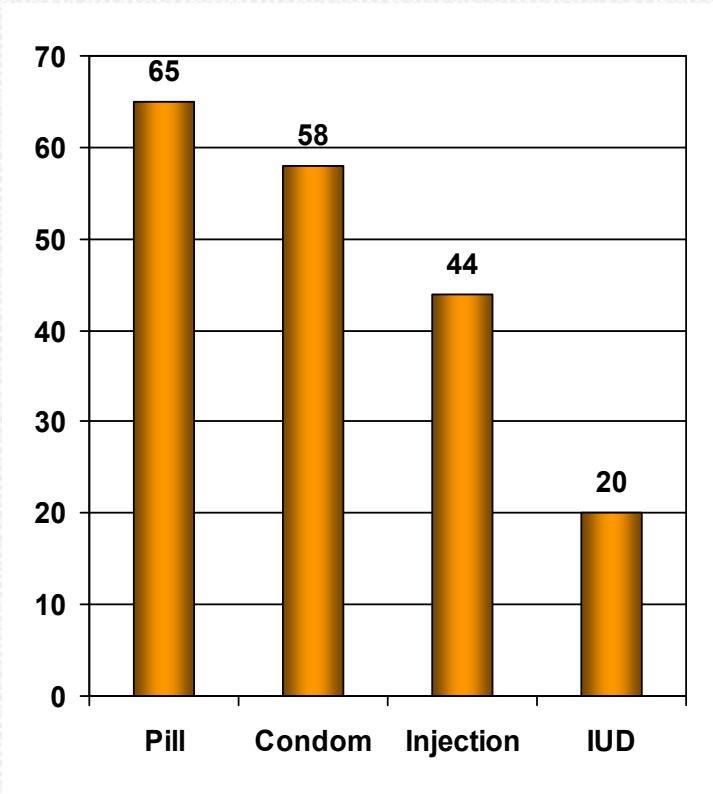
% Women or men **continuing** FP methods at one year

Tubal ligation	**~100%**
Vasectomy	**~100%**
Implants	**94%**
IUD	**84%**
OCs	**52%**
Injectables	**51%**
Periodic abstinence	**51%**
Condoms	**44%**

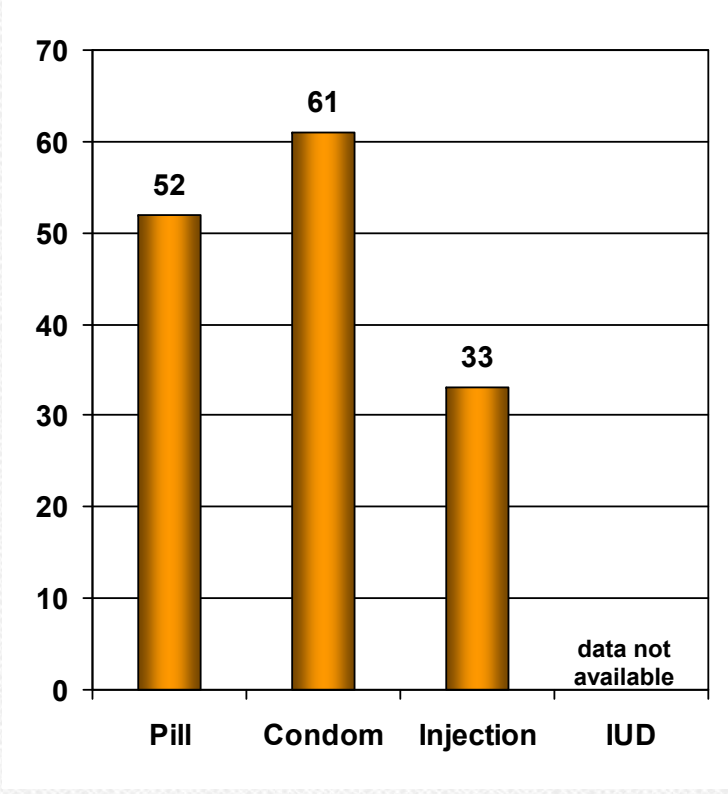
Source: The ACQUIRE Project 2007. Reality √, from DHS data, worldwide

Suboptimal quality & use:
high discontinuation rates in LAC

Peru



Guatemala



Discontinuation within 1 year

Source: MEASURE/DHS, Peru DHS Survey, 2004-2008.

Source: CDC, Guatemala RHS Survey, 2002

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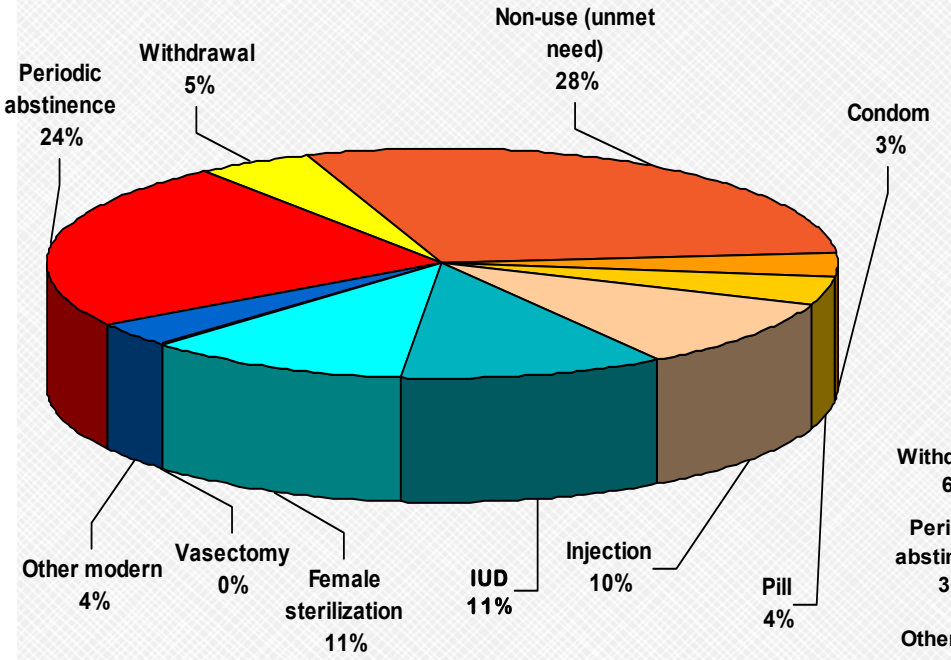
Suboptimal fit with reproductive intentions

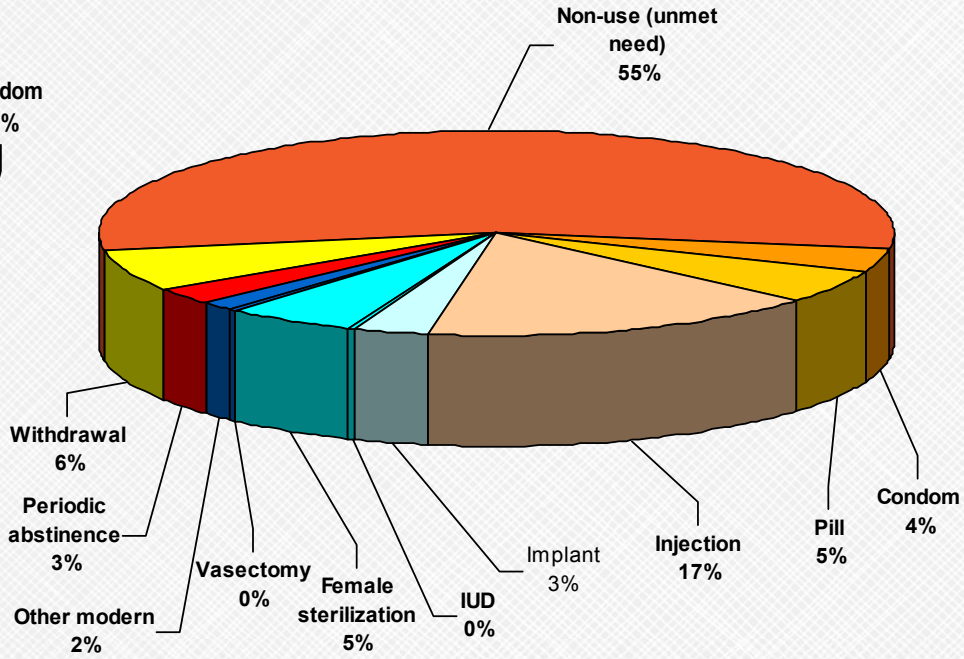
Bolivia



Demand for FP to limit (60% of all women)

Source: MEASURE/DHS, Bolivia DHS Survey, 2003.

Haiti



Demand for FP to limit (41% of all women)

Source: MEASURE/DHS, Haiti DHS Survey, 2006.

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Part III. What's new in contraception
of relevance to LAC?

1. Injectables
2. Hormonal Implants
3. IUDs (CuT 380A, LNG-IUS)
4. Female Sterilization
5. Vasectomy
6. Emergency Contraception

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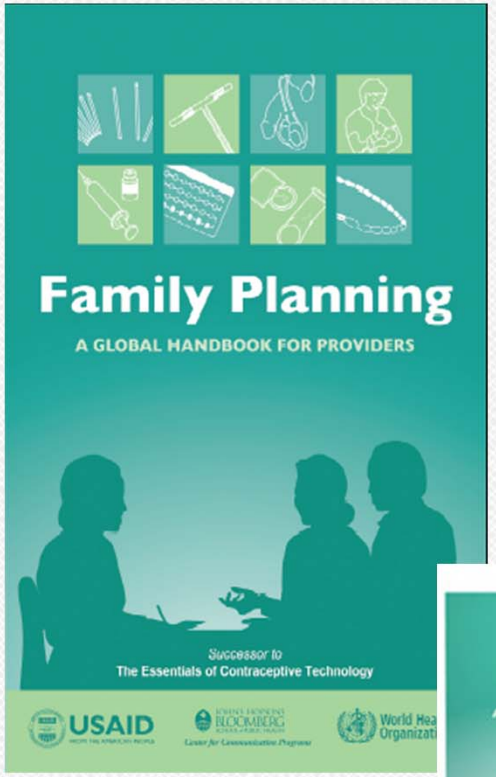
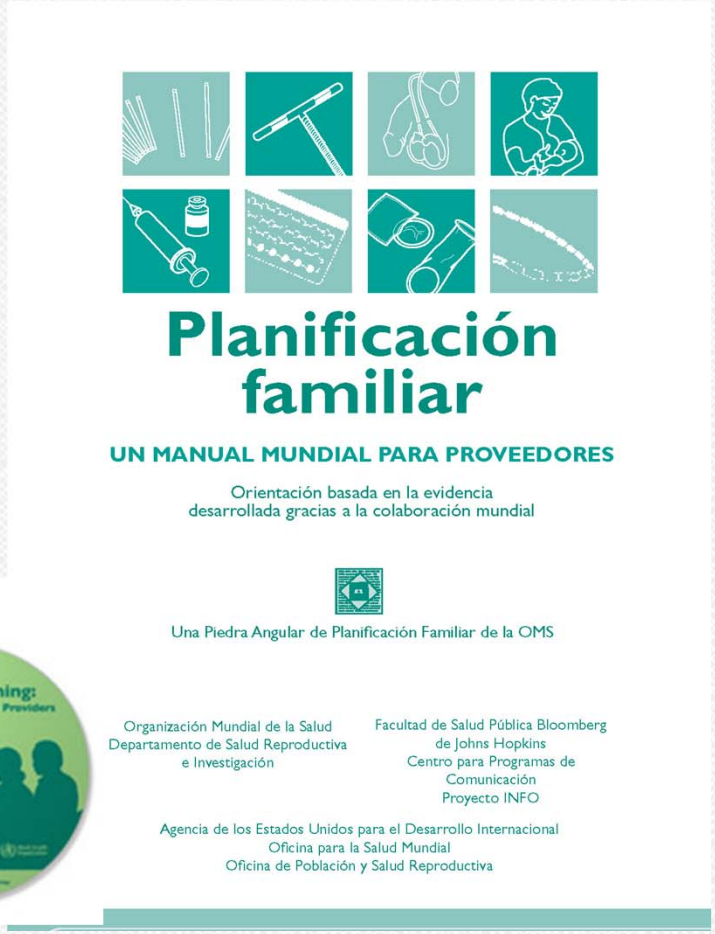
WHO FP handbook: En español, para usted





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1. Injectables: Key characteristics

- High use, rising popularity in LAC [MWRA]:
  - Nicaragua 23% (2006), was 6% (1998) ; Colombia 13% (2007), up from 4% (2000)
  - El Salvador 11% (2002), up from 0.4% (1985) ; Honduras 14% (2005-06)
  - Bolivia 11% (2008), up from 1% (1998)
- Safe and suitable for almost all women
  - MEC Category 1, age 18-45; (younger or older: Category 2)
  - Any parity; post-abortion, or PP (if breastfeeding, 6 wks PP); HIV-infected, or with AIDS
- Mechanism of action: prevents ovulation, thickens cervical mucus
- Use-effectiveness: 3 pregnancies per 100 women-yrs of use
- Counseling important re bleeding changes

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DMPA / "Depo": New developments

- "Grace period" extended by WHO (OK up to 4 weeks late)
- ↓ Bone density (temporary, reversible, no Δ in MEC [WHO, 2005])
- No association with HIV acquisition or progression
- Community-based provision of injectables:
  - WHO, 2009: "Safe and effective"

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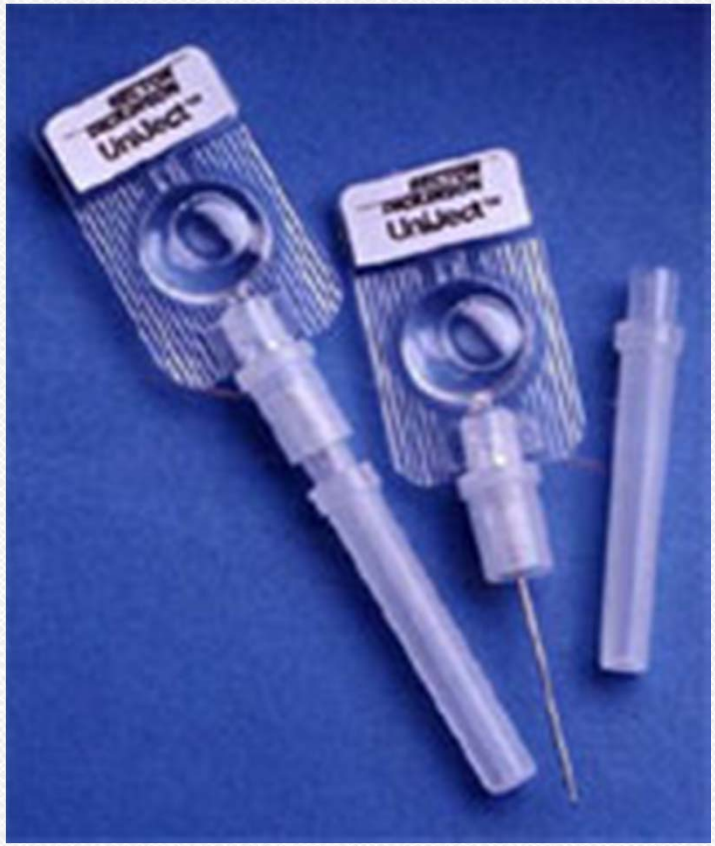
New formulation of Depo-Provera:
Depo-subQ Provera 104, for delivery with Uniject

Potential "home run"



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Depo-subQ Provera 104:

- New formulation for subQ injection
- 30% lower dose (104 mg vs. 150 mg)
- Fewer side effects
- Same effectiveness, same length of protection (>3 months)
- Approved by USFDA (2005) and UK
- Potential for home- and self-injection
- Available to USAID in 2011?

Uniject:

- Single dose, single package
- Prefilled, sterile, non-reusable
- Short needles for subQ injection (easier use by non-clinical personnel)
- Compact; easy to use and store

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2. Hormonal implants

- Small, progestin-releasing, subdermal rods
- WHO MEC Category 1 for nearly all women
- Highly effective (pregnancy rate ~ 1 / 2000 in 1st yr)
- Labeled effective for 3-5 years, depending on implant type
- Continuation rates high

  (**if** good counseling and proper side effects management)
- Gaining popularity as price ↓↓

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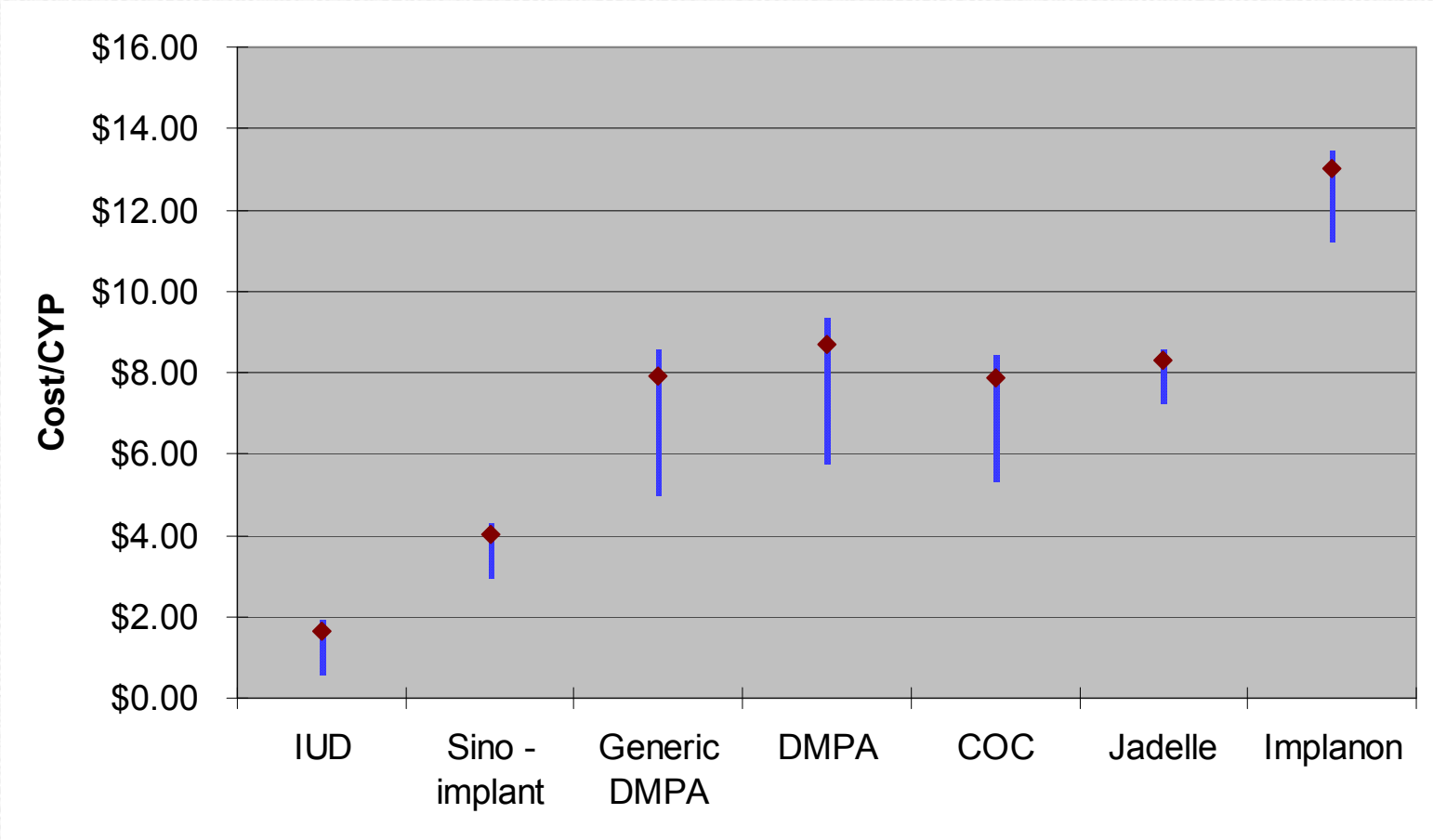
New hormonal implants:
Comparison of Sino-implant, Jadelle, Implanon

	Sino-implant (II) 	Jadelle 	Implanon 
Manufacturer	Shanghai Dahua Pharmaceutical	Bayer HealthCare	Schering Plough / Organon
Formulation	150 mg levonorgestrel In 2 rods	150 mg levonorgestrel In 2 rods	68 mg etonogestrel In 1 rod
Mean Insertion & Removal time	Insertion: 2 min Removal: 4.9 min	Insertion: 2 min Removal: 4.9 min	Insertion: 1.1 min Removal: 2.6 min
Labeled duration of product use	4 years	5 years	3 years
Trocars	Disposable	Autoclavable / Disposable	Pre-loaded disposable
Cost of implant (US$)	**$8.00**	$24	$20
Cost per Year (if used for duration)	$2.00	$4.80	$6.70

Registration status of Sino-implant, world & LAC

Cost per CYP comparable, by FP method



*Direct costs include the commodity, materials and supplies, labor time inputs and annual staff salaries. The height of each bar represents the range of cost per CYP across the 13 USAID priority countries, while the diamond shows the average value.

3. IUDs: Key characteristics

- Reframing: almost all women can use an IUD
  - Good for "spacers" and "delayers," as well as "limiters"
  - Good option for HIV+ women
- Highly effective (>12-13 yrs): "Reversible sterilization"
- More service cadres can provide (because non-surgical)
- Most cost-effective method (after ~ 2 yrs), yet …
- Provider concerns ("myths"):
  - Pelvic inflammatory disease (PID), infertility, HIV/AIDS
- Thus "The IUD has the worst reputation of all methods -- except among those using it!"

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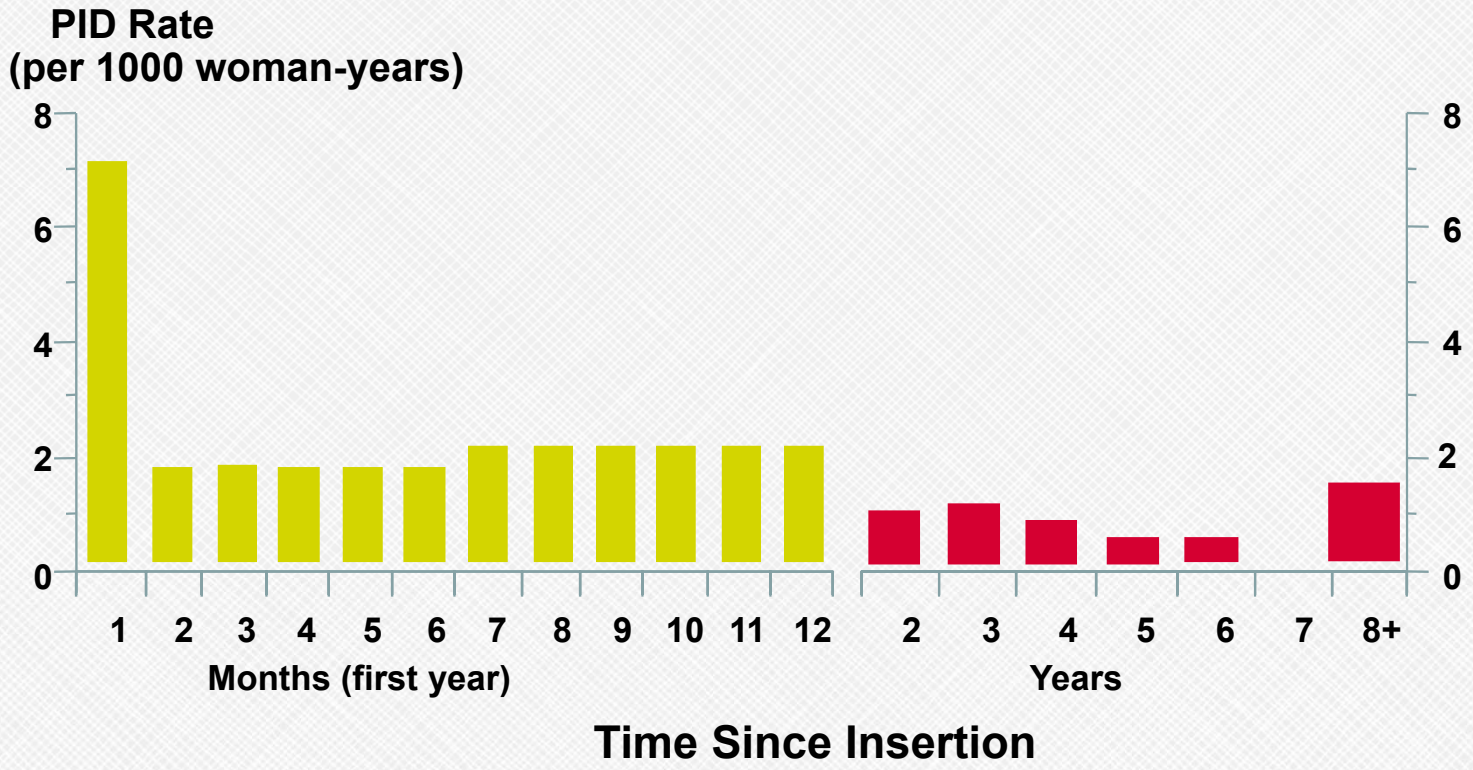
IUD and risk of PID: Very Low (far lower than providers realize)

PID Incidence Rate by Time Since Insertion



Source: Farley et al, 1992, in FHI 2004
Data from Mexico and Thailand

IUD and other risks

- Infertility associated with IUD?: No:
  - Study done in Mexico (Hubacher et al, *NEJM*, 2001)
  - Infertility due to Chlamydia, not the IUD
  - IUD-associated infertility: "immeasurable and not of PH significance"
- IUD use associated with HIV/AIDS?: No:
  - IUD use does not increase risk of HIV acquisition
  - Use of IUD by HIV-infected women is safe

    (same—low—rates of overall and infectious complications)
  - IUD use in HIV+ woman does not ↑risk to HIV-neg. male partner
- Challenge: these facts not widely known; and hard to change "truths"

Latest WHO Medical Eligibility Criteria:
IUD use in clients with STIs or HIV/AIDS

Condition	Category	
	Initiation	Continuation
Increased general risk of STI (high prevalent setting)	2	2
High *individual* risk of STI	3	2
Current chlamydial or GC infection, or purulent cervicitis	4	2
HIV positive	2	2
AIDS	3	2
AIDS and clinically well on ARV	2	2

Source: WHO, *Medical Eligibility Criteria*, 2008

LNG-IUS: “the best of both worlds”

Oral contraceptives

- Very effective
- Reduction of menstrual loss
- Reduction of pelvic inflammatory disease

Intrauterine devices

- No daily action needed
- Long-acting
- Estrogen-free
- Rapidly reversible

Levonorgestrel Intrauterine “system”

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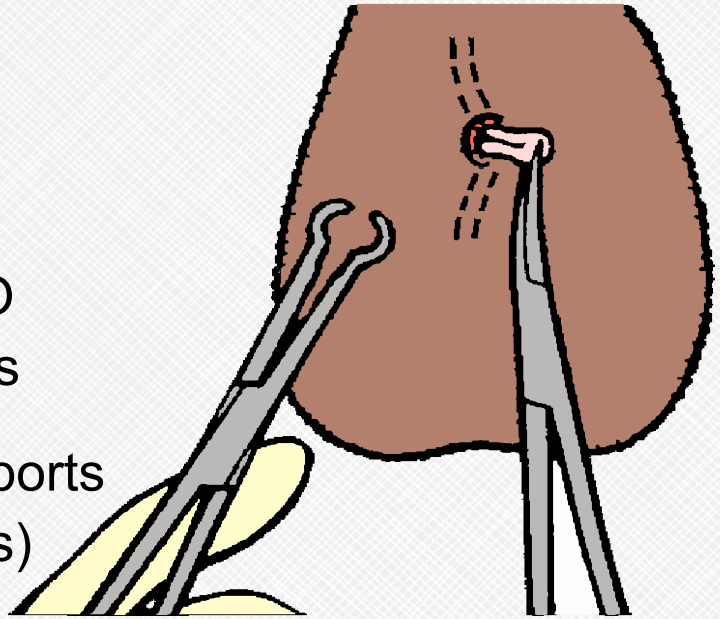
4. Female Sterilization

- Highly effective, comparable to vasectomy, implants, IUDs
- No medical condition absolutely restricts eligibility
- Should not be "lost" in excitement over implants
- Many women rely on it in many countries
- Risk of failure (pregnancy), while low:
  - continues for years after the procedure
    (18.5/1000 at 10 years; almost 2/100)
  - does not diminish with time
  - higher in younger women

5. No Scalpel Vasectomy (NSV)

- NSV better than incisional method
- Small puncture; *vas deferens* pulled through skin and transsected
- Almost all men eligible
- Not effective immediately — new WHO guidance: backup method for 12 weeks
- Very effective (0.2-0.4% failure; but reports of 3-5% failure; counseling implications)
- Very safe: 5-10% minor complications (pain, infection, bleeding)



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6. Emergency Contraception (EC)

- Method of *preventing* pregnancy *after* unprotected sex
- Safe and suitable for all women
- Hormones of regular OCs are used (in higher dosage)
  - Preferred: one dose: POPs (1.5 mg LNG): ↓ risk 89% (1 in 100 pregnant)
  - COCs: 2 doses 12 hrs apart (EE 100 mcg, LNG 0.5 mg): ↓ risk 75% (2 in 100)
- Inhibits ovulation; does NOT interfere with implantation, nor interrupt established pregnancy
- "EC is contraception, not abortion" (is not RU-486)
- Approved by USFDA but not provided by USAID

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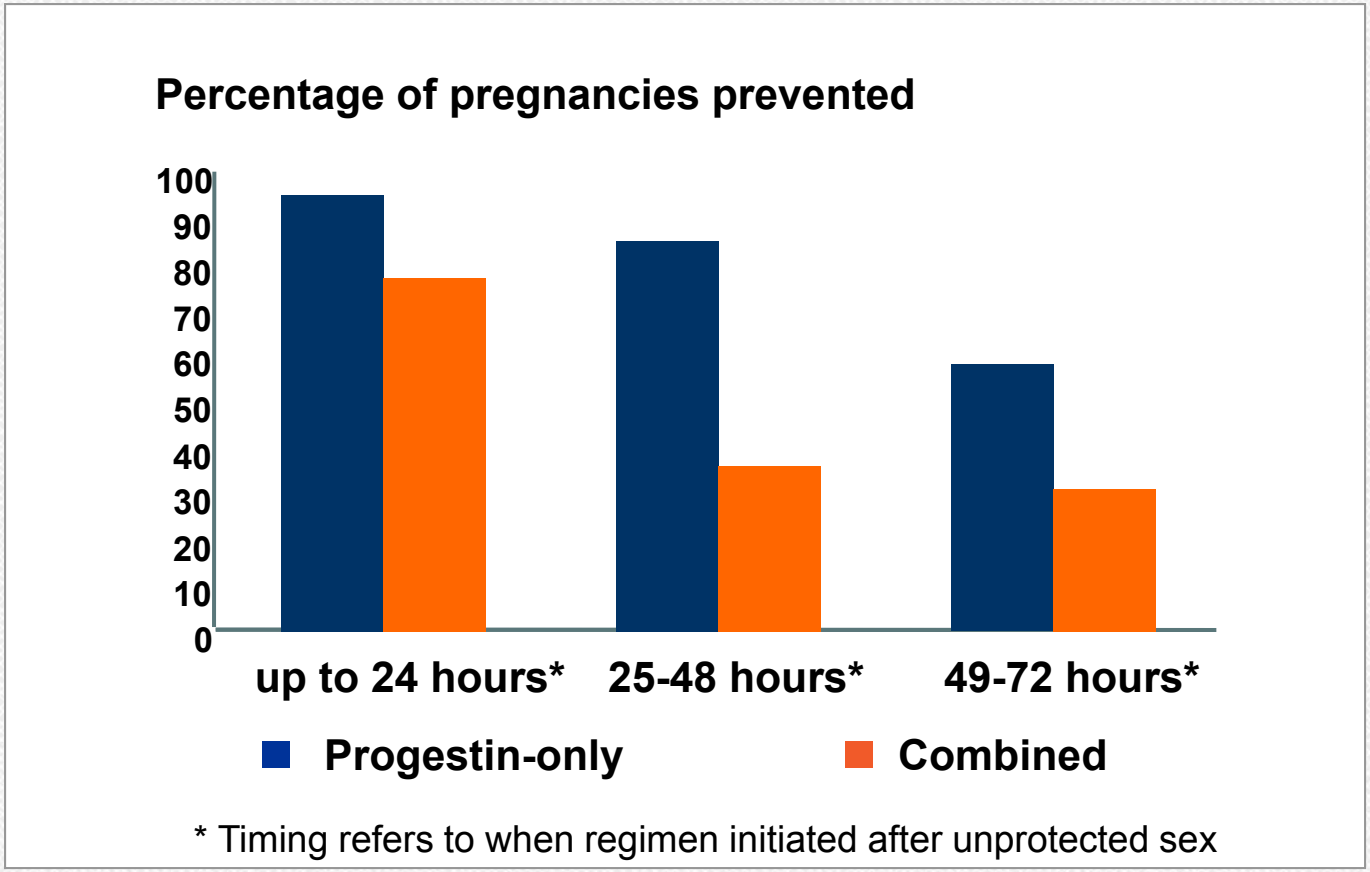
ECPs: Most Effective When Taken Early
"The Sooner, the Better"



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

Contraceptive & Non-Contraceptive Benefits

- ↓ risk of ectopic pregnancies by > 90% (all methods)
- ↓ menstrual cramps, pain and blood loss (all hormonals)
- ↓ risk of ovarian cancer (COCs)
- ↓ risk of endometrial cancer (COCs, IUDs)
- ↓ symptomatic PID (COCs, implants, injectables)
- ↓ symptoms of endometriosis (all hormonals)
- Alternative to hysterectomy for menorrhagia (LNG-IUS)
- FP: Safer than pregnancy and delivery (all methods)
- Reframing: “The pill is safer than aspirin”

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