

Contraceptive Technology Update (CTU): What's New Out There, What Are the Implications?

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Our Challenge

“In health care, invention is hard, but dissemination is harder”*

“Mastering the generation of good changes is not the same as mastering the use of good changes”*

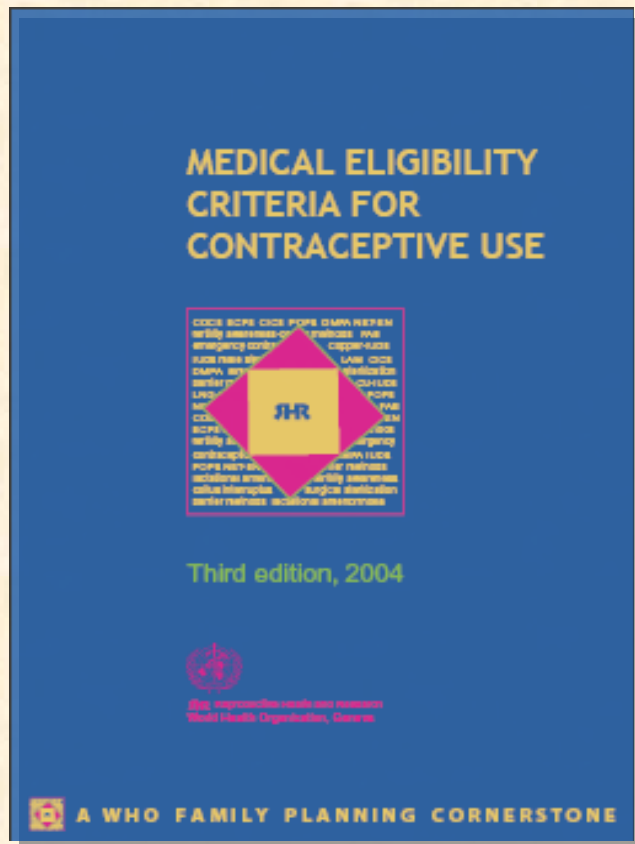
*Berwick, JAMA, April 16, 2003, Vol 289, no. 15

Outline of Presentation

- I. WHO's evidence-based guidance for contraceptive use (MEC)
- II. Latest information / thinking / new developments about FP methods
- III. Evidence about fostering change (esp. in medical / clinical settings)

I. WHO's Evidence-Based Guidance for Contraceptive Use

Medical Eligibility Criteria for Contraceptive Use (MEC, 2004)



- Covers 19 methods, 120 medical conditions
- ~ 1700 recommendations on who can use various contraceptive methods
- Gives guidance to programs & providers for clients with medical problems or other special conditions
- Informs national guidelines, policies and standards with best available evidence
- Helps reduce medical policy and practice barriers
- Helps lead to improved quality and use of FP methods and services

What Question Is Answered by the MEC?

In the presence of a given **condition** or **client characteristic**, e.g., STIs or HIV/AIDS can a particular FP method be used?

And with what degree of caution or restriction, as reflected in four **classification categories** or gradations based on risks / benefits?

WHO Medical Eligibility Criteria, Classification Categories

Classification Category	With Clinical Judgment	With Limited Clinical Judgment
1	No restriction: Use method in any circumstances	Yes Use the method
2	Generally use: benefits generally outweigh risks	Yes Use the method
3	Generally do not use: risks outweigh benefits	No Do not use the method
4	Unacceptable health risk: method not to be used	No Do not use the method

II. New Findings and Thinking about Specific FP Methods

Methods to be Considered:

1. Sterilization (FS / vasectomy)
2. IUDs
3. Implants
4. Injectables
5. Emergency Contraception
6. Standard Days Method

1A. Female Sterilization (FS)

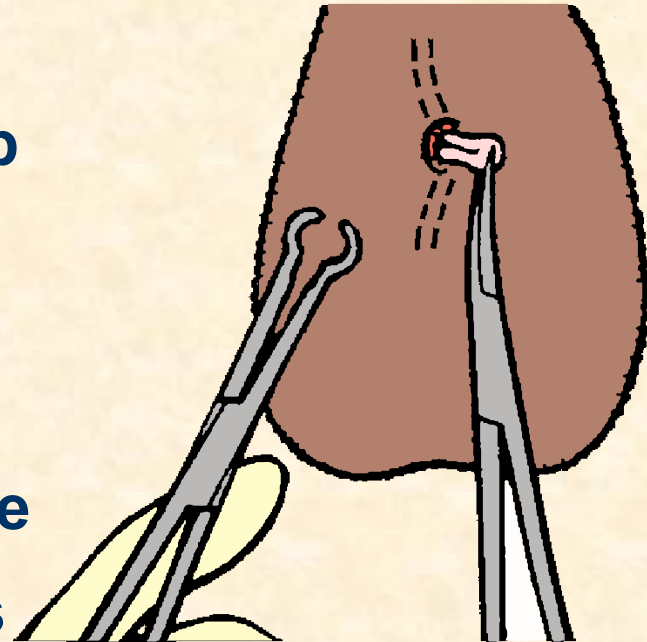
Female Sterilization

- Highly effective, comparable to vasectomy, implants, IUDs
- 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
 - is higher in younger women
- No medical condition absolutely restricts a person's eligibility for FS

1B. Vasectomy

No Scalpel Vasectomy (NSV): Characteristics

- Small puncture; *vas deferens* pulled through skin
- Very safe; few restrictions
- Minor complications (post-op and chronic pain, infection and bleeding): 5-10%
- Less with NSV than with incisional technique
- Major morbidity/mortality rare
- No adverse long-term effects
- NSV not “new” (1972) — yet only got to 51% in U.S. in 2004



Vasectomy (cont.)

- Effectiveness comparable to FS, implants, IUDs
- Not effective immediately—WHO now recommends use of backup contraception for 3 months after the procedure (i.e., no longer “ ... or 20 ejaculations”).
- Failure (pregnancy) commonly quoted at from 0.2% to 0.4%, but rates as high as 3-5% have been reported. Has counseling implications ...

2. IUDs (Cu-T 380A)

IUDs: Effectiveness and Safety

- Highly effective, comparable to FS, V
 - “Reversible sterilization”
 - 12-13 yrs with CU-T (FDA labels for 10)
 - Cheaper and easier to provide than FS or V
 - Quickly and easily reversible, with immediate return to fecundability
- Very safe for almost all women (including: PP, PA, or interval; BF; HIV-infected; young; nulliparous; women who can't use hormonals)

IUD: Other Considerations

- More service cadres can provide (because non-surgical)
- Good for both “spacers” and “limiters”
- Greater availability = greater choice
- Good option for HIV+ women
- Most cost-effective method (> 2 yrs), yet ...
- “The IUD has the worst reputation of all methods ... except among those using it”

Not Only Clients Have “Myths”: Latest Evidence about Providers’ Concerns

The “Big Three” provider concerns:

1. **Pelvic Inflammatory Disease (PID)**
2. **Infertility**
3. **HIV/AIDS**

New evidence is reassuring

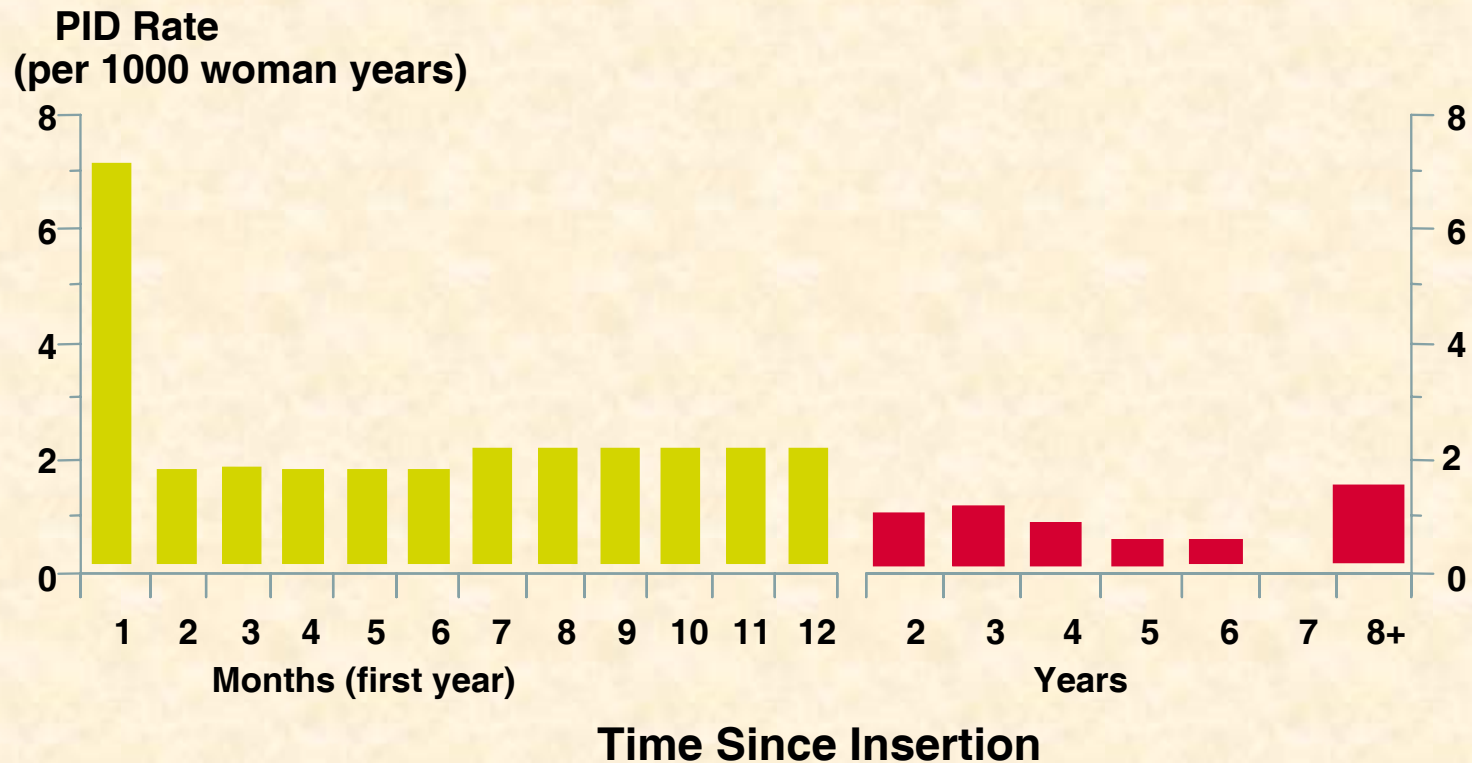
Challenge: “dissemination,” “acceptance,”
appropriate behavior change by providers

Concern: Does IUD Cause PID?

- We know the IUD needs an accomplice—sexually-transmitted organisms *Chlamydia* and *gonococcus* (i.e., PID is not caused by the device itself or by its string)
- 2 possible mechanisms, raises 2 questions:
 - Q 1: Risk from IUD insertion process? &/or
 - Q 2: Risk from post-insertion bacterial exposure, i.e., Does having IUD in place facilitate later PID?

Risk of PID: Very Low and Far Lower Than Many Providers Erroneously Believe

PID Incidence Rate by Time Since Insertion



Source: Farley et al, 1992, in FHI 2004

But What About Risk of PID in High-Prevalent STI Settings?

- Perhaps WHO data included only low risk women? (Study done in Thailand and Latin America)
- What about in low resource settings, where STI testing is not feasible?
- But no prospective studies exist, thus we need to (can only) estimate risks

Modeling the Attributable Risk *

High Risk Setting of 10% Cervical Infection

Simple Screening Questions



Only 1 in 667 would
get PID from IUD
(1.5 cases/1000)
0.15%

No Screening



Only 1 in 333 would
get PID from IUD
(3 cases/1000)
0.30%

* Shelton, Lancet 2001

Summary: Emerging View on IUD and PID

- Insertion process, due to presence of sexually transmitted bacteria, increases short-term risk of PID in some women (those at high risk of STIs)
- IUD does not appear to facilitate development of PID in post-insertion period
- Overall risks are **very small**
- Even in high-STI settings, risks appear **small (and much smaller than typically believed)**
- Our challenge: these facts are not widely known; and it's hard to change pre-existing “truths”

Concern: Does IUD Use Cause Infertility?

Evidence: IUD Not Associated with Infertility*

- Mexico: study of nulligravid infertile and primigravid women
- Similar patterns of previous Cu-IUD use
- Blood tests for chlamydial antibodies:
infertile women: twice the % of antibodies
- Thus, real infertility “culprit” not IUD but *Chlamydia trachomatis* (and *Gonococcus*)
- IUD and infertility link: *immeasurable* and “not of public health significance”

* Hubacher et al., *N Engl J Med* 2001

Concern: Is IUD Use by HIV-Infected Women Safe? Evidence: Yes

- Cohort studies in Kenya
- Compared HIV-infected and HIV-non-infected women using IUDs
- Findings: Same **low rates** of **overall** (7-10%) and **infectious** (0.2-2%) complications
- Conclusion: HIV does not appear to increase risk of IUD-related adverse events, inc. PID

Sinei et al, *Lancet*, 1998

Morrison et al., *Br J Obstet Gynaecol* 2001

Concern: IUD in HIV+ Woman Might ↑ Risk to HIV-Negative Male Partner

- Ancillary study to Kenyan cohort
- Asks does presence of IUD increase cervical shedding of HIV? (Increased shedding a proxy for increased risk of being infective.)
- Finds cervical shedding of HIV is not increased with IUD use
- Inferential conclusion: IUD use by HIV+ women appears safe for HIV-neg partner

Richardson et al., *AIDS* 1999

Changes in the WHO MEC for use of Copper IUDs in HIV/AIDS Clients

HIV/AIDS	2 nd Ed. Category	2004 Category	
		I	C
High Risk of HIV	3	2	2
HIV-infected	3	2	2
AIDS	3	3	2
Clinically well on ARV therapy		2	2

Overview: Current (2004) Medical Eligibility Criteria for IUD Use in Clients with STIs or HIV/AIDS

Condition	Category	
	Initiation	Continuation
Increased general risk of STI (high prevalent setting)	2	2
High <i>individual</i> 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

Progesterone-Releasing Intrauterine Systems (IUS)

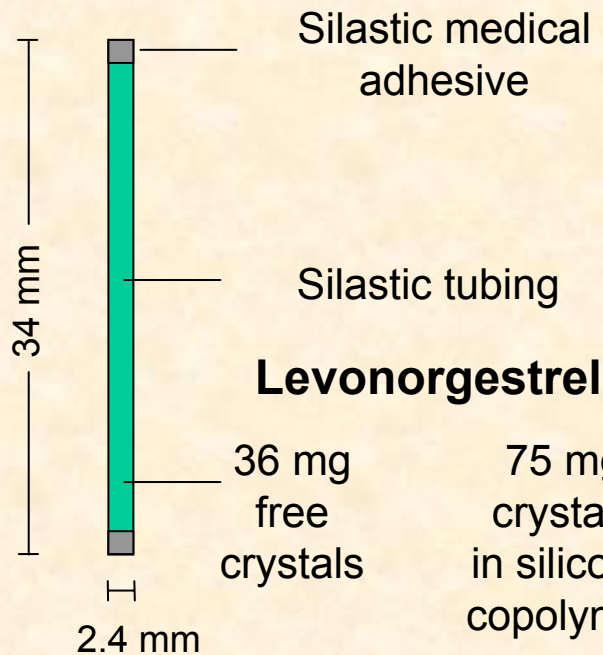
- Mirena® — continuous release of a small amount of the progestin, levonorgestrel (same hormone in Norplant and Jadelle)
- Effective 5 years / Failure rate in 1 year: ~0.1-0.2%
- Same benefits and side effects of progestins
- May reduce menstrual cramps and flow.
- Reduced flow may reduce iron deficiency anemia.
- Foundations considering supporting it.
- USAID: too expensive, trying to develop generic

3. Implants (Norplant, Jadelle, Implanon)

Norplant vs Jadelle vs Implanon

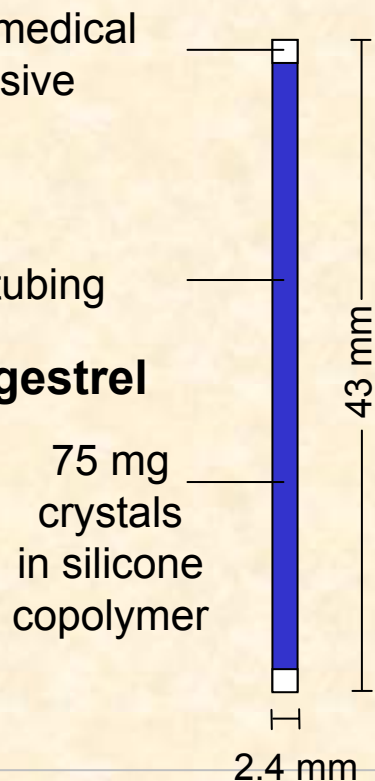
Norplant (6 capsules)

216 mg LNG



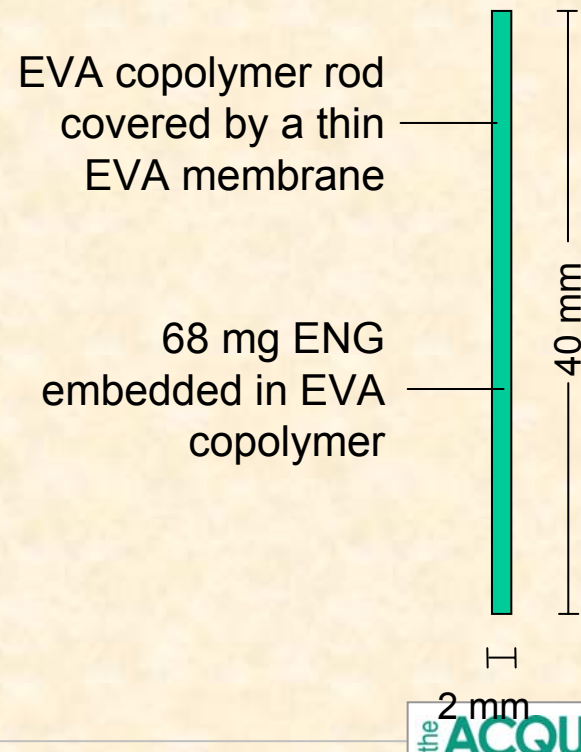
Jadelle (2 rods)

150 mg LNG



Implanon (one rod)

68 g etonogestrel
(ENG, 3-ketodesogestrel)



Comparison of Norplant[®], JADELLE[®] and Implanon[®]

Norplant[®]

- 6 capsules
- Effective 7 yrs
- 1-yr failure: 0.05% (1 in 20,000); 5-yr. failure 1.6%
- Reg. approval in 62 countries
- Insertion time: 4.3 min (0.8-18.0)
- Removal time: 10.2 min (1.3-50m)
- Cost: \$27

Jadelle[®]

- 2 rods
- Effective 5 years
- 1-yr failure: 0.05% (1 in 20,000); 5-yr failure 1.1%
- Regulatory approval in 11 countries
- Insertion time: 2 min
- Removal time: 4.9 min \pm 3.5 minutes
- Cost: \$29

[Sinoplan: \$5]

Implanon[®]

- 1 rod
- Effective 3 years
- Regulatory approval in 25 countries
- Insertion time: 1.1 min (0.03-5.0)
- Removal time: 2.6 min (0.2 – 20.0)
- Cost: comparable; AID RFA out now

4. Injectables

Injectables:

Names, Lengths, Content

- Progestin-only injectables:
 - Depot-medroxyprogesterone acetate (DMPA; “Depo-provera”; Megestron®
 - 150 mg given IM every three months
 - also SQ formulation, lower dose (104 mg); CBD ...
 - NET-EN: norethindrone (or norethisterone) enanthate, Noristerat®) given every two months
- Combined injectable contraceptives (CICs, progestin plus estrogen) — given monthly:
 - Cyclofem® (MPA, 25mg plus estradiol, 5 mg)
 - Mesigyna® (50 mg Norethindrone enanthate, plus 5 m.g. estradiol)

Depo-Provera

- Women of any age and parity can use it (MEC Cat. 1, age 18-45; Cat. 2, if younger or older)
- Start first 7 days after LMP, or can use any time reasonably sure woman not pregnant
- Usable immed PP if not BF; or 6th wk PP if BF
- Usable immediately PAC
- No association of Depo use with HIV acquisition (2005, FHI/NICHD Study)
- Bone density: WHO consultation, July 2005

Depo in CBD

- Important growth area for contraception
- FHI/STC study in Uganda with CRHWs
 - Comparing CRHWs vs nurses in clinics
 - Quality similar
 - Second injection slightly better for CRHWs

Depo in Uniject

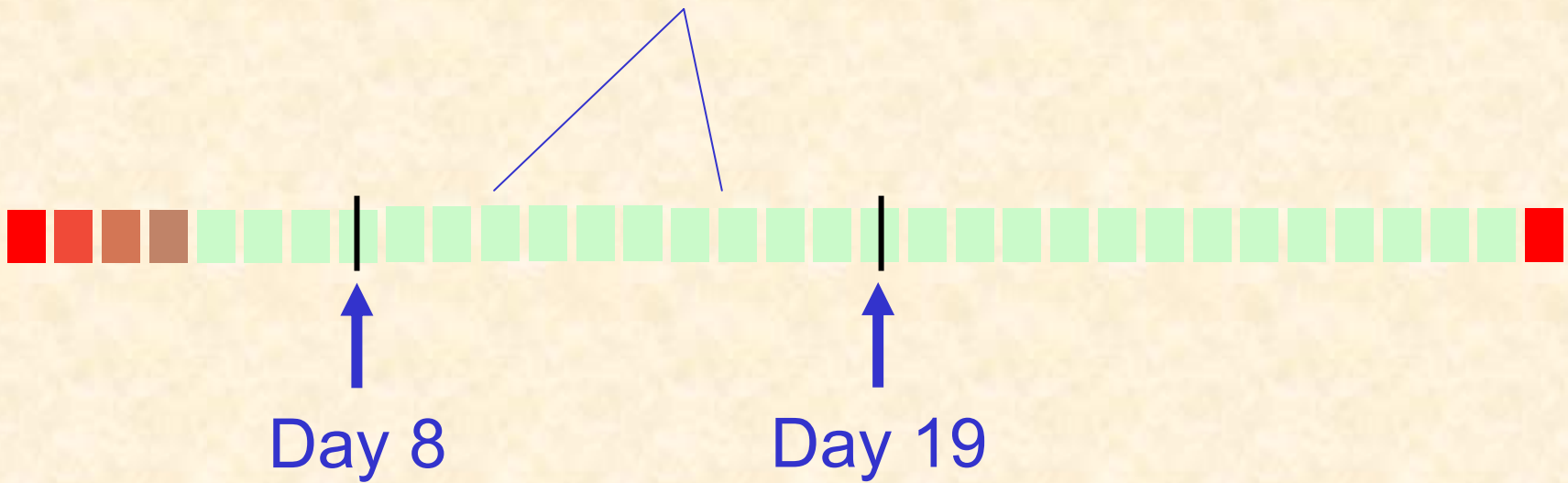




5. Standard Days Method (SDM)

Simple Fertility
Awareness-Based
Approach to Family Planning

Determining the Fertile Window



Standard Days Method

- Identifies days 8-19 of the cycle as fertile
- Is appropriate for women with menstrual cycles between 26 and 32 days long
- Helps a couple plan or prevent pregnancy by knowing which days they should or should not have unprotected sex

Standard Days Method

Is used with CycleBeads®, a color-coded string of beads to help a woman:

- Track her cycle days
- Know when she is fertile
- Monitor her cycle length



Contraceptive Failure of User-Directed Methods

% of women who became pregnant during 1st year of use

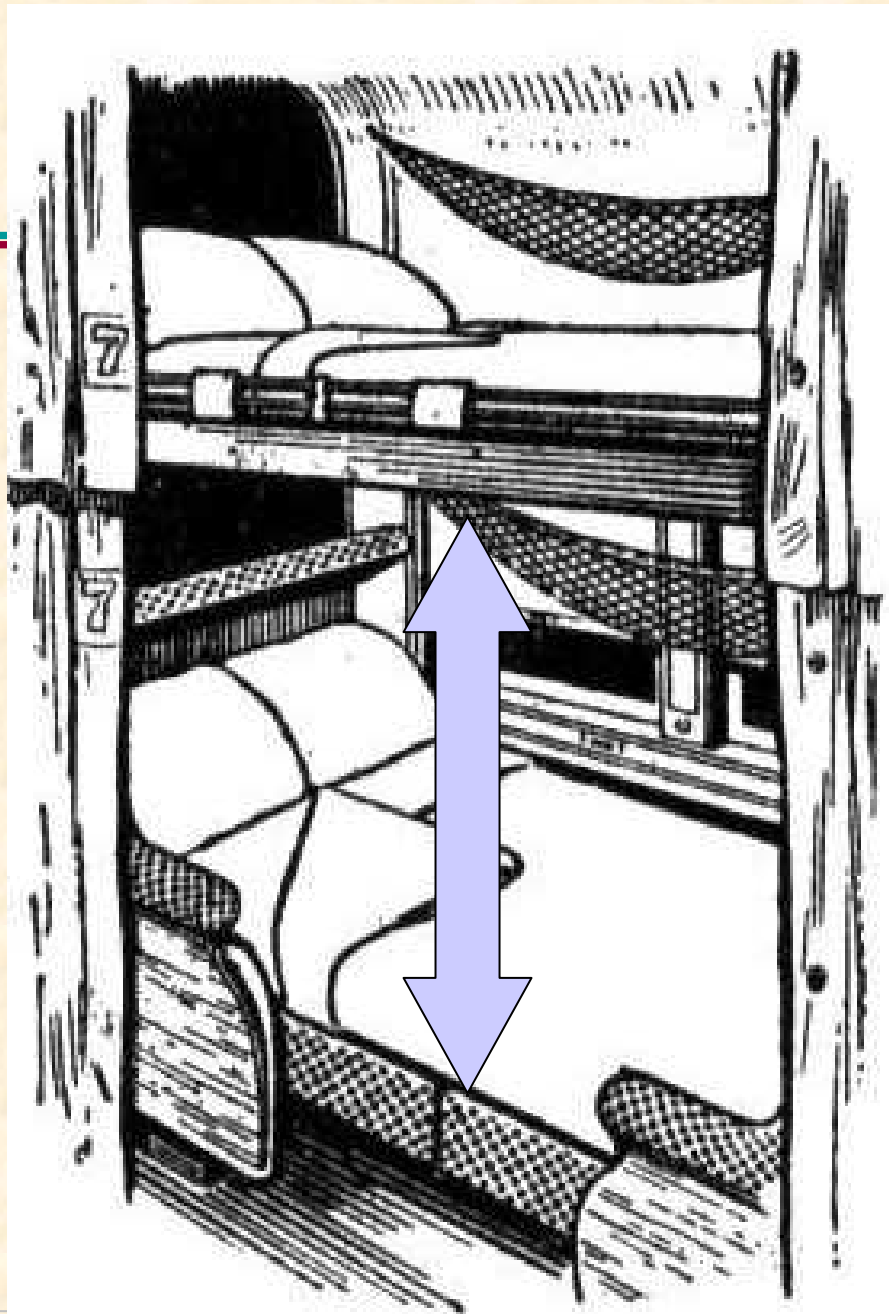
	Correct Use	Typical Use
No Method	85	85
Spermicides	18	29
Diaphragm	6	16
Condom	2	15
OC	.3	8
Standard Days Method	5	12

Source: Adapted from Contraceptive Technology, 18th edition, 2004

SDM - What does it cost?



- Less expensive than most other methods (only IUD is less per CYP)*
- Counseling takes about 20 minutes
- Training: in-service contraceptive updates, pre-service curriculae
- USAID working with manufacturer to ensure best price, efficient procurement and delivery for CycleBeads
- CycleBeads can be included in IEC budgets for bilaterals, centrally-funded projects
- Technical assistance from AWARENESS (Georgetown Institute for Reproductive Health)



6. Emergency Contraception (EC)

What is Emergency Contraception (EOC)?

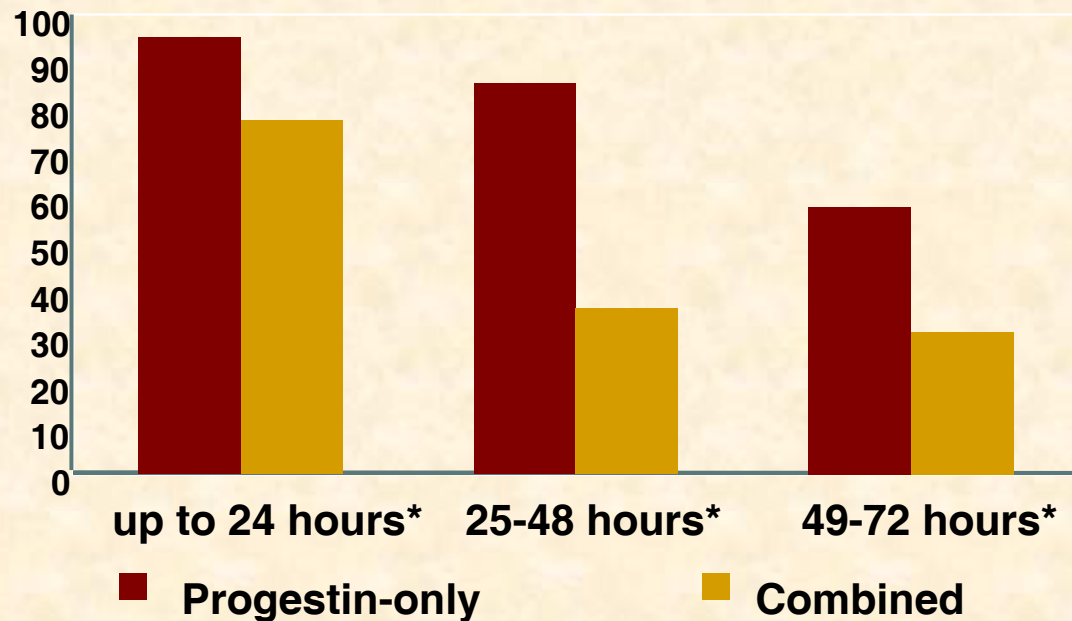
- Method of *preventing* pregnancy *after* unprotected sexual intercourse
- Mechanism of action: Predominantly and probably only affects ovulation.
- Hormones of Regular OCs, used:
 - in a special higher dosage
 - within 120 hours (5 days) of unprotected sex
- EC pills do *not* interrupt an established pregnancy
- (IUDs can also be used for up to 7 days after unprotected sex)
- Not RU-486

Types of ECPs

- **Progestin-only OC's** – in preferred regimen one dose of 1.5 mg levonorgestrel (or can be in 2 doses of 0.75mg, 12 hrs apart) → **88% reduction in risk** (1/100 will get pregnant); less side effects (nausea and vomiting) than with COCs, 6% vs 23%
- **Combined OCs: 2 doses of pills** containing ethinyl estradiol (100 mcg) & levonorgestrel (0.5 mg) **taken 12 hrs apart** → **75% reduction in risk** (2/100 vs. 8/100 will get pregnant)

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.

III. Fostering Change in Medical Settings: Some Evidence-Based Considerations and Their Implications for Our Work

The Nature of Medical Settings

Medical settings, systems, “culture” typically:

- Conservative: *Primum non nocere*:
 - great fear of “harm of doing” (“iatrogenic” illness) vs.
 - low concern / awareness of “**harm of not doing**”
- Hierarchical
- Curative-oriented; prevention and PH have lower priority & status
- Unreceptive to change, so change is slow

The Slow Pace of Change in Medical Settings: Evidence

- “Then”: scurvy/British navy/264 yrs (1497-1865)
- “There”: common in “developing countries”
- “Here” and “now”: U.S. examples
 - C-sections and hysterectomies
 - Treatment of heart attacks: took 11 yrs for 51% of American MDs to adopt correct rx.
 - NSV (51% only in 2004; yet devised in 1972; WHO still calling it a “new” method in 2003)

Why the Slow Pace of Change in Medical Settings?: Some Reasons

1. Lack of perceived need for change (“What’s worked for me is working”)
2. Lack of provider motivation (e.g., lack of perceived benefit to ↑ services; org. of work)
3. Ignorance of:
 - latest scientific findings
 - risks / benefits of methods (e.g., IUD)
 - concept of relative risk (FP side effects vs. risk of maternal morbidity /mortality)

Service Delivery Challenge: *Medical Barriers*

“... policies or practices, derived at least partly from a medical rationale, that result in scientifically unjustifiable impediment to, or denial of, contraception.”



Shelton, Angle, Jacobstein, *The Lancet*, Volume 340, November 28, 1992.

Types of Common Medical Barriers

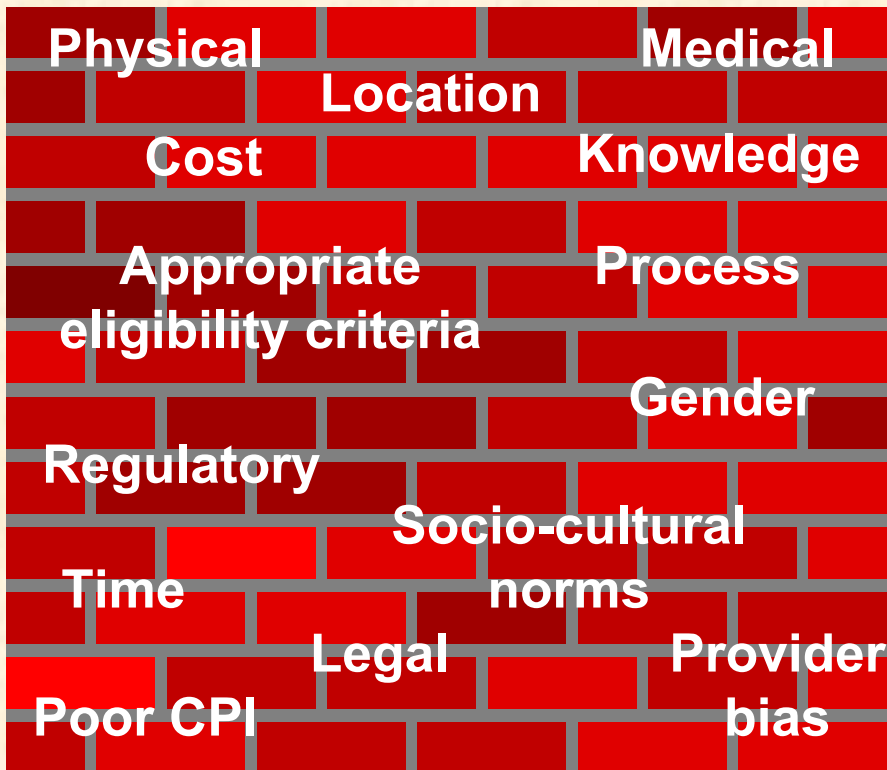
- *Provider bias* against (or for) the method
- Limitations on *which provider cadre can provide* the method
- *Inappropriate eligibility restrictions*
 - Age (“Not for the young”)
 - Parity (“No nullips need apply”)
 - “Can’t be post-partum or post-abortion”

Types of Common Medical Barriers (cont.)

- *Process hurdles*
 - Mandatory and unnecessary routine F/U
 - Marriage/spousal consent requirements
- *Unsubstantiated “contraindications”* (e.g., exaggerated/disproportionate fear of pregnancy or of STIs), operationalized, e.g., as
 - “Must be menstruating”
 - “Can’t have vaginal discharge”
 - “IUD not good for HIV+ women”
 - “IUD not suitable for Africa”

Also Many Other Barriers to FP Access and Quality We Must Address:

Barriers to effective family planning services



Outcomes when barriers are overcome:

➔ ↑ ↑ Access to services

➔ ↑ ↑ Quality of services

➔ ↑ ↑ Contraceptive choice



Why Talk About Change?

- We are “change agents”: it’s what we do when we “do development”
- Any PH “intervention” requires behavior change
- Principles & dynamics of behavior change are:
 - Empirically-based
 - Proven, valid, across time, place, sector
 - Influence rate and sustainability of adoption
 - Roadmap to more strategic/better programming
 - Yet often forgotten by programmers, donors, TA providers, and implementers [i.e., “us”]

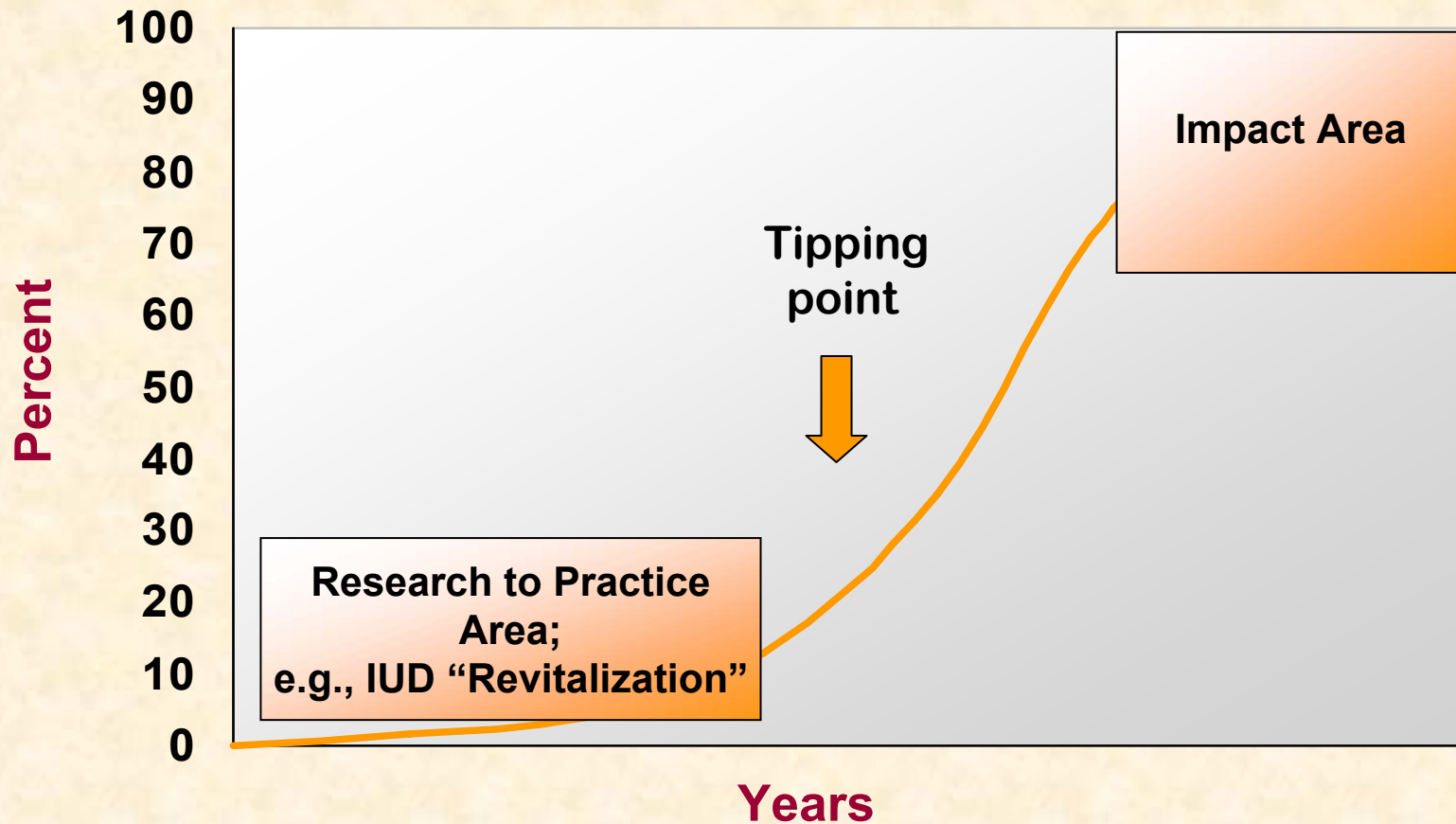
A Useful Theory of Change: The Diffusion of Innovations

Four elements, in *every* behavior change (i.e., program) effort:

- 1) “an *innovation*
- 2) *communicated through channels*
- 3) *over time*
- 4) *among members of a social system.*”

Rogers, E., 1995

Dynamics of Diffusion: The Tipping Point



The Three Main “Clusters of Influence” in Innovation Diffusion

- I. **What: Perceptions** of the innovation
- II. **Who:** Characteristics of the adopters
- III. **How: Contextual** factors, e.g.,:
 - » Communication
 - » Leadership
 - » Management/supervision
 - » Policies and guidelines

I. Perceptions of the Innovation

The five most influential properties of a given innovation; its:

- perceived 1. Benefit
- perceived 2. Compatibility
- perceived 3. Simplicity
- perceived 4. “Trialability”
- perceived 5. Observability

Together: 49-87% of variance in rate and/or extent of change

1. Perceived Benefit of the Innovation:

- Single most important variable influencing rate and extent of adoption of new behavior
- “What’s in it for me?”
- “Perceived” = eye of beholder / “changee” (NOT the change agent)
- Implies there are many “truths”
- Implies we need more “empathy”

1. Perceived Benefit of the Innovation:

- The greater *perceived* relative advantage, the more rapid the rate of adoption & change:
 - Diffusion of cell phone in sub-Saharan Africa
 - Diffusion of Depo and non-diffusion of the IUD
 - Non-embrace of VCT
- Sub-characteristics of this are the perceived:
 - Degree of economic profitability; low initial cost
 - Decrease in discomfort; ↑ in social prestige
 - Savings in time and effort; immediacy of reward**

Potential Adopters are NOT Empty Vessels



2. Perceived Compatibility of the Innovation:

- Avoid “Empty Vessel Syndrome”
- Compatibility with values, beliefs, norms, history, future needs of potential adopters (individuals and organizations), in context of their social systems
- If perceived more compatible = more apt to diffuse
- Language re innovation key: “Copper-T” / Korea; “No-va T” or Chevy Nova / Latin America
- Local analogues to FP Methods
- Beliefs around menstruation
- “Yes, but ... may not be true for ‘our’ women’

3. Perceived Simplicity of the Innovation:

- Innovations perceived as “simple” spread (diffuse) faster than ones seen as complex
 - Hence impulse to adapt [and almost always also to **simplify**]
 - Local adaptation is nearly universal in successful adaptations: not “spread” or “replication” or “scale-up,” but “reinvention”

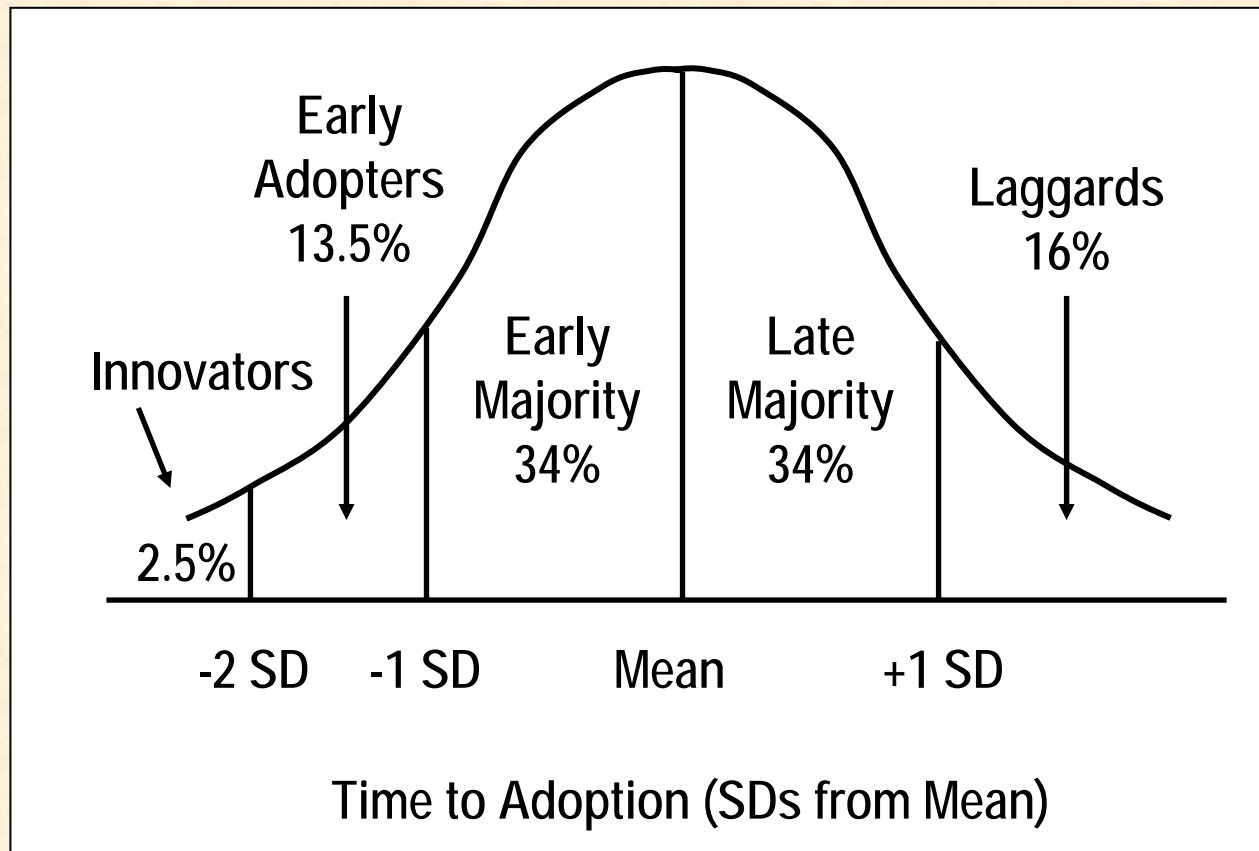
4. Perceived Trialability of the Innovation:

- Trialability (“pilot testability”): positively related to rate of adoption of a new behavior. [Agriculture]
- Innovations that can be tried on the “installment plan” are adopted more quickly than ones that are not divisible.
- More important in early stages

5. Perceived Observability of the Innovation:

- “Degree to which results of an innovation are visible to potential adopters”
- The easier to see an innovation, the more likely its adoption
 - Applicable to “pilots”
 - Preventive innovations less observable
 - FP by its nature generally less “visible”

II. Characteristics of the Adopters of Innovations



Characteristics of Early Adopters

Programmatically key because:

- Opinion leaders
- Locally well-connected socially
- Cross-pollinators (of ideas)
- Resources & risk tolerance to try the new
- Watched by others (thus crucial to dynamics of spread)
- Often chosen as leaders & representatives

The Three Main “Clusters of Influence” in Innovation Diffusion

- I. Perceptions of the innovation
- II. Characteristics of the adopters
- III. **Contextual factors**
 - Management/supervision
 - (Job) incentives
 - Leadership
 - Communication

Change Considerations: Find and Support Early Adopters

- Identify, invest in, support/nurture Early Adopters (individual providers and individual org. units)
 - As respected opinion leaders,
 - Can act as change agents/champions
 - We need to know who potential ones are
- Make Early Adopters' activity observable
 - Social channels important
 - Local networks important
 - Promote face-to-face interactions

Change Considerations: Learn from Past Mistakes

- “Research fallacy” (rational paradigm of science): “Build it and they will come” — not!
- “Training fallacy”: You have a performance problem? — “Training is the answer” — is it?
- Services fallacy: “We need to get services everywhere, now” — is that realistic? feasible?
- A pilot activity – is not (necessarily) a pilot: ask first “Who’s interested? How are they involved?”
- Something not called a “pilot” may still be one – e.g., many of our “project activities” are pilots

Change Considerations: Pilots, Demonstrations, “Positive Deviants”

- Pilot/demonstration/replication needs to be planned for up-front
- Pilots need to reflect program realities (WHO, contraceptive introduction, 1997)
- Identify, replicate, adapt good initial efforts
- “Rollout” or “Scale-up” IS diffusion
- Need to / good opportunity to / include policy-makers, decision-makers, future implementers, & convert them to champions

Change Considerations: Understand How Actors “See” the Change You Want to Introduce

- If perception = reality:
 - understand how a proposed change is “seen” by all the various actors in the system
 - Understand their “truths” about the benefits and/or aversiveness of the proposed change, and intervene accordingly
 - Address their reward systems, needs, fears, myths
- “We must walk in their shoes
... or else we will fail”

Change Considerations: Remember, There Are Two Experts in the Room



Source: JHU/CCP Photoshare

