Who Gets Prevention? Will It Have Impact?

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Family Health International

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Acknowledgments

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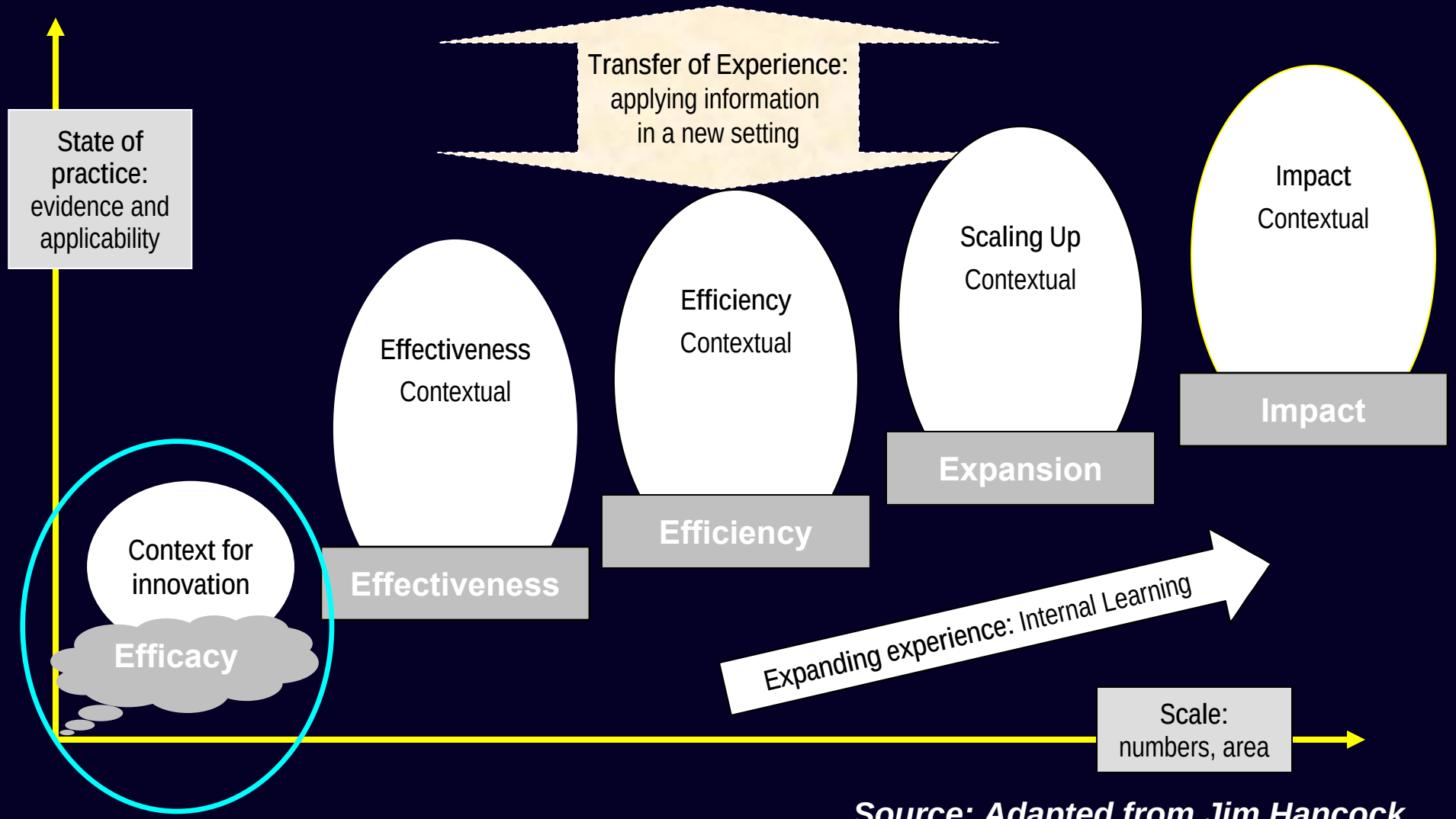
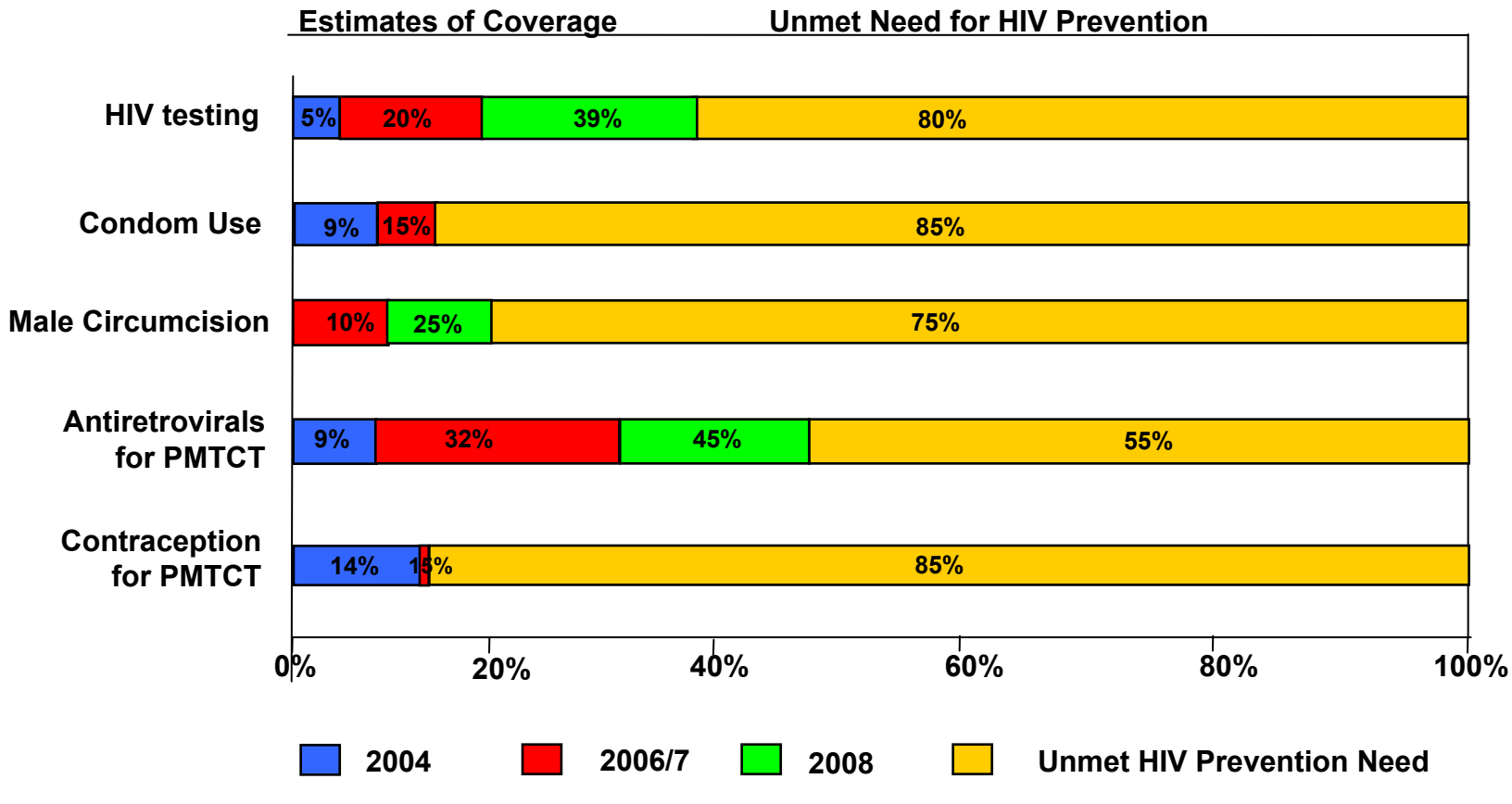
The Scale-up Ramp



Source: Adapted from Jim Hancock

Access to HIV Prevention Tools – Low Resource Countries, 2004-2008



Sources: UNAIDS, 2004; UNGASS, 2008; WHO, 2009

Effective HIV Prevention: We Need to Know Three Things

- Whether the intervention is acceptable outside trial settings
- Can the intervention be implemented in a large scale program
- Will the intervention have public health impact?

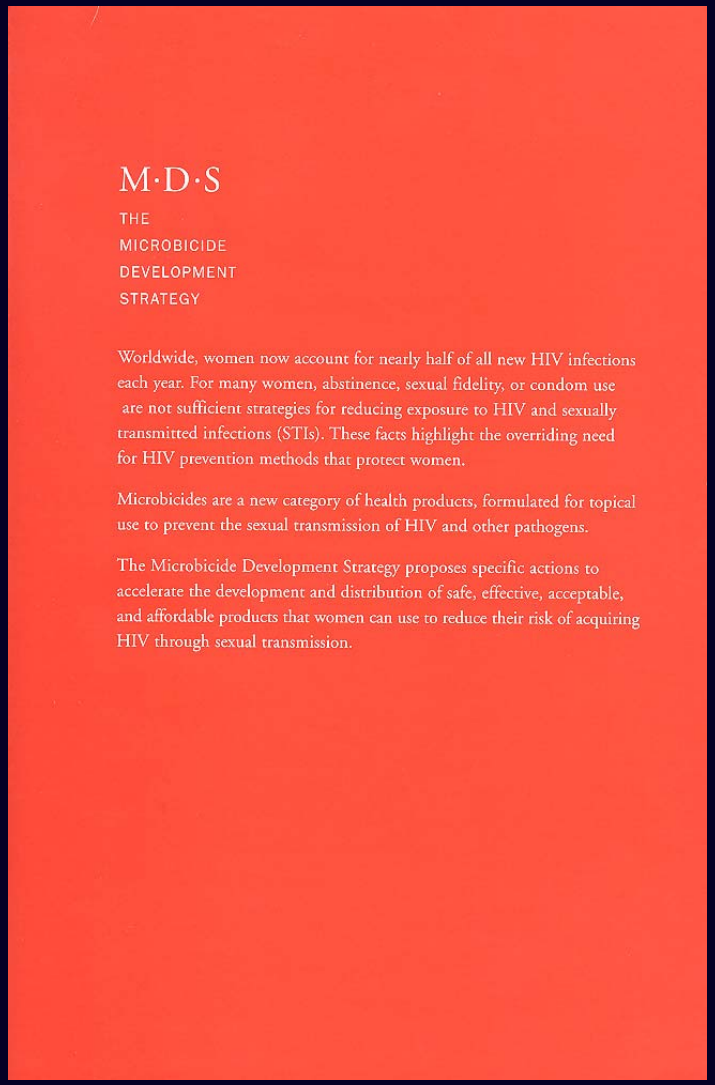
The Situation

- VOICE outcome
  - What if Truvada works?
  - What if Tenofovir works?
  - What if TDF gel works?
  - What if they all work?
- Who Gets The Product(s)?
- Will it/they have any PH impact?

The Planning

- 2006 – Microbicide Development Strategy
- 2007-2009 – IAS PrEP Planning Meetings
- 2009 – PRO2000 Preparation Meeting
- 2008-2010 – CDC's PrEP Planning Process

The Microbicide Development Strategy



M·D·S

THE
MICROBICIDE
DEVELOPMENT
STRATEGY

Worldwide, women now account for nearly half of all new HIV infections each year. For many women, abstinence, sexual fidelity, or condom use are not sufficient strategies for reducing exposure to HIV and sexually transmitted infections (STIs). These facts highlight the overriding need for HIV prevention methods that protect women.

Microbicides are a new category of health products, formulated for topical use to prevent the sexual transmission of HIV and other pathogens.

The Microbicide Development Strategy proposes specific actions to accelerate the development and distribution of safe, effective, acceptable, and affordable products that women can use to reduce their risk of acquiring HIV through sexual transmission.

Today's Outline

- Efficacy and Effectiveness
- The Prevention Cascade
- Targeted Use
- Prevention Politics

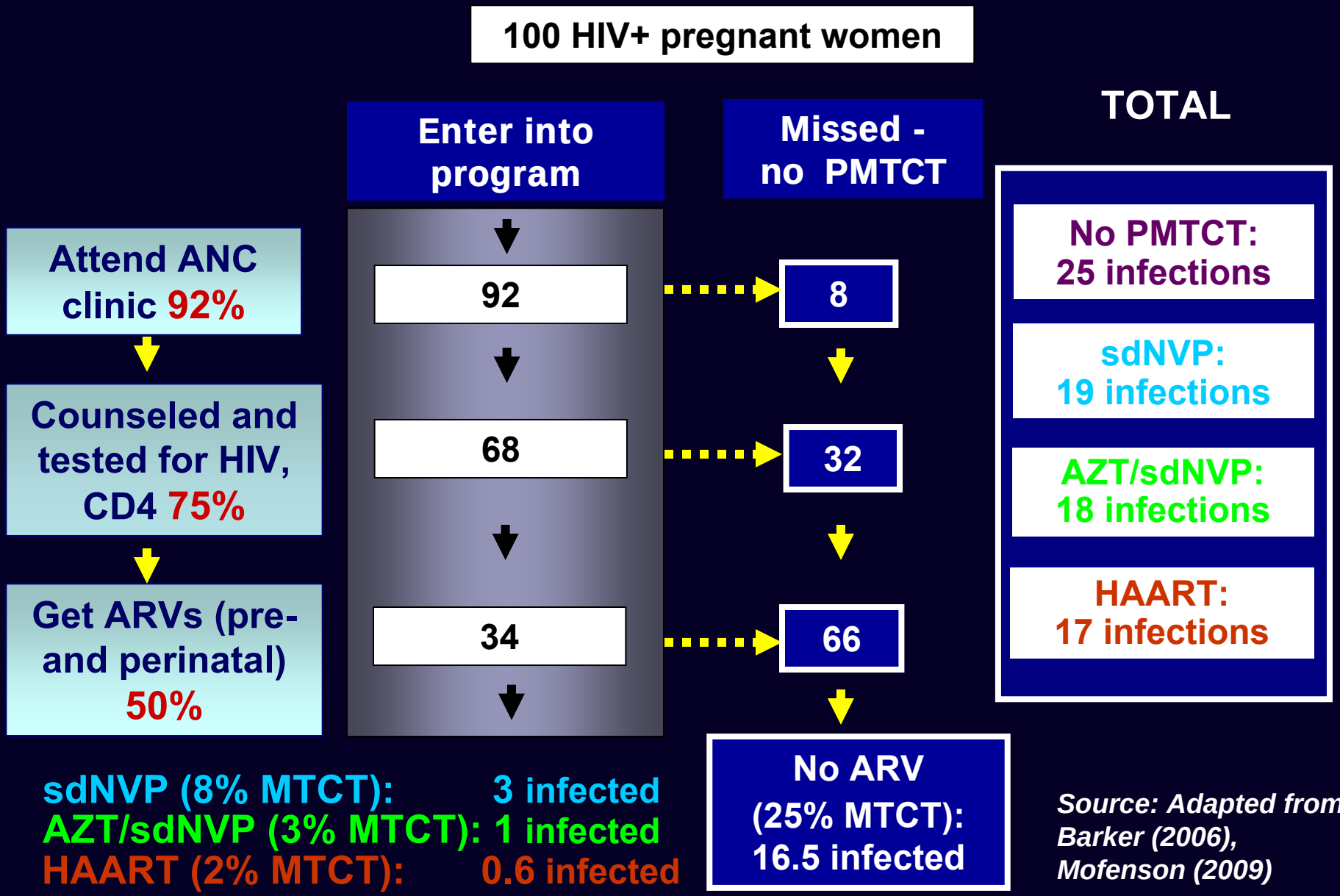
Adherence and Access – Level of Impact on Efficacy and Effectiveness

	Efficacy	Effectiveness
Adherence - Individual	Perfect Use	Typical Use
Access - Population	Clinical Trial Setting	Scale-Up

The Prevention Cascade

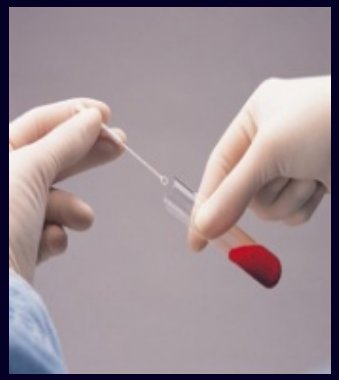
- A mix of adherence and access factors
- The ultimate determinant of PH impact
- PMTCT example
- Microbicide/PrEP extrapolation

PMTCT: Number of Women Completing Cascade



Source: Adapted from Barker (2006), Mofenson (2009)

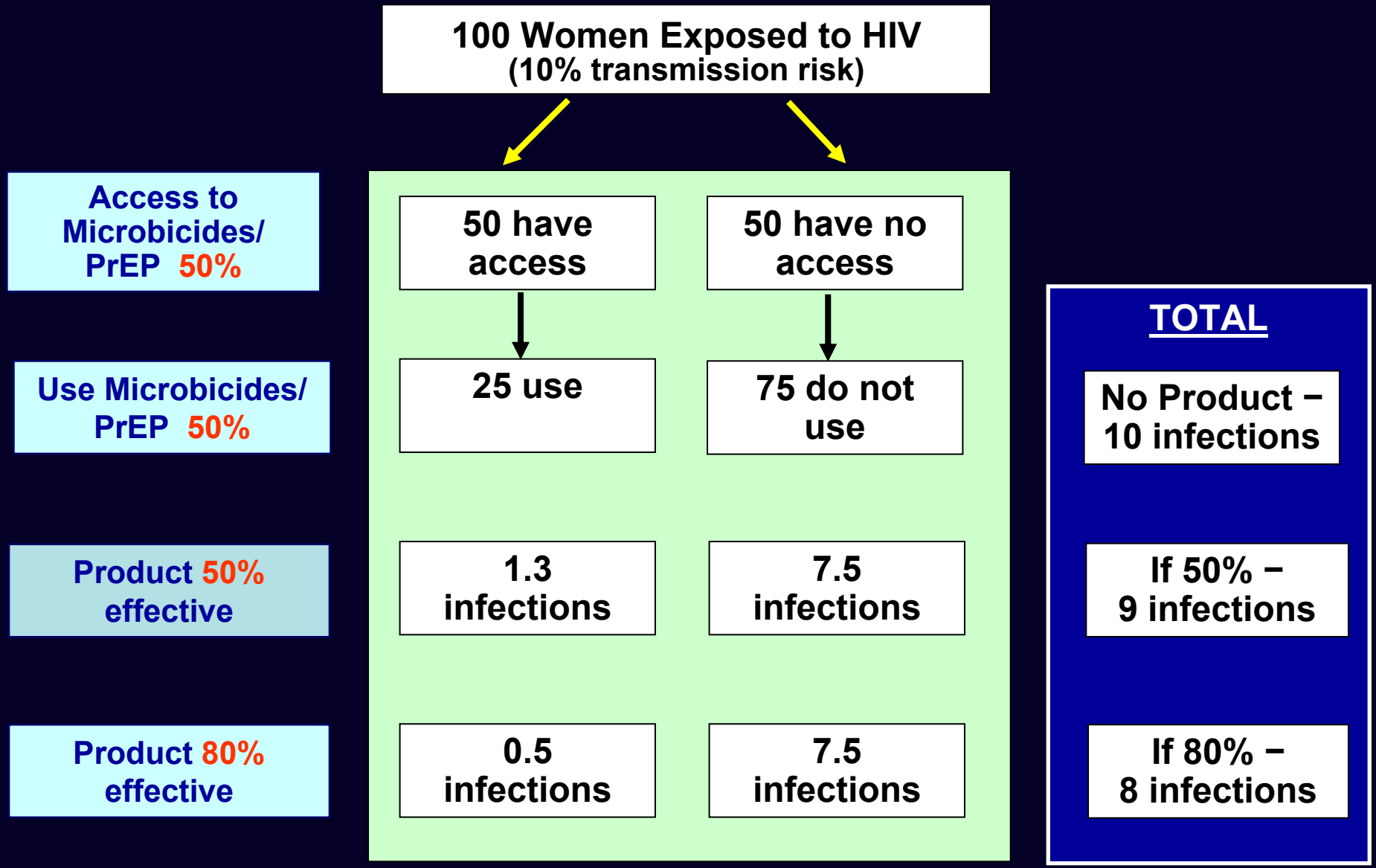
Impact of PMTCT Programs is More than the ART Regimen Used



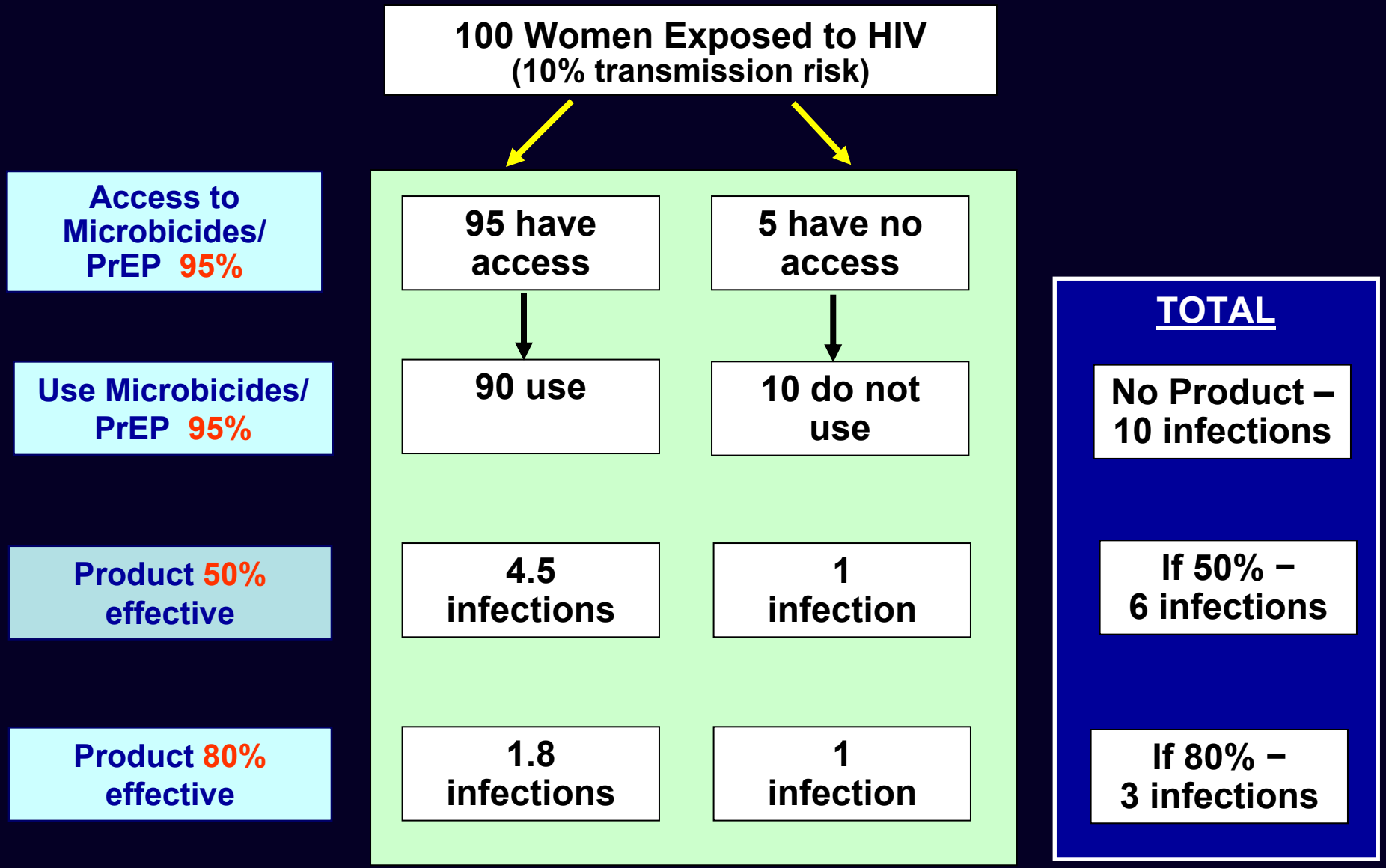
- Regardless of what ART regimens recommended, they must get to and be accepted by the woman
- In 2008, only 45% of known HIV-infected pregnant women in LRC received ART for PMTCT
- Program impact is more related to the effectiveness of the cascade than the efficacy of the ART regimen

Source: Mofenson (2009)

The Microbicide/PrEP Cascade – 50% Access/Adherence



The Microbicide/PrEP Cascade – 95% Access/Adherence



The Microbicide/PrEP Cascade – Conclusions

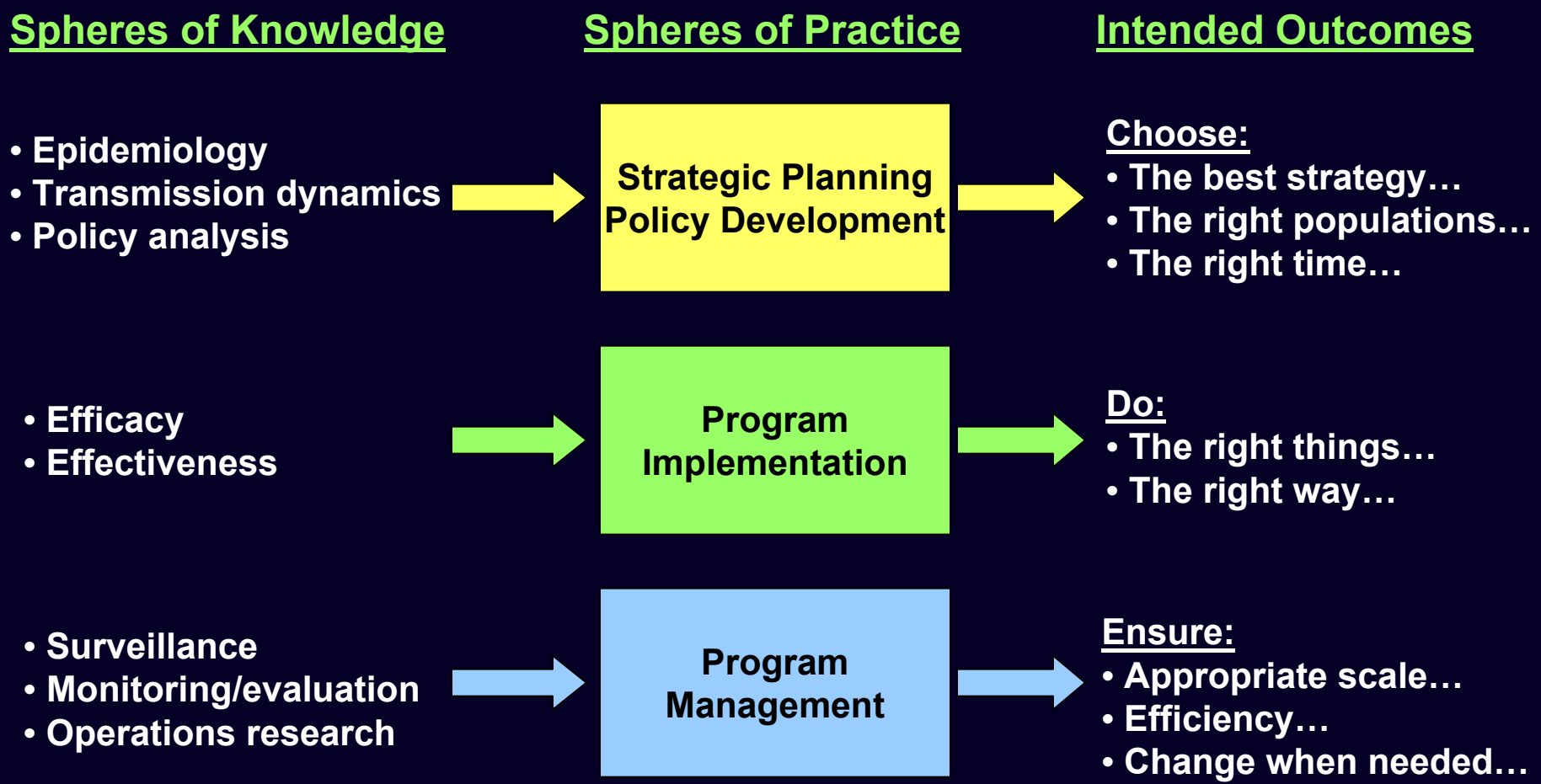
- Number of infections prevented is more affected by access and adherence than by increased product effectiveness
- Behavioral and health services delivery factors crucial to product impact
- Evidence is needed now to improve access when product proven effective
- Implementation Science – NIH semantics
- Program Science – Evolving semantics

Implementation vs. Program Science

- Implementation science — how to ensure access to evidence-based interventions
- Program science also addresses:
  - Strategic focus and timing (with whom, when, for how long?)
  - Mix of interventions
    - To achieve synergy
    - To avoid antagonism (disinhibition)
  - Processes to optimize coverage and quality

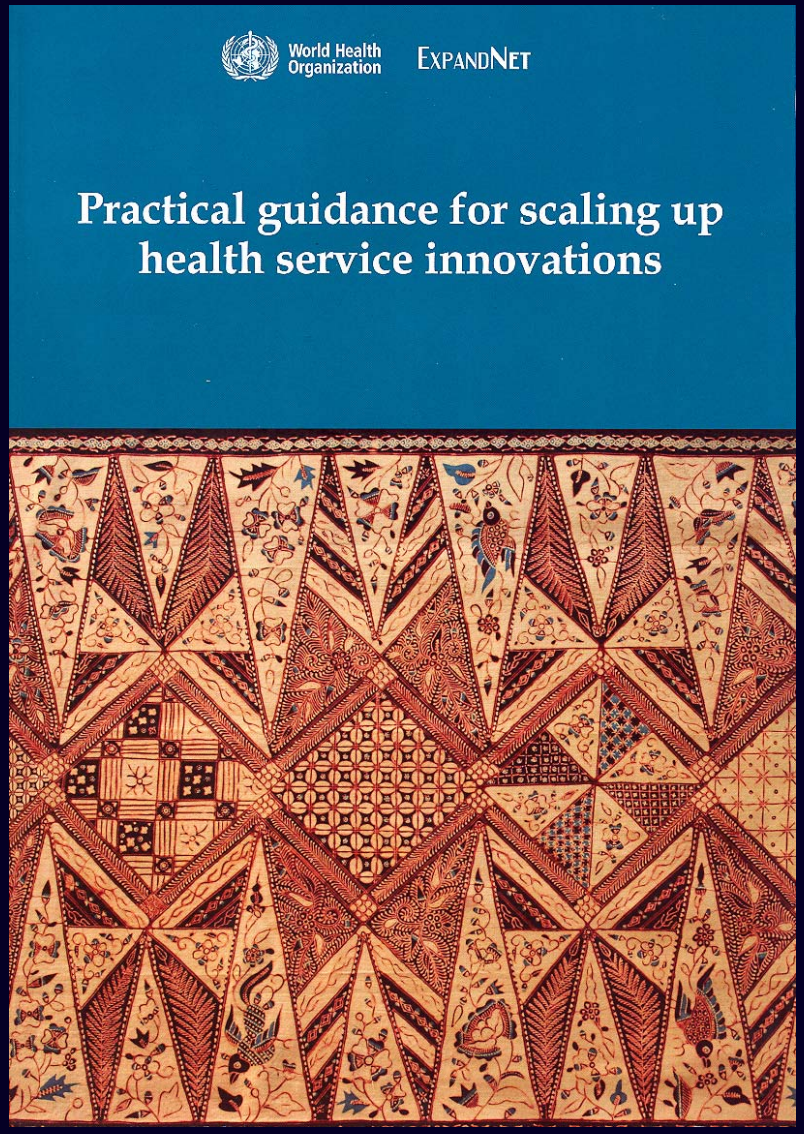
Source: Blanchard (2010)

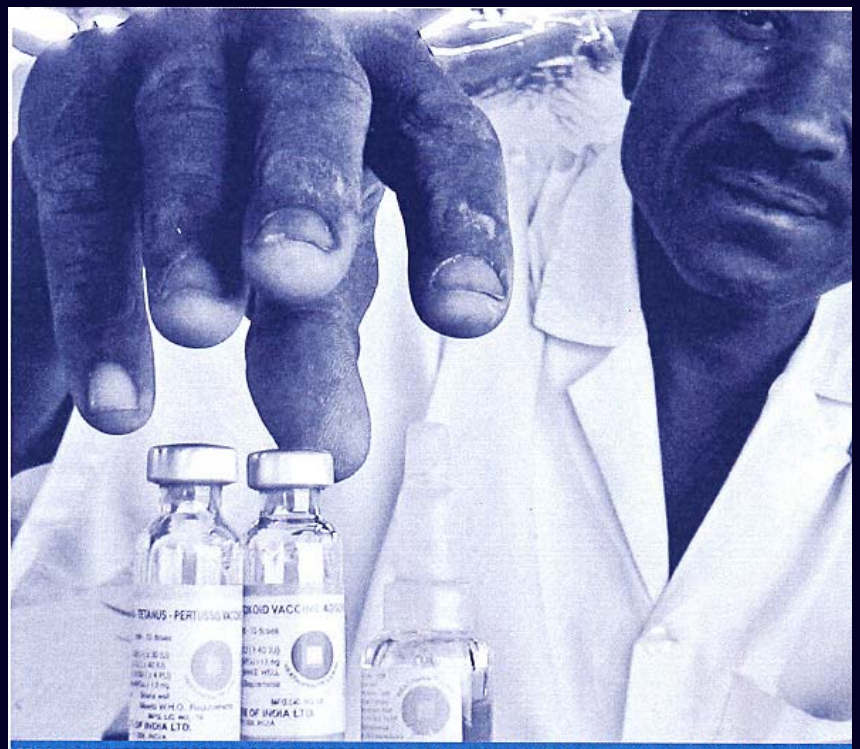
From "Implementation Science" to "Program Science" – A Simple Model



Source: Blanchard (2010)

The ExpandNet Approach





ACCESS ACCESS ACCESS

How do good health technologies get to poor people in poor countries?

Laura J. Frost & Michael R. Reich

Who Gets Prevention – Targeting Orals

- Not for general use
  - Resistance concerns
  - Cost
  - Safety
  - Sharing
- Focus on high-transmission intervals
  - Discordant couples trying to conceive
  - Weekend raves
  - Young women in SSA
  - Transient sex workers

Who Gets Prevention – Targeting Topicals

- Wider use
  - Fewer resistance, safety concerns
  - More coitally-linked
- Pleasure as a motivator
  - J & J commercial experience
  - Microbicide trial cessation experience

Prevention Politics

- Flat trajectory of global HIV resources
- New HIV infections annually exceeds HIV treatment incidence
- The HIV problem continues to worsen
- We need targeted prevention now
- “More AIDS prevention for the resources”

Current MTN Efforts

- Safety and effectiveness (MTN trials)
- Acceptability and adherence (BWRG)
- Manufacturing capacity/distribution (MTN working with Gilead)
- Marketing (MTN beginning to consider this with the next talks)

Is this enough?

Conclusion

- Dynamic field beyond product development
- Broad lessons already learned
- Program science as an emerging field
- MTN implications – ?? Program Science Working Group