

# “No Butts About It”

## Rectal Microbicides and HIV Prevention for Anal Intercourse



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**Regional Director**

**UCLA Program In Global Health**

**Latin America**

**Steering Committee member, IRMA**

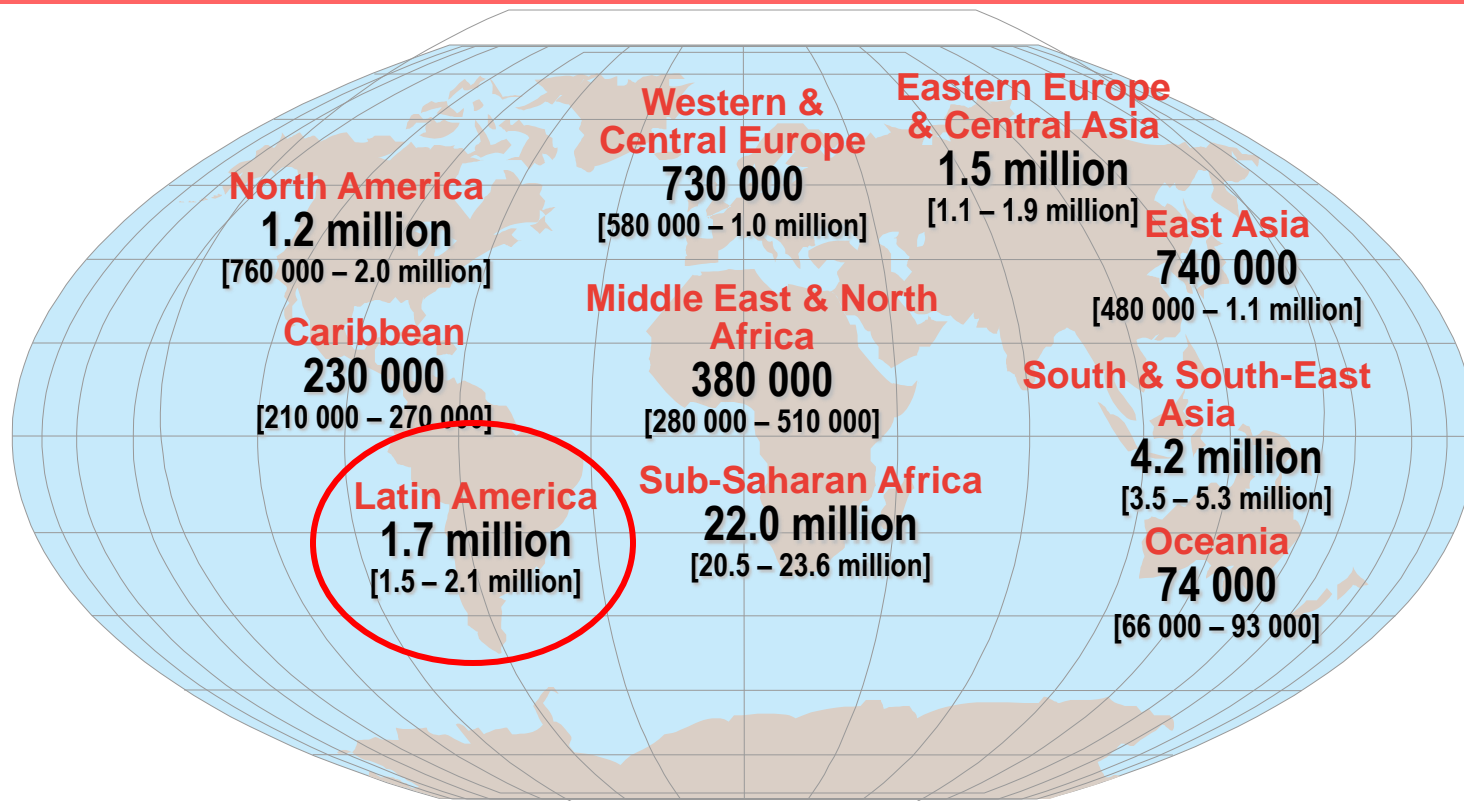
**Centre for Evidence Based Intervention  
Multidisciplinary Seminar Series**



**27 October, 2009**

- **Panorama of HIV**
- **If condoms work, why do we need new prevention technologies?**
- **Microbicides: What are they and how do they work?**
- **Who would use a RM? Who has Anal sex?**
- **Vaginas and Rectums**
- **Research overview**
- **Focus on Latin America**
- **Advocacy**

## Adults and Children Living with HIV: 2007

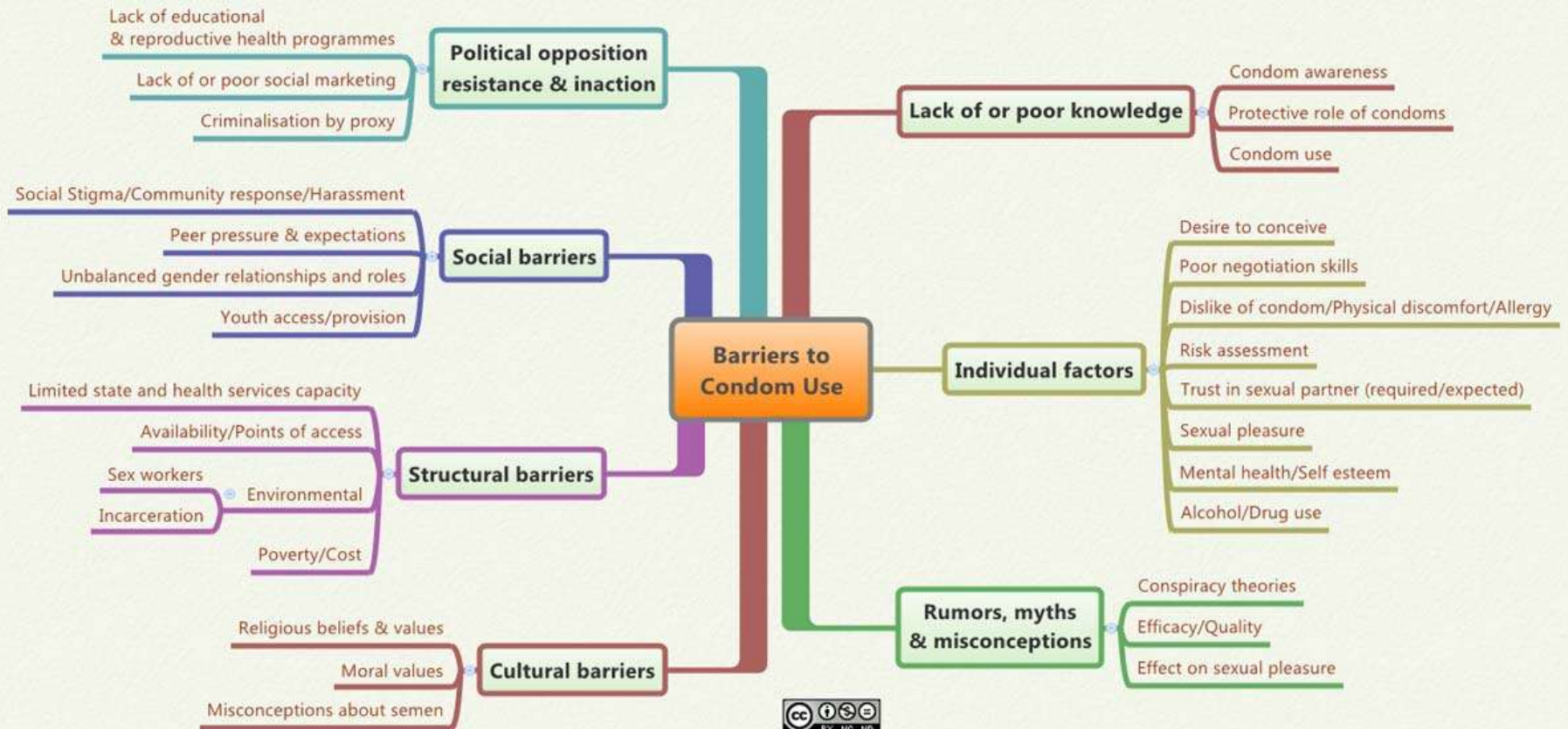


**Total: 33.2 million (30 – 36 million)**

- **33.2 million people living with HIV/AIDS**
- **2.5 million new infections each year (about 7,000 infections per day)**
- **Women account for about half of all new infections (globally)**
- **Over 25 million people have died**
- **About 95% live in developing countries**
- **About 90% do not know their status**

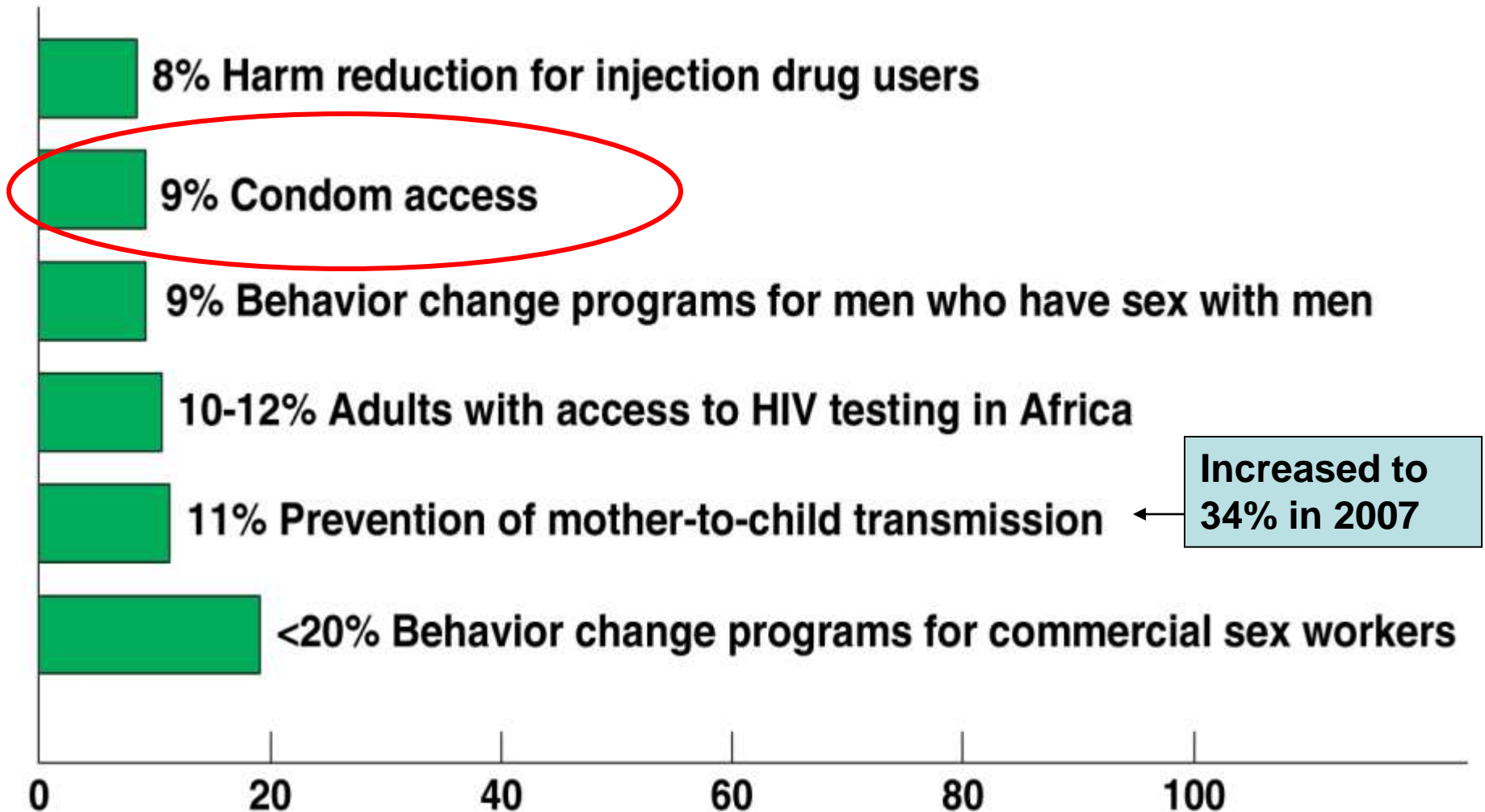
*Q.*

If condoms work, why  
do we need new  
prevention  
strategies?



(c) peripheries 2009

# Percentage of Individuals at Risk with Access to HIV Prevention



# What if we had a complete HIV toolkit?

## Prior to exposure

- Rights-focused behaviour change
- Voluntary counselling and testing
- STI screening and treatment
- Male circumcision (MSM?)
- **Preventive Vaccines**
- **ART to prevent infection (PREP)**

## Point of transmission

- Male and female condoms and lube
- ART to prevent perinatal transmission
- Clean injecting equipment
- ART during exposure or soon after (PEP)
- **Cervical barriers**
- **Vaginal and rectal microbicides**

## Treatment

- Improved antiretroviral therapy
- Treatment for opportunistic infections
- Basic care/nutrition
- Prevention for positives (P4P)
- Education and behavior change
- **Therapeutic vaccines**

*“Combination prevention is essential since HIV prevention is neither simple nor simplistic.”*

Coates et al / Lancet, 2008

## Car Safety prevention Toolkit



+



+



+



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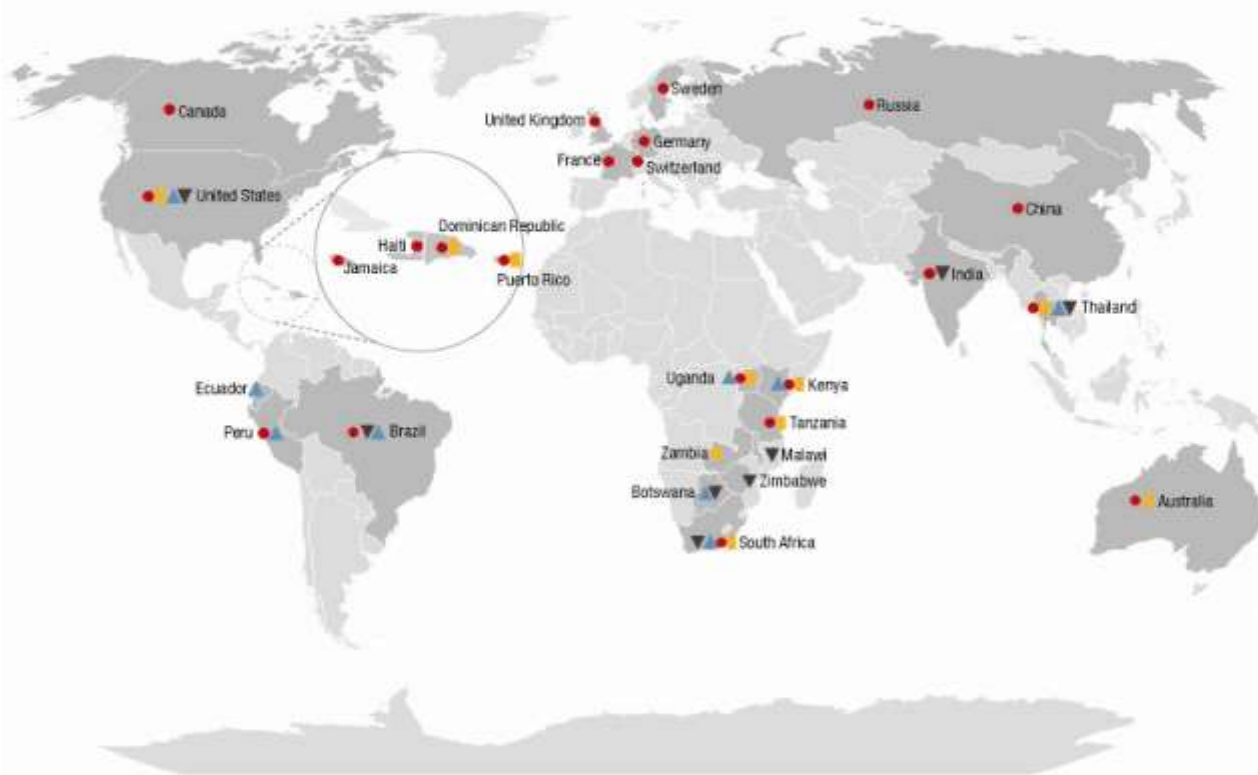
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**Px Wire:** A Quarterly Update on HIV Prevention Research

**AVAC**  
Global Alliance for HIV Prevention  
Volume 2 | No. 2  
April-June 2009

**ONGOING TRIALS OF NEW PREVENTION OPTIONS WORLDWIDE**



- Australia
- ▼ Botswana
- ▼ Brazil
- Canada
- China
- Dominican Republic
- ▲ Ecuador
- France
- Germany
- Haiti
- ▼ India
- Jamaica
- ▲▼ Kenya
- ▼ Malawi
- ▲▼ Peru
- ▼ Puerto Rico
- Russia
- ▼▲ South Africa
- Sweden
- Switzerland
- ▼ Tanzania
- ▼ Thailand
- ▲▼ Uganda
- United Kingdom
- ▼ United States
- Zambia
- ▼ Zimbabwe

● VACCINES ■ MICROBICIDES ▲ PRE-EXPOSURE PROPHYLAXIS ▼ PARTNER TREATMENT  
○ New □ New △ New ▽ New

BIOMEDICAL HIV PREVENTION RESEARCH: A COMPREHENSIVE TIMELINE OF EFFICACY TRIAL RESULTS\*

2007	2008	2009	2010	2011	2012+
<p><b>CONRAD CELLULOSE SULFATE</b> Phase II trial to evaluate the effect of cellulose sulfate gel on vaginal HIV transmission in women (Benin, India, South Africa, Uganda, Zimbabwe) <i>Trial stopped early. No evidence of benefit. There were more infections among women using the gel than those using placebo, but this was not statistically significant.</i></p>	<p><b>HIV-2 SUPPRESSION (HPTN 030)</b> Phase III trial to evaluate suppressive acyclovir treatment for the reduction of HIV infection in HIV-2 seropositive women and men who have sex with men (Peru, South Africa, US, Zambia, Zimbabwe) <i>No evidence of benefit.</i></p>	<p><b>HPTN 035</b> Phase II/IIIb trial to evaluate the safety and effectiveness of the vaginal microbicides, BufferGel and 0.5% PRO 2000/5 gel, to prevent HIV infection in women (Malawi, South Africa, US, Zambia, Zimbabwe) <i>There were fewer infections in women using PRO 2000 than women using the placebo gel, but the difference was not statistically significant. No evidence of benefit in women using BufferGel.</i></p>	<p><b>CDC 4323</b> Phase II trial to evaluate the clinical and behavioral safety of once-daily oral TDF among men who have sex with men (US) <i>Release of results expected February in 2010</i></p>	<p><b>CDC 4940</b> Phase II trial to evaluate the safety and efficacy of once-daily oral TDF/FTC to prevent HIV infection in heterosexual men and women (Botswana)</p>	<p><b>PARTNERS PrEP</b> Phase II trial to evaluate the safety and efficacy of two different strategies to prevent HIV transmission in HIV-serodiscordant couples: once-daily oral TDF and once-daily oral TDF/FTC (Kenya, Uganda)</p>
<p><b>PH CELLULOSE SULFATE</b> Phase II trial to evaluate the safety and effectiveness of cellulose sulfate gel to prevent HIV infection in women (Nigeria) <i>Trial stopped following announcement of data from CONRAD trial. No evidence of safety concerns or of effectiveness.</i></p>	<p><b>MALE CIRCUMCISION IN HIV-POSITIVE MEN</b> Large-scale trial to evaluate the safety of male circumcision and its potential protective effect for HIV-negative female partners of HIV-positive circumcised males (Uganda) <i>Trial stopped enrollment, December 2008. No statistically significant conclusions could be drawn from sample size. However, men who resumed sex prior to sexual healing were more likely to transmit HIV to their female partners.</i></p>	<p><b>PARTNERS IN PREVENTION</b> Phase II study to evaluate the effect of suppressive acyclovir treatment for HIV-2 on HIV transmission in HIV-serodiscordant couples (Botswana, Kenya, Rwanda, South Africa, Tanzania, Uganda, Zambia) <i>No evidence of reduced rates of HIV transmission, but there were reduced rates of genital ulcers and HIV analitis.</i></p>	<p><b>CDC 4379</b> Phase II/III trial to evaluate the safety and efficacy of once-daily oral TDF to prevent HIV infection in injecting drug users (Thailand)</p>		<p><b>HPTN 052</b> Phase II trial to evaluate the effectiveness of two antiretroviral treatment strategies to prevent HIV transmission in HIV-serodiscordant couples (Botswana, Brazil, India, Malawi, South Africa, Thailand, US, Zimbabwe)</p>
<p><b>MIRA</b> Phase II trial to evaluate effectiveness of the female diaphragm to prevent HIV infection (South Africa, Zimbabwe) <i>No evidence of benefit.</i></p>	<p><b>CARRAGUARD</b> Phase II trial to evaluate the safety and efficacy of the microbicide Carraguard to prevent HIV infection in women (South Africa) <i>No evidence of benefit.</i></p>	<p><b>ALVAC-AIDSVAX (RV 144)</b> Phase II trial to evaluate the safety and efficacy of a prime-boost vaccine strategy (ALVAC plus AIDSVAX) to prevent HIV infection (Thailand) <i>Release of results expected in October 2009.</i></p>	<p><b>iPEX</b> Phase II trial to evaluate the safety and efficacy of once-daily oral TDF/FTC to prevent HIV infection among men who have sex with men (Brazil, Ecuador, Peru, South Africa, Thailand, US)</p>		<p><b>FEM-PrEP</b> Phase II trial to evaluate the safety and effectiveness of once-daily oral TDF/FTC for HIV prevention in women (Kenya, South Africa, Tanzania, Zambia)</p>
<p><b>STEP (HVTN 502/Merck 023)</b> Phase IIb test-of-concept trial to evaluate safety and efficacy of Merck's A65 candidate (Australia, Brazil, Canada, Dem. Rep., Haiti, Jamaica, Peru, Puerto Rico, US) <i>Trial halted immunizations, September 2007. Data analysis found no evidence of benefit and potential for increased risk of HIV infection among A65-seropositive, unimmunized men; follow-up continues.</i></p>		<p><b>MDP 301</b> Phase II trial to evaluate the safety and efficacy of the 0.5% PRO 2000/5 to prevent HIV infection in women (South Africa, Tanzania, Uganda, Zambia) <i>Release of results expected in November 2009.</i></p>	<p><b>CAPRISA 004</b> Phase IIb trial to evaluate the safety and effectiveness of 1% tenofovir gel to prevent HIV infection in women (South Africa)</p>		<p><b>VOICE (MTN-003)</b> Phase IIb trial to evaluate the safety and effectiveness of three different strategies to prevent HIV in women: once-daily oral TDF, once-daily oral TDF/FTC, and 1% tenofovir gel (South Africa, Uganda, Zambia, Zimbabwe)</p>
<p><b>PHARMBILI (HVTN 503)</b> Phase IIb test-of-concept trial to evaluate the safety and efficacy of Merck's A65 candidate (South Africa) <i>Trial halted enrollment and immunizations, following Step; follow-up continues.</i></p>					<p><b>HVTN 505</b> Phase II test-of-concept trial to evaluate the safety and effect on post-HIV infection viral load of the VRC01 DNA prime / A65-boost vaccine strategy in HIV-negative, A65-seronegative and circumcised men who have sex with men (US)</p>

■ VACCINE  
■ PRE-EXPOSURE PROPHYLAXIS (PrEP)  
■ HERPES SIMPLEX VIRUS 2 (HSV-2) TREATMENT/SUPPRESSION  
■ MICROBICIDE  
■ MALE CIRCUMCISION  
■ CERVICAL BARRIER METHOD  
■ PARTNER TREATMENT  
 TRIAL COMPLETED OR STOPPED

To view this timeline online with trial details please visit [www.avac.org/timeline-website](http://www.avac.org/timeline-website).  
 Trials listed here are subject to interim analysis throughout the length of the trial.  
 \* The trial end-dates listed in this table are estimates. Due to the nature of clinical trials the actual dates may change.

**Q.** What is a  
microbicide?

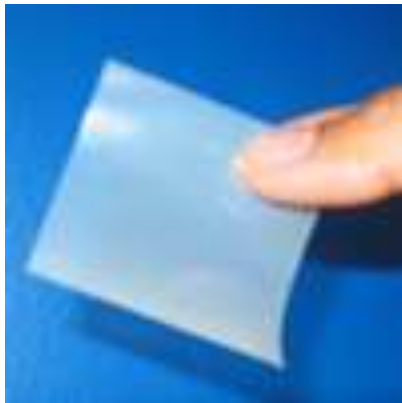
**a.** A microbicide is a  
topical product that could  
reduce the risk of HIV and  
other sexually transmitted  
infections when applied /  
inserted prior to anal or  
vaginal sex.



Gel



Vaginal Ring



Film



Suppository



Enema

- Different mechanisms of action to prevent HIV infection
- Each mechanism attacks HIV at vulnerable points to disrupt infection
- Microbicides can generally be grouped together as either “broad spectrum” or “HIV specific”

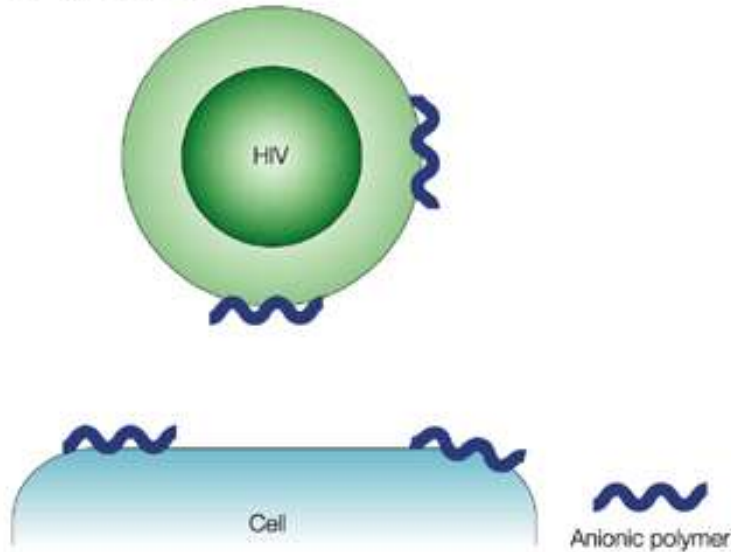
## Broad spectrum

- Prevents HIV from entering healthy cells by creating a barrier between the cell and HIV
- Can strengthen the vagina's natural defense system
- Kills the virus by attacking it

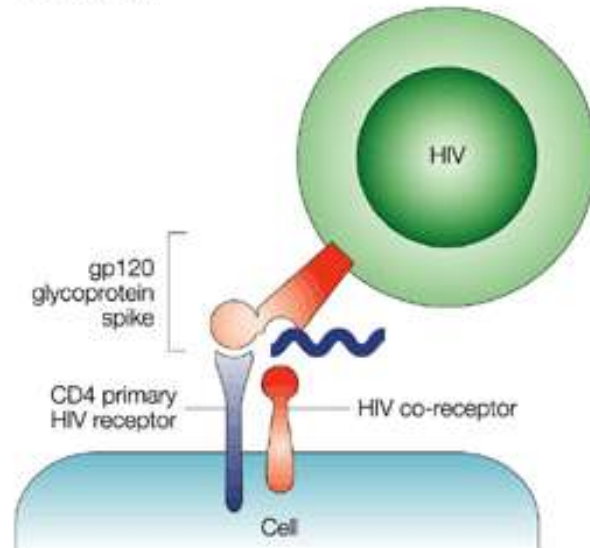
## ARV-based (HIV specific)

- Blocks specific proteins of HIV so that it cannot bind with a healthy cell
- Blocks receptors on healthy cells so that HIV cannot bind with them
- Deactivates key components of the HIV to inhibit replication

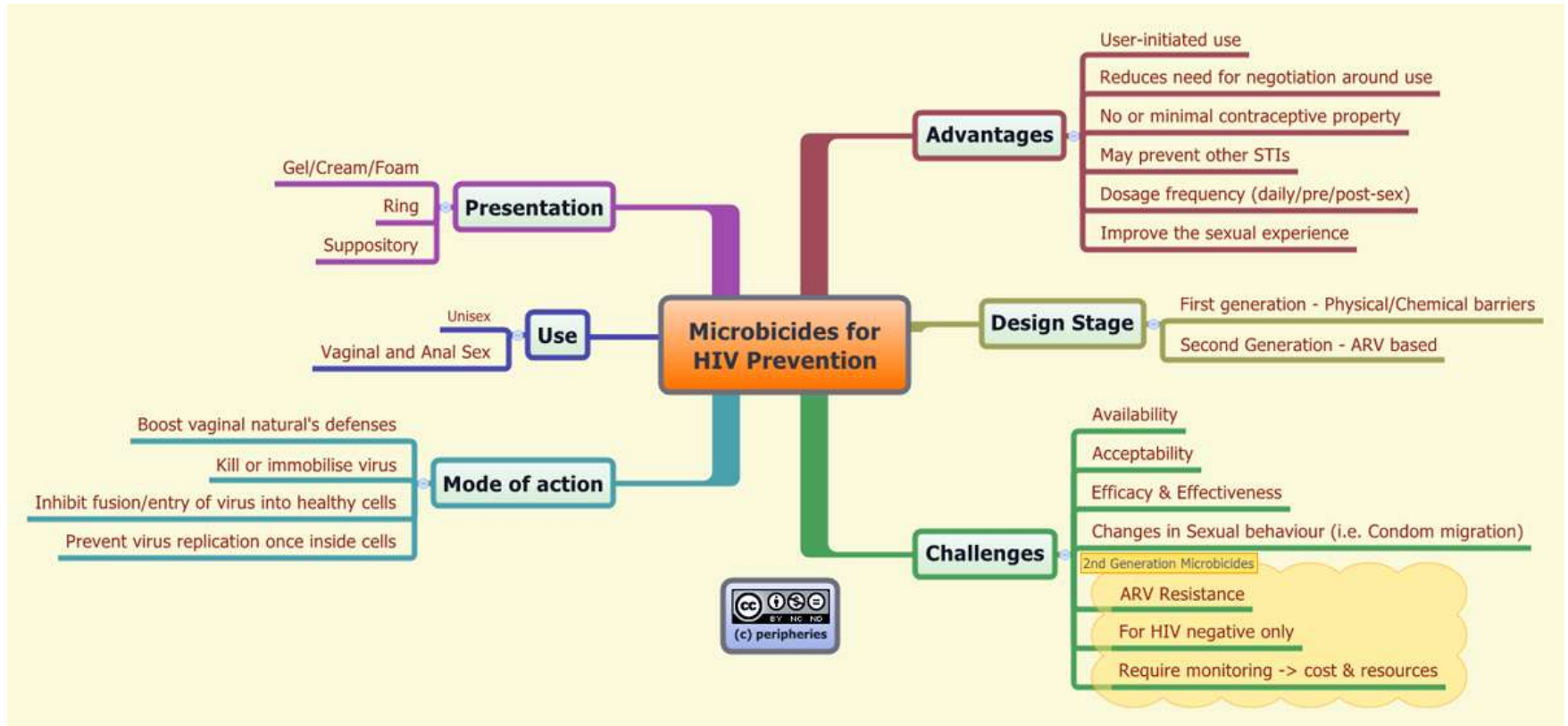
**a Non-specific**



**b Specific**



Nature Reviews | Drug Discovery



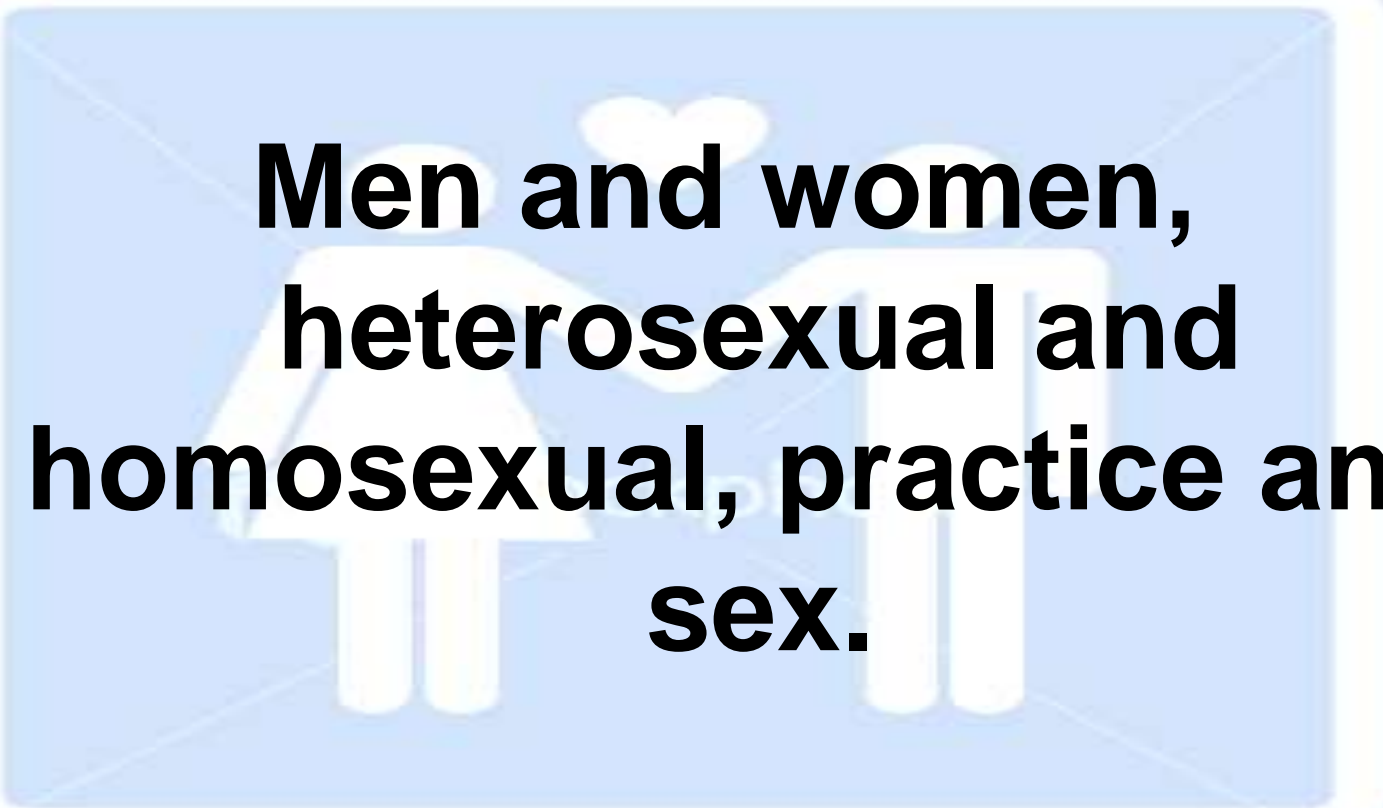
**Q.** Why the interest in  
**rectal** microbicides?

Who has anal sex?

*a.*

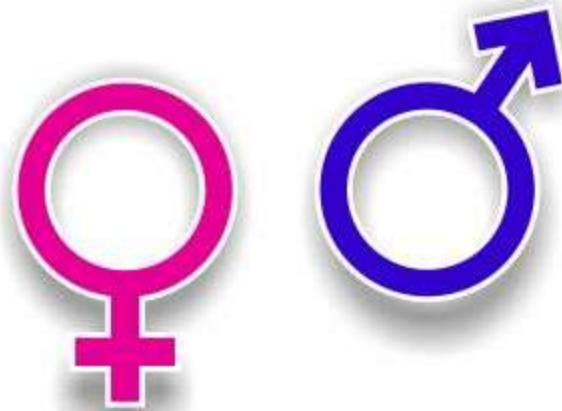
**1. Anal sex is common – both heterosexual and homosexual**

**2. The rectum is different than the vagina**



**Men and women,  
heterosexual and  
homosexual, practice anal  
sex.**

# Heterosexual Anal Intercourse (AI)



- “There is a common misconception that anal sex is practised almost exclusively by gay men. This is certainly not the **case...about one third of heterosexual couples try it from time to time.**”
- It is thought that about 10 per cent of heterosexual couples have anal intercourse as a more regular feature of their lovemaking. **In absolute numbers, more heterosexual couples have anal sex than homosexual couples, because more people are heterosexual.**”

- **Prevalence of AI among heterosexuals not well defined:**
  - **Varies regionally by age, population, co-risk**
  - **AI is relatively common globally, 5 – 10% in gen. pop. and up to 30-50% of women with other HIV risks engage in AI**
- **UAI\*** may be significant source of HIV transmission, including regions where the epidemic is labelled “heterosexual”
- **Volume unprotected AI est. 7x higher in het compared to gay/MSM in US (conservative estimate)**

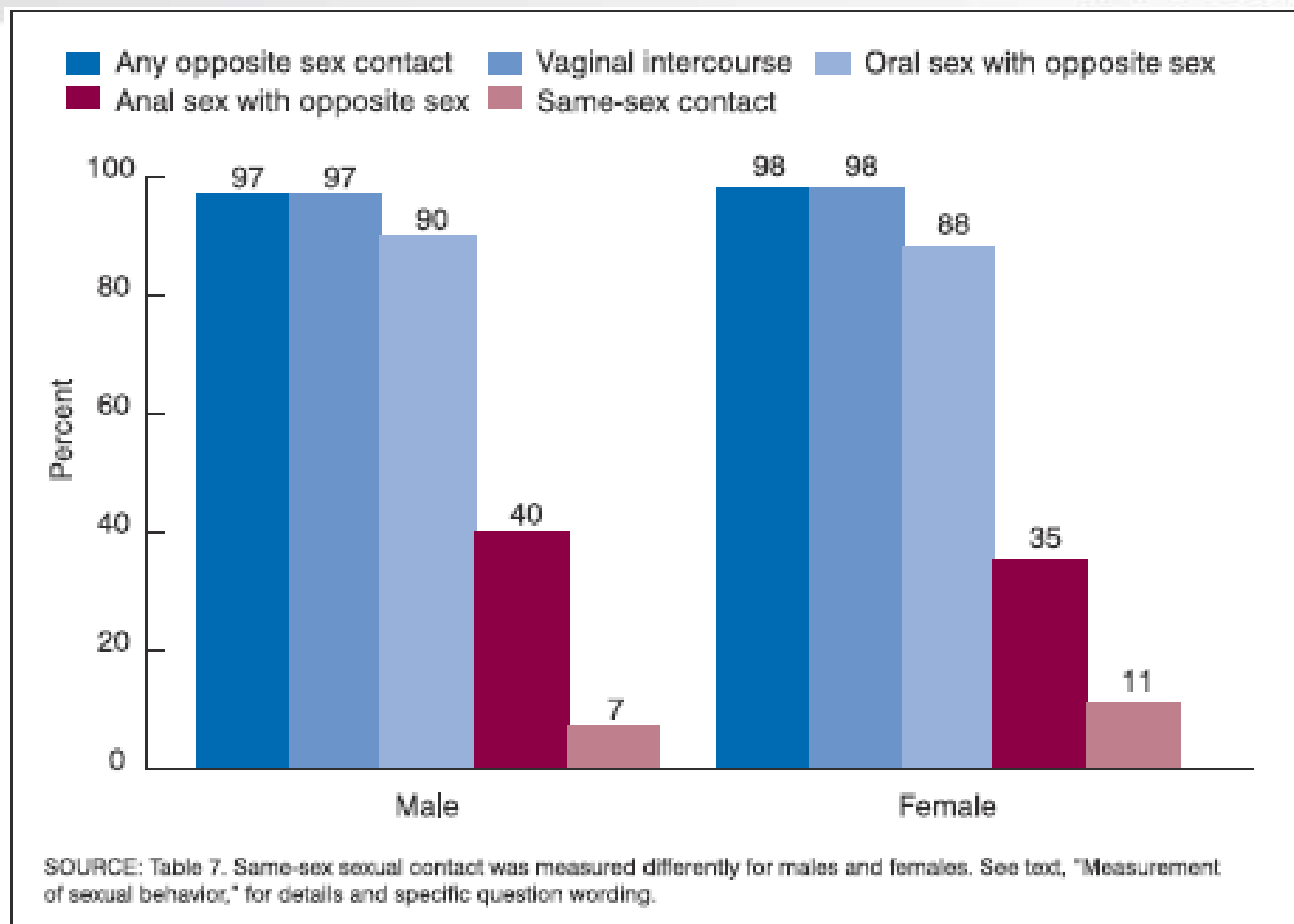
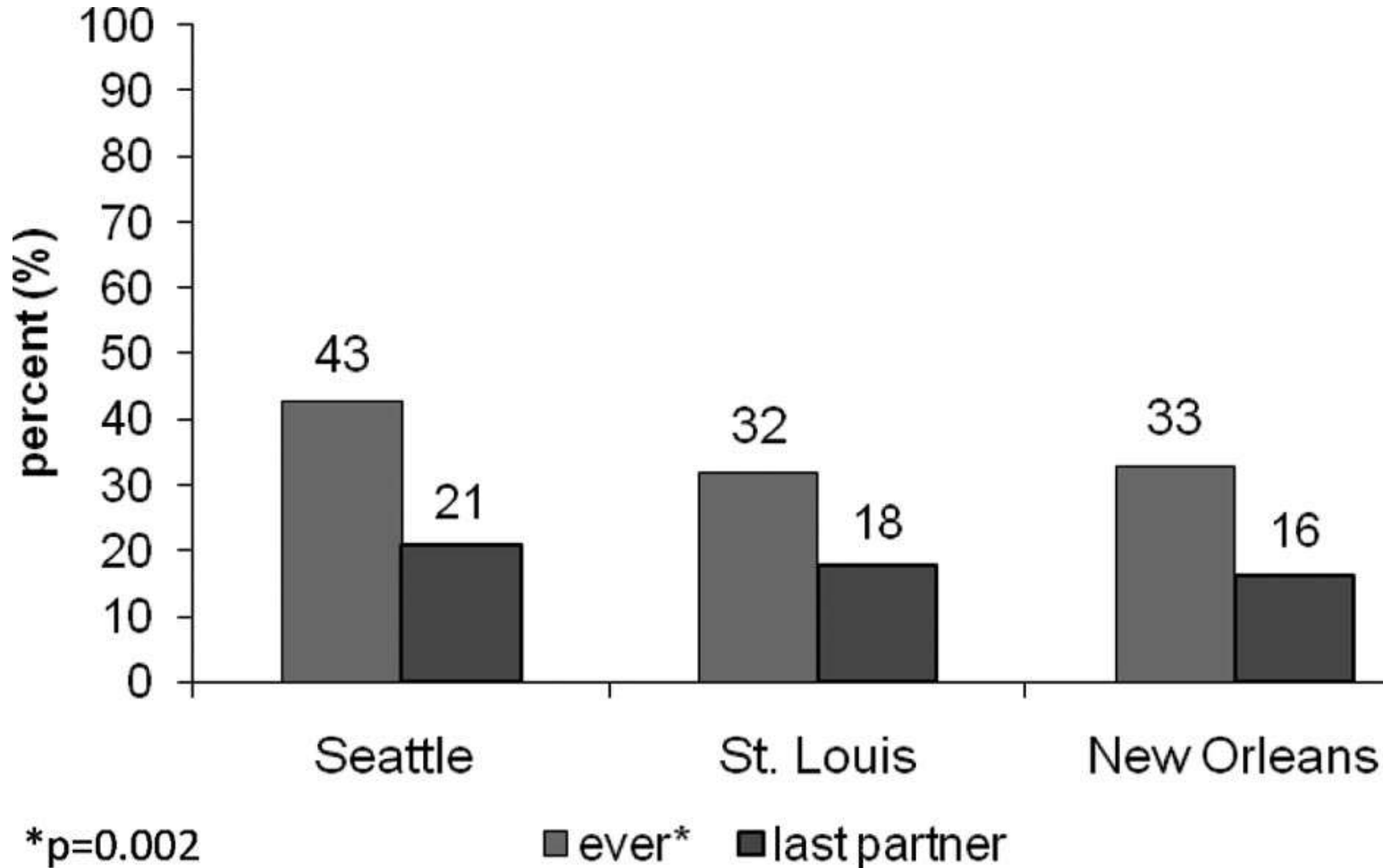


Figure 4. Percentage of males and females 25–44 years of age who have had each type of sexual contact: United States, 2002

# % Reporting AI ever and with last SP in 3 US cities



# Anal intercourse (AI) A heterosexual behavior



Brazil: 7,794 anonymous  
HIV testing clients (general  
population): 40% AI

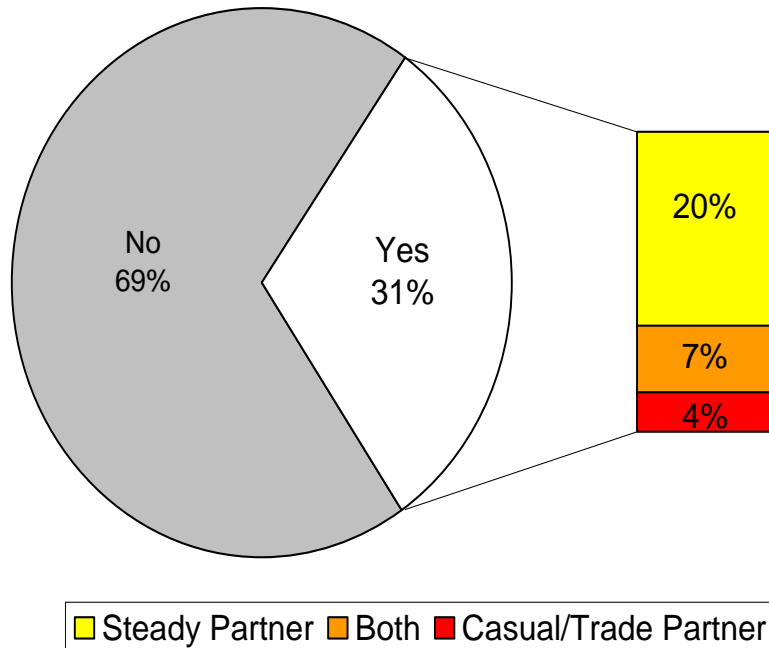


South Africa: Female sex  
workers between Durban  
and Jo'burg: 43% AI

– **Chicago data – COIP**

- **Study of young IDU, 15 – 30, recruited from 2000 – 04**
  
- **Analysis restricted to female, at least one sex partner in past 3 mo. (N= 233, 90% of females in sample)**
  - **Anal intercourse: 31% 3 mos prior to interview**
    - » **86% w/ closest male partner**
    - » **35% w/ casual, including trade**
  
  - **Condom use:**
    - » **60% w/casual never used condom**
    - » **85% w/main partner never used condom**
  
    - » ***AI did not vary by race/ethnicity, age, education.***

Figure 1. Anal sex among female IDU



**Author's Conclusion: *Anal sex is common among women who are at elevated risk for sexual contact with HIV+ men due to their own drug use, association with high-risk drug users, or residence in neighborhoods with high levels of HIV infection. Interventions to reduce the heterosexual transmission of HIV should place a major emphasis on anal sex.***

## Women's Experiences with Anal Sex: Motivations and Implications for STD Prevention

- Emily Maynard, Alex Carballo-Diéguez, Ana Ventuneac, Theresa Exner and Kenneth Mayer
- **CONTEXT: Heterosexual anal intercourse is a highly efficient mode of HIV transmission, yet little is known about the contexts in which women engage in it, or when and with whom they use condoms. Similarly, sexuality and reproductive health research has paid little attention to female desire and pleasure-seeking.**
- **METHODS:** In-depth interviews were conducted in Boston in 2006 with 28 women who reported having had unprotected anal intercourse in the last year with a man who was HIV-positive or whose serostatus was unknown. Sexual scripting theory guided analyses of their experiences with and motivations to practice anal intercourse.
- **RESULTS: Participants engaged in anal intercourse for a wide variety of reasons: to experience physical pleasure, enhance emotional intimacy, please their male partners or avoid violence. Male partners usually initiated anal sex. Anal intercourse often occurred in the context of vaginal and oral sex. Among reasons women cited for not using condoms were familiarity with their partner and feeling that condoms made anal sex less pleasurable. Knowledge of HIV and STD risks did not appear to encourage condom use.**
- **CONCLUSIONS:** Women who perceive condom use during anal sex as limiting their pleasure or intimacy may be at increased risk for acquiring HIV. Consequently, interventions to promote safer anal intercourse must find a way to increase the use of barrier methods without decreasing pleasure or perceived intimacy between sexual partners.



- Among U.S. gay and MSM, most report AI: 76-90%.
- **U.K.: 48.8% UAI (Gay men's health survey, 2002; N=16,000)**
- **U.S.: 48-54% UAI (Project Explore, 2002; N=4,295)**
- **Gay and MSM still make up the bulk of HIV infections in the West, Latin America, S. America. (Africa? Developing world?)**
- **STD rates confirm high prevalence of UAI**
- **Higher prevalence of HIV compared to heterosexual pop = more risk/act UAI**
- **9% of MSM in 2006 received any type of prev (global, UNAIDS)**

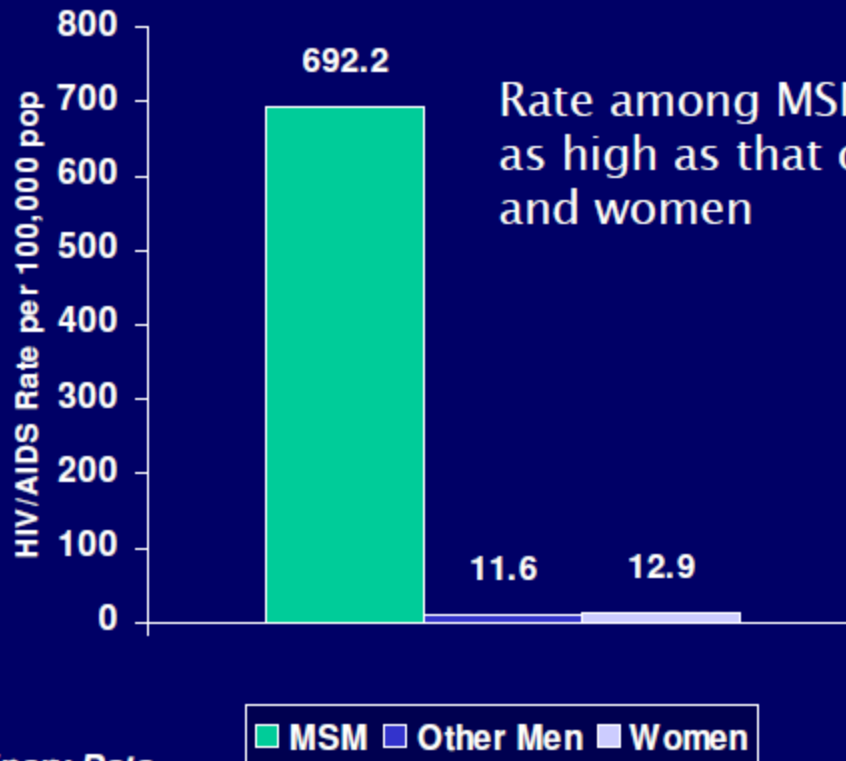


- **MSM, HIV, and the Road to Universal Access—How Far Have We Come?** [amfAR – AIDS 2008]
  - **Globally, MSM are 19x more likely to be infected with HIV than general pop**
    - **Data from 128 countries submitted to UNAIDS, 44% (56) failed to provide any MSM data**
    - **71% (91) of countries no info on % MSM contacted by HIV prevention groups**



- **Less than 1 percent of \$669 million reported in global prevention spending targeted MSM [2006, UNAIDS]**
  - **The International Lesbian and Gay Association's 2009 report on state-sponsored homophobia - lesbian or gay risks jail time in 80 countries and death penalty in five**

## HIV diagnosis rates among MSM, other men, and women--34 states, 2007



Rate among MSM is >50 times as high as that of other men and women

*Preliminary Data*

### Future Directions and Updates from the Division of HIV/AIDS Prevention: Surveillance, Epidemiology, and Laboratory Science

Amy Lansky, PhD, MPH Deputy Director

Surveillance, Epidemiology and Laboratory Science


Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

CDC National HIV Prevention Conference, August 24, 2009

***An act of unprotected,  
receptive anal intercourse is  
5 – 80 times more likely to  
result in HIV transmission than  
an act of unprotected vaginal  
intercourse.***

# Rectums and Vaginas

# What makes the rectum so special?

<b>Vagina</b>	<b>Rectum</b>
Most of the epithelium is 40 cell layers thick	Very fragile epithelium, 1 cell layer thick. 
Fewer CD4 cells than rectum	More inflammatory cells under surface (CD4 receptors)
Acidic pH	Alkaline, rather than acidic pH
Enclosed pouch	Open-ended tube

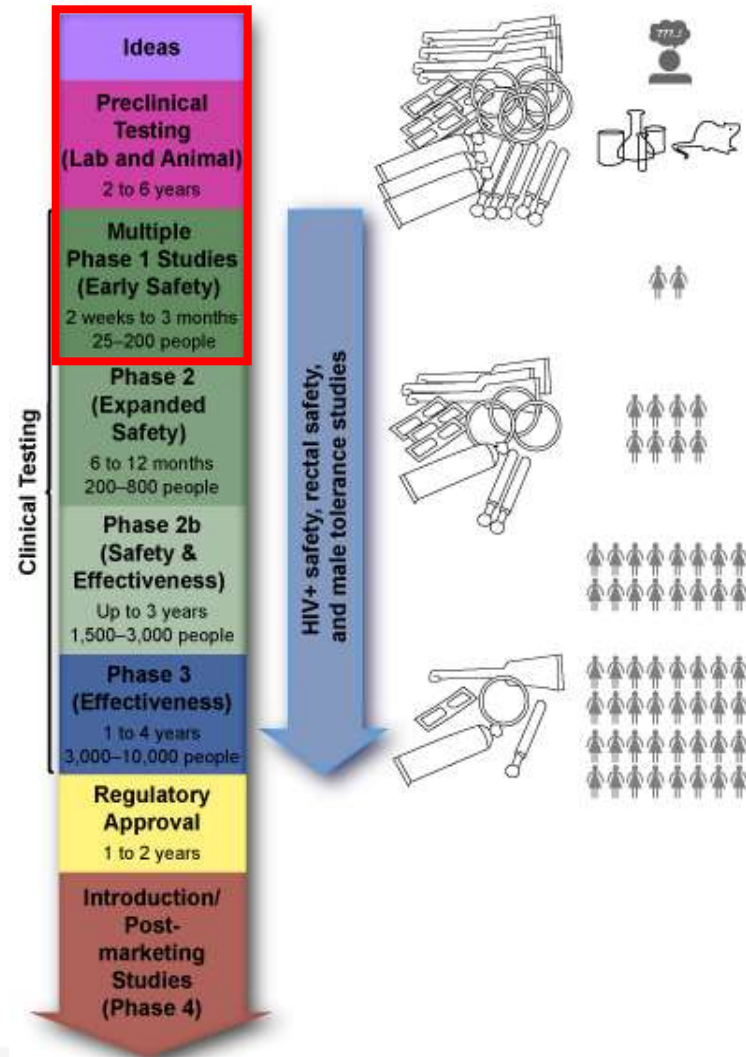


# The current Rectal Microbicide Research Agenda and Pipeline

- **Projects to establish a pipeline, incl. pre-clinical (explants, macaques)**
- **Behavioral, social research (anal sex)**
- **Rectal modeling**
- **Anal health**
- **Acceptability**
- **Applicator and delivery system development**

- **Baseline parameters for inclusion in rectal trials**
- **Facilitate regulatory pathway**
- **Establish rectal safety of sexual lubricants**
- **Formulation research, pharmacokinetics**
- **Phase I safety trials**

The Microbicide Development Process



# Future Phase 1 RM Safety Studies

Product	Status	Timeline	Sponsor
MTN-007	<b>Pending</b>	Q2 2009	NIAID/DAIDS
RMP-02/ MTN-006	<b>Open to accrual</b>	Q2 2009	NIAID/DAIDS
VivaGel	Planned	Q4 2009	NIAID/DMID
PRO-2000	Planned	Q4 2009	MDP MRC-UK
UC-781 (RF)	Possible	Q4 2010	TBD

- A Phase 1 rectal microbicide safety and acceptability trial of topically applied tenofovir compared with tablet
- Study population
  - 18 sexually abstinent HIV negative men and women
- Study products
  - Oral
    - Tenofovir
  - Topical
    - 1% vaginal formulation of tenofovir
    - Hydroxyethyl cellulose (HEC) placebo gel

- Phase 1 randomized, double-blinded, placebo-controlled rectal safety and acceptability study of tenofovir 1% gel
- Approximately 60 sexually (RAI) abstinent, HIV-negative adult men and women
- Four study arms:
  - 1% vaginal formulation of tenofovir
  - Hydroxyethyl cellulose (HEC) placebo gel
  - 2% nonoxynol-9 (Ortho-Gynol II)
  - No product arm

- Safe candidates (Phase -1) move to Phases 2, 2b and 3; implies finding suitable study populations
- Design rectal specific applicator
- Conduct acceptability studies that are culturally competent

- Phase 2 studies
  - RAI sexually active men and women
  - Higher risk populations
  
- Phase 2B studies
  - 3% seroincidence MSM populations
    - North America
    - Latin America
    - Africa

- Parallel to clinical trials, it is essential to understand the potential acceptability of future products
- Important issues:
  - Product and behaviour / social specific

- **Comfort with anal products** (current use, e.g. lubricants for AI)
- **Sexual repertoire:** when and how would the product be incorporated into anal intercourse?
- **Stigma:** how would this impact product distribution?

- Physical characteristics: e.g., colour, odor, flavour, cost, viscosity
- How will it be dispensed? Fingers? Plunger? Suppository? Enema?
- How often will it need to be used?
- How long does protection last?

- Acceptability and preference research as only available from US
- Need country/culture specific data, particularly since expanded RM studies will include non-US populations

- High HIV prevalence in MSM
- Most HIV transmitted via during UAI

Country	Adult (15-49) HIV prevalence percent	MSM HIV prevalence percent (95% CI)
Peru	0.61	12.2 (11.7-12.7)
Argentina	0.65	12.1 (10.8-13.8)
Brasil	0.58	14.4(12.6-16.2)
Ecuador	0.31	15.1 (12.8-17.4)
Mexico	0.32	25.6 (24.8-26.5)
Jamaica	1.5	20-30 (not avail.)

- Among MSM, a RM that is colourless and flavourless would likely be used if available and affordable among lubricant users for AI
- Nonetheless, around 50% of respondents didn't use lube during last AI (would they if it were available?)

**“Acceptability of Rectal Microbicides (RM): Barriers and facilitators of RM use among men who have sex with men in 4 South American Cities.”**

Will systematically explore RM with:

1. Gay-identified MSM
2. Non-gay MSM
3. Sex workers
4. Male-to-female transgendered persons

# Study Sites



<b>Aim</b>	<b>To examine / evaluate</b>	<b>Method (N)</b>
<b>1</b>	The acceptability, attitudes, knowledge, and potential motivators and barriers to using a RM and participating in RM clinical trials among MSM; including culture-specific customs, beliefs, and stigma related to anal intercourse and the feasibility of recruiting participants to participate in RM clinical trials.	Focus groups (16)  In-depth interviews (48)
<b>2</b>	The relative importance of varying characteristics (e.g., cost, route of administration) of a hypothetical RM among MSM.	Conjoint analysis (16)
<b>3</b>	The knowledge and awareness of RM among public health officers, academicians, decision-makers and community leaders; including feasibility regarding future RM trials and product dissemination.	Key Informant Interviews (48)

- Each method has strengths and weaknesses; mixing methods allows for greater elucidation of the topic and increases confidence in trends observed
- Conjoint analysis collects quantitative and presents scenarios that match “real life” decision making process

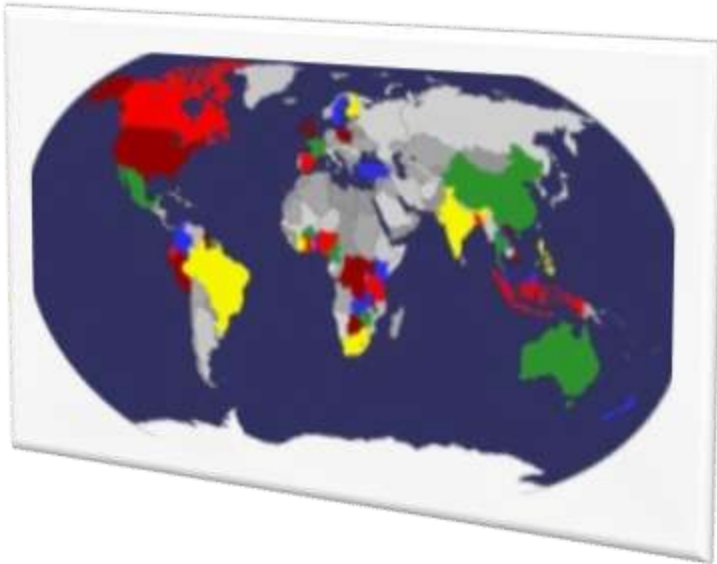
## Experimental Design for Conjoint Analysis: Hypothetical Rectal microbicides

Hypothetical Microbicides	Effective-ness	Prescription requirement	Side Effects	Frequency of Use	Product Formulation	Dose/ Volume	Cost USD
1	40%	Sold OTC	none	every day	gel	35	\$0.30
2	80%	Sold OTC	none	every day	liquid	15	\$5.00
3	40%	Rx needed	some	every day	gel	15	\$5.00
4	80%	Rx needed	some	every day	liquid	35	\$ 0.30
5	40%	Rx needed	none	before sex	liquid	35	\$5.00
6	80%	Rx needed	none	before sex	gel	15	\$ 0.30
7	40%	Sold OTC	some	before sex	liquid	15	\$ 0.30
8	80%	Sold OTC	some	before sex	gel	35	\$5.00

# Advocacy



# The global force in rectal microbicide advocacy



**800+**  
**members**

**60+**  
**countries**

**6**  
**continents**

**AFC**  
**secretariat**

# Steering Committee

**23 members**  
**10 countries**

- Researchers
- Advocates
- Community members
- Nigeria**, Kenya, **South Africa**, **US**, **Peru**, **Malaysia**, **Canada**, **UK**, **Netherlands**, **Australia**



**Kadiri Audu, Community VC, Dr. Ian McGowan, Scientific VC**

# IRMA Goals



Advocate expanded efforts to support valid, evidence-based scientific inquiry within strategic framework including all new prevention technology

- Take a critical eye
- Ask tough questions
- Convene and solicit diverse perspectives
- Demand accountability

# Advocacy Goals

## Accelerate Research

- **Diversify funding sources for RM research**
- **Encourage testing of additional commercial lubricants for rectal safety**
- **Advocate for increased research into global anal intercourse**



# Advocacy Goals

## Other new prevention technologies

- **Participate in collaborative efforts, prevention research networks**



## Convene diverse perspectives

- **Develop Global Rectal Microbicide Development Plan.**

# Key Activities

Website, blog, FB, Twitter

[rectalmicrobicides.org](http://rectalmicrobicides.org), [@rectalmicro](https://twitter.com/rectalmicro)

- Highly active moderated listserv
- **Teleconferences**
  - Next is Dec 4, “Efficacy and Effectiveness - What is Good Enough? Who decides?” (4P Local / Toll free number)
- Lube Survey – 8,945 responses from 107 countries in 6 languages

## Rectal Microbicide Advocates



# Advocacy Highlights

IAS 2009, Cape Town, Satellite Session:

## Rectal Microbicide Development - An African Perspective

Sunday, 19 July  
10:15am – 12:15pm

International Convention Centre (CTICC)  
Convention Square  
1 Lower Long Street  
Room SR 4  
Capetown

The meeting will describe the role of anal intercourse (AI) in HIV transmission and recent research towards the development of rectal microbicides for the prevention of AI-associated HIV infection. Where possible the speakers will include data from the African continent.



**Chris Beyrer, US - [Epidemiology of HIV among MSM in Africa: Implications for rectal microbicides](#)**

**Ian McGowan, US - [Development of rectal microbicides](#)**

# Publications

## M2008 – New Delhi [Also in Spanish]



## Rectal Microbicides: Investments & Advocacy



- **Total investments = US\$34M**
- **About US\$7M per year**
- **U.S. public sector contributed 97.4% of overall funds**
- **Philanthropic and private sectors 2.6%**



# Needs estimate

Conservatively, rectal microbicide field probably needs 5 candidates over 10 – 15 years

Will require minimum US \$350M, or at least \$35M/year for 10 years

Therefore, annual spending needs to increase 5X

# Rectal Microbicide Advocacy

**Developing safe, effective, and acceptable rectal microbicides as quickly as possible for the women and men who need them globally requires the concerted efforts of advocates, researchers, policy makers and funders from all parts of the world.**



# Rectal Microbicide Advocacy: Become an Advocate



## 5 to 10 minutes

Visit our website and blog  
Sign up for the listserv

## 30 to 60 minutes

Dial in to a teleconference  
Download a presentation

## Time and passion!

Join an IRMA workgroup – 2010 report

Join the IRMA SC

Join IRMA ALC, Nigeria, etc

Provide resources! Currently, *RM advocacy is not adequately supported by funders*

SAVE THE DATE!

May 22-25, 2010  
Pittsburgh, Pennsylvania, USA

[www.microbicides2010.org](http://www.microbicides2010.org)



M2010

MICROBICIDES:  
Building Bridges  
in HIV Prevention

**Jerome Galea**  
**[jgalea@ucla.edu](mailto:jgalea@ucla.edu)**

**UCLA Program in Global Health**  
**<http://www.globalhealth.med.ucla.edu/>**

**International Rectal Microbicide Advocates**  
**<http://www.rectalmicrobicides.org>**