



# Why Do We Still Need Microbicides?

Sharon Hillier, PhD and Ian McGowan, MD, PhD

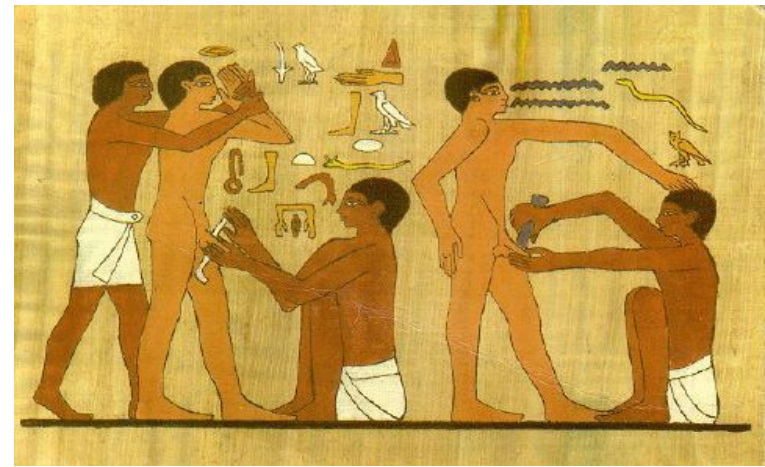
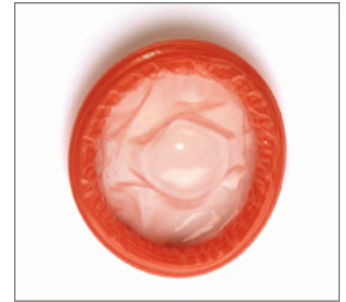
MTN Principal Investigators

University of Pittsburgh School of Medicine

February 25, 2014 Washington DC

# Proven HIV Prevention Strategies

- Use of male condoms
  - Receptive partners (vaginal and anal) often cannot control condom use by their male partners
- Circumcision
- Very effective for insertive partner but limited data supporting decreased HIV in women or MSM



# Proven HIV Prevention strategies

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- Treatment as prevention
  - Highly effective in HIV serodiscordant couples
  - However, most people at risk have limited knowledge of their partner's HIV status or control of whether their partner is virologically suppressed
- PrEP
  - Highly effective in known HIV serodiscordant couples due to high product adherence
  - Less effective in younger, high risk people whose partner status is unknown (FemPrEP and VOICE)

# The Unmet Need in Women

- Young unmarried women living in S Africa still have high HIV incidence despite the rollout of treatment programs
  - Women in the placebo group of CAPRISA-004: 9.7%
  - Seroincidence among former CAPRISA participants following the completion of the trial and access to gel in the open label extension study: 10% per year
- Incidence in young, unmarried women in VOICE 3- 10X higher than in older, unmarried women
- Much higher incidence than serodiscordant couples

# Incidence of HIV Acquisition in VOICE

	South Africa	Uganda / Zimbabwe
Age <25 y	8.7 (7.6, 10)	2.6 (1.1, 5.1)
≥ 25 y	4.7 (3.8, 5.8)	0.8 (0.4, 1.7)
Married	0.9 (0.2, 2.7)	0.9 (0.4, 1.7)
Unmarried	7.5 (6.6, 8.4)	2.8 (1.1, 5.7)

Incidence per 100-person-years (95% C.I.)

# What Women Are Telling Us

- They highly value the reproductive health services which we provide
  - Contraception
  - STI and HIV screening
  - Cervical cancer screening
- They know that using condoms reduces risk of HIV and STIs but it is very difficult to maintain consistent condom use
- There is stigma associated with use of ARVs
  - Even for a vaginal product it can be difficult to explain to a partner or family member what it is and why it is being used

# What Would Make It Easier for Women to Use HIV Prevention?

- Give them what they want- products that meet their reproductive health needs
  - Family planning methods with “stealth” ARVs
  - Helps to manage the stigma associated with ARVs for prevention
- Sustained delivery or on demand products depending on a woman’s circumstances
  - Must be discrete and low cost



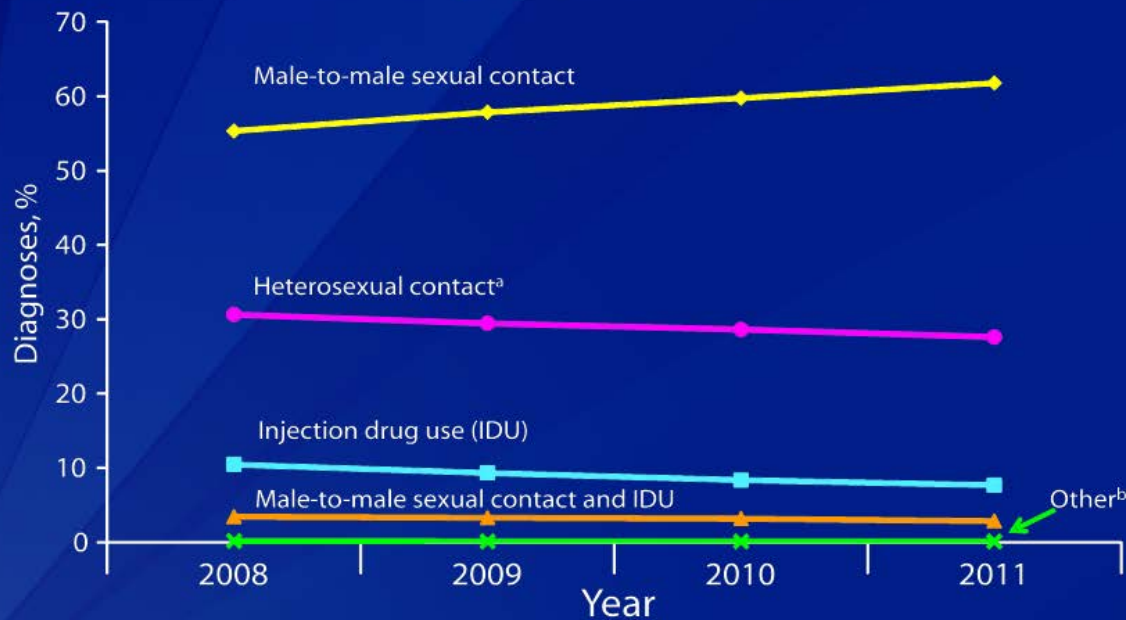
# Why Do we Still Need a Rectal Microbicide ?

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# The HIV/AIDS Epidemic in 2014

## Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2008–2011—United States and 6 Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

<sup>a</sup> Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

<sup>b</sup> Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.



# HIV Prevention Options

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- Behavioral modification
  - Abstinence
  - Serosorting
- Diagnosis and treatment of STIs
- Condoms
- Circumcision
- Treatment as prevention
- Oral PrEP

# PrEP Efficacy in MSM

- The iPrEx study
  - 2,499 MSM and male-to-female transgendered women randomized to Truvada or placebo
  - 44% reduction in HIV acquisition
  - PK analysis only detected drug in 51% of participants
  - Increased efficacy in subgroup who took Truvada

# PrEP Roll-Out Still Quite Limited

Sister Eden's Salon for Sluts *presents ...*

## Truvada Whore?!

### PEP, PrEP &

### the Brave New World of Safer Sex



# Strong Rationale for Rectal Microbicides

- Unprotected receptive anal intercourse (RAI) is the highest risk sexual activity for HIV transmission
- Use of lubricants common in MSM
- Murine and non human primate studies have shown proof of concept that rectal application of ARV microbicides can prevent SIV/HIV infection
- Phase 1 rectal PK/PD studies demonstrate dose dependent explant protection

# The Method Mix

- One size does not fit all
- At risk individuals may wish to choose from
  - Condom use
  - Oral PrEP
  - Treatment as prevention
  - Long acting injectable PrEP
  - Rectal microbicides
- We will know much more after MTN-017