



# **AVAC's HIV Prevention Research Webinar Series**

*Beyond the Clinical Trial: The role of social  
science, behavior, vaginal and rectal practices  
and the implications for implementation*

Speakers: Judy Auerbach and James McIntyre

Moderator: Jim Pickett

*July 17, 2010*

# **Not Just a Handmaiden: The Critical Role of Social Science in Microbicides and Other Prevention Research**

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Advocates Network Webinar*

[sfaf.org](http://sfaf.org)

# Not Just a Handmaiden



# Core Issues

- Acceptability
- Adherence
- Control
- Covert Use
- Pregnancy

# Acceptability: What Have We Learned?

- Acceptability:
  - *is variable*
  - *is not static over time*
  - *has different attributes, some which matter more than others*
  - *Is not a good predictor of actual use*

# Adherence: What Have We Learned?

- Adherence:
  - *Rates are variable (41%-92% in recent studies)*
  - *Varies within trials by site, partnership type, sex act, context of trial*
  - *Is measured differently in different studies*
  - *Is reported inconsistently by study participants*
  - *Is patterned*
  - *Depends on participants' understanding of product use*
  - *Is affected by participants' beliefs about efficacy of product*
  - *Is affected by sexual, vaginal, and rectal practices*
  - *Is affected by gender and relationship dynamics*

# Control & Covert Use: What Have We Learned?

- Control and Covert Use:
  - *are important to some women, but not to others*
  - *importance varies by population, site, relationship type*
  - *“control” is an alien concept or has nuanced meanings*
  - *covert use is undesirable to many women & men*

# Pregnancy: What Have We Learned?

- *Not much behavioral and social research*
- *Notion of “intention” may not be meaningful*
- *Expectations & desires about fertility & parenthood are deeply rooted and normative and usually override concerns about disease prevention*
- *Triple or quadruple “protection” required in trials may be unreasonable and unrealistic*

# Social Science Contributions: What Have We Learned?

- *Practices are more relevant than behaviors*
- *Practices are imbued with meanings, values, beliefs*
- *HIV is relational; and relationships are dynamics*
- *Interventions (trials) are part of and not separate from “real life”*
- *Practices, meanings, relationships, and environments are variable and not static*

# “Critical” Social Science Contributions

- Medical research is socially embedded and it produces social relations.
- Trials and technologies affect people and communities and vice-versa.
  - *Interrogate how technology is incorporated by people in local contexts*
  - *Elucidate contextually-specific ways in which research and participants are intertwined*

# Conclusion

- Biomedical research on HIV prevention tools and technologies must be complemented and informed by social science within and outside the context of clinical trials.
- A more meaningful investment by funders in social research—theoretical, qualitative, quantitative—is needed to answer core questions related to the potential and real effectiveness of new technologies and tools for stemming HIV epidemics.



# From Research to Reality: Implementation of Biomedical Prevention

**James McIntyre**

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# The State of HIV Prevention Strategies: 2010



Condoms  
Male Circumcision  
ARV Prophylaxis: PMTCT

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ARV Prophylaxis: PEP, PrEP  
Microbicides  
Counselling & Testing  
Vaccines

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HSV-2 Suppressive therapy  
Cervical Barriers  
STI Treatment

*HIV PREVENTION STRATEGIES*

## From ABC to A-Z

- Need to acknowledge the false divide between “biomedical” and “behavioural” strategies
- Implementation of successful biomedical interventions also provide opportunities to refocus on behaviour modifications, including:
  - Strategies to reduce HIV risk linked to alcohol use
  - Delaying sexual debut
  - Decreasing HIV risk from drug abuse, including needle exchange programmes
  - Reducing the risk from multiple concurrent partnerships
- Need to acknowledge the convergence between “treatment” and “prevention” strategies

# Using the lessons from current strategies to help implement new ones

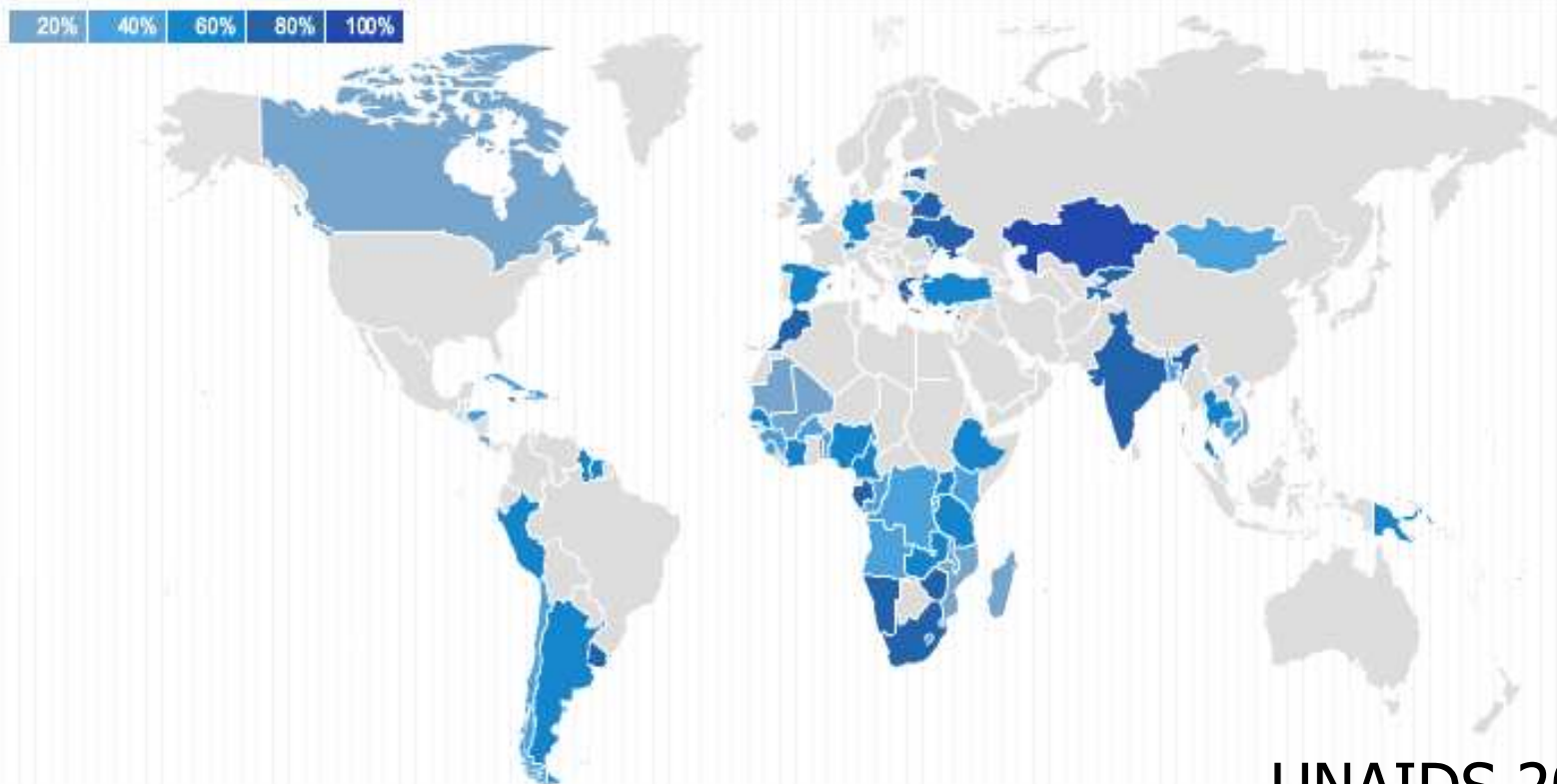


# Condom use

Upwards of 13 billion per year estimated need

**MAPPING PROGRESS** towards Universal Access

Percentage of women and men aged 15-49 who had more than one sexual partner in the past 12 months reporting the use of a condom during their last sexual intercourse



UNAIDS 2010

# Male Circumcision: bridging from research to reality

- Estimated that one HIV infection could be prevented for every five to 15 men circumcised in settings with high levels of HIV and low rates of male circumcision, at a cost of US \$150 to \$900 per HIV infection averted over 10 years
- Since 2007, WHO and UNAIDS have recommended male circumcision as an important HIV prevention strategy in countries with high rates of heterosexual HIV transmission and low rates of male circumcision.
- As of end-2008, all 13 priority countries in sub-Saharan Africa had established policies and programmes to expand male circumcision.

UNAIDS/WHO/SACEMA Expert Group on Modelling the Impact and Cost of Male Circumcision for HIV Prevention, PLoS Med, 2009

WHO: Towards universal access: scaling up priority HIV/AIDS interventions in the health sector : progress report 2009

# MMC Service Delivery Update, Jan 2010

Country	Botswana	Kenya	South Africa	Swaziland	Zambia	Zimbabwe
Begin date	Apr 2009	Sept 2008	Jan 2008	Jan 2008	July 2009	May 2009
No. of MC's	4326	90 396	14 253	5122	16 801	3000
No. of MCs Nov – Dec 09	580	<b>36 000</b>	1547	1816	6171	1510



## Lessons from medical male circumcision for other new prevention technologies

Need to address concerns about:

- Partial protection, risk compensation, behavioural inhibition
- Promotion of combination protection
- Gender equity
- Stigma and discrimination
- Competition for financial, human and service resources
- Mobilising demand and ensuring supply

Hankins 2009

# Preventing mother-to-child transmission of HIV: Lessons of success and failure

- PMTCT led the way with combination prevention approaches:
  - in promoting a four-pronged “combination prevention” approach.....
  - in using “treatment” for prevention.....

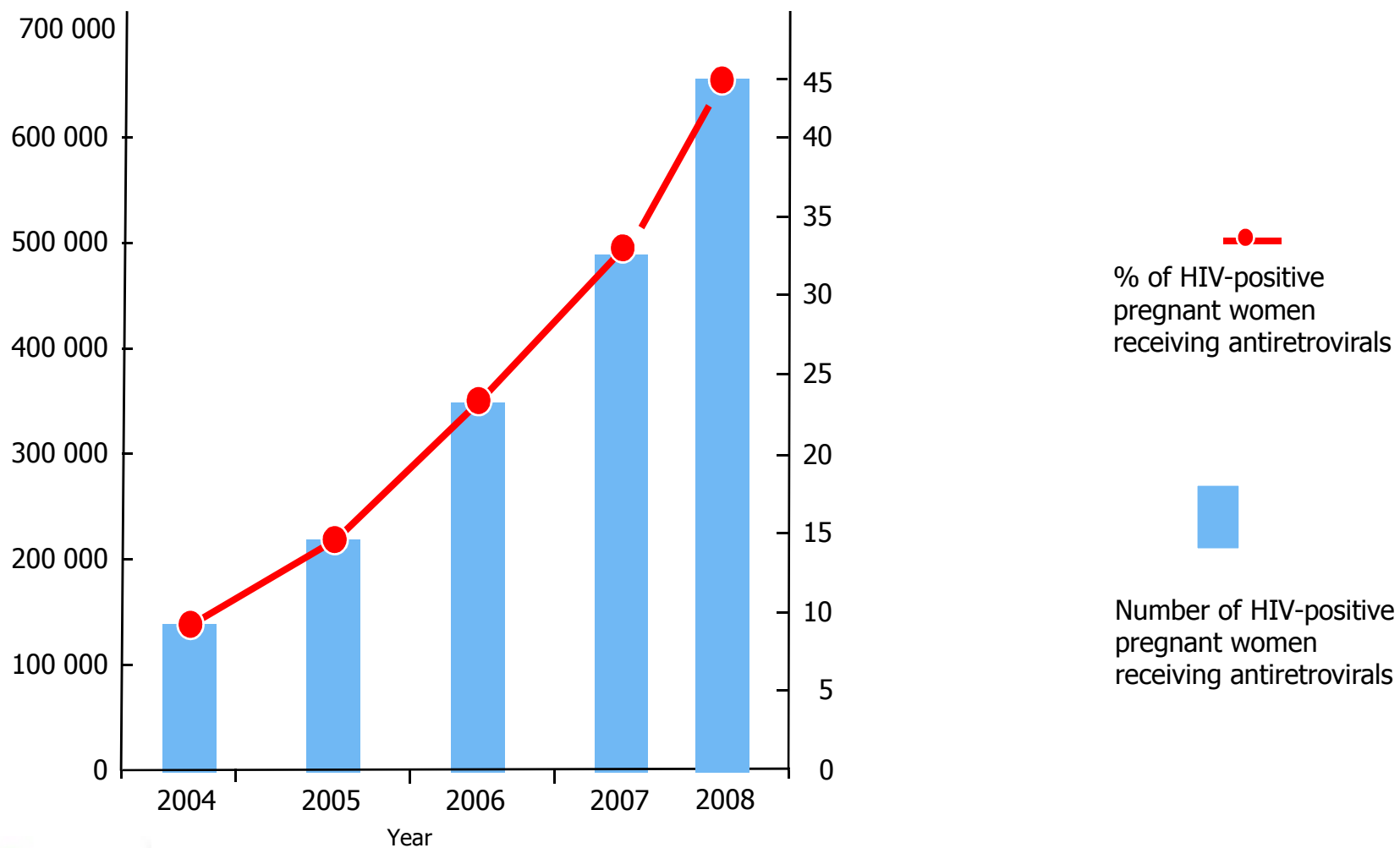


## The need for effective PMTCT programmes

- 1,000 new infections in children each day:
- Approximately:
  - <1 per day in Europe
  - <1 per day in United States
  - 70 per day in Asia
  - >900 per day in Africa



# Number and percentage of HIV-positive pregnant women receiving antiretroviral prophylaxis, 2004–2008



# Building the bridges to implement new prevention interventions

- Learning from current interventions before implementing new ones
- Working towards combination prevention strategies

Long term prevention interventions such as microbicides, PREP or “test and treat” need:

- strong health systems
- lifelong behaviour adaptation
- constant vigilance
- consistent and adequate funding

## The guideline challenge

Guidelines are not rules, but:

International guideline processes are long and increasingly complex

Compliance with WHO normative guidance and international pre-qualification processes are essential for some funding sources

It is essential to work with guideline groups as early as possible



.....the code is more what you'd call "guidelines" than actual rules.....

Captain Barbossa: Pirates of the Caribbean:  
The Curse of the Black Pearl (2003)

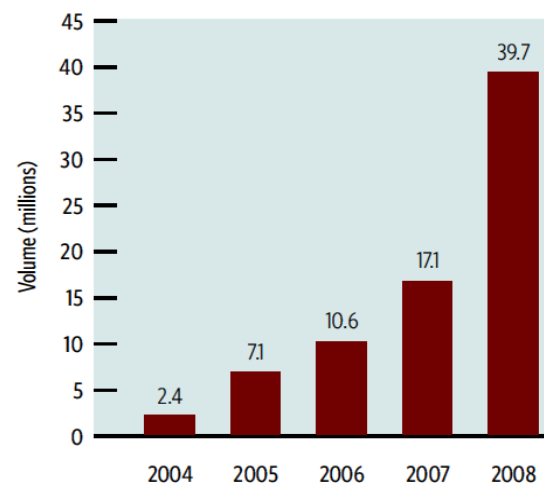
## The regulatory challenge

- Use of antiretrovirals, which are licensed for treatment, for prophylaxis may be regarded as “off-label” use
- Regulatory approvals are complex, require multi-national coordination and will require buy-in from regulatory authorities, manufacturers, funders and other stakeholders
- Regulatory approvals require detailed research data, and may need a range of data across gender, age groups, pregnancy status and long term safety

## Testing, testing, testing....

HIV testing will be a central need for any biomedical prevention implementation plan:

- Who tests?
- How?
- Where?
- How often?
- Who pays?
- Who checks quality?
- What is the referral path for positives?



Transaction volumes of rapid HIV tests, 2004–2008

WHO: Towards universal access: scaling up priority HIV/AIDS interventions in the health sector : progress report 2009

In 39 low- and middle-income countries, including 19 sub-Saharan African countries, the total reported number of HIV tests more than doubled between 2007 and 2008.

## Avoid the Treatment vs. Prevention concerns

PMTCT services have shown the tensions that can develop between prevention and treatment sectors

- Who “owns” tenofovir?
- How long will it take to get other drugs for prophylaxis?
- Can ARVs for prevention be justified while more than half of those in need do not access to antiretroviral treatment?
- Consider the possible virological consequences of antiretroviral prophylaxis up front
- NVP resistance issues damaged the credibility of PMTCT programs and delayed rollout
- Plan for combination regimens where possible

## Don't underestimate the stigma of taking ARV

- Adherence to PMTCT interventions, even as short-term and simple dosing regimens, has been affected by the stigma of “treatment”, and the fear of side effects
- Community education and preparation is crucial to success



# Don't wait for governments: mobilise communities and health workers

- In PMTCT services, nurses and other health workers have been major barriers to scale up
- In condom distribution, health workers' attitudes, especially towards young people, have been a major barrier
- Need to clarify values upfront



## Good regimens are not enough: health systems matter

- Health systems are in crisis
- Good regimens need to reach the people
- Relying on broken health systems won't work
- Somewhere over the counter?
  
- Need for innovative alternatives now:
- Community distribution
- New technology (cell phones, internet)

# Frugal innovation: Challenging "practice as usual"



Tata Nano Car:  
< \$2000



XO-1 Laptop:  
< \$100



ChotuKool  
Refrigerator:  
< \$70

## Proof of concept programmes

Persuading governments and funders to take interventions to scale requires good proof-of-concept delivery programmes

PMTCT and ARV treatment scale up were preceded by well run and well publicised proof of concept programmes such as Médecins Sans Frontières and MTCT-Plus

Innovative approaches are key to addressing a diversity of settings and diverse populations e.g. pregnant women, prisoners, MSM

Post-trial access programs following on from current clinical trials may help provide these

Wafaa El Sadr, 2009  
Susan Kim, 2010

## Consider who pays

- The lesson from PMTCT is that even a “free” or inexpensive drug intervention may not be rolled out at scale
- Innovative long term funding plans need to be established now for new interventions – several examples may help:
  - UNITAID -short term catalytic funding to impact on the market – not invested in HIV prevention technologies at present
  - GFATM – slower moving process to get approval for future rounds, country driven

Do we need something new?



## Implementation planning requires:

- Coordination
- Collaboration
- Communication
- Country ownership
- Community support



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...for thoughts and slides

