

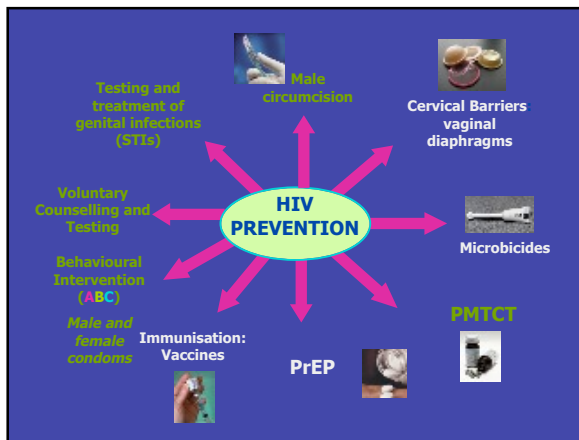
## HIV Prevention Research Challenges in the Real World

Anna Forbes, Global Campaign for Microbicides  
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### What do we need to know...

- ❖ Are they Safe for all potential users and uses:
  - Women, men, adolescents, pregnant women, HIV-positive people, injection drug users
  - Systemic, vaginal or rectal applications
- ❖ Effective for key groups of users
- ❖ Compatible with condoms and other prevention methods
- ❖ Contraceptive or not

Notes: These are questions that we hope can be answered by clinical testing. Additional information, such as user behavior, acceptability and formulation preferences, partner attitudes toward use, etc. must also be established through concurrent social science and behavioral research.



Notes: Historically, we've been locked into thinking about only condoms. In birth control, for example, there are multiple methods. We need to apply this thinking to HIV prevention. So people can choose what works for them and best suited for their lifestyles. Items in green are the ones we have answers about, the ones in white are still being studied.

### Prevention trials differ from Treatment trials

#### HIV Treatment trials:

- ❖ Enroll those needing treatment -- individual urgency
- ❖ Proving a positive impact on disease
- ❖ Historically, strong activist "PUSH" on researchers for community involvement

#### HIV Prevention trials:

- ❖ Enrolling healthy people – maybe no immediate benefit to individual
- ❖ Proving a negative
- ❖ Historically, done in less powerful, less communities -- researchers "PULL" in community involvement

Notes: Tx trials has more individual urgency, people might be resistant to multi drugs and need new options. Participants are not looking at immediate benefits in prevention trials. Tx trial has immediate measurements such as viral load changes. Prevention trials try to prove a negative, that something didn't happen. Politically different – in tx trials there was a huge push from activists. Prevention trials have been quieter.

**BUT “same hot button” issues.....**

- ❖ Stigma associated with being “at risk”
- ❖ Gender inequality and how to resolve
- ❖ How best to involve affected communities
- ❖ How best to protect human rights
- ❖ Finding the balance...

Notes: There are lots we can learn from Tx activists.

Stigma, what it means to associate with risk -- when I enroll in a trial will my neighbors think I have HIV, Can I enroll without my husband knowing about it.

All trials brings up issues of human rights, how can we protect participants and balance the need to find answers.

**Specific challenges in PrEP because:**

- ❖ No paradigm for PrEP: difficult to explain
- ❖ User-initiated, hard to measure adherence
- ❖ Healthy people reluctant to take pill every day
  - Fear of side effects of HIV drugs
- ❖ Retention challenges
  - Healthy, mobile population moves out of town
  - Changing jobs and job responsibilities

Notes: Why should taking a pill prevent me from getting HIV?

When you get a vaccine, the doctors knows you’ve received it, but when you were given a pill, researchers doesn’t know if you’ve actually taken it. Motivation is also an issue.

**Specific challenges in vaccines because:**

- ❖ No good animal model
- ❖ Very hard to find approach that works
  - Neutralizing antibody approach (VAXGEN) failed
  - One T-cell based vaccine failed (STEP)
- ❖ Cross-clade immunity highly unlikely
- ❖ Effect duration (how long protection lasts) still uncertain

Notes: No animal research that can show conclusively that a vaccine will work in humans.

It’s important to note that only one vaccine product based on the T-cell concept failed, not the entire approach. Different types or “clades” are out there in different parts of the world, it looks unlikely that one vaccine will work for all different clades.

**Specific challenges in microbicides because:**

- ❖ New idea – not familiar like “pills” or shots”
- ❖ User-initiated, hard to measure adherence
- ❖ Involves talking about vaginas, rectums, sex and power
- ❖ Fears about side effects – especially impact on fertility
- ❖ No early “markers” exist to predict protection
- ❖ Gender inequality makes “negotiating” trial participation and condom use difficult for many participants
- ❖ High pregnancy rates during trials
  - Can participants who get pregnant continue using test product?

Notes: It's something you can insert, more like a contraceptive. It's about Sex and other messy topics.

Early marker - we don't know what to look for in the blood or secretions that can tell us if something works. We are right at the edge of knowing what is working. Once we know this, we'll be able to look at a lot of data we current have and evaluate which product will work. Don't know if product is safe for the fetus, so women are being asked to discontinue using the product.

### Challenges in Common

- ❖ Partial efficacy
  - Difficult to measure
  - Difficult to explain
- ❖ Fear of dis-inhibition and condom migration
- ❖ Therapeutic misconception
- ❖ Working to assure successful product will be accessible

Notes: How can we tell if something is 30 or 40% effective, that it's due to the product and not condom use. How to communicate that condoms are the most effective, if you can use it, please do. But if you can't, this product might be somewhat effective.

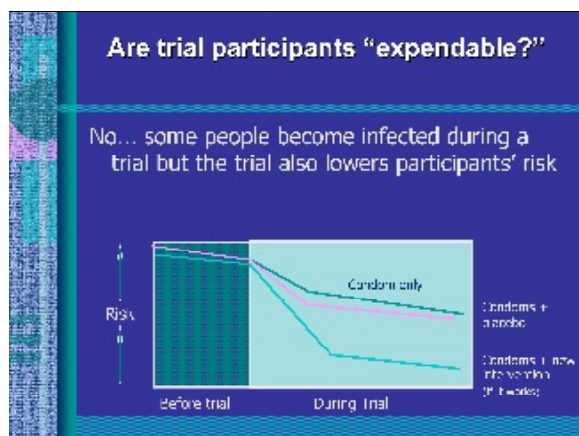
Incentives for using condoms might be lessened.

Therapeutic misconception - people might still think because the doctor gave this to me, it must be good for something, maybe I won't need to use the condom with it.

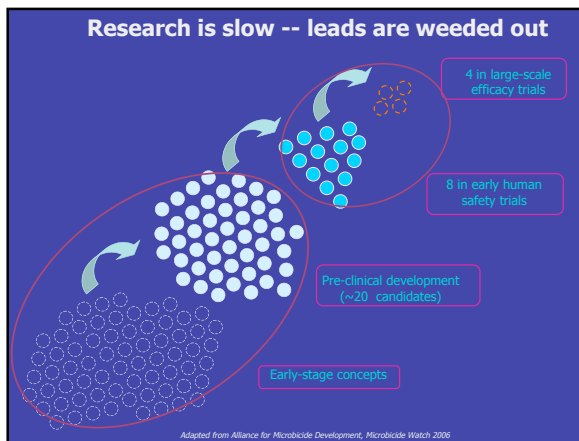
### Community support = Avoiding even the perception of exploitation



Notes: This is a headline in South African when one of the microbicide trials failed. People need to be clear about the messages, that women were not put in risk for getting involved in the trials.



The trial hasn't caused the infection - participants are coming in regularly getting STI screenings and treatment, condoms, counseling, all the best prevention services we know how to provide. Trial participants are actually at a lower risk of getting infected than the general population because of this. The researchers are perceived to be biased because they want answers, so they cannot convince the participants. We need community members to convey this important message.



It takes a lot of early stage concepts, you can take 5,000 concepts and get to 1 final product to test. Has to drop out the ones that don't work.

### Advocacy successes so far include....

- ❖ Adequate Standard of Care in trials
  - including contraception at microbicide trial sites & sexual health care for participants
- ❖ On-going access to care for HIV positive people screen out of trial participation & those who seroconvert during a trial
- ❖ Changes to make Informed Consent work better

Notes: People who seroconvert during the trial will be care for. It's taken a lot of advocacy to make sure of this. At least in the microbicide trials, access to care and treatment, contraceptives etc. are guaranteed.

There are ongoing struggles about informed consent, without overwhelming them with paper work. The community has been very heavily involved in demanding other kinds of information delivery like videos, etc.

### Role of GCM & other advocacy NGOs

- ❖ Create tools and trainings to help build research literacy and advocacy capacity
- ❖ Help pinpoint key issues -- provide background information and analysis to help frame discussions
- ❖ Provide rapid information on breaking issues to keep everyone up to date
- ❖ Create opportunities for training and strategizing