

## GC NEWS 107#

### HPTN 035 and more!!!

**GC News is a forum for international exchange on women's HIV prevention options activities which aims to build a more informed and integrated movement for microbicides, PrEP and other user-initiated HIV prevention tools with a focus on women.**

#### In this Issue:

##### Highlighted Resources

Take a look at GCM's comprehensive resources on the recent trial results of HPTN 035  
FAQs

##### Research Updates

HPTN 035 – how good is the good news?

##### Advocacy in Action

GCM South Africa engages with HIV positive advocates

##### Upcoming Events

GCM at the South Africa AIDS Conference, 2009

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#### Highlighted Resources

GCM's resources on HPTN 035 including FAQ and notes from our advocacy call can be found at the following link:

<http://www.global-campaign.org/HPTN-035.htm>

#### Research Updates

##### HPTN 035 – how good is the good news?

###### Global

The recently released results of the US National Institutes of Health HPTN 035 trial (multi-site clinical trial of two candidate microbicides) constitute glad tidings for the HIV prevention research advocacy community. The results were presented by the trial's Protocol Chair, Dr. Salim Karim on February 9 at the 2009 Conference on Retroviruses and Opportunistic Infections (CROI) in Montreal, Canada. On February 11, Dr. Karim -- joined by Ms. Neetha Morar (Clinical Manager of the South African Medical Research Council HPTN 035 site) and Dr. Sheena McCormack (Chief Investigator of the Medical Research Council's MDP 301 trial) - answered advocates questions during a GCM advocates call. The call, in which 75 advocates from a dozen countries participated, explored in detail some of the technical and ethical aspects of the trial results and the meaning of these results for the wider HIV prevention research field. Notes from the call are available at <http://www.global-campaign.org/HPTN-035.htm>.

The trial found that women who were offered PRO 2000 gel plus condoms had 30 percent fewer HIV infections than those offered condoms only or condoms plus a placebo gel. This makes HPTN 035 the first study to yield data suggesting that a candidate microbicide might actually work in women. Another candidate product, BufferGel, was also tested in this trial

but did not show any protective effect. Women using BufferGel had basically the same rate of infection as those using the placebo gel or no gel at all.

While a very encouraging trend, this 30% reduction in HIV seroconversions did not reach the level of statistical significance. In other words, there was not enough evidence to assure that the trend was definitely caused by use of the product and could not have occurred simply by chance.

On the call, Dr. Karim reported that a number of additional analyses performed on the 035 data suggest that PRO 2000 does have a protective effect. In particular, one analysis shows that women classified as high gel-users (those who used the gel more than 85% of the time) but who also reported low condom use appeared to have a 78% reduction in HIV infection. He emphasized, however, that these sorts of analyses are prone to inaccuracy (known as bias) because they are based on analysing small, selected sub-groups of the data and do not have the benefits of randomisation that a wider analysis has.

What, then, does this news mean for our field? Essentially it creates hope and suspense that may be resolved by the findings of another PRO 2000 trial now nearing completion. The UK-funded Microbicides Development Programme's trial called MDP 301 has enrolled nearly 9,400 women (three times the number of HPTN 035 participants) in South Africa, Tanzania, Uganda and Zambia. The results of MDP 301 are scheduled to be released in November 2009. Because they will be based on so much more data, we hope that they tell us clearly whether PRO 2000 is effective or not (and if so, how effective it is).

Neetha Morar noted during the February 11 call that the HPTN 035 results were particularly welcome because "the microbicides field for a decade has had very bad news". But, she added, "there should not be a too high expectation on the MDP trial. We need to prepare communities that the MDP results could swing either way."

The response at the CROI conference amongst scientists and advocates alike also pinpointed the need to maintain realistic expectations and refrain from jumping to conclusions about PRO 2000's effectiveness at this time. But the glimmer of hope provided by the 035 results has generated substantial discussion about what a 30% - 40% effective microbicide might mean to the HIV prevention field, and where, how and who might use it. These are important questions to address while we await the results of MDP 301.

Dr. McCormack told advocates on February 11 that the MDP trial should yield data suitable for a submission for licensure, if they show that PRO 2000 is both safe and effective. She added that the team is "working to have the result by the beginning of November." Advocates, therefore, need to prepare for a variety of scenarios and have a clear path ahead for when these results are released.

For more information on the trial results of HPTN, including a comprehensive FAQ written for Advocates, go to: <http://www.global-campaign.org/HPTN-035.htm>

## **Advocacy in Action**

### **GCM South Africa engages with HIV positive advocates South Africa**

On February 11, GCM held a workshop in Johannesburg with the Positive Women's Network with the aims of 1) nurturing a cadre of PLWHA prevention advocates 2) providing an update on microbicides development process and progress and most importantly 3) providing a platform to discuss some of the concerns from the PLWHA community about new prevention technologies.

The workshop covered basics of microbicides, potential benefits for positive women, how the clinical trial process is conducted, and ethical and social concerns associated with various

prevention methods. Prudence Mabele, Founder and Executive Director of the Positive Women's Network, went on to share advocacy messages with the participants and GCM staffer Samu Dube proposed a way forward for collective advocacy on HIV prevention research.

Dr. Dube noted that 'the treatment movement offers an opportunity for prevention activists to scale up information dissemination on new prevention technologies'. The scientific literacy skills and expertise built up among treatment advocates should be seen by prevention advocates as a great resource to learn from and draw on as the prevention research field progresses in developing ARV-based technologies.

The workshop was deemed a success by facilitators and participants, with one participant expressing the need 'to build stronger campaigns together, build the capacity of communities through 'Trainings of Trainers' workshops and identifying the need to see more in depth sessions of this nature.'

Thanks goes to all those who participated and in particular to Prudence Mabele and the Positive Women's Network.

## Upcoming Events

### 2 April, South Africa

At the upcoming Southern African AIDS Conference (March 31 – April 3) in Durban:

MMCI Coordinator, Deborah Baron, will be chairing a media training entitled '**Trial and Error: HIV Prevention Clinical Trials and the Media**' on April 2 at 11:00am.

GCM and AVAC are co-convening a session entitled '**Community Involvement in Clinical Trials – Watchdogs or Rubber Stamps?**' to assess the role of communities in current and future HIV prevention clinical trials. This session is scheduled for 3:30 pm on April 2.