



**Global Campaign  
FOR Microbicides**

## Welcome to GC News 106

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.

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### Highlighted Resources

#### Global

**The Microbicides Media and Communications Initiative is pleased to announce the launch of the official [MMCI website!](#)**

The Microbicides Media and Communications Initiative (MMCI) is a unique multi-partner collaboration housed at the Global Campaign for Microbicides designed to help the wider microbicides field anticipate and respond proactively to the communications challenges posed by the conduct of large scale effectiveness trials in Africa and other resource-limited settings.

Highlights on the website include:

**[Media and news coverage:](#)** Balanced and accurate reporting is essential to the development of the HIV prevention research and development field. MMCI monitors media coverage of microbicides and HIV prevention research, focusing on trial host countries and communities where rumors and sensationalized media can undermine ongoing and planned trials.

**[Communications resources:](#)** Both the microbicides and wider HIV prevention research fields are dynamic and continuously evolving. The resources section provides templates and other

communications tools to equip advocates, communicators and all members of the HIV prevention research community with essential background information and skills to effectively communicate around microbicides development. Links to prevention research sponsors, communications and advocacy groups are also listed.

**Events calendar:** Tracking conferences, events and clinical trials testing microbicides and related prevention research methods, the on-line calendar also includes a feature to easily add events to your iCal or Outlook calendar. Additionally, we list media and journalist training opportunities for advocates and health journalists interested in advancing their scientific understanding of the prevention research field.

The website is continually being updated, with new resources and media coverage added regularly. To visit the website, please go to: <http://www.mmci-communications.org/>

## Research Updates

### India

#### Looking Ahead : CONRAD's plans for testing HIV incidence in India

CONRAD (a program of the US-based Eastern Virginia Medical School) is working in collaboration with India's Council of Medical Research (ICMR) to conduct a series of cross sectional surveys to estimate HIV incidence rates among women in three states in India. The primary objective of this project is to determine if the HIV incidence rate is high enough in any of the study sites to make them suitable venues for clinical trials of HIV prevention technologies, including vaginal microbicides.

In 2006, a CONRAD-sponsored trial of the candidate microbicide Cellulose Sulfate stopped enrolling study participants in Chennai, India because the HIV incidence rate (number of new HIV infections occurring in the trial community) was so low that it would have been unlikely to determine whether or not the product had any protective effect if the trial had continued. Obviously, the lower-than-expected incidence was good news for the community and may, in part, have been a reflection of the success of HIV prevention counseling and other services provided by the trial to study participants.

However, a 2007 National Family Health Survey conducted in India by the National AIDS Control Organization (NACO) showed that six Indian states (Andhra Pradesh, Manipur, Uttar Pradesh, Karnataka, Maharashtra and Tamil Nadu) have high HIV burden. The CONRAD/ICMR study proposes to assess the potential for conducting effectiveness trials of microbicides by measuring the incidence rate among women at highest risk of infection at two trial sites in each of three of the high prevalence states identified by the NACO survey. These sites are in the cities listed below and located in the following states:

Mumbai and Pune in Maharashtra;

Bagalkot and Belgaum (near Bangalore) in Karnataka; and

Hyderabad and Guntur in Andhra Pradesh.

The CONRAD/ICMR study will assess this by using the BED assay (a detuned antibody assay) as a screening tool to estimate how recently each participant became HIV positive. For confirmation, they will use a second test called an Avidity Index and shows that a high degree of reliability whether the HIV infection occurred within the last six months or longer ago than that. Taken together, these two tests allow researchers to estimate which infections in the survey are

new and, thus, to derive an estimate of incidence. While they do tend to over-estimate incidence somewhat, and are less than perfect, they are currently the only alternative to the much slower process of following cohorts of women over time to determine how many of them seroconvert.

This study will also engage participants in answering other important questions including measuring the prevalence of other sexually transmitted infections in the population (and, of course, treating those that are identified); assessing participants' willingness to participate in future HIV prevention trials; and gauging the host community's need for female-controlled options for HIV prevention.

These studies should get off the ground in April of 2009 and is expected to enroll a total sample size of 4500-6000 women (with approximately 1000 women enrolling per site).

## **Advocacy in Action**

### **South Africa**

#### **PrEP – talking about the realities, Salim Karim and Cheryl Baxter of CAPRISA, South Africa write about the challenges of the implementation of PrEP**

The next big hope for the HIV prevention research and development field is pre-exposure prophylaxis, or PrEP. Soon there will be more volunteers enrolled in PrEP trials than in microbicides and vaccine trials combined. Results from the first PrEP trial are expected in early 2010, which means that the field needs to consider issues of implementation and roll-out now. It is clearly time to start talking seriously about how PrEP might be implemented in the “real world.” GCM, in particular, is concerned about the potential impact of PrEP roll-out on women.

Mathematical models suggest that the rate of new HIV infections in 2020 would be one-fourth of what we see now, if a 90%-effective PrEP product was made available to 75% of the at-risk population. While an exciting prospect, it is important to remember that people to whom oral PrEP is prescribed would take their pills daily, without fail, for as long as they are at risk of acquiring HIV.

In a paper published in the recent issue of *Future Medicine*, Salim Karim and Cheryl Baxter from the Centre for the AIDS Programme of Research in South Africa (CAPRISA) talk about some of the challenges of large-scale PrEP roll-out, including current the lack of proper infrastructure to provide the necessary medical monitoring and counseling to at-risk populations.

Giving antiretroviral drugs to healthy people, for example, raises a number of safety concerns. Not only will people taking PrEP need to be watched for side effects caused by the medication, but they will need to be tested regularly for HIV. Should someone unknowingly continue to take an ARV for prevention after becoming infected with HIV, it is possible that she or he could develop a drug-resistant strain of the virus. If this occurred, it could limit a person's treatment options; the ARV used for PrEP would no longer be effective against the strain of HIV in the person's body. For more information on why and how this occurs, please see the Global Campaign's fact sheet, “Understanding HIV Drug Resistance”, posted on our website at <http://www.global-campaign.org/EngDownload.htm>. As Karim and Baxter point out, current PrEP trials will not be able to assess the extent to which HIV drug resistance may or may not be a problem. Thus, they conclude, “if PrEP is shown to be effective, serious thought will have to be given to setting aside a class or (or classes) of ARVs for use in prevention only.”

Another set of factors that could influence how well PrEP works in the real world is access and adherence (taking the drug regularly, as prescribed). Adherence to antiretroviral treatment is high

among HIV-positive people in most settings, with proper counseling and support. Otherwise healthy HIV-negative people, however, may not feel the same level of urgency to take their pills regularly. In addition, despite data that suggest a decrease of risky sexual behaviours during one trial in Ghana, many advocates and researchers are concerned that people may “feel safe” on PrEP and, therefore, decrease their condom use. Messaging to reinforce the fact that PrEP is only likely to partially protective, even with perfect adherence, is thus vitally important. Without investing money to incorporate and expand proven adherence programmes, Karim and Baxter argue, large-scale roll-out of PrEP is unlikely to ensure that at-risk individuals will take the medication consistently and correctly.

All of this will require considerable planning and investment. Karim and Baxter conclude by arguing for integrating increased safety monitoring, expanded HIV testing, and improved adherence and risk-reduction counseling into existing HIV prevention and treatment programs as one method for reducing costs and promoting comprehensive HIV services. Although challenging, integration of these essential components is by no means impossible.

At the Global Campaign, we have always recognized that the key to making such systemic changes happen is political will. We have proven with regard to ARV pricing and access and in many other cases, when advocates and communities become involved; generate the necessary demand; and refuse to accept the status quo -- systemic change can and does happen.

To see a copy of the full article please go to  
<http://www.futuremedicine.com/doi/full/10.2217/17584310.3.1.3>

## **Upcoming Events**

### **Global**

#### **Feb. 3 Johannesburg, South Africa**

GCM's Africa Program Director Samu Dube will conduct a training on microbicides at the Positive Women's Network. For more information on microbicides please e-mail [info@global-campaign.org](mailto:info@global-campaign.org)

#### **Feb 18 – 20, New Delhi, India**

GCM India staff Paramita Kundu and Nandinee Bandyopadhyay will convene a consultation with “key population” consultants to obtain their input in the Vaginal Health Training Module they are developing. This module is designed to be easily integrated into on-going training efforts around sexual and reproductive health, family planning, STI control and other HIV prevention programs. When completed, GCM will make it available to partner and ally organizations worldwide to help promote the informed use of vaginally applied products, including future microbicides.