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GC News is a forum for exchange on new HIV prevention options, especially for women.

Global

Leaving the Global Campaign: Anna Forbes' Parting Thoughts

Research Updates

CDC Changes Course of PrEP Study Due to Challenges
CAPRISA 004 Trial Completed; Targets Achieved and Exceeded
Disappointment and Progress: PRO 2000 Results

GCM and Partners in Action

In Memory of Dr. Radium Bhattacharya

GCM's Highlighted Activities of the Month

African HIV Prevention Research Advocacy Partners' Forum

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Global

Leaving the Global Campaign: Anna Forbes' Parting Thoughts



Anna Forbes

I stepped down as Deputy Director of the Global Campaign for Microbicides on 8 January 2010—a sad and also exciting transition for me. I was there in 1998 when we formed GCM, and have been working at GCM full time since 2000. This has been a decade filled with travel, learning, hard work and some of the best co-workers and colleagues on the planet. But now it is time to move on. I will be going back to consulting and will stay focused on women, HIV and prevention. I will doubtlessly cross paths with many of you again and I look forward to that.

In my last GC News article, I want to say *why* I am convinced that microbicides will make an earth-shattering difference. My belief in this kind of transformation is evidence-based—because I have seen it happen twice in my lifetime.

In 1972, I was 17 years old and a Planned Parenthood intern. Oral contraceptives had been available for barely a decade, and we were still 18 months away from a court decision that would legalize abortion

across the US. I saw the fear and hardship of women who traveled to another state for safe abortions and the deadly horror of the illegal ones. And yet, the “old heads” in the office (as I then cavalierly regarded my elders) talked about how much more frequent this suffering had been before the pill. I saw the difference one new tool can make in women’s lives.

The second time I saw this transformation was in 1996. I got my first AIDS job in 1985, working with smart, brave, dedicated people to set up a community-based AIDS services organization (ActionAIDS in Philadelphia). But they kept dying. With drugs that could only treat the symptoms, I watched many of my friends, co-workers, mentors, and clients waste away and die in terrible pain. After a decade of this, I was nearing despair.

Then, suddenly, I began bumping into people on the street who knew me -- but whom I didn’t recognize. They had been skin and bones the last time I saw them and now they were looking well. People called the advent of combination therapy “the Lazarus effect”. The joy of it was beyond description. As with the birth control pills, the side effects of the first generations of ARV cocktails were brutal – and still are for many people. But still, it was a reprieve.

On 11 February 2009, we had a quick foreshadowing of what this might feel like in the microbicides world when we heard the HPTN 035 results. Although premature, that rush of hope only reinforced my faith in the promise of microbicides. One South African trial site investigator e-mailed me that day to say trial participants at her site “celebrated in true Zulu style” upon hearing the news that PRO 2000 might actually work. They were dancing.

I am one of the old heads in this field now. And I am more determined than ever to play my part in transforming HIV risk for women who live in the teeth of this epidemic. In my lifetime, I want to hear that women are dancing because – this time for real – we have a microbicide.

Anna can now be contacted at annaforbes@earthlink.net.

Research Updates

CDC Changes Course of PrEP Study Due to Challenges

The CDC announced on 15 December 2009 that, due to unanticipated challenges, it is now revising the protocol of the TDF2 Botswana Study, one of several clinical trials around the world studying [Pre-Exposure Prophylaxis](#). This trial is being conducted by [BOTUSA](#), a partnership between the Botswana Ministry of Health and the U.S. Centers for Disease Control and Prevention.

The trial was designed to show whether taking an anti-retroviral drug (ARV) pill daily could reduce HIV negative participants’ risk of acquiring HIV. To test a combination tenofovir-emtricitabine pill (brand name [Truvada®](#)), the trial enrolled heterosexual men and women volunteers between the ages of 18 and 39.

Researchers concluded however, that the study would not be able to determine efficacy (whether the strategy works for HIV prevention or not) due to two significant challenges. First, **the HIV incidence rate proved to be lower than expected** in this study population. This is in part due to declining HIV rates in the nation overall. Since the trial began, Botswana has experienced a 25% drop in HIV prevalence among this age group – which is certainly good news. The low rate of infection observed among trial participants is also due in part to extensive HIV prevention counseling, condoms and other services provided by the trial to all participants.

The second factor is **low retention rates among this highly mobile population of young adults**. If a significant number of participants drop out, the effect of the intervention cannot be correctly

calculated. Factors contributing to the low retention rates in this trial included pregnancy, participants moving out of the area, and the amount of time required for study visits. BOTUSA attempted to overcome this problem by adding weekend clinic hours, increasing participant reimbursements, and strengthening their participant retention procedures. While these steps resulted in improved retention, it was not enough to assure that the trial would produce valid efficacy data.

The trial will, however, still be able to assess the *safety* of Truvada use among participants, any changes in risk behavior, and participants' *ability to adhere* to the requirement of taking a daily pill. This information will help to guide planning for PrEP introduction if PrEP is proven effective in other trials.

BOTUSA's plans for completing the safety and adherence portions of the trial and the necessary follow-up with all trial participants are currently being discussed and finalized with the Botswana Ministry of Health, as well as with participants and community advisory boards. Final plans will be submitted for approval to the scientific and ethical review boards in Botswana and the U.S. in January 2010. A final report of the study findings is expected later in 2010.

For more information on the status of the Botswana TDF2 PrEP Study, click on the following link: <http://www.cdc.gov/hiv/prep/resources/factsheets/botswanatdf2.htm>

CAPRISA 004 Trial Completed; Targets Achieved and Exceeded

Co-Principal Investigators Quarraisha and [Salim Karim](#) announced on 11 December 2009 that the [CAPRISA 004](#) trial was closing one month ahead of schedule because it had met or exceeded its targets.

Designed as a Phase IIb trial to assess the safety and effectiveness of 1% tenofovir gel as a vaginal microbicide, the CAPRISA 004 study enrolled the first of its 900 participants in late May 2007 and the last participant in early January 2009. Conducted in the KwaZulu-Natal Province of South Africa, the trial retained 94% of its participants through trial completion (exceeding its goal of 90%). The final post-trial visits are scheduled to occur in the first quarter of 2010.

Since this is the first effectiveness study of an [antiretroviral drug](#) formulated as a microbicide, these post-trial visits are essential to determine whether any HIV infections could have been masked by use of the tenofovir gel. For example, the antibody response may appear muted, with a viral load below detection, making the person look as if they were not infected when in actuality they had seroconverted. At this time, it is only a theoretical possibility that infection could be masked by the presence of tenofovir—the purpose of the post-trial visits is to determine if there is any empiric evidence for this.

The study has also collected sufficient data to have the statistical power it needs to make a meaningful comparison between the effectiveness of tenofovir versus a placebo gel. Announcement of these results is expected in July at the [Vienna AIDS 2010 Conference](#) and are highly anticipated, especially in the wake of the [MDP 301 PRO 2000 trial results](#) announced in early December 2009.

Participants who became HIV positive, during the trial are receiving counseling and high-quality medical care and treatment, including antiretroviral therapy and psychological and social support, from CAPRISA's AIDS Treatment Programme and other local AIDS treatment services

Like advocates everywhere, GCM would like to congratulate the CAPRISA 004 study teams for their hard work and, most of all, to the women who joined this trial. Each one of these volunteers has made a significant contribution to HIV prevention research. In his announcement, Pro Vice-Chancellor (Research) at the University of KwaZulu-Natal and Principal Investigator, Dr. Salim Karim, stated that, "[w]e are crossing our fingers that we have a positive result - we are all painfully aware of how important this result could be to the future lives of hundreds of thousands of women, especially the most-disenfranchised young women at highest risk of HIV infection in Africa."

The CAPRISA 004 study is a collaborative effort between the Centre for the AIDS Programme of Research in South Africa (CAPRISA), based at the University of KwaZulu-Natal in Durban, South Africa; Family Health International; and CONRAD. It is funded by the United States Agency for International Development and the South African Department of Science and Technology through LIFELab in South Africa.

Disappointment and Progress: PRO 2000, a non-ARV-based candidate microbicide, not shown to prevent HIV infection. Other HIV-prevention R&D continues.

On 14 December 2009, the Microbicides Development Programme (MDP) announced the results of the Phase III clinical trial of its candidate vaginal microbicide, PRO 2000.

In anticipation of the trial results, the Global Campaign for Microbicides (GCM) had created an [advocacy brief](#) describing the trial and the issues raised by the research. Many of these issues relate to access and licensure and will hold true for any future product that shows safety and effectiveness.

Upon release of the study results, GCM organized a [conference call](#) for advocates to learn of the trial results and discuss their implications directly with researchers from MDP and peer advocates in the field.

What did we learn from the trial?

The MDP 301 PRO 2000 trial showed that women who were assigned to use the microbicide candidate before sex, did not benefit from protection against HIV compared to those assigned to use a placebo gel. While this outcome is tremendously disappointing, we congratulate the MDP team on a well-organised study that incorporated robust clinical and social science analysis and community advocate perspectives. [Lessons from this trial](#), combined with those from the smaller [HPTN 035 trial](#) of PRO 2000 gel, will continue to inform the field.

Although much of the reporting was responsible and well-balanced, a number of inaccurate reports emerged—particularly from Zambia—that were later picked up elsewhere and may have generated misunderstandings and concerns about the trial’s protocol and outcomes. GCM and members of the Microbicides Media and Communications Initiative (MMCI) have worked with stakeholders in Zambia and globally to correct these inaccuracies and prevent further confusion.

What’s next?

We believe that the HIV-prevention product development field—including pre-exposure prophylaxis (PrEP) and ARV-based and non-ARV-based microbicides—offer tremendous promise. As part of our role to increase understanding of and support for HIV-prevention research and advocacy, GCM continues to work closely with trial sites, study sponsors, government agencies, and advocacy organizations. The current pipeline includes the testing of tenofovir disoproxil fumarate (TDF) and also TDF combined with emtricitabine (Truvada) as oral PrEP, as well as TDF as a topical microbicide. Results from these trials should be announced over the next two years.

How you can help?

If you can help increase awareness of the realities of HIV-prevention research, let us know. You may want to post accurate messages about the MDP results and other research to-date on your website and in your newsletters to your members and constituents. You may want to speak about microbicide trials at upcoming meetings or in discussions with reporters. Let GCM know if we can help you communicate the importance of this work on the lives of women and their partners everywhere. Email us at info@global-campaign.org.

GCM and Partners in Action

In Memory of Dr. Radium Bhattacharya

By Bobby Ramakant

With sorrow, we report that Dr. Radium Bhattacharya, the founder-president of [Indian Network of NGOs on HIV/AIDS](#) (INN) passed away on 20 December 2009.

Dr. Radium was one of the first to step forward in the 1980s to mount India's response to HIV/AIDS. She was a scientist, an organizer and a relentless advocate for over two decades and will be sorely missed by her colleagues in India and around the world.

Working tirelessly to increase partnerships and civil society representation in India's AIDS response, she most notably founded INN in 1994 and nurtured its growth over the last 16 years, engaging a vibrant network of more than 500 non-governmental organizations.

Under her leadership, INN raised awareness about the need to increase HIV prevention options for women, spotlighting the role of microbicides and female condoms at its 2001 National Convention. Dr. Radium's efforts led to the establishment of India's National Working Group on Microbicides as well as a range of high-profile events and dialogue that connected over a thousand people across the Indian sub-continent.

GCM Director Yasmin Halima commented on Dr. Radium's role as an ally and advisor to the Global Campaign's work in India. "We stand on the shoulders of giants – and in the field of microbicides, Dr. Radium's work deserves to be recognized as such. Without the tireless effort of those who dedicate their lives for the right of women to protect themselves against HIV, our work would not be possible. She shared our conviction that civil society must be equal partners in the search for effective microbicides," she added.

GCM's Highlighted Activities of the Month

African HIV Prevention Research Advocacy Partners' Forum 3-5 February 2010, Nairobi, Kenya

In an effort to facilitate connections among participants and make linkages across advocacy related to specific HIV prevention research in Africa, GCM will partner with AVAC to facilitate the African Prevention Research Advocacy Partners' Forum, to take place 3-5 February 2010. The two organizations will bring together individuals who are involved in AVAC and GCM's HIV prevention research advocacy programmes to share experiences, develop a common understanding across programmes and prevention interventions, prepare for trial results expected in 2010, and build their individual capacity as prevention advocates.