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Welcome to the *Global Campaign News*! The *Global Campaign News* is a forum for international exchange on microbicide activities and information with an aim to build a more informed and integrated movement for microbicide development and other prevention options against HIV and other sexually transmitted infections. This and previous issues of *GC News* are available online at *http://www.global-campaign.org/gcarchives.htm*

In this issue:

Resource Mobilization

Long-awaited microbicides branch at U.S. National Institutes of Health

North America

On 23 July, the U.S. National Institutes of Health (NIH) formally approved plans to establish a microbicide branch. The branch, would be dedicated to microbicide research and development within the NIH's National Institute of Allergy and Infectious Diseases, thereby creating a single line of administrative accountability and providing direction to ensure microbicide research and development is prioritized.

This announcement signals a long awaited victory for microbicide advocates. Microbicide research at NIH has long been conducted under several institutes with no single line of administrative accountability and highly variable levels of interest and commitment across institute leadership. Now, the question looms: What does this mean for the future of the Microbicide Development Act?

The NIH decision is a welcome development, but it does not diminish the need for Congress to pass the MDA. It is, instead, the first step on the road toward strengthening and coordinating the federal government's microbicide research and development efforts.

The MDA will ensure the coordination within and among all of the relevant federal agencies – the National Institutes of Health, the U.S. Agency for International Development, and the Centers for Disease Control and

Prevention. The MDA will also help establish and sustain the allocation of a reasonable and reliable level of resources. Finally, enactment of the MDA will provide clear and lasting evidence that funding research on microbicides is a priority, and that Congress is interested and will engage in continued oversight of microbicide programs.

Tracking European investment in microbicides

Europe

The European secretariat of the Global Campaign, with assistance from the AIDS Vaccine Advocacy Coalition, Alliance for Microbicide Development, and International Partnership for Microbicides has compiled a chart of all the funding committed to microbicides research to date from European sources.

This new EU investment tracking sheet, which will be updated regularly, shows all the major national and regional research programs in Europe and the major donors behind them. The UK continues to be Europe's largest donor to microbicides, but Ireland and the Netherlands are the largest donors per capita. The newest European investors to the field are Belgium, France and Germany. The funding shown reflects commitments up to the year 2012.

The new investment tracking sheet can be downloaded at http://www.global-campaign.org/EngDownload.htm. Any questions or additions can be sent to rwebb@path.org.

Research updates

Many of the articles in this section are reports from the International AIDS Society conference in Sydney, Australia. You can visit http://www.ias2007.org/ to view all of the conference abstracts and http://www.kaisernetwork.org/ias2007/ to download presentations, podcasts, and film clips from key presentations.

What do we know (and not know) from the MIRA trial?

Global

As reported in the last issue of *GC News*, the results of the MIRA (Methods for Improving Reproductive Health in Africa) diaphragm study were released in Sydney last month. In summary, in the context of a comprehensive HIV prevention package offered to all participants, the trial found no additional protective benefit against HIV infection from providing the diaphragm plus lubricant in the intervention arm.

We wanted to share with you a presentation by Dr. Nancy Padian, the MIRA Trial's principal investigator, because it not only provides a great overview of the trial, but also offers insight into what the results do NOT tell us. More specifically, the MIRA trail could not assess:

- Whether the cervix is most vulnerable
- Whether a diaphragm is as good as a condom
- Whether a diaphragm is better than nothing
- Whether other cervical barriers might have worked better
- Whether a barrier would be more effective with a microbicide

We invite you to read Dr. Padian's full presentation is available for download at:
http://www.kaisernetwork.org/health_cast/uploaded_files/WESS304-Padian.pdf
For more information about the MIRA trial, visit: http://www.global-campaign.org/MIRA.htm

Emerging challenges in designing prevention research from IAS

Global

On 23 July, researchers and advocates gathered at the IAS conference to review the current status of HIV prevention research and the future challenges in trial design and implementation.

The panel included presentations from Quarraisha Abdool Karim from Columbia University South Africa, from Willard Cates, Family Health International (U.S.), Andrew Nunn from the Medical Research Council in UK, and Veronica Miller from the Forum for Collaborative HIV Research at George Washington University, US. The panel was facilitated by Kim Dickson of the World Health Organization, Renee Ridzon of the Bill and Melinda Gates Foundation, and Mitchell Warren of the AIDS Vaccine Advocacy Coalition.

A podcast, video, transcript and powerpoint slides available for this panel at:
http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=2237

Daily aciclovir doesn't reduce HIV risk in HSV-2-infected women - was poor adherence the reason?

Global

The following is an excerpt of an article written by Michael Carter, on 23 July 2007.
The article is published with permission from www.aidsmap.com

Anti-herpes simplex virus-2 (HSV-2) therapy with daily aciclovir does not protect women against infection with HIV, according to the results of a randomised controlled trial conducted in Tanzania presented to the Fourth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Sydney on July 23rd.

Dr Debby Watson-Jones, of the London School of Hygiene and Tropical Medicine, told the conference that almost identical HIV incidence was observed in the aciclovir and placebo arms of the study. However, approximately 50% of the women provided with acyclovir failed to achieve the target 90% adherence to their daily therapy, and when the investigators looked at their data again - controlling for adherence - they found a non-significant trend towards lower HIV incidence amongst women with optimum levels of adherence. Dr Watson-Jones suggested that poor adherence could have contributed to the disappointing results of the study.

The association between infection with HSV-2 (the virus that causes genital herpes) and the risk of HIV acquisition has been well-studied. A recent meta-analysis found that individuals with HSV-2 infection had a three-fold increase in their risk of HIV acquisition, and it has been estimated that approximately half of all HIV infections can be attributed to HSV-2.

Furthermore, it is known when HIV-positive individuals have episodes of symptomatic HSV-2 disease - genital herpes - these are longer and more severe than in HIV-uninfected individuals. Some studies have also found that infection with HSV-2 is associated with an increase in HIV viral load in genital fluids.

It has been suggested that individuals infected with HSV-2 could reduce their risk of HIV infection by taking ongoing suppressive anti-herpes therapy. Investigators from London and Tanzania therefore designed a 30-month randomised, placebo controlled trial to see if daily anti-herpes treatment consisting of a daily oral dose of 400mg of aciclovir reduced the risk of HIV infection.

A total of 820 HIV-negative women, all of whom were infected with HSV-2, were recruited to the study in a mining district of Tanzania. Women who worked in bars and guest houses were targeted for inclusion in the study because of their high risk of HIV due to “opportunistic sex work”.

The women were screened for HIV and other sexually transmitted infections at baseline and randomised to the aciclovir or placebo arms. They were followed up at three monthly intervals when they were provided with further study treatment packs, condoms and safer sex counselling. At follow-up, the women were also offered HIV testing.

Information about the importance of adherence was provided to the women, and to monitor, adherence pill counts were conducted. In addition, there were two random urine tests to monitor aciclovir levels.

Women in the two arms of the study were well-matched at baseline, although women in the aciclovir arm were slightly more likely to report a history of transactional sex (40% versus 34%).

Study end-points were infection with HIV, pregnancy, or the completion of 30-months follow-up.

Approximately 60% of women completed the study. The investigators' intent-to-treat analysis showed that a total of 8% of women seroconverted for HIV, with almost identical proportions of women in the aciclovir and placebo arms diagnosed with the infection. The HIV incidence rate was 4.29 per 100 person years in the aciclovir arm and 4.25 per 100 person years in the placebo arm.

An on-treatment analysis was also performed. Once again, there was no significant difference in HIV incidence in the aciclovir arm (4.46 per 100 person years) and the placebo arm (3.99 per 100 person years).

However, Dr Watson-Jones then presented data on adherence to aciclovir therapy. These data showed that approximately 50% of patients in the treatment arm had 90% or better adherence to treatment, with a further 19% taking between 75% and 90% of their pills. Women with 75% or better adherence to aciclovir therapy had an odds ratio of HIV infection of 0.58, but the confidence intervals meant that this reduction in risk was not statistically significant.

Disappointment with the study's findings was expressed by Dr Watson-Jones. She speculated that poor adherence to therapy may have been a factor in the results and suggested that more intense follow-up (as often as every two weeks) could improve adherence and thereby help to reduce HIV incidence. It is, however, perhaps worth noting that adherence of 70% has been observed in trials examining other prevention technologies such as microbicides and pre-exposure prophylaxis, and the sub-optimal adherence seen in this aciclovir trial may be indicative of levels of adherence that would be achieved in a "real-world" setting.

References

Watson-Jones, D et al. *Impact of HSV-2 suppressive therapy on HIV incidence in HSV-2 seropositive women: a randomised controlled trial in Tanzania* Fourth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, abstract MOAC104, Sydney, 2007.

For the full article, visit: http://www.aidsmap.com/en/news/78947268-AFEB-41D7-88AB-A41FCD208C3A.asp

New technique for detecting cervical cancer

Global

A simple technique using nothing more than cotton swabs and vinegar could help prevent the deaths of more than 250,000 women a year. Cervical cancer – a sexually transmitted disease caused by the human papilloma virus (HPV) – is the leading cause of cancer-related mortality in the developing world. Early diagnosis and treatment is key, but current screening and treatment technologies, such as Pap smears and the newly approved HPV vaccine, are too costly to be used widely in resource-poor countries. Fewer than five per cent of women in Africa, Asia and Latin America are screened for cervical cancer, as compared to 70% of women in North America and Europe.

In 1999, researchers in the U.S. and Zimbabwe showed that trained nurse-midwives who wiped a patient's cervix with acetic acid (white vinegar) accurately detected more than three-fourths of pre-cancerous and cancerous lesions; tissue harboring such lesions turned white when exposed to vinegar, and could be easily seen during a visual inspection of the cervix.

In a study recently published in the British medical journal *The Lancet*, researchers in India and France have built upon that finding to show that this method – visual inspection of the cervix using acetic acid (VIA) – is as effective as Pap smears for detection of cervical cancer and dysplasia. In the study, 49,311 sexually active women in Tamil Nadu were randomized to receive VIA or existing cervical screening and care. Women who were VIA-positive were offered further treatment, including cryotherapy to remove any lesions, or a referral if they had invasive cancer. Women who underwent VIA had a 25 percent reduction in cervical cancer incidence and a 35 percent reduction in deaths compared with the women who received standard screening and care.

As promising as these results are, however, it is important to note that the *Lancet* study was performed at a clinic with dedicated staff and in an area where treatment for cervical cancer was readily available. The VIA screening method is simple and cheap, but many women in resource-poor countries still lack access to basic medical services, let alone treatment and care for cervical dysplasia or cancer. As always, technologies are only useful if they are not only effective but also available, affordable and acceptable to the people who need them.

HPTN 035 trial completes enrollment
Africa / North America

On 25 July, the HPTN announced that they have completed enrollment of the last of the 3,100 participants for the Phase 2/2B trial of 0.5% PRO 2000 and BufferGel®. 3100 women have been enrolled in Blantyre, Chitungwiza-Harare, Durban, Hlabisa, Lilongwe, Lusaka, and Philadelphia. For more information on this trial, please visit http://www.hptn.org/research_studies/hptn035.asp

Understanding the news about VivaGel
Global

Over the past several weeks, Global Campaign staff have received several questions about recent news articles about VivaGel, a candidate microbicide being developed by Australian company, StarPharma. These articles (in Sydney's Daily Telegraph, planetout.com, and EDGE Boston) have been quite positive in tone, but have not provided many specifics.

The articles describe StarPharma's announcement that VivaGel has shown a promising results in vitro (in the lab) as having potential activity against HIV and HSV. Naturally, we all hope that this promise is borne out and that the products is, in fact, effective in humans. But we must also recognize that several products that have appeared highly effective in pre-clinical studies have not actually produced the same level of result in human trials.
It is important to note that no human effectiveness trials on VivaGel are yet underway. It is still in Phase 1 safety trials. You can check its status (and that of any microbicide in clinical trials) at the Alliance for Microbicide Development's database at http://secure.microbicide.org/NetReports/ClinicalTrialsOngoingByProduct.aspx

This is an extremely useful resource to check when you see headlines like this. As advocates, we need to keep this kind of coverage in perspective and help others understand that such hopeful language does not (unfortunately) mean that access to a successful microbicide is right around the corner. Good news about product leads is always good to hear—but needs to be understood in context.

Advocacy in action

GCM Steering Committee meets to chart out future strategic directions
Global

The Global Campaign Steering Committee is comprised of 16 leading advocates and researchers who provide vital feedback to the secretariat about the workings of the GCM and the wider needs of the field. Each Steering Committee member commits to a three year term and to representing the geographic region in which GCM operates.

From 9-11 July, the Global Campaign for Microbicides Steering Committee held their annual meeting in Amsterdam. The Steering Committee members examined findings from GCM's recent strategic review, and provided

input into our new strategic plan. The discussion focused on several topics including the scope of GCM's work, our relationships with other groups, and our role in key areas of work such as resource mobilization and capacity building.

The Steering Committee members also took the time to thank their outgoing chairperson, Kim Dickson of the World Health Organization, and welcome their new chairperson, Dazon Dixon Diallo, founder and president of SisterLove, Incorporated, based in the US and South Africa. The GCM executive committee – Kim Dickson, Shira Saperstein, Moniek van der Kroef, and Francoise Welter – will work closely with the Director of the campaign and the chairperson in the coming year.

Three members are rotating off the Steering Committee this year: Gaye Tharawan, Margaret Muganwa, and Promise Mthembu. We are most grateful to these talented advocates who have been an essential part of our work, and we look forward to working with them in other capacities for many years to come.

We are also happy to announce and welcome the two newest additions to the Global Campaign Steering Committee for 2007: Monruedee Laphimon and Mayowa Joel.

Monruedee Laphimon is Programme Coordinator for the Southeast Asia Consortium on Gender, Sexuality and Health, where she is responsible for Training and research on gender, sexuality and sexual health in Southeast Asia and China. She is also a member of the Thai Women & HIV/AIDS Networks, working with the issue of women's sexual and reproductive health and rights advocate and activist. Her field of practice is gender, sexuality and sexual & reproductive health and rights.

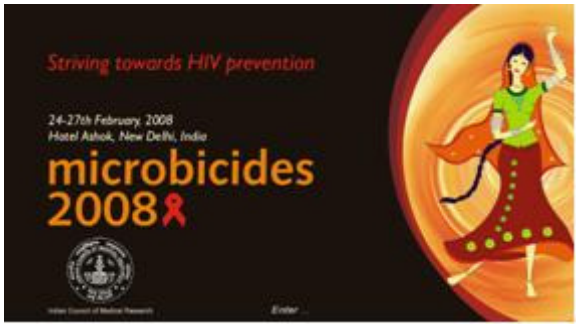
Mayowa Joel is a trained peer health educator with over 10 years experience in promoting development programmes especially sexual and reproductive health including HIV & AIDS prevention and treatment among young people. He is currently the Executive Director of the Communication for Development Centre, Nigeria and was formerly a programs manager at the Youth Action Rangers of Nigeria (YARN) in Lagos.

Visit: www.global-campaign.org/governance.htm to see a list of the full steering committee roster.

Conference announcement

Microbicides 2008 - registration, abstracts, and scholarships available

Global



Microbicides 2008 conference will take place from 24-27 February 2008 in New Delhi, India. Visit the Microbicides 2008 conference website—www.microbicides2008.com—to register, submit abstracts for consideration, and apply for scholarship. Please also note the following important dates:

- Last date for Early Bird Registration: 30 October 2007
- Last date for Abstract submission: 30 September 2007
- Last date for submission of Scholarship application: 30 September 2007

Global Campaign events at ICAAP 2007

Asia/Pacific

The 8th International Congress on AIDS in Asia and the Pacific (ICAAP) will be held from 19 to 23 August 2007 in Colombo, Sri Lanka. GCM will be participating in a number of events during the conference, and we invite you to join us if you will be at the conference. Find out more information about the new prevention technologies

symposium., the skills building workshop on microbicides, and our poster presentation at: http://www.global-campaign.org/India-events.htm

Highlighted Resources

New report on lessons from the introduction of contraceptive technologies

The International Partnership for Microbicides has recently published a new report entitled: "Planning for the Microbicide Access in Developing Countries: Lessons from the Introduction of Contraceptive Technologies". This historical review recounts the introduction experiences of three contraceptive technologies (the IUD, Norplant and the Female Condom), and highlights lessons for future microbicide introduction. Several of the themes from the July 2007 Microbicide Access Forum that took place in Nairobi are discussed. This document is available online at: http://www.ipm-microbicides.org/pdfs/english/ipm_publications/2007/ipm_rh_paper_en_20070730v6.pdf.

Global Campaign goes French!

The Global Campaign for Microbicides is happy to announce an updated and improved French section of our website: http://www.global-campaign.org/fr.htm These pages include a range of information on microbicides, other prevention options and the work of the Campaign in French. Don't forget to check out the updated French download centre including fact sheets designed to help advocates learn and teach others about microbicides. We invite you to use this information or forward it to your French speaking contacts and networks. We welcome the adaptation and reproduction of these materials for local audiences, and we look forward to circulating any new materials that you create via our website.

We welcome your input and contributions for future issues! Please send emails to: info@global-campaign.org.
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