



Global Campaign News – Issue #98 4 August 2008

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>

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Research update

NIH to Postpone and Redesign PAVE 100 HIV Vaccine Trial Global

Last week, the US National Institute of Allergy and Infectious Diseases (NIAID) announced that it would not move ahead with the PAVE 100 HIV vaccine trial. The original PAVE 100 study was a test-of-concept efficacy trial of a "prime-boost" vaccine combination developed by NIAID's Vaccine Research Center (VRC). Under the VRC's "prime-boost" approach, trial participants receive a series of three DNA immunizations followed by a single booster immunization using adenovirus type 5 (Ad5) as a vector. Vectors, often disabled viruses and are used to carry the elements of a vaccine into the body. In this case, the vector (Ad5) is a common cold-carrying virus that is used to carry elements of the HIV virus.

The trial was scheduled to begin in October 2007 and would have enrolled over 8,500 volunteers in the United States, South America, the Caribbean and Africa. However, following the premature closure of the STEP and Phambili trials of Merck's Ad5-based vaccine in late 2007, the original PAVE 100 protocol was modified. Analyses of the STEP trial results seemed to suggest that people who received the vaccine who also had high levels of pre-existing antibodies to Ad5 might become more susceptible to acquiring HIV infection after receiving the vaccine candidate. So, for safety reasons, the PAVE 100 study was redesigned to enroll only participants who lack a pre-existing immunity to Ad5.

NIAID has now decided to forego the planned test-of-concept efficacy PAVE 100 HIV study in favor of a smaller and more focused study looking at whether the vaccine has an effect on HIV viral load among people already living with HIV. At this time, it is unclear what this future study will look like. Our colleagues at the AIDS Vaccine Advocacy Coalition (AVAC) have called upon NIAID to "...clarify and engage in public debate around what a smaller evaluation of the VRC strategy might entail." For more information about the PAVE 100 study and AVAC's response, please visit <http://www.avac.org/pave.htm>.

T-1249 Shows Potential as Vaginal Microbicide North America

In a report published last week in the *Proceedings of the National Academy of Sciences*, researchers at Tulane University successfully used a vaginal gel containing T-1249 (an antiretroviral similar to those used to treat HIV) to protect monkeys from infection with SHIV (a genetically-modified virus, similar to HIV). This study shows promise for future use of antiretrovirals like T-1249 (which work to block the HIV virus from fusing with healthy CD4 cells) in candidate microbicides.

Researchers tested T-1249 alone and in combination with other similar antiretrovirals known as 'entry inhibitors'. It was found that gels containing T-1249 in combination with other entry inhibitors were more effective at blocking SHIV infection than gels containing T-1249 alone. These data support the idea of using T-1249 together with other compounds to create 'combination products'.

More research is needed, and questions about the economic feasibility of using a relatively expensive compound like T-1249 in a vaginal microbicide remain. The Global Campaign will continue to follow the progress of this and other potential microbicide candidates in partnership with the Alliance for Microbicide Development. For more information on microbicide candidates in pre-clinical and clinical development, please visit the Alliance for Microbicide Development's *Microbicide R&D Database*, http://www.microbicide.org/cs/microbicide_rd_database.

Highlighted Resources

Alliance Initiates an Inventory of Lubricant and Spermicide Products

*** Reprinted by request from the Alliance for Microbicide Development*



Dear Colleagues,

The Alliance is initiating work toward a comprehensive inventory of lubricating products (applied directly to the vagina or rectum), including spermicides, that are on the US domestic and international markets. This inventory will seek to include detailed information on regulated products, such as those available over-the-counter (OTC) and by prescription, with ingredients and safety (preclinical and clinical) data where available. All unregulated products will be compiled by country in a separate list, and distributors will be contacted for follow-up information.

Please contribute! To help in this work, we are seeking information from all advocates, agencies, countries, developers, and researchers. To supply information, please send any and all details (such as product name, website, ingredients, manufacturer contact information, etc.) to Stephanie Tillman at stillman@microbicide.org. When available, please also fax or mail product labels, boxes, and flyers to 301-588-8390 or our address at the footer. We appreciate any information you can provide.

To note: We have received feedback that in countries where clinical trials of candidate microbicides have taken place, there are products on the market with names similar to those being tested. If you are aware

of these products, please send this information to the Alliance, who will include it in the inventory and bring it to the attention of appropriate agencies.

Thanks for your support! We look forward to publicly providing this information once the inventory is substantially complete.

New Resources from the International Women's Health Coalition

The International Women's Health Coalition (IWHC) has just released three new publications addressing women's health and vulnerability to HIV/AIDS and sexual violence. The first two publications listed are part of IWHC's series on Young Adolescents' Sexual and Reproductive Rights. To view the complete series, please visit <http://iwhc.org/resources/youngadolescents>.

Triple Jeopardy: Female Adolescence, Sexual Violence, and HIV/AIDS

<http://iwhc.org/resources/youngadolescents/triple-jeopardy.cfm>

Child Marriage: Girls 14 and Younger at Risk

<http://iwhc.org/resources/youngadolescents/childmarriage.cfm>

(Available in English, Spanish, Portuguese, and French)

Women and Risk of HIV/AIDS Infection

<http://iwhc.org/resources/hivaidfactsheet.cfm>

The International Women's Health Coalition (IWHC) envisions a world where women are free from discrimination, sexual coercion, and violence; where they make free and informed choices on sexuality and reproduction; and where health information and services are accessible to all.

To learn more about IWHC, please visit <http://iwhc.org>.

Advocacy in action

Buzz Cafés Take Off in the UK Europe

Adapted from a model in East Africa, the UK African Microbicides Working Group organised its first buzz café entitled *The Power of Desire: How to Talk About Desire and Make Sex Sexier*. The buzz café is a space for members of the working group to meet and develop their scientific literacy and social research knowledge in an informal and relaxed atmosphere.

Held at Coffee, Cake & Kink ('the only kinky cafe gallery in the UK'), the buzz café explored social marketing for existing technologies such as male and female condoms. The invited speaker was Anne Philpott of The Pleasure Project, which aims to promote 'safer sex that feels good'. Working group members heard briefly from Anne about her work and then participated in interactive activities, including one that involved them 'selling' condoms and lubricants to one another in way that gets across the message of safer sex in a manner that oozes sexiness and draws you to want to use the products.



The informal and friendly environment stimulated conversation and enabled working group members to comfortably discuss the importance of developing social marketing strategies for microbicides *before* they become available. It stimulated creativity and participants began acting out potential adverts for microbicides! Participants felt that while microbicides are being developed, advocates can begin exploring how they will be marketed so that they are accessible to women who need and want them once they are available.



The working group meets quarterly; and the next buzz café will focus on young people and their receptiveness to sexual health messages. Young people are increasingly affected by HIV. How can we promote their leadership in HIV prevention? We hope our second buzz café will also educate and empower us to accurately address new scientific and social research areas, which enable us to be more informed and creative microbicides advocates. We will be holding the second buzz café in the largest bookshop in Europe (5th View in Piccadilly Circus) and we have an exciting 'expert' nearly confirmed!

To learn more about The Pleasure Project, please visit www.thepleasureproject.org. For further information about our buzz cafés, please email Mary Lima mary.lima@ttht.org.uk.

** Photos courtesy of Georgina Caswell*

PEPFAR Signed into Law North America

On July 30, 2008, President Bush signed into law the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008. The law – which reauthorizes the President's Emergency Plan for AIDS Relief (PEPFAR) at \$48 billion – marks a significant step in addressing these three global health challenges.

The reauthorization of PEPFAR explicitly recognizes the urgent need for new HIV prevention technologies, such as microbicides. It includes positive language regarding microbicide development and distribution, and calls on the three US government agencies – the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the US Agency for International Development (USAID) – to participate in this process.

Another exciting piece of the PEPFAR reauthorization is that it strikes down the US ban on issuing travel visas to people living with HIV. The statute, which had been in effect in the US since 1987, permanently banned people living with HIV/AIDS from entering the country. A provision in the PEPFAR reauthorization lifts this onerous ban and is a positive step in strengthening US leadership in the global fight against HIV/AIDS.

Although the reauthorization of PEPFAR funding represents a positive step forward, there are still policies within the bill which contradict best practice in HIV prevention. These include arbitrary funding guidelines directing countries to spend pre-set percentages of total PEPFAR funds on treatments or behavior change initiatives; lack of integration of family planning with HIV prevention and treatment services; and mandatory endorsement of an "anti-prostitution" pledge for recipients of US funding that further stigmatizes vulnerable populations.

For more information on these policies, please visit: <http://www.rhrealitycheck.org/blog/2008/07/10/fix-pepfar-prevent-hiv-infections>.

For more information on PEPFAR, factsheets from the Global AIDS Alliance can be found at:

PEPFAR Fact Sheet (Short Version):

http://www.globalaidsalliance.org/page/-/PDFs/PEPFAR%20II%20Fact%20Sheet_Short_FINAL.pdf

PEPFAR Fact Sheet (Long Version):

http://www.globalaidsalliance.org/page/-/PDFs/PEPFAR%20II%20Fact%20Sheet_Long_FINAL.pdf

GCM Steering Committee Meeting in Soweto, South Africa

On July 16-18, the Global Campaign for Microbicides held their annual Steering Committee Meeting in Soweto, South Africa. Soweto is a cluster of townships in the southwest of Johannesburg and considered the largest black urban settlement in Africa. With a population of over 2 million people, it is also home to many HIV prevention clinical trials, including the former MIRA diaphragm study, Phambili vaccine study, and Orange Farm male circumcision study.



During the meeting, steering committee members visited one of the clinical trial sites operated by the Reproductive Health & Research Unit (RHRU) south of Soweto in a semi-urban area called Orange Farm. The site is currently running a large-scale microbicide study testing the safety and efficacy of the candidate microbicide PRO 2000.

The site visit offered steering committee members an opportunity to meet with staff members and experience the site as a potential volunteer would. Members were walked through the participant enrolment process, including receiving a mock informed consent session, as well as undergoing sessions with an adherence counsellor, social scientist, community liaison officer, and pharmacist. For many, the visit offered a first-hand glimpse into the day-to-day logistics and challenges entailed in running large-scale clinical trials.



The rest of the meeting took place at Walter Sisulu Freedom Square, the historic site where the South African Freedom Charter was signed in 1955. Each morning, the group walked from their hotel across the square through an open-air African market to their nearby meeting room. Passing by the African women selling fruits and vegetables each morning provided a humble reminder to the members of the women for whom they advocate for new HIV prevention options.

** Photos courtesy of Shira Saperstein*

The Global Campaign Conducts Science and Ethics Training in Rwanda

On 2-5 June, the Global Campaign for Microbicides presented a series of training workshops at Projet Ubuzima, an international non-governmental organization in Kigali, Rwanda established in 2003 by the Center for Poverty-related Communicable Diseases of the Academic Medical Center of the University of

Amsterdam (CPCD-AMC), the International Partnership for Microbicides (IPM), and a number of Rwandan institutions, to conduct studies related to the prevention and treatment of HIV and other sexually transmitted infections.

Global Campaign staff was invited by Project Ubuzima and the CPCD-AMC to provide training workshops as part of a project funded by the Europe Developing Countries Clinical Trials Partnership (EDCTP) to develop the capacity of the site's staff and Community Advisory Group (CAG) members to conduct HIV trials including microbicides research.

Deputy Director Anna Forbes and Science and Ethics Officer Sean Philpott co-facilitated the training, with the help of Pauline Irungu, the Global Campaign's East Africa Coordinator and Marie Michelle Umulisa, Community Outreach and Recruitment Manager for Project Ubuzima.

Three workshops were offered: a refresher course for members of the Project Ubuzima CAG as a follow-up to a similar GCM-provided course offered in 2006; and two science and ethics training workshops for Project Ubuzima staff, including staff physicians, clinical nurses, laboratory technicians and managers, and community outreach coordinators. A total of 12 CAG members and 17 Project Ubuzima staff participated.

Tailored to the background and experience of the participants, each day-long session was designed to give participants an understanding of the science and ethics of microbicide clinical trial research. In particular, these workshops focused on the logic of ethical reasoning and the existing guidance that governs trans-national research. Each workshop also offered participants the opportunity to apply these principles through a critique of case studies and clinical research protocols, thus helping to prepare them for the work of assessing and giving input on study design and implementation.

We welcome your input and contributions for future issues! Please send emails to: info@global-campaign.org. If you would like to unsubscribe to the *Global Campaign News*, please reply to this e-mail with the subject line: UNSUBSCRIBE