



Global Campaign News – Issue #65 6 April 2006

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 STIs. This and previous issues of *GC News* are available online at <http://www.global-campaign.org/gcnews.htm>

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New data regarding the potential impact of using lemon or lime juice vaginally was presented at a special panel convened as part of the Alliance for Microbicide Development's annual meeting on 28 March 2006. Carol Lackman-Smith presented the results of a pre-clinical study conducted by Southern Research Institute (US); research that was previously presented at the Conference on Retroviruses and Opportunistic Infections in Denver in February^[i].

Lackman-Smith and her colleagues conducted pre-clinical research to compare the cytotoxicity (cell-damaging effect) and anti-HIV activity of lemon and lime juice to that of the spermicide Nonoxynol-9 (N-9). When tested on cervical explant tissue (cells obtained from routine hysterectomies that have been kept alive in lab cultures), results indicated that the lemon and lime juices caused damage to cells comparable to that of N-9. Additional results showed that the concentration of lemon or lime juice that induced cell damage was equivalent to the concentration needed to inhibit HIV replication. Thus, when the concentration was reduced to a point where no cell damage occurred, there was little or no effect on HIV replication. Finally, the authors noted that even a 20% concentration of either lemon or lime juice had the effect of inhibiting Lactobacilli, naturally-occurring bacteria that help keep the vagina healthy.

These findings suggest that we should be concerned about whether lemon or lime juice is safe for use as a vaginal microbicide. Since N-9 has already been ruled out as a candidate microbicide because of its tendency to cause cell damage with repeated use, it seems unlikely that a product causing even more irritation than N-9 would be a good candidate. In a separate study, Dr. Robin Shattock of St. George's Hospital, London, has shown that lemon and lime juice may well be irritating to cells in the penis and male urethra^[iii].

This concern about safety is further supported by preliminary findings presented by Christine Mauck of CONRAD in Arlington, Virginia (US). Dr. Mauck and colleagues have just concluded a clinical trial in which 48 sexually abstinent women volunteers used lime juice vaginally. Divided into four treatment groups, they used 100%, 50% and 25% concentration of juice, and one group used plain water as a control. Each group inserted their assigned test fluid twice daily for six consecutive days during two menstrual cycles. In one cycle, it was inserted via a douche and, in the other, via a modified tampon soaked in the fluid.

The results of this safety trial are still being analyzed and will be presented at the Microbicides 2006 conference in Cape Town, South Africa, at the end of April. Dr. Mauck reported, however, that the preliminary findings suggest a dose-dependent effect on the vaginal epithelium (cells lining the vagina) – meaning that the level of vaginal irritation and damage noted among the women using the 50% and 100% concentrations of lime juice was higher than that experienced by the women using the 25% concentration or plain water.

The studies performed at Southern Research Institute showed that juice concentrations less than 50% could result in the death of cells in culture. In addition, the preliminary clinical safety data suggest that the 50% and 100% juice concentrations may damage vaginal tissues. Taken together the laboratory and human testing data suggest the need for caution in the assumption or use of these juices as microbicides to prevent HIV transmission until a complete presentation of the analysis of the human testing is available. We will provide a more complete report of the CONRAD study after Microbicides 2006. Stay tuned!

Sources:

^[i] Carol Lackman-Smith*¹, B Snyder¹, K Luckenbaugh¹, et al. “*In vitro* assessment of efficacy and cytotoxicity of natural substances proposed as vaginal microbicides against sexual transmission of HIV”. Poster presented at 13th Conference on Retroviruses and Opportunistic Infections, Paper 894, February 6, 2006.

^[ii] Robin Shattock, L Fischetti., P Fletcher P., et al. “Development of a human penile tissue explant model to evaluate safety and efficacy of Microbicide candidates”. Poster presented at IAS Conference on HIV Pathogenesis and Treatment, Abstract no. MoPp0104, July 25, 2005.

Global Campaign ethics training invited to Rwanda Africa

On 23-24 March, the Global Campaign presented its course on ethical reasoning and HIV prevention trials at Projet Ubuzima, the site of the phase one microbicide trial in Kigali, Rwanda. We were invited by the site staff to assist them in orienting their newly-formed Community Advisory Group (CAG) by facilitating a workshop and discussion on research ethics, ethical reasoning, and issues in microbicide trials, thus better preparing them for the work of assessing and giving community input on the study protocols and implementation.

Global South Coordinator Megan Gottemoeller co-presented the training with John Mutsambi, an experienced community liaison staffer working for the HIV Prevention Trials Network site in Zimbabwe. John brought his experience in presenting the ethics training developed by Family Health International (FHI) to the task – as well as his considerable expertise as a trainer and facilitator. John and Megan jointly designed their agenda to meet the needs of the Projet Ubuzima participants. The CAG members are focusing on creating an informed consent process that ensures participants' ongoing comprehension of the study protocol, risks and benefits, and protecting participants' right to autonomy and confidentiality.

While the Global Campaign trainings on clinical trial ethics are custom designed to meet the specific needs of the audience, they focus on familiarising participants with the logic of ethical reasoning and the existing guidance that governs trans-national research. The content emphasises that, because ethical principles are sometimes in conflict, the work of ethics is to resolve how different principles should be balanced and interpreted in particular situations. The course builds participants' capacity to advocate for themselves effectively in negotiations with research entities, governmental policy-makers and others.

To date, our ethics course has been incorporated into trainings put together by the Nigerian HIV Vaccine and Microbicide Advocacy Group (NHVMAG), the European AIDS Treatment Group (EATG) and researchers at the London School of Hygiene and Tropical Medicine. A training requested by Thai advocates is being planned for the autumn of 2006.

European partners gather to discuss strategy and critical issues Europe

On 12-14 March, European partners of the Global Campaign met at PATH offices in Ferney-Voltaire, France (outside of Geneva) for a regional strategy meeting. A diverse group of eleven representatives from Belgium, Spain, the UK, Denmark and Ireland met together with Global Campaign staff to discuss the direction GC Europe will take in the coming year and how GC Europe fits into the wider Campaign globally, and also within advocacy on HIV/AIDS and sexual and reproductive health and rights in the region. Representatives of the International Partnership for Microbicides, the Stop AIDS Alliance, and the most recent partner, the European AIDS Treatment

Group were present to help inform the discussion of how best to collaborate with other pan-European advocates working on these issues.

Those attending the meeting had a chance to view the *Giving Women Power Over AIDS* exhibit which will tour European capitals throughout 2006-07 and receive a new European Partners Manual which contains the campaign materials and resources for use in local settings. A number of hot topics were discussed, including rectal microbicides, the removal of N-9 from condoms and lubricants in Europe, and increasing linkages with treatment advocacy. It was decided that three working groups should be formed to take advocacy forward: one to reach out to key constituencies such as positive people and African communities; one to focus on rectal microbicides advocacy; and one to develop messages for the upcoming UNGASS and Toronto conferences.

The European partners expressed great appreciation for the efforts that the staff has made to date on lobbying the EU and in responding to concerns and new issues. A few partners expressed concern about the exhibit title, "Giving Women Power Over AIDS; noting that power is a complex issue and that no one tool, such as microbicides, can be expected to fully empower women. We discussed various viewpoints on this issue and the need to adjust how our messages are articulated in various cultures and settings to best meet the needs of those we are trying to reach.

A terms of reference (TOR) for GC Europe was drafted which confirms the right of partners to adapt Campaign materials to suit their local needs, but also the responsibility to accept compromise in the interests of a common global message.

To access new European resources and a calendar of upcoming events and activities, visit: www.global-campaign.org/GCEurope.htm

New fact sheet engages African American women in microbicides advocacy North America

In collaboration with African-American Women Evolving, Black AIDS Institute, Black Women's Health Imperative, NASTAD's African-American Advisory Committee, SisterLove, and SisterSong, the Global Campaign is pleased to announce a new fact sheet intended to engage the African American community in microbicides advocacy. The fact sheet provides a brief introduction to the HIV/AIDS epidemic in the African American community, explains how microbicides would help bolster prevention options, and then emphasizes that African American women could play a vital role in making microbicides a reality. The fact sheet also includes several key messages that need to be conveyed clearly regarding condoms, men, safety, and access.

The Global Campaign for Microbicides appreciates the support of these prominent groups in providing this critical information to African-American communities. The fact sheet is currently available at the Global Campaign download centre: www.global-campaign.org/download.htm, and will be available on additional websites soon.

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.
