



Global Campaign News – Issue #41 Sept 14, 2004

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

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Global Campaign's New "Product Watch" Research

Every day, advocates around the world ask about the candidate microbicides that are furthest along in the pipeline:

- Who developed the microbicide?
- How does the microbicide work?
- Where is it being testing?
- Who is running the trial?
- Has the trial started?
- How many people will be enrolled?
- Is it going to be contraceptive?
- Will it protect people from other STIs?

The Global Campaign has created a new Product Watch that concisely answers these questions for the products that are furthest along in the research pipeline. Candidate microbicides that are in Phase II/IIB and III trials have been included in this product watch: Buffergel, Carraguard, Cellulose Sulfate, PRO 2000, and Savvy.

The Product Watch complements the Alliance for Microbicide Development's extensive database and updates on all candidate microbicides in clinical trials, appearing in the Alliance Weekly News Digest on the first week of every month. Access the most recent Global Campaign product watch is available at our download center: <http://www.global-campaign.org/download.htm>. Please send updates and input for additions to: info@global-campaign.org

UK Microbicides Development Program (MDP) drops 'Emmelle™' Research

On September 10th, the Microbicide Development Programme (MDP) announced that it would be dropping one of two candidate microbicides from the Phase III trial it plans to launch in four African countries in 2005. The trial was due to compare the fusion inhibitor Emmelle™ (dextrin2 sulfate), manufactured by British biotech ML Laboratories, with a similar microbicide, Pro-2000. The MDP will still proceed with the planned Phase III, but will now compare two concentrations of Pro-2000 (.5% and 2%) to see which is most effective at preventing HIV transmission.

As a result, ML Laboratories will now discontinue any further research into Emmelle. S.W. Sim, Chairman of ML commented: "Naturally we are disappointed that Emmelle™ gel will not be included in the proposed trial, particularly in view of its favourable safety profile, however we fully understand and accept the constraints associated with publicly funded programmes. The economics of developing microbicides are well understood and

are such that ML would not contemplate progressing Emmelle™ gel into Phase III studies without the essential public funding to support the large scale clinical trial required. In the interests of public health we wish the Microbicides Development Programme every success in their efforts to identify and develop a clinically acceptable microbicide.”

Europe facing AIDS epidemic

Europe

Adapted from articles by Marit Ruuda in EUObserver.com and Oana Lungescu in BBC News online, 9/9/04

In a new report, the European Commission recently warned that Europe's AIDS problem is worsening as the rate of incident infections in some new member states approach the highest in the world. The EC report notes that Europe is fast becoming a frontline in the global battle against AIDS. Nor is the epidemic confined to the new member states. The proportion of newly reported HIV cases has also doubled in Western Europe since 1995.

In a statement accompanying the release of the report, David Byrne, the outgoing Commissioner for Health and Consumer Protection, reiterated the urgent need for greater efforts in prevention, including projects to develop microbicides and vaccines, better coordination of national strategies and access to affordable treatment for those living in poorer European countries. The new Health Commissioner, Pavel Telička, stressed that HIV/AIDS is not just a problem for Africa and the developing world: "We have a serious epidemic beginning to resurface right here in parts of Europe. The EU must provide political leadership for the continent-wide action needed to avert this".

On 16th-17th September, health ministers and experts across the EU and its eastern neighbours will gather in Lithuania to build a consensus on Europe-wide actions to combat HIV. Mr Telicka called on EU health ministers to show political leadership by investing more in prevention and making better use of \$1.5bn (£840m) that the EU has set aside to fight the communicable diseases HIV/AIDS, malaria and tuberculosis.

Over the Counter Lubes shown Cytotoxic in Rectal Mouse Studies

Science

In the June 2004 issue of *Sexually Transmitted Disease* (pages 346-349) Kristen Sudol and David Phillips of the Population Council published “Relative Safety of Sexual Lubricants for Rectal Intercourse”, describing the impact of several over-the-counter lubricants (including the three under discussion in 2002) on rectal epithelia. Using a mouse model, they tested the degree to which internal application of various products caused cells in the rectal lining to slough (peel) off, leaving the rectum more vulnerable to infection.

They found that DeLUBE and KY-Plus were most likely to cause damage to the rectal lining. Viamore, Vagisil and Astroglide were relatively less cytotoxic (capable of killing cells) but, nevertheless, caused a significant degree of rectal damage. They noted that, “the only products that do not exhibit any cytotoxicity are Carraguard and methylcellulose, which are not yet commercially available.”

Sudol and Philips speculate that the preservatives and excipients found in lubricants may be the agents causing cytotoxicity – noting that the Carraguard and methylcellulose formulations contain just enough preservative to pass the FDA’s preservative effectiveness tests and no other excipients. Based in this, they hypothesize that the amount of preservatives and/or excipients added to other lubricants may be excessive. While human studies still need to be done to confirm these data, the authors note that historically there has been strong correlation between human and mouse rectal studies.

KY Plus, an N-9 containing lubricant, is no longer on the market. As advocates, we need to help publicize these recent findings, especially with regard to the risk potentially associated with DeLUBE (manufactured by E-Gal Corporation).

We can also help people understand that while Viamore, Vagisil and Astroglide are less potentially cytotoxic, they have not been tested as microbicides and should not be inserted rectally in the quantities in which candidate vaginal microbicides are generally applied (3-5 ml. – the amount contained in standard vaginal applicators). We must

emphasize that the FDA has only approved their sale as sexual lubricants -- products designed to be applied in very small amounts externally (on the vulva or penis), not internally by applicator.

These findings also underscore the need for rectal safety trials in humans of existing and future sexual lubricants and microbicides. Since lubricants are an important tool for reducing the risk of rectal tearing and condom breakage, it would be extremely helpful to know which lubricants pose the least risk of rectal cytotoxicity.

UK Campaign looks ahead to 2005

Europe

On the 17th September, the UK Campaign for Microbicides will hold an Advocates Training Day in West London that will address progress made to date and the challenges that lie ahead. Hosted by the National AIDS Trust and the Terrence Higgins Trust (THT), the day will focus on the UK Microbicide Development Program and how the UK Campaign can work with researchers to advance their common aims. Speakers will include some of the leading scientists in the microbicide field, Dr Robin Shattock, Dr Charlotte Watts and Dr Alan Stone.

In the afternoon, workshops will examine the issues related to new clinical trials, updates in the field and the recent efforts to develop joint advocacy on microbicides, treatments and vaccines (MTV). The day will close with developing a plan of action for the next 12 months. For more information, please contact Rebekah Webb at: rwebb@global-campaign.org or +32 2507 1221.

New report on Social Research in Vaccines and Microbicides

Research

Commissioned by the National AIDS Trust with financial support from International AIDS Vaccine Initiative (IAVI), *Making Connections* argues that social science research should be carried out in parallel to, and in support of, scientific research into vaccines and microbicides. The report, prepared by Marsha Rosengarten and Dean Murphy, highlights the importance of social science research to assist in:

- Increasing the effectiveness and efficacy of new vaccine and microbicide candidates through research on product acceptability;
- Ensuring safe, ethical and cost- and time-effective clinical testing of suitable candidates; and
- Ensuring the development and/or maintenance of safe sex and injecting programmes alongside the testing and implementation of approved products.

The report provides insights into all three aspects goals, but does not specify the styles of research required. Instead, it lays out the territory for research and the critical role that social research can play in facilitating all stages of scientific research. The report is intended for anybody working in the field of vaccine and microbicide advocacy and research. We encourage you to disseminate it to anyone who may be interested. You can access the document at the bottom of the following webpage: <http://www.nat.org.uk/publications/policy.cfm>.

Safe sex is good sex - a lesson for HIV prevention

Global

By Katy Backes, Cervical Barrier Advancement Society and Ibis Reproductive Health

During the International AIDS Conference in Bangkok, we attended a thought-provoking session that offered a new angle for work in the field of HIV prevention. This session, called "Can we have safer sex if we don't know how to have good sex?" focused on promoting safer sex by focusing on the prime motivators for actually having sex: desire and pleasure. The session also served as a launching point for The Pleasure Project, an educational resource promoting safer sex to men and women. Speakers included several individuals currently involved in HIV/AIDS prevention programs and sexual health work.

Dr. I. S. Gilada, from the People's Health Organisation of India presented the idea of using the Kama Sutra to teach safer sex. He uses the phrase, "Many postures with one is better than one posture with many" to express a unique prevention message.

Population Services International (PSI) in Cambodia is currently incorporating sexual pleasure into their social marketing strategy for lubricant. Supriya Pillar, presenting on behalf of PSI Cambodia, noted that PSI's market research shows that incorporating pleasure and hope into prevention messages can positively affect uptake of new methods. Lessons learned by PSI in marketing lubricant in Cambodia may be useful for those planning microbicide introduction strategies.

Dr. Graham Neilsen of Family Health International (FHI) presented the experience of working with the Australian Health Service and distributing a book called "Out There" to young gay men in Australia. The book used common language, detailed descriptions, and sexy photos to help instruct readers on how to have better, safer sex. Graham also spoke about our own "erotophobia" in the field of HIV/AIDS and how those feelings may bring about "internal censorship" of strategies and ideas that incorporate pleasure.

Sue O'Sullivan, author and activist working with the International Committee on Women with AIDS, read excerpts from her own erotic writing and commented on the importance of considering sexuality and sexual pleasure for people living with HIV/AIDS.

Anne Philpott, who chaired the session, described her work with erotic film producers in the UK and their work to incorporate sexy images of male and female condoms and lubricants into their films. She also showed a clip from "Modern Loving," a safe erotic film about to be launched in the UK. She also shared information on how men and women in different cultures (from Ghana to Sri Lanka) eroticize the female condom and incorporate it into lovemaking. For example, some sex workers capitalize on their clients' desire to touch their genitals before sex and charge more for allowing the client to insert the female condom.

A lively discussion followed where participants asked for more advice on how to include pleasure in their programs, and there was an enthusiastic exchange of information including tips for use of lubricant and dialogue on the availability of sex toys.

For our part, we found this discussion to be particularly relevant to the development and promotion of female-initiated HIV prevention methods. If desired, program administrators and policymakers have the ability to avoid the stigma of associating a prevention method with disease and infidelity. The pleasure angle provides the opportunity to focus instead on the potential for prevention methods to make sex safer and more pleasurable.

More information on The Pleasure Project is available at www.the-pleasure-project.org

Ethical issues involved in the Cambodia Tenofovir trials

Asia

In Issue #40 (August 20, 2004 edition), we relayed the news that the Cambodian government had stopped a trial to test whether once-daily oral use tenofovir could prevent HIV negative people from becoming infected. Tenofovir is an anti-retroviral drug currently licensed for treating HIV positive individuals. The clinical trial was to begin to explore the possibility of using it as pre-exposure prophylaxis, or PREP, a strategy whereby healthy individuals at high risk of HIV take a drug prior to exposure for the purpose of blocking infection if they are exposed to HIV. Some people think of PREP as an "oral" microbicide. Tenofovir is the first drug to enter clinical trials specifically for pre-exposure prophylaxis.

Controversy erupted when members of the Women's Network for Unity, a local sex workers union protested what they perceived to be inadequate assurances for women who may become sick during the trial. Fearing that Cambodian citizens were being exploited for scientific research, the Prime Minister of Cambodia halted the trial.

The issues raised by this trial cancellation -- what happened, what should have happened, and where things went wrong (and right) -- is of incredible importance to the entire HIV field. It has implications for other prevention trials, citizen involvement in research, and the hopes of finding new tools for fighting this horrible epidemic.

The Global Campaign is in the process of gathering information about the chain of events and concerns that led to the cancellation of the trial. Our goal is to seek insights and lessons that could be useful for implementing future trials.

We have been working for several years to engage activists, communities, policy makers and other stakeholders in discussions around microbicides in those countries where microbicide trials are, or will be, occurring. This type of country preparedness and community involvement work is essential to generating informed debate and authentic negotiation between communities and researchers – discussions that lead to an equitable resolution of differences so that trials can proceed ethically and effectively. By collecting more solid information on what was and was not done in preparation for this trial, what the issues were at hand, and how different groups understood the issues, we hope to analyze this case study and learn from it.

The fact that the Women's Network for Unity and the other community members most directly affected by the trial (those being recruited to participate in it) were able to articulate their demands, protest effectively and make their concerns heard is a testament to the power of organizing and we applaud their determination. At the same time, stopping a trial is, necessarily, a costly setback in terms of time, money and possibly lives – one that might have been avoided if the proper groundwork for discussion and debate had been cultivated.

As a field, we need to look closely at what actually transpired and use that information to develop recommendations to guide future trials. Such recommendations -- developed collaboratively and supported by consensus -- should help us avoid further trial cancellations and delays. Since we know that the cost of delay is paid in human lives, the task of learning from our mistakes and building processes for preventing future ones has to be given priority.

For more information on the Global Campaign's work on community mobilization and ethical issues in microbicide trials, please see http://www.global-campaign.org/ethics_community.htm

We welcome your input and contributions for future issues!

Correspondence can be addressed to info@global-campaign.org.

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