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

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Research Updates

Male circumcision and HIV prevention trials: What's the connection?

Global

After three clinical trials showed that being circumcised greatly reduced men's risk of acquiring HIV, the World Health Organization (WHO) and The Joint Programme on HIV/AIDS (UNAIDS) issued guidelines in 2007 calling for male circumcision to be regarded as part of a comprehensive HIV prevention package. While welcomed, this recommendation is proving challenging to implement.

Furthermore, a trial in Uganda investigating whether any reduction in HIV risk occurred among women as a result of their male partners' circumcision did not show a direct benefit for women. Still, many researchers believe that, over time, women will benefit *indirectly* as male circumcision programs are implemented in countries that now have high HIV prevalence and low circumcision rates. The reasoning is that, when more men are circumcised, fewer men will seroconvert and eventually this reduction in HIV incidence among men will result in fewer women being exposed to HIV through unprotected sex.

Kenya, Uganda, and a few other African countries are slowly introducing male circumcision programs. Some researchers are now asking about how circumcision should be included as part of the prevention package offered in other HIV prevention technology trials. One strategy is to provide participants with

referral information that they can take to their male partners, advising them of where and how to access circumcision services.

At the Microbicide Trials Network's recent annual meeting, Dr. Robert Bailey, Principal Investigator for the male circumcision trial in Kisumu, Kenya, argued that only providing information at trial sites is not sufficient. He urged trials enrolling high-risk women to provide couples counseling on male circumcision to all participants, as well as information to the male partners on how to access free, high quality medical circumcision.

This proposal raises many issues for consideration. Data from one circumcision trial suggested that HIV-positive men who are circumcised and resume sex before the wound completely heals may be *more* likely to transmit HIV to their sexual partners. Also, many women participating in microbicide studies may not have one regular partner but multiple partners. Even those with one primary partner may not be able to negotiate abstinence for the 6-8 weeks required for the circumcision wound to heal completely. Other issues include the potential difficulty of gathering informed consent (even just for the couples counseling) from study participants' male partners and the cost implications of including circumcision as a trial-provided benefit.

Despite these factors, microbicide and pre-exposure prophylaxis (PrEP) studies need to determine how they will address male circumcision in their study protocols. Some studies, for example, may choose to track the circumcision status of trial participants' partners. Others may simply offer information on male circumcision as a part of their prevention package.

Mathematical modeling has suggested that 100% uptake of male circumcision in Sub-Saharan Africa could avert 5.7 million new infections over 20 years. When we consider that 2.7 million new infections are now occurring annually, we can see that this is substantial (although it must also be considered in light of the unlikelihood that any new prevention tool could achieve 100% uptake).

Male circumcision is an exciting HIV prevention tool that should be scaled up responsibly. At the same time, new prevention methods that are initiated by, and effectively protective of, receptive sex partners (whether female or male) are still urgently needed.

Highlighted Resources

Dramatic lessons from trial closures in Cambodia and Cameroon

Asia

In 2004-05, the HIV prevention world was rocked by the suspension and cancellation of PrEP effectiveness trials in Cambodia and Cameroon as a result of protests led by advocates speaking on behalf of the trial communities. The activists questioned how the research was being conducted and challenged the fundamental ethics of the research.

The Global Campaign for Microbicides (GCM) has just launched two case studies recounting these tumultuous episodes and extracting lessons for current and future research. By capturing the political backdrop against which the controversies arose, GCM pinpoints the underlying and unaddressed conflicts that led to the costly collapse of the two Phase 3 trials.

"Even though these are case studies, they actually read like mystery stories," said Moriah Fund Deputy Director Shira Saperstein. "I really couldn't wait to see how they turned out". As PrEP trials move toward completion this year, these case studies offer a timely look at what has changed and what remains unaddressed. They are available on-line at http://www.global-campaign.org/.

Research Rashomon: Lessons from the Cameroon Pre-exposure Prophylaxis

Trial Site by Elizabeth McGrory, Andrea Irvin and Lori Heise

Preventing Prevention Trial Failures: A Case Study and Lessons for Future Trials from the 2004 Tenofovir Trial in Cambodia by Anna Forbes and Sanushka Mudaliar

BETA publishes two articles about microbicides and vaccines
Global

In its winter/spring 2009 issue, BETA (the San Francisco AIDS Foundation's "Bulletin of Experimental Treatment for AIDS") published two articles of significant interest to HIV prevention advocates. "AIDS Vaccine Research and Advocacy: An Update" by Emily Bass, Cindra Feuer, and Mitchell Warren of the AIDS Vaccine Advocacy Coalition describes how the field is changing in the "post-STEP era" and what needs to happen next as it presses forward.

In "Microbicide Development: Positive Women's Concerns", the Global Campaign for Microbicide's (GCM) Deputy Director, Anna Forbes looks at the issues and concerns that positive women have expressed regarding microbicide research. Working in collaboration with the International Community of Women with HIV/AIDS and GNP+ (The Global Network of People living with HIV/AIDS) GCM has also formulated the advocacy steps needed to address them and the vital roles that women living with HIV can and should play to ensure that microbicide trials advance as effectively and inclusively as possible.

These articles can be accessed in the current issue of BETA on-line at http://www.sfaf.org/beta/2009_win.

GCM in Action

Expanding the prevention package: Who decides and how?
Africa

On 26-28 March, the Global Campaign for Microbicides (GCM), in collaboration with The Joint Programme on HIV/AIDS (UNAIDS) and the US Centers for Disease Control and Prevention (CDC), hosted a consultation of over 50 researchers, advocates, and policymakers on the "Standards of Prevention in HIV Prevention Trials" in Kampala, Uganda. The goal of this meeting was to bring together researchers, advocates, policymakers, and regulators to explore the challenges of providing clinical trial participants with a comprehensive HIV prevention package. Such a package currently includes male and female condoms, risk-reduction counseling, and STI screening and treatment. In the future, however, it may also include circumcision, and novel prevention tools like vaginal and rectal microbicides, PrEP, and/or vaccines.

Current international guidelines for HIV prevention trials – most notably the 2007 UNAIDS/WHO Guidance Document: *Ethical Considerations in Biomedical HIV Prevention Trials* – argue that trial participants must have access to proven HIV prevention strategies. Although few researchers and advocates would disagree that trial participants should have access to proven methods, these guidelines are unclear as to the point at which as-yet-unproven HIV prevention tools like microbicides, vaccines, and PrEP should be judged as meeting these criteria.

GCM and its partners met in Uganda to address this gap, exploring the question of when and under what circumstances investigators in HIV prevention trials are ethically obligated to make new tools available to all study participants. After three days of presentations, participatory exercises, and facilitated discussion, meeting participants identified several points of agreement regarding how and when to add new HIV prevention tools to the standard prevention package provided to all trial participants. Included in these points of agreement were:

- Consensus criteria useful for evaluating the effectiveness and safety of new prevention tools – these criteria will be circulated in June 2009.
- Agreement that on-going PrEP trials should continue, in the hope of shedding light on the prevalent routes of HIV transmission occurring in different trial populations.
- Recognition of the need for improved communication and negotiation with all stakeholders, including study participants and the trial community, when considering the addition of a new HIV prevention tool to the standard prevention package. Meeting participants endorsed the idea of holding a series of regional meetings with a broader range of stakeholders to develop a standardized process for how community consultation and negotiation should occur with regard to standards of prevention in HIV prevention trials.

GCM is currently drafting the meeting report and consensus document. In the meantime, copies of the meeting agenda, the list of participants, background materials, and PowerPoint presentations from the consultation are all available at http://www.global-campaign.org/prevention-consult.htm.

What is GCM Doing this Month?

Skills building workshop for civil society: Kisumu Kenya
12-13 May, Kenya

In collaboration with the Family Health International/Fem-PrEP trial sites and the Kenya Medical Research Institute, GCM is conducting a workshop for civil society advocates and other stakeholders in Nyanza Province, Kenya. Designed to build advocacy skills, this session will also explore strategies that civil society can use to increase their involvement in research to develop new woman-initiated HIV prevention options.

HIV prevention research update for TAC Women's Leadership: Johannesburg, South Africa
12 May, South Africa

On 12 May, GCM will present an update for Treatment Action Campaign (TAC) members on the status of research to develop microbicides and other new prevention technologies. Organized in collaboration with TAC Women's Rights Campaign Coordinator Nomfundo Eland, this update will be presented by GCM's newest Programme Officer, Noma (Lucky) Barnabas. At the request of TAC's Women's Leadership sector, this session will also focus on exploring advocacy issue and advocacy strategy development.