

HIV Trends and Women's Sexual Health

June 2006



**Positive Women's
Network**

A summary of articles with a women-centred focus on HIV, sexually transmitted infections, prevention issues and more. Please contact the source cited or Positive Women's Network if you'd like more information.

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Prevention Issues and Challenges

Highlights from Microbicides 2006

The Fourth International Microbicides Conference (Microbicides 2006) took place from 23-26 April in Cape Town, South Africa with more than 1,300 participants. The biggest conference thus far, the event confirmed the increased interest in the microbicides field. Reflecting trends in the broader field, community interests and needs have finally joined center stage at the conference with a dedicated track in addition to a significant share of the plenary discussion. Additionally, rectal microbicides gained increased attention throughout the conference and in a dedicated symposium. Although it is difficult to capture all of the information and networking that took place at the conference in this summary here are a few of the highlights, as well as links you can follow for more information.

High profile plenary speakers highlight the accomplishments of the field, but continuing urgency. The conference plenaries featured presentations by such eminent figures as Archbishop Emeritus Desmond Tutu, Justice Edwin Cameron of South Africa's Supreme Court of Appeals, renowned women's and children's rights advocate Graça Machel, CNN's Charlayne Hunter-Gault, three African governmental Ministers and one European Ambassador - as well as several notable scientists.

In her opening address to the conference, Graça Machel invited a truly global effort with political leadership, financial resources, and community mobilisation from both developed and developing countries. "We know all too well in this part of the world what happens when profits take precedence over lives. We do NOT want to repeat the struggles in the efforts to get affordable access to anti-retroviral treatment to people living with AIDS." She also emphasized the need for a strong

women's movement to take part in the effort: "We must move from rhetoric to action. We must demand the enforcement of laws that protect women. We must say, individually and collectively, enough is enough." Throughout the conference, nothing was more evident than the sense of urgency with which all participants - scientists, policy-makers and civil society advocates alike - approach this work.

Dialogue on Nonoxynol-9 with advocates and researchers

Advocates, community members, policy makers and researchers had an opportunity to talk about lessons learned and outstanding questions about the Nonoxynol-9 trials at a session organized by the African Microbicides Advocacy Group, Gender AIDS Forum, and Nigerian HIV Vaccine and Microbicides Advocacy Group. An outcome report from the meeting will be produced shortly to summarize the dialogue and include next steps.

Positive Women's Panel highlight research needs

The Global Campaign and the International Community of Women Living with HIV/AIDS co-convened a roundtable session called "HIV Positive Women and Microbicides". Among the issues raised by the positive panelists was the importance of doing safety trials among HIV positive women, given that microbicides are likely to be used by women who don't know their status as well as by those using them for secondary prevention. If these safety trials aren't done, how will women know what to expect in terms of side effects, possible drug interactions and the impact that a microbicide could have on a positive woman's vaginal ecology?

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Highlights from Microbicides 2006 continued

Panelists also asked how data would be gathered on potential drug resistance issues among positive women using an ARV-based microbicide.

Another area of expressed concern was the potential benefits and risks a microbicide could have for positive women wishing to become pregnant. When non-contraceptive microbicides become available, women living with HIV may want to use them to protect their partners while attempting to conceive. When and how will research be done to see what safety issues this might raise for both the woman and her future baby?

While research is underway to answer some of these questions (specifically pharmaco-kinetic studies to assess the probability of drug resistance developing), the scientists on the panel acknowledged that research to answer other questions has barely begun.

Rectal microbicides report calls for significant increase in funding

The first-ever report tracking rectal microbicide research and development expenditures, "Rectal Microbicides, Investments and Advocacy" was released by the International Rectal Microbicide Working Group (IRMWG) at a special symposium titled "Rectal Microbicides - A New Frontier in HIV Prevention". According to the report, funding for rectal microbicide research rose from US\$2 million in 2000 to \$34 million in 2006. The full report is available at www.lifelube.org

Scientific research focuses on safety and new ideas

The scientific sessions in Tracks A and B reiterated that assessment of safety is a "moving target" even though all candidate products are subjected to rigorous safety studies. Frequent genital examinations, colposcopy, blood testing and participant reporting of symptoms are the main tools currently used to gather safety data. While extremely useful, these measures can also be difficult to interpret. So researchers are now examining the potential utility of other bio-markers such as inflammatory cytokine levels to determine which ones provide reproducible and clinically relevant safety data.

Researchers in these tracks also reported on the diversity of compounds now in the microbicides pipeline. The first generation of candidates (those now in Phase 2B and 3 trials) are expected to display relatively broad activity against a range of STIs and partial efficacy against HIV. They are also coitally dependant products requiring insertion prior to sex.

The second generation candidates, most of which are based on anti-retroviral drugs, may allow for increased specificity and potency against HIV. They may also be formulated as coitally independent products that could be delivered by once-daily application or through sustained release devices like vaginal rings that remain in place for a month or more. This second generation, however, may lack effectiveness against other STIs. They also raise the possibility of drug resistance if used by women who are HIV positive - an issue currently under investigation.

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Highlights from Microbicides 2006 continued

Rapid movement was reported in strategies for creating these second and third generation products including progress in developing CCR5 blockers and combinations of fusion inhibitors (CCR5, gp120 and gp41 blockers) that have shown increased vaginal protection in animals. There is strong consensus in favor of combination products - both to increase efficacy against HIV and to generate products that are effective against HIV and other STI — especially HSV, a known co-factor in HIV transmission.

One of the most exciting future directions under discussion is a proposal to develop a mucosal vaccine specifically targeted to activate immune cells in the vaginal epithelium. If such a vaccine could be formulated for delivery as a needle-free, topical product, it could potentially be combined with a microbicide and, thus, re-boosted every time the microbicide is applied. Such a method might confer immunity specifically in the vagina — the most probable site of infection for women — and eventually induce whole body immunity. Led by Robin Shattock of St George's Hospital, London, an international team of researchers has embarked on the creation of such a product. This consortium is funded for the next five years and hopes to have a candidate ready to enter clinical trials within that time.

Social scientists address male involvement, pregnancies in trials, and standards of care.

Currently, more than 15,000 HIV negative women are enrolled in vaginal microbicide trials. The challenges these trials face include high pregnancy rates among participants (which requires the immediate discontinuation of test product use), the unreliability of self-reported adherence to protocol,

and lower than expected HIV incidence in trial areas (clearly a benefit to the population but also a complicating factor in terms of measure the test product's impact).

While male involvement has always been encouraged, the idea of mandating partner consent or involvement in trials recruiting women has been resisted because it impedes the woman's right to make an autonomous choice about trial participation. The value of involving men was addressed repeatedly, however, in the case studies presented. Providing men who are interested with information about the trial and test product can help assure adherence to the trial protocol as well as the safety and well-being of participants whose partners may react negatively if they are uninformed. The provision of male partner and couple counseling to those who want it is now perceived as vital for adherence and acceptability.

The issue of post-trial care for participants who sero-convert during an HIV prevention trial was also a hot topic. Solomon Benetar, a noted South African ethicist, said that the field has made real "moral progress" in this area. Dr. Gita Ramjee (one of the conference chairs) described the arduous work being done at the HIV Prevention Research Unit of the South African Medical Research Council to create and sustain networks capable of assuring such care in a resource poor settings.

Links for more information:

The official conference website has daily summaries and the text from a few of the plenary speeches: www.microbicides2006.org

Source: Global Campaign News, Issue 66 (May 15, 2006) Global Campaign for Microbicides www.global-campaign.org/gcnews.

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Increasing Practice in Southern Africa of Male Circumcision To Prevent HIV Transmission

The New York Times on Friday examined the increasing practice in Southern Africa of male circumcision, which can be a "simple and possibly potent weapon" against HIV transmission (LaFraniere, New York Times, 4/28). A study published in the November 2005 issue of PLoS Medicine of men living in South Africa finds that male circumcision might reduce the risk of men contracting HIV through sexual intercourse with women by about 60%. Male circumcision also might reduce the risk of HIV transmission from HIV-positive men to their female partners, according to a study of couples in Rakai, Uganda (Kaiser Daily HIV/AIDS Report, 4/25). Some health workers in Zambia and Swaziland are working to widen access to circumcision to meet what they call a "burgeoning demand" for the procedure, the Times reports. In Zambia, surgeons at the University Teaching Hospital in Lusaka began offering the procedure for roughly \$3 about 18 months ago. About 400 people request circumcision at the hospital every month, eight times as many as the facility can perform, according to Kasonde Bowa, a urologist at the hospital. Surgeons at the hospital are calling for the government to make the procedure available nationwide. In Swaziland, the Ministry of Health and Social Welfare in January sponsored a workshop to train 60 doctors in the procedure after demand for circumcision spiked (New York Times, 4/28). According to the Baltimore Sun, after a health advocacy group in Swaziland promoted no-cost circumcisions for one day in January at a clinic,

"stunned doctors had to hand out circumcision rain checks to pacify the shoving, yelling crowd" (Goering, Baltimore Sun, 4/28).

Caution

Some policy makers are "holding back" enthusiasm about circumcision as an HIV prevention tool until the World Health Organization endorses it, the Times reports. WHO officials say the evidence about circumcision is not definitive enough to include the procedure in HIV prevention methods, and they are reluctant to recommend the procedure until the results of two trials in Kenya and Uganda are released. The results of the trials, involving 8,000 people, could be released by the end of June, according to the Times. WHO officials also say that even if the studies confirm that male circumcision prevents HIV transmission, the procedure still would have to be used in conjunction with other prevention strategies, including testing, condom use, faithfulness to one partner and abstinence until marriage. In addition, some advocates are concerned that the studies might lead people to undergo unsafe circumcisions by traditional healers (New York Times, 4/28).

Source: Kaiser Daily HIV/AIDS Report - Friday, April 28, 2006

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Circumcision, Fidelity More Effective HIV Prevention Methods Than Condoms, Abstinence, Researchers Say

Promoting male circumcision and fidelity to one partner seems to be more effective at curbing the spread of HIV than promoting abstinence and condom use, USAID researcher and technical adviser Daniel Halperin said last week, the Chicago Tribune reports. As Halperin and other researchers analyze 20 years of studies on HIV/AIDS throughout Africa, they have tried to "put aside intuitions, emotions, ideologies and look at the evidence in as coldhearted a way as we can," Halperin said.

During a speech at a meeting of the Southern African HIV Clinicians Society in Johannesburg, South Africa, Halperin said he and his colleagues discovered that regular sex partners rarely use condoms, and abstinence merely delays HIV infection among young people by one or two years. For example, condom use in Ghana and Senegal seems to have helped in the reduction of the spread of the HIV, which in those countries is particularly prevalent among commercial sex workers and their partners. However, condom use in South Africa and Botswana has had little effect in reducing those countries' HIV epidemics — which have reached the general population — because regular sex partners rarely use condoms consistently.

In comparison, faithfulness to one partner has worked at reducing HIV prevalence in Uganda and Kenya, according to Halperin. Because a person is more likely to transmit HIV during the first three weeks of contracting the virus, an HIV-positive person who has just one partner during that time is likely to pass the disease to that one person. But if an HIV-positive person in the highly infectious stage

has many sexual partners at a time, "the virus spreads like wildfire" as those people in turn have sex with other people, Halperin said. In addition, circumcision has been shown to reduce male-to-female HIV transmission by 60% to 75% (Goering, Chicago Tribune, 4/23).

A study published in the November 2005 issue of PLoS Medicine of men living in South Africa finds that male circumcision might reduce the risk of men contracting HIV through sexual intercourse with women by about 60%. Male circumcision might also reduce the risk of HIV transmission from HIV-positive men to their female partners, according to a study of couples in Rakai, Uganda (Kaiser Daily HIV/AIDS Report, 2/9).

Source: Kaiser Daily HIV/AIDS Report - Tuesday April 25, 2006

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Pope Orders Condoms Study in AIDS Fight

Pope Benedict has asked senior theologians and scientists to prepare a document that examines the use of condoms as a means of preventing HIV transmission, according to the head of the Vatican's health care ministry.

"Soon, the Vatican will issue a document about the use of condoms by persons who have grave diseases, starting with AIDS," Cardinal Javier Lozano Barragan said in an interview published yesterday in La Repubblica newspaper.

The Vatican currently opposes the use of condoms as part of its teachings against contraception, arguing that abstaining from sex is the only safe way to stop the spread of HIV/AIDS. But the issue has divided the church's top officials. In the

interview, Barragan called it a "very difficult and delicate subject which warrants prudence."

Barragan's announcement comes just days after Cardinal Carlo Maria Martini, a contender in last year's papal elections, suggested that condom use is the "lesser evil" in the fight against AIDS.

Barragan declined to anticipate any outcome of the study, and it is not clear whether the report will lead to a fundamental shift in church policy.

Source: CDC HIV/STD/TB Prevention News Update 04/24/2006
Original source: The Guardian (London) (04.24.06): Barbara McMahon

Vatican Denies Reports That It Plans To Release Document Easing Ban on Condom Use To Prevent Spread of HIV

Vatican officials have denied reports that the Vatican plans to release a document easing its ban on condom use to prevent the sexual transmission of HIV, Time Magazine reports (Israely, Time, 5/8). The statements come after Cardinal Javier Lozano Barragan, head of the Pontifical Council for Health Pastoral Care, in an interview published last month in Rome's La Repubblica said Pope Benedict XVI has asked the council and other scientists and theologians to study condom use as a means of HIV prevention, and that the Vatican will release a document on the subject soon (Kaiser Daily HIV/AIDS Report, 4/27).

Barragan over the weekend said the council only is drafting an internal study of the issue, ac-

ording to Kenya's Daily Nation. The council lacks the "competency to present a document to the Church," Barragan said, adding, "It is the Holy Father who has the competency or whoever he entrusts." Barragan said once the study is complete, "[t]here might or might not be" a document released (Daily Nation, 5/1).

Meanwhile, South African Catholic Bishop Kevin Dowling — who supports condom access to prevent the spread of HIV/AIDS — last week expressed hope that the study would lift the ban on condom use. "It would in fact be an ethical imperative to use condoms in order to preserve and protect life," he said (Religion News Service/Washington Post, 4/29).

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Vatican Denies Reports continued

Two-Thirds of Roman Catholic Priests in England, Wales Support Condom Use

In related news, 65% of Roman Catholic clergy in England and Wales believe that the use of condoms to reduce the sexual transmission of HIV is acceptable, according to a survey conducted by London's Sunday Telegraph, the Telegraph reports. The survey of 100 priests also finds that 43% of respondents say the Catholic Church should reconsider its position on contraception (Day/O'Brien, Sunday Telegraph, 4/30).

Editorials, Opinion Piece

Several newspapers recently have published editorials and opinion pieces related to the Vatican's announcement. Some of these are summarized below.

Baltimore Sun: Even though the "Vatican has only called for a study" to investigate its condom use policy, the findings of such an investigation could have a "profound impact" on curbing the spread of HIV in developing nations, a Sun editorial says. There are numerous reasons for the Vatican to change its "blanket opposition to condom use," and, while the investigation might "raise sensitive theological questions," the policy shift would "promote the doctrine of life," the editorial concludes (Baltimore Sun, 5/1).

Newark Star-Ledger: The commissioning of

a study evaluating the Vatican's condom use policy shows that it is "evaluating the importance of condoms and AIDS," a Star-Ledger editorial says. However, the U.S. "continues to attach strings to federal funding for the fight against global AIDS," the editorial says, adding that countries that receive U.S. grants must stress abstinence-until-marriage and faithfulness-in-marriage programs as the primary mode of prevention. While abstinence until and faithfulness in marriage are important, "condoms should not be a distant third part of the strategy," the Star-Ledger says, concluding, "Forty million people worldwide have been infected by an adaptable virus that is spread by sex and the rigidity of those who should be leading the fight against it" (Newark Star-Ledger, 4/29).

James Carroll, Boston Globe: "No Vatican policy could have stopped the spread of [HIV], but there can be no doubt that Vatican rejection of condoms, and its aggressive campaign against condom use, helped that spread, especially in areas of the world where Catholic influence is high," Globe columnist Carroll writes. The announcement that the Vatican is calling for a review of its condom use policy is being viewed as an improvement on its current policy, but even if the Vatican were "to change its position now," Catholics still must deal with the fact that the "rejection of condom use has been killing people," Carroll writes (Carroll, Boston Globe, 5/1).

Source: Kaiser Daily HIV/AIDS Report - Monday, May 1, 2006

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AIDS Increases Among Women; Sexual Control Absent

At the UN's 2006 High Level Meeting on HIV/AIDS this week, conferees will be told many women and girls still have no choice in sexual matters and are catching up to men in numbers of new HIV infections.

"In every single region of the world, the proportion of women among those being infected with HIV is increasing," said Dr. Peter Piot, UNAIDS executive director.

Of the more than 38 million people with HIV, 17 million are women and 13.5 million of them are in Africa. "We know that in many societies now the biggest risk factor is to be married at an early age, always with an older man. The irony is that marriage is becoming a risk factor for HIV, and the majority of women, in Thailand, in East Africa, are now only infected by their only sex partner, their husbands," Piot said.

Piot noted in particular the "absence of female-controlled methods" of prevention. Microbicides stand the best chance of offering such

a method. Research on microbicides continues, with a product possibly available by 2010, according to the UN.

The 630-page UN report is frank in its discussion of HIV transmission and prevention. But the UN meeting's final statement is expected to sidestep some delicate issues, as did the document issued at the end of the 2001 special session on AIDS. "The same issues that were most contentious in 2001 are still contentious," Piot said. Some participants - including Islamic nations, some Catholic countries, and the Bush administration - balk at mentioning homosexuals, drug users, and sex workers.

"The argument is that they are illegal in many countries and that mentioning even those groups will be an endorsement," according to Piot, who said these are referred to simply as "vulnerable groups."

Source: CDC HIV/STD/TB Prevention News Update 05/31/2006
Original Source: Reuters 05.30.06): Evelyn Leopold