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Alphabet of prevention technologies expanding, but no 'magical solution'

Edwin J. Bernard, Wednesday, August 23, 2006

Now that a vaccine against HIV is not expected within the next decade, an expanding array of other prevention technologies - which now includes microbicides, male circumcision, cervical barriers, PrEP, and genital herpes suppression - were extensively debated at the Sixteenth International AIDS Conference held in Toronto last week, but there remain an array of practical and ethical challenges to research and implementation, according to the Global HIV Prevention Working Group, co-chaired by Dr Helene Gayle, who also co-chaired the Conference.

"The data we are seeing this week highlight the urgent need to accelerate prevention research in order to study all reasonable strategies and expand the number of options available to us," she said, adding that "we must also seize the opportunity that treatment scale-up presents to integrate prevention programmes into new and evolving systems of HIV care."

However, during Tuesday's plenary, *Prevention: proven approaches and new technologies*, Dr. Cristina Pimenta of the Brazilian Interdisciplinary AIDS Association warned against the "particularly worrisome" tendency to see biomedical interventions as "quick" and "magical solutions to HIV/AIDS prevention" which "deflect or redirect attention away from the fundamentally political barriers that have been erected in recent years by some governments and agencies impeding the implementation of proven effective educational approaches, such as condom use and harm reduction."

Rather, she argued, they "should be considered as complementary preventive measures for the transmission of HIV but not a stand alone or absolute solution." Dr Pimenta also suggested that the most effective prevention programmes emphasise community empowerment and ensure access to tools - like condoms and harm-reduction for injecting drug users - that are scientifically proven to reduce the risk of HIV transmission.

Dr Gita Ramjee of the South African Medical Research Council, who provided an overview of current and future prevention technologies, also emphasised that prevention cannot exist in a cultural and political vacuum and said that the best way forward is "the synergistic use of social, behavioural, biomedical and barrier methods," which "can only happen with community involvement and leadership at all levels."

She also noted that HIV prevention research faces significant financial, logistical, and ethical obstacles that, if not quickly addressed, could delay the completion of critical clinical trials. "Trials of potential microbicides and other new HIV prevention approaches are hugely complex undertakings," she said. "We face challenges on a number of fronts - the world's ability to conduct these trials is reaching maximum capacity, and current clinical trial ethical guidelines were not written with today's HIV prevention research in mind."

'ABC' plus 'CDEFGHI'

Dr Ramjee outlined a number of approaches to HIV prevention that have been in use over the past two decades. These include the use of male and female condoms; voluntary counselling and testing; the prevention of mother-to-child transmission; harm-reduction, such as needle exchange; and behavioural interventions, known as the 'AB' part of 'ABC' - abstain and be faithful.

She then proceeded to outline other biomedical prevention technologies that may soon expand the limited alphabet approach. "I would like to believe that HIV prevention soon will be more than 'ABC'," she said. "We will add one more 'C' for circumcision. We will add 'D' for diaphragm, 'E' for [pre- and post-exposure prophylaxis; 'F' for female controlled microbicides; 'G' for genital tract

infection control; 'H' for HSV-2 suppression; and 'I' for immunity by vaccines."

Circumcision

Male circumcision was one of the most discussed topics at the Toronto conference, and the focus of several presentations examining both the efficacy and cost-effectiveness of implementation in sub-Saharan Africa.

It also made headlines around the world when President Clinton spoke about the need to overcome the obstacles to scaling-up male circumcision in populations where it is currently not considered acceptable on cultural or religious grounds. "Should this be shown to be effective," he told the conference, "we will have another means to prevent the spread of the disease and to save lives, and we will have a big job to do. It is important that as we leave here we all be prepared for a green light that could have a staggering impact on the male population but that will be frankly a lot of trouble to get done."

The excitement over male circumcision is based on trial results from South Africa which were first presented a year ago at the Third International IAS Conference on HIV Pathogenesis and Treatment in Rio de Janeiro. However, results of three further clinical trials from Uganda and Kenya will be available in 2007 and 2008.

However, not everyone is convinced that circumcision is a worthwhile prevention tool. One of the few dissenting voices came from a study by Way and colleagues that used demographic data to examine the association between male circumcision and HIV infection in eight sub-Saharan African countries. It found that in most countries there was a higher prevalence of HIV infection amongst circumcised men, and that circumcision was only significantly protective in Kenya.

Cervical barriers

The Methods for Improving Reproductive Health in Africa (MIRA) study is currently examining whether the use of a cervical barrier, or diaphragm - in this case the *Ortho All-Flex* diaphragm containing *Replens* gel (an acidifying buffer) - can prevent HIV infection in 5445 HIV-negative women. The study is taking place at four sites in two countries, South Africa and Zimbabwe, and is funded by USAID/Gates Foundation. Dr Ramjee is the principal investigator at two of the sites that are run by the Medical Research Council of South Africa.

"The theoretical basis is that the upper genital tract may be susceptible to HIV infection so if you cover the cervix then you may reduce the risk of HIV infection," she told the conference. "The trial recruitment is complete and the study is going to end next month. We are hoping the results will be out in June 2007."

PrEP

There was much excitement and coverage of pre-exposure prophylaxis (PrEP) in Toronto, based on the preliminary results of a study from Family Health International which hinted that PrEP might work in humans. Three further oral tenofovir (*Viread*) PrEP trials are currently enrolling: one in male and female Thai IDUs; one in high-risk women in West Africa; and one in gay men in the United States.

However, primate studies have shown that the dual combination drug *Truvada*, which contains tenofovir and FTC could be more effective and the protocols of two new PrEP studies - in young men and women in a very high prevalence region of Botswana, and in men who have sex with men in Peru - have been altered to include this drug instead.

There are many questions about scaling-up PrEP, not least whether it actually works. Despite the current lack of availability of tenofovir and *Truvada* for use as anti-HIV therapy in low-and middle-income countries, several studies found that it may well be cost-effective if used as PrEP.

Dr Ramjee also pointed out that there are many other unanswered questions. "Will it lead to resistant virus for future therapy options?" she wondered. "What is the level of the adherence required? Would it be acceptable for otherwise healthy people to take chronic medication? Is there potential for abuse of PrEP among those people who refuse to and do not want to use condoms."

Microbicides

Although few new data were presented at the conference on vaginal and rectal microbicides, they emerged as one of the biggest prevention stories of the conference, thanks to the publicity given to them by Bill and Melinda Gates at the opening ceremony.

The first microbicides could be available as soon as 2010, noted Dr Ramjee, which is many years before a preventative vaccine would be available. "There is urgent need for HIV prevention among women and microbicides would do just that," she added.

She added that there are currently between 30 and 40 microbicides candidates in preclinical development; fourteen in early safety trials and five in clinical, large-scale efficacy trials, the majority of which have been conducted in sub-Saharan Africa. Some of the first results will be presented before the end of 2007.

(For much more detail on current and developing microbicides see **aidsmap's** extensive reports from Microbicides 2006, held in Cape Town, South Africa last April.)

HSV-2 suppressive therapy

The use of antiviral drugs such as aciclovir to prevent genital herpes (HSV-2) recurrences is now being seen as a possible large-scale prevention strategy. The conference heard results from a French study conducted in Burkina Faso which found that daily valaciclovir significantly decreased HIV viral load in the blood and genital secretions of women not on anti-HIV treatment and of women receiving antiretroviral treatment.

Two further large placebo-controlled trials are currently examining HSV-2 suppressive therapy. One (HPTN O39) examines the effect of daily aciclovir on susceptibility to HIV acquisition in 3277 HIV-negative women and gay men at nine global sites, and is funded by the US National Institutes of Health. Results are expected next year.

The other (Partners in Prevention) also uses daily aciclovir and this time includes 3000 sero-different couples (where one partner is HIV-positive at enrolment) at fourteen sites in sub-Saharan Africa. Enrolment is 70% complete, so results are not expected until 2008, possibly at the next International AIDS Conference in Mexico City.

Ensuring future access

All of these approaches are examined in greater detail in a report from the Global HIV Prevention Working Group entitled, *New Approaches to HIV Prevention: Accelerating Research and Ensuring Future Access*, which can be downloaded in full here. The Working Group includes leading public health experts, clinicians, researchers, and people affected by HIV/AIDS, and is co-convened by the Henry J Kaiser Family Foundation and the Bill & Melinda Gates Foundation.

The report's authors expand on Dr Pimenta's concern that the world is unprepared to ensure widespread access for these new prevention technologies, and recommend that individual countries, international agencies, and major donor organisations need to prepare now for the immediate rollout of any of the new HIV prevention approaches once they are proven effective in clinical trials. They recommend that major new donor funding will be needed to pay for the prevention tools, train healthcare providers, conduct public education campaigns, and monitor effectiveness.

The report also emphasises the importance of using new prevention approaches in combination with existing prevention strategies.

Reference

Way A et al. *Is male circumcision protective of HIV infection?* Sixteenth International AIDS Conference, Toronto, abstract TuPe0401, 2006.

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