



Advocacy to accelerate ethical research & global delivery of AIDS Vaccines and other HIV prevention options

Issue Backgrounder:

Male Circumcision for HIV Prevention: Implications for Women

Overview

In March 2007, WHO/UNAIDS released recommendations confirming that adult male circumcision, although only partly protective, now be recognized as an additional important intervention to reduce the risk of heterosexually acquired HIV infection in men. The recommendations concluded that there is strong evidence from three randomized controlled trials and other data that male circumcision reduces the risk of heterosexually acquired HIV infection in men by approximately 60%.

Given that women and girls remain most affected by HIV worldwide, it is absolutely critical to ask: *What do these findings mean for women?*

There answers to this question are still emerging. At present, information continues to be gathered from long-term follow up in communities where trials took place, and as programs begin to scale-up in various settings. As these activities continue, it is critical to consider the potential benefits and concerns surrounding male circumcision for HIV prevention and its implications for women.

Some potential benefits:

- In the randomized clinical trials, men's risk of HIV infection dropped by 60 percent. This is the individual benefit of the intervention. If male circumcision for HIV prevention is scaled up in high HIV prevalence areas, where there are low rates of male circumcision, fewer men would acquire HIV infection thus reducing the risk of exposure to their female partners. This process is termed secondary protection and it translates into a potential population-level benefit for the intervention over the long-term. Male circumcision also reduces rates of genital ulcer disease and STIs in men; here, too, there could be a secondary benefit for women because these infections are cofactors for HIV transmission.

- Long-term observational studies in Rakai, Uganda that looked at male-to-female HIV transmission suggested that women's risk of acquiring HIV from their HIV-positive partners dropped by roughly 60 percent if those partners were circumcised. These data were from a study that pre-dated the randomized controlled trial. In this case, the HIV positive men who had been circumcised at birth. However, other observational data from studies in different settings do not confirm these findings. In addition, as is discussed below, the findings from the randomized controlled trials of male circumcision in HIV-positive men are not as clear.
- Male circumcision is an intervention that brings men into contact with the health services. Historically, it has been difficult to reach men with information and services related to HIV, STIs and sexual and reproductive health. Well-designed male circumcision programs could use the intervention as an entry point for a range of other services including couples counseling, domestic violence interventions, condom promotion, et cetera.
- One trial in Rakai, Uganda found that women with circumcised male partners had lower rates of genital ulceration, bacterial vaginosis and trichomonas infections, which are benefits to the woma

Alongside these benefits, there are also concerns:

- The data available from the one randomized clinical trial of male circumcision in HIV positive men to date suggest that circumcision did not protect female partners from HIV. Among couples who resumed sex before the man's circumcision wound was completely healed, transmission of HIV to their female partners was higher than men who delayed resumption of sex and higher than uncircumcised, HIV-positive men.
- While there are some limited data from clinical trials about how male circumcision affects condom use, alcohol use and number of sexual partners among circumcised men, these are limited as they come from clinical trials in which men received regular counseling and condom access. Additional information is needed on the risk behaviors that have already been measured and on other factors such as coercive sex and domestic violence.
- How will male circumcision, a surgical intervention that requires clean equipment and specific training for practitioners, be integrated into other HIV prevention offerings? What will the impact be on counselors, health professionals, community educators and advocates, including HIV-positive women, who are working in other areas of HIV treatment, prevention and care?

There is also a clear need to increase communication around what is known and unknown, and to ensure the engagement of a wide variety of women's and community groups with research findings and ongoing work.

Some questions to address include:

- In follow-up studies and initial scale up activities, what is the willingness of men seeking circumcision to be tested for HIV prior to surgery? Among those who undergo testing, what is the relative prevalence in men who are willing (or decide) to be circumcised versus those who are unwilling (or decide not) to be circumcised?
- What are the components of the counseling process prior to surgery and what strategies are used with participants who decline to be tested and still want to undergo circumcision?
- Among men who HIV positive and undergo male circumcision, what is the counseling process around the need to delay intercourse before wound healing—and how is the efficacy of different approaches to this issue being evaluated as scale-up proceeds?
- What is the experience with women's involvement in VCT activities and/or counseling related to male circumcision? What's known about strategies for improving uptake of couples counseling and testing as part of the pre-surgery process?

Additional over-arching issues and questions of relevance to both women and men include:

- How to develop messages around male circumcision, its risks and benefits; its place in the spectrum of proven prevention options; and its impact on women's ability to negotiate safer sex with spouses, stable and casual partners.
- How do cultural practices (acknowledging that they are dynamic and evolving) – impact on practices, identities or assumptions about being a man or a woman or a child in relation to male circumcision and medical male circumcision? How may these cultural practices inform work on medical male circumcision as a possible HIV prevention strategy
- Impact of male circumcision on women's risk of acquiring HIV from recently circumcised, HIV positive partners (who may or may not know their status and may or may not wait for full wound healing before resuming sexual activity).
- Impact of the procedure on men's behavior—rates of risk behavior, coercive sex, condom use, et cetera

- Involvement of HIV-positive and HIV-negative women in developing and disseminating messages and in follow-up and operations research
- Development and expansion of existing research on men's and women's sexual satisfaction and pleasure pre- and post male circumcision (what questions are asked, how, by whom, how are the data used to make cases for/against male circumcision?)
- Impact of new male circumcision programmes on national- and community-level priority-setting around HIV prevention, and on staff at health facilities that may be asked to add male circumcision to existing services
- Impact on cultural rituals that may include traditional circumcision as a rite of passage
- How to make decisions about policies and programmes to encourage circumcising infants and young children

Does circumcision of HIV-positive men alter women's risk of acquiring HIV?

To date, there has been one randomized, controlled trial looking at safety and efficacy of male circumcision in HIV positive men. This trial was conducted in Rakai District, Uganda. HIV positive men and men were randomized into two arms. One study arm offered circumcision immediately; the other 'control arm' asked men to wait 24 months for surgery, and offered it to them at the end of the trial. Men in both arms received condoms, STI treatment, HIV testing and risk-reduction counseling at every visit. They were also counseled about delaying sex post-surgery until the wound was completely healed. At each study visit, counselors also emphasized that the volunteers should not assume that male circumcision provided any benefit in terms of reducing risk of transmitting or acquiring HIV and that they should continue to reduce risk using proven strategies.

In December 2006, an independent Data and Safety Monitoring Board recommended that the trial pause surgeries. The DSMB stated that, based on the highly-similar incidence rates in the trials two study arms, the study would not be able to produce a statistically significant answer. This is known as a *futility finding*. At a later interim analysis, The DSMB also noted a trend towards increased rates of HIV infection in women partners of circumcised HIV positive men who resumed sex before complete wound healing. The data set from this trial has expanded since 2006 as follow up of study volunteers continued. The conclusions that can be drawn from this study are:

- HIV positive men who are circumcised and who resume sex before the wound is completely healed appear to be more likely to transmit HIV to their female partners than uncircumcised HIV positive men

- The procedure is safe for HIV positive men: rates of surgically related complications were comparable between the HIV-infected men in this study and the HIV-negative men enrolled in a companion study, also conducted in Rakai, Uganda, which looked at circumcision for HIV prevention in HIV negative men
- HIV positive men took longer to heal after surgery compared to their HIV negative counterparts
- Circumcision reduced rates of genital ulcer disease among both HIV positive men and HIV negative men compared to their uncircumcised counterparts, and reduced ulceration in female partners of circumcised men

These are data from a single study. They cannot be used as the basis for generalized conclusions. But they also raise issues which should be considered as programs roll out and additional research is developed.

The WHO/UNAIDS document “New Data on Male Circumcision and HIV Prevention: Policy and Programme Implications” provides some guidance on regarding circumcision and HIV status. It states that HIV testing or knowledge of one’s HIV status should not be a prerequisite for male circumcision. This recommendation was made on the basis of concerns that restricting male circumcision at medical points of service to HIV negative men would stigmatize HIV positive men and perhaps lead them to seek surgery from poorly trained providers, increasing the risk of surgical complications and possible of transmitted HIV to their partners. The recommendations also state that male circumcision for HIV-positive men is not recommended, but should not be denied, unless it is medically contraindicated. The WHO/UNAIDS document also emphasizes that men should be counseled to learn their status, and that providers should emphasize the importance of delaying sex until full wound healing. They also state that, where ever possible, male circumcision should be linked to counseling and testing for the man and/or the couple.

These recommendations will be put into practice in various ways as specific countries roll-out male circumcision programmes. It is critical that this roll-out explore and evaluate various options for minimizing women’s risk of acquiring HIV from male partners who seek circumcision and do not wait for complete wound healing before resuming sex. Women’s groups and leaders can play an important role in developing messages and educational materials to address these issues in specific contexts. Disseminating clear and accurate information about male circumcision among strong women’s networks that have been created by grassroots organizations, HIV-positive women, young women and other groups will greatly increase the likelihood that the benefits of this intervention will be realized, and the risks associated with misinformation are minimized for both women and men.

What is known at this time about male circumcision and its impact on men’s sexual and risk taking behavior?

There have been three randomized, controlled trials of male circumcision for HIV prevention to date. All of them have gathered data on men's rates of condom use and sexual activity and risk behaviors pre- and post-circumcision. Below are brief summaries of some of the findings:

- In the Orange Farm trial in South African, it was found that the men who received circumcision reported significantly more sexual contacts than the men in the control arm, who did not receive circumcision at the start of the trial. As the investigators noted in their discussion, "While the protective effect of circumcision remained despite this increased risk, this should be a concern when considering implementation of male circumcision as a means of preventing HIV infection.
- In the Rakai trial, mens' reported rates of condom use went up in both the intervention and control arms over the course of the trial. Alcohol use was higher in the control arm (uncircumcised men) versus the intervention arm.
- In the Kenya trial, rates of condom use increased and numbers of partners and unprotected sex acts decreased from baseline in both control and intervention arm. The decrease was *greater* in the control arm (uncircumcised men); there was less of a shift from baseline over all in the intervention arm (circumcised men).

More information is needed and will be gathered over the long term follow up of these study participants and from some of the pilot programs that have started more recently.

An Opportunity and a Challenge

Female and male condoms remain the two proven biomedical options for reducing risk of sexual transmission. In the absence of a successful vaccine, microbicide or other available preventative option, and in the context of ongoing work to expand funding for and understanding of structural interventions that address gender-based violence, poverty, human rights and other issues, the news about the male circumcision trials is particularly important.

Just as the scientific findings are welcome, they also raise many questions with respect to women and affected communities that need to be further investigated.

Male circumcision is still a new intervention. It presents an opportunity to engage men around HIV prevention, to expand couples counseling, and to build and/or strengthen programmes that seek to transform sexual and gender norms. Historically, it has been difficult to bring men into the health services for HIV education and frank conversations around sex and sexuality, and in this sense the enthusiasm surrounding male circumcision is a positive development that could lay the foundation for innovative programming.

In order to seize this opportunity, women's concerns, ideas and priorities must be heard, alongside those of men from different age groups, cultural backgrounds and religions.

Programmes must be adequately resourced and developed with forward-thinking monitoring strategies that can help shed light on some of the critical unknowns such as rates of coercive sex, condom use, HIV transmission (among positive men) pre- and post-circumcision.

Male circumcision must be considered in light of the lessons learned from the nearly thirty years of the AIDS epidemic and placed within the continuum of HIV prevention, treatment, and care strategies that currently exist. These lessons include the need to engage and address both sexual partners as part of comprehensive prevention and treatment programming; the specific socio-cultural and structural aspects of women's vulnerability that necessitate complex responses; and the cultural, religious, and geographic factors which must be considered as part of successful introduction of any new intervention.

It will be critical to emphasize male circumcision as adding to, rather than replacing, any other proven strategy, including male and female condoms, behavioral and structural interventions. Women's groups and advocates have raised concerns about the diversion of resources from proven prevention to new male circumcision programmes. While there is, at this time, limited evidence that these shifts are taking place, it is essential to address the concerns and to actively monitor and respond to both the rhetoric and reality around male circumcision (and other new prevention strategies as they emerge).

More than two decades into the AIDS epidemic, it is clear that there are no "silver bullets" when it comes to prevention. The benefits of each new strategy depend on context-specific introduction that is based on the input of an array of community members: men and women, religious leaders, traditional medical providers, researchers, policy makers and others. With these perspectives as guiding principles, there is reason to hope that male circumcision can be an important addition to the existing range of options for preventing the spread of HIV.