



EMBARGOED: Wednesday, 28 March, 12.00 GMT, 14.00 CET

New Data on Male Circumcision and HIV Prevention: Policy and Programme Implications

WHO/UNAIDS Technical Consultation
Male Circumcision and HIV Prevention: Research Implications for Policy and
Programming Montreux, 6- 8 March 2007

Conclusions and Recommendations

Introduction

At the end of 2006, an estimated 39.5 million people were living with HIV and 4.3 million became newly infected with the virus that yearⁱ. Prevention must be greatly prioritized in the response to AIDS and efforts are being made to find new prevention technologies to bolster the package of already known effective prevention methods. Male circumcision is one of these new potential methods, along with vaginal microbicides, pre-exposure prophylaxis with antiretroviral medication, herpes suppressive therapy, cervical barrier methods and HIV vaccinesⁱⁱ.

A number of observational studies indicate that circumcised men have lower levels of HIV infection than uncircumcised menⁱⁱⁱ. On 13 December 2006, the United States of America National Institutes of Health announced that two trials assessing the impact of male circumcision on HIV risk would be stopped on the recommendation of the Data Safety and Monitoring Board. The trials being carried out in Kisumu, Kenya, and Rakai District, Uganda revealed at least a 53% and 51% reduction in risk of acquiring HIV infection, respectively^{iv v}. These results support findings published in 2005 from the South Africa Orange Farm Intervention Trial, sponsored by the French National Agency for Research on AIDS, which demonstrated at least a 60% reduction in HIV infection among men who were circumcised^{vi}.

WHO and UNAIDS convened an international consultation to review the results of the three randomised controlled trials and other evidence on male circumcision and HIV prevention, to discuss the policy and programme implications, and to make recommendations regarding public health issues. This document summarizes the principal conclusions and recommendations of the meeting.

Objectives

The specific objectives of the meeting were:

1. To review the results of the 3 randomised controlled trials and other data on the efficacy, safety and acceptability of male circumcision for HIV prevention.
2. To inform participants about the outcomes and recommendations of several recent meetings leading up to the consultation, including the 'Regional consultation on male circumcision and HIV prevention (Nairobi, November 20-21, 2006)', 'Strategies and approaches to male circumcision programming' (Geneva, December 5-6, 2006) and 'Perspectives from social science on male circumcision for HIV prevention' (Durban January 18-19, 2006).
3. To determine the policy and programme implications of the evidence on male circumcision and reduced risk of HIV infection for different settings (in relation to HIV prevalence and patterns of male circumcision)

ⁱ UNAIDS/WHO AIDS Epidemic Update: December 2006.

ⁱⁱ Global HIV Prevention Working Group *New approaches to HIV prevention: Accelerating research and ensuring future access*. Bill and Melinda Gates Foundation & Henry. J. Kaiser Family Foundation 2006.

ⁱⁱⁱ Weiss HA, Quigley M, Hayes R. Male circumcision and risk of HIV infection in sub-Saharan Africa: a systematic review and meta-analysis. *AIDS* 2000;14:2361-70.

^{iv} Bailey C, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. *Lancet* 2007;369: 643-56.

^v Gray H, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in young men in Rakai, Uganda: a randomized trial. *Lancet* 2007;369:657-66.

^{vi} Auvert B, Taljaard D, Lagarde E, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med* 2005;2(11):e298.

Participants

The international consultation was attended by experts representing a wide range of stakeholders, including government representatives, researchers, civil society representatives, gender experts, human rights and women's health advocates, young people, funding agencies and implementing partners.

Conclusions and Recommendations

Conclusion 1: The research evidence is compelling

The research evidence that male circumcision is efficacious in reducing sexual transmission of HIV from women to men is compelling. The partial protective effect of male circumcision is remarkably consistent across the observational studies (ecological, cross-sectional and cohort) and the three randomized controlled trials conducted in diverse settings.

The three randomised controlled trials showed that male circumcision performed by well-trained medical professionals was safe and reduced the risk of acquiring HIV infection by approximately 60%.

The efficacy of male circumcision in reducing female to male transmission of HIV has been proven beyond reasonable doubt. This is an important landmark in the history of HIV prevention.

Recommendations :

1.1 Male circumcision should now be recognized as an efficacious intervention for HIV prevention.

1.2 Promoting male circumcision should be recognized as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men.

Conclusion 2: Male circumcision does not provide complete protection against HIV

Male circumcision does not provide complete protection against HIV infection. Circumcised men can still become infected with the virus and, if HIV-positive, can infect their sexual partners. Promoting and providing safe male circumcision does not replace other interventions to prevent heterosexual transmission of HIV but provides an additional strategy.

In all three randomized controlled trials HIV incidence was considerably lower in the intervention (circumcised men) than in the control group (uncircumcised men), but nevertheless remained high overall (0.7 to 1.0 per 100 person-years in circumcised men). This high incidence persisted in spite of intensive safer sex counselling, condom provision and the management of sexually transmitted infections. This underlines the need to strengthen comprehensive HIV prevention programmes even further.

It is not known whether male circumcision reduces the sexual transmission of HIV from men to women. Although a reduction in HIV incidence among men will eventually result in lower prevalence in men and therefore less likelihood that women will be exposed to HIV, currently there are insufficient data to know whether male circumcision results in a direct reduction of transmission from HIV-positive men to women.

Recommendations:

2.1 Male circumcision should never replace other known methods of HIV prevention and should always be considered as part of a comprehensive HIV prevention package, which includes: promoting delay in the onset of sexual relations, abstinence from penetrative sex and reduction in the number of sexual partners; providing and promoting correct and consistent use of male and female condoms; providing HIV testing and counselling services; and providing services for the treatment of sexually transmitted infections.

Conclusion 3: Correct communication and messages on male circumcision are critical

Now that male circumcision has been confirmed to lower the risk of heterosexual HIV acquisition among men, the demand for safe circumcision services from men is expected to increase. It is therefore critical to ensure that clear and correct information on the continuing need for other HIV prevention measures is also provided. This will be necessary to prevent men developing a false sense of security and engaging in high-risk sexual behaviours which could undermine the partial protection provided by male circumcision.

Communities, and particularly men opting for the procedure and their partners, require careful and balanced information and education materials that underline that male circumcision is not a 'magic bullet' for HIV prevention but is complementary to other ways of reducing risk of HIV infection.

The message that men who resume sexual activity before wound healing may be at higher risk of HIV infection, or if HIV-positive, at higher risk of infecting their sexual partners needs to be strongly conveyed.

The message that male circumcision is very different from female genital mutilation also needs to be emphasized. Female genital mutilation has serious adverse effects on the health of women and on obstetric outcomes and, unlike male circumcision, has no demonstrated medical benefits.

Recommendations:

3.1 Global, regional and national level communication strategies need to ensure that clear and consistent messages are disseminated and that male circumcision is promoted within the context of comprehensive HIV prevention strategies.

3.2 Messages need to be developed to ensure that men opting for the procedure, and where possible, their partners are counselled that male circumcision is only partially protective and therefore they need to continue to use other effective measures of HIV prevention.

3.3 Messages and counselling should stress that resumption of sexual relations before complete wound healing may increase the risk of acquisition of HIV infection among recently circumcised HIV-negative men and may increase the risk of HIV transmission to female partners of recently circumcised HIV-positive men. Men who undergo circumcision should abstain from sexual activity for at least six weeks after the operation. Ideally, medical inspection should be conducted to check that wound healing is complete. Thereafter, other HIV prevention strategies, including the correct and consistent use of male and female condoms, should be promoted and adhered to, as for uncircumcised men.

3.4 Messages should be carefully tailored, culturally sensitive, draw on local language and symbols, and be appropriate to the particular level of development and understanding of the population groups for which the messages are designed. Messages should be addressed to both men and women.

3.5 Clear messages should be developed to inform communities about what is known and what is not known about male circumcision, including lack of data on direct protection for women, or for either partner during anal sex with men or women.

Conclusion 4: The socio-cultural context should inform male circumcision programming

There are a wide range of socio-cultural issues to consider in the context of introducing or expanding the availability of male circumcision services. These issues differ according to circumcision history and practice in different communities.

The major determinant of circumcision globally is religion; almost all Muslim and Jewish men are circumcised. In addition, substantial numbers of males are circumcised for cultural reasons. Male circumcision has strong cultural importance in certain communities; it may be performed in different ways with differing results (from a small cut to complete removal of the foreskin), and it frequently forms part of religious and cultural practices surrounding birth or transition of boys to manhood.

Broad community engagement is required to introduce or expand access to safe male circumcision services. This also serves as a means of communicating accurate information about the intervention, notably that male circumcision provides only partial protection against the risk of acquiring HIV.

Recommendations:

4.1 Countries and institutions promoting male circumcision for HIV prevention should ensure that it is promoted and delivered in a culturally appropriate manner that minimizes stigma associated with circumcision status.

4.2 Countries and international development partners should make resources available to support community and stakeholder consultations, involving traditional practitioners in places where they perform male circumcision to ensure engagement and participation of all relevant partners in the design of safe male circumcision programmes.

4.3 The socio-cultural implications of male circumcision should be assessed at national and local levels with the participation of key stakeholders and taken into account in the design and implementation of policies and programmes.

Conclusion 5: Human rights, legal and ethical principles must guide service delivery

As is the case with medical and health procedures generally, promoting male circumcision for HIV prevention raises human rights, legal and ethical issues. Taking a human rights-based approach to the development or expansion of male circumcision services requires measures that ensure that the procedure can be carried out safely, under conditions of informed consent, and without coercion or discrimination. Such measures should already be features of good medical care.

Communities where male circumcision is introduced have a right to clear and comprehensive information about what is known and not known about male circumcision and HIV prevention. Men opting for male circumcision have the right to receive full information on the benefits and risks of the procedure.

Recommendations:

5.1 Countries should ensure that male circumcision is provided with full adherence to medical ethics and human rights principles. Informed consent, confidentiality and absence of coercion should be assured.

5.2 Where male circumcision is provided for minors (young boys and adolescents), there should be involvement of the child in the decision-making, and the child should be given the opportunity to provide assent or consent, according to his evolving capacity. Depending on the local laws, some mature minors may be able to give independent informed consent. Parents who are responsible for providing consent, including for the circumcision of male infants, should be given sufficient information regarding the benefits and risks of the procedure in order to determine what is in the best interests of the child.

5.3 Before policy makers and programme developers promote male circumcision for specific population groups, they should justify the reasons after conducting an analysis of the ethical and gender implications; this analysis should be conducted in consultation with members of such population groups, stakeholders and other critical decision makers.

5.4 Countries considering the introduction or expansion of male circumcision services for HIV prevention should ensure that appropriate laws, regulations and policies are developed so that male circumcision services are accessible, provided safely and without discrimination.

Conclusion 6: The gender implications of male circumcision as an HIV prevention method must be addressed

In all male circumcision programmes, policy makers and programme developers have an obligation to monitor and minimize potential harmful outcomes of promoting male circumcision as an HIV prevention method such as unsafe sex, sexual violence, or conflation of male circumcision with female genital mutilation.

The expansion of safe male circumcision services provides an opportunity to strengthen and expand HIV prevention and sexual health programmes for men, it also provides a means to reach a population that is not normally reached by existing services.

Recommendations:

6.1 Policy makers and programme managers should maximize the opportunity that male circumcision programmes afford for education and behaviour change communication, promoting shared sexual decision-making, gender equality, and improved health of both women and men.

6.2 Policy makers and programme developers should adopt approaches to the scale-up of male circumcision services that include the goals of changing gender norms and roles and promoting gender equality; programme managers should monitor and minimize potential negative gender-related impacts of male circumcision programmes.

6.3 Male circumcision service provision should be used as an opportunity to address the sexual health needs of men, and such services should actively counsel and promote safer and responsible sexual behaviour.

Conclusion 7: Programmes should be targeted to maximize the public health benefit

The population level impact of male circumcision will be greatest in settings (countries or districts) where the prevalence of heterosexually transmitted HIV infection is high, the levels of male circumcision are low, and populations at risk of HIV are large. A population level impact of male circumcision on HIV transmission in such settings is not likely until a large

proportion of men are circumcised, although benefit to the individual is expected in the short term. Modelling studies suggest that universal male circumcision in sub-Saharan Africa could prevent 5.7 million new cases of HIV infection and 3 million deaths over 20 years^{vii}.

The greatest potential public health impact will be in settings where HIV is hyperendemic (HIV prevalence in the general population exceeds 15%), spread predominantly through heterosexual transmission, and where a substantial proportion of men (e.g. greater than 80%) are not circumcised.

Other settings where public health impact will be considerable include those with generalized HIV epidemics where prevalence in the general population is between 3% and 15%, HIV is spread predominantly through heterosexual transmission and where relatively few men are circumcised.

In settings with lower HIV prevalence in the general population, including where HIV infection is concentrated in specific populations at higher risk of HIV exposure, such as sex workers, injecting drug users or men who have sex with men, limited public health benefit would result from promoting male circumcision in the general population. However, there may be individual benefit for men at higher risk of heterosexually acquired HIV infection such as men in sero-discordant partnerships and clients presenting at clinics for the management of sexually transmitted infections. There is insufficient evidence to suggest that circumcision reduces HIV transmission among men who have sex with men.

In high HIV prevalence settings, greatest public health impact will result from prioritizing expansion of male circumcision services for younger males (for example between the ages of 12-30 years), among whom HIV prevalence may still be relatively low but incidence could be high now, or in subsequent years. Priority could also be given to HIV-negative men of any age who have indications of being at higher risk for HIV, such as men presenting with sexually transmitted infections.

The public health benefits of male circumcision will be realized at different time intervals depending on the age group that is prioritized for circumcision; boys and young men before sexual debut are a relatively easy group to reach but measurable impact is not likely to be realized for over 10 years; if older boys and men up to age 30 years are prioritized a more rapid effect can be expected. Circumcision of neonates, in whom the procedure is simpler and less risky, can be considered as a longer-term strategy to promote circumcision in the general population, but impact of this strategy on HIV incidence would not be expected for at least 20 years.

Recommendations:

7.1 Countries with hyperendemic and generalized HIV epidemics and low prevalence of male circumcision should identify priority geographic settings where male circumcision is likely to have the greatest impact on the HIV epidemic and progressively expand access to safe male circumcision services within the context of ensuring universal access to comprehensive HIV prevention, treatment, care and support.

7.2 Such countries should consider scaling up access to male circumcision services as a priority for adolescents, young men, and as indicated by the local epidemiology and other considerations, older men at particularly high risk of HIV.

7.3 Since neonatal circumcision is a less complicated and risky procedure than circumcision performed in young boys, adolescents or adults, such countries should consider how to promote neonatal circumcision in a safe, culturally acceptable and sustainable manner.

^{vii} Williams BG, Lloyd-smith JO, et al. the potential impact of male circumcision on HIV in sub-Saharan Africa. *PLoS Med* 3 (7):e262.

7.4 Countries with other HIV epidemic situations should carefully consider the potential impact that promoting male circumcision and expanding safe circumcision services will have on their HIV epidemic.

7.5 Careful monitoring and evaluation of male circumcision service delivery for possible untoward effects such as increases in unsafe and unprotected sex and increases in sexual violence should be undertaken to ensure that programmes promoting male circumcision for HIV prevention meet their desired objectives.

7.6 Male circumcision services should not be delivered in isolation, but as part of a recommended minimum package which includes information about the risks and benefits of the procedure, counselling about the need to adopt and maintain safer sex practices, access to HIV testing, condom promotion and provision, and the management of sexually transmitted infections.

Conclusion 8: Health services need to be strengthened to increase access to safe male circumcision services

Health systems in developing countries are weak and there is a shortage of skilled health professionals. The development and expansion of male circumcision services for HIV prevention should not disrupt health systems and the implementation of other health programmes.

The safety of male circumcision depends on the setting, equipment and expertise of the provider. When circumcision is performed in clinical settings under aseptic conditions, by well trained and adequately equipped health care personnel, complication rates are low. High rates of complications have been found when male circumcision is provided by untrained, poorly equipped providers and in some traditional settings. Male circumcision should not be scaled up without assurance of quality and safety of services and appropriate follow-up of clients.

Integrated approaches to deliver male circumcision services with other essential HIV and sexual health services are most likely to be sustainable in the longer term. However, vertical, stand-alone programmes that provide the recommended minimum package of services may be useful in the short term to expand access to safe male circumcision services and to train providers in standardized procedures, especially where demand is high and health systems are weak.

Recommendations:

8.1 Needs assessments should be undertaken to describe and map out the anticipated scope of male circumcision scale-up, human resource and training needs, infrastructure, commodities and logistic requirements, costs and funding, and systems for monitoring, evaluation and follow-up.

8.2 Training and certification of providers should be rapidly implemented to increase the safety and quality of services in the public and private sectors.

8.3 Supervision systems for quality assurance should be established along with referral systems for the management of adverse events and complications.

8.4 Information on traditional practices is required and ways should be found to engage traditional practitioners to improve the safety of their services and counselling on sexual and reproductive health.

8.5 Appropriate service delivery models depend on the context and should be determined locally.

8.6 If vertical programmes are established in order to rapidly expand access to safe male circumcision services, there should be a clear strategy to ensure that these services are integrated into strengthened health systems as soon as it is feasible.

Conclusion 9: Additional resources should be mobilized to finance the expansion of safe male circumcision services

HIV prevention programmes are still under resourced and male circumcision requires new and additional investment if it is to be expanded. The financial resources required to rapidly and safely expand male circumcision services for HIV prevention are large and will require efficiency in the use of existing resources and the commitment of additional resources by countries and donors.

The cost of service at the point of delivery can be a barrier to men seeking safe male circumcision services and needs to be addressed. Based on early studies, the cost-effectiveness of male circumcision is comparable to other HIV prevention strategies.^{viii}

Recommendations:

9.1 Countries should estimate the resources needed, develop costed national plans and allocate resources for male circumcision services without taking away resources from other essential health programmes.

9.2 In view of the large public health benefit of expanding male circumcision services in countries with generalized HIV epidemics, such countries should consider providing male circumcision services at no cost or at the lowest cost possible to the client, as for other essential health services.

9.3 Bilateral and multilateral donors should consider male circumcision as an important, evidence-based intervention for HIV prevention and allocate resources accordingly.

9.4 Countries that decide to promote male circumcision for HIV prevention should ensure that existing resources are used as efficiently as possible and that sufficient resources are allocated to establish services that will be sustainable for the long term.

Conclusion 10: Promoting circumcision for HIV-positive men is not recommended

A randomized controlled trial of circumcision among HIV sero-discordant couples in Rakai, Uganda, has recently stopped recruitment on the advice of the Data and Safety Monitoring Board because of concern that numbers would be inadequate to show a protective effect^{ix}. The trial was undertaken because prior observational studies suggested that circumcised HIV-positive men might be less likely to transmit HIV to their female partners than uncircumcised HIV positive men. Preliminary results from the trial showed no significant difference in HIV transmission from circumcised HIV positive men compared to uncircumcised HIV-positive men. Participants will continue to be followed and it is still possible that a benefit of reduced risk of transmitting HIV infection could be realized several months or years after the operation. Preliminary data from the trial suggested that recently circumcised HIV-positive men who resumed sexual activity before certified wound healing were more likely to transmit HIV than those who waited until complete wound healing, but this observation was based on very small numbers.

^{viii} Kahn JG, Marseille E, Auvert B. Cost-effectiveness of male circumcision for HIV-prevention in a South African setting. *PLoS Med* 3(12):e517

^{ix} Rakai Health Sciences Program. Study presents new information on male circumcision to prevent spread of HIV in Africa. Press release March 6, 2007.

All men undergoing male circumcision, regardless of HIV status need to understand the importance of abstaining from sex until complete wound healing.

There is currently insufficient evidence of individual or public health benefit to recommend male circumcision for HIV-positive men. Since persons with severe immunodeficiency may have increased complication rates following surgery, male circumcision in HIV-infected men should only be recommended when it is medically indicated.

Recommendations:

10.1 Based on the current available evidence, male circumcision is not recommended for HIV-positive men as an intervention to reduce HIV transmission to women.

10.2 If medically indicated, male circumcision should be provided to all men irrespective of HIV status.

10.3 If male circumcision is requested by men with HIV infection following in-depth counselling on the known risks and benefits, it should not be withheld unless it is medically contraindicated.

10.4 HIV testing should be recommended for all men seeking male circumcision, but should not be mandatory.

Conclusion 11: Research is needed to guide programme implementation

Additional research is needed to inform the development, implementation and monitoring of male circumcision programmes. It is important to conduct operations research as services are scaled up to determine the most effective ways to provide and sustain services. Research gaps need to be identified and prioritized in order to obtain further information for policy development and implementation of safe and sustainable male circumcision programmes. A separate consultation will be necessary to delineate global, regional and national research priorities.

Recommendations:

11.1 Further research should be conducted to clarify the risks and benefits of male circumcision with regard to HIV transmission from HIV-positive men to women, for men who have sex with men and in the context of heterosexual anal sex. The safety of male circumcision in HIV-positive men should be studied further.

11.2 Operations research should be conducted as services are scaled up to determine the best models and packages for service delivery in different epidemic settings, for different population groups and at different ages, how to achieve optimum quality services, including effective counselling methods, and to document changes in HIV-related individual and community perceptions and behaviours.

11.3 More information should be gathered on the resource needs required to expand safe male circumcision services.

11.4 Other potential benefits or risks of male circumcision, including the potential protective effects of male circumcision on other sexually transmitted infections, should be investigated.

11.5 Simpler and safer methods for performing male circumcision in resource-limited settings, including the use of suture-less, blood-free procedures and devices, need to be developed and assessed.