

## PRESS STATEMENT

# Statement on Kenyan and Ugandan trial findings regarding male circumcision and HIV

## -- Male circumcision reduces the risk of becoming infected with HIV, but does not provide complete protection--

Statement developed by the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), the World Bank and the UNAIDS Secretariat.

**Geneva, 13 December 2006** – The Joint United Nations Programme on HIV/AIDS and its Cosponsors, WHO, UNFPA, UNICEF and the World Bank, note with considerable interest today's announcement by the US National Institutes of Health that two trials assessing the impact of male circumcision on HIV risk are being stopped on the recommendation of the NIH Data Safety and Monitoring Board (DSMB).

The two trials, funded by the US National Institutes of Health, were carried out in Kisumu, Kenya, among men aged 18-24 years and in Rakai, Uganda, among men aged 15-49 years. The trials, which completed enrolment of patients in 2005, were stopped by the DSMB evaluating the results of interim analyses. The role of the DSMB is to assess progress of the trials and recommend whether to continue, modify or terminate them. Although no detailed results have been released at this time, the National Institutes of Health statement makes it clear that the studies are being stopped because they revealed an approximate halving of risk of HIV infection in men who were circumcised.

The results support the findings of the South Africa Orange Farm Intervention Trial, funded by the French Agence Nationale de Recherches sur le SIDA (ANRS) and published in late 2005, which demonstrated at least a 60% reduction in HIV infection among circumcised men.

A further trial to assess the impact of male circumcision on the risk of HIV transmission to female partners from HIV-infected men, led by researchers at Johns Hopkins University, is currently under way in Uganda, with results expected in 2008. The effect of male circumcision on reducing the risk of HIV transmission among men who have sex with men has not been studied in a randomized controlled trial.

WHO and the UNAIDS Secretariat will rapidly convene a consultation to examine the results of these trials to date and their implications for countries, particularly those in sub-Saharan Africa and elsewhere with high HIV prevalence and low male circumcision levels.

Although these results demonstrate that male circumcision reduces the risk of men becoming infected with HIV, the UN agencies emphasize that it 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. Male circumcision should never replace other known effective prevention methods and should always be considered as part of a comprehensive prevention package, which includes correct and consistent use of male or

female condoms, reduction in the number of sexual partners, delaying the onset of sexual relations, and HIV testing and counselling.

It is anticipated that news of these results will heighten interest in male circumcision from governments, non-governmental institutions, and the general public in a number of countries, in addition to increasing demand for male circumcision services. WHO, the UNAIDS Secretariat and their partners will review the detailed trial findings and will then define specific policy recommendations for expanding and/or promoting male circumcision. These policy recommendations will need to take into account:

- cultural and human rights considerations associated with promoting circumcision;
- the risk of complications from the procedure performed in various settings;
- the potential to undermine existing protective behaviours and prevention strategies that reduce the risk of HIV infection; and
- the observation that the ideal and well-resourced conditions of a randomized trial are often not replicated in other service delivery settings.

Countries or health care institutions which decide to offer male circumcision more widely as an additional way to protect against HIV infection must ensure that it is performed safely by well-trained practitioners in sanitary settings under conditions of informed consent, confidentiality, risk reduction counselling and safety. These countries or institutions must also ensure that male circumcision is promoted and delivered in a culturally appropriate manner and that sufficient and correct information on the continuing need for other HIV prevention measures is provided. This will be necessary to prevent people from developing a false sense of security and, as a result, engaging in high risk behaviours which could negate the protective effect of male circumcision.

In order to support countries or institutions that decide to scale up male circumcision services, WHO, the UNAIDS Secretariat and their partners are developing:

- 1) Technical guidance on ethical, rights-based, clinical and programmatic approaches to male circumcision
- 2) Rapid assessment toolkits for a) determining circumcision prevalence, determining acceptability, identifying key providers, and estimating costs and b) monitoring numbers of circumcisions performed, their safety, and their potential impact on sexual behaviour
- 3) Guidance on training, standard setting, certification, and accreditation.

WHO, UNFPA, UNICEF, the World Bank, the UNAIDS Secretariat and their partners will continue to work together to support governments and other development partners and to provide coordinated, consistent and up-to-date guidance for service delivery, including for the monitoring and evaluation of services and follow-up of men who have been circumcised. These groups will also work cooperatively to identify the best means of increasing the delivery of safe circumcision services in countries that choose to do so.

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The statement from the NIAID News and Public Information Branch can be found on [http://www3.niaid.nih.gov/news/newsreleases/2006/AMC12\\_06press.htm](http://www3.niaid.nih.gov/news/newsreleases/2006/AMC12_06press.htm).

The WHO statement can be found on <http://www.who.int/mediacentre/news/statements/2006/s18/en/index.html>.