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Joint Note for the Media WHO/UNAIDS/UNICEF/UNFPA/WB/18
17 August 2006

MALE CIRCUMCISION UPDATE

ONGOING CLINICAL TRIALS ARE KEY TO VALIDATING THE LINK BETWEEN MALE CIRCUMCISION AND PROTECTION AGAINST HIV INFECTION

As trials continue, UN agencies work to ensure that current male circumcision practices are safe

Toronto – In June 2006, the US National Institutes of Health announced that, following an interim review, two ongoing trials in Uganda and Kenya examining the link between male circumcision and the risk of acquisition of HIV infection in men should be continued. The trials are scheduled to end in July 2007 and September 2007 respectively. Data from these studies will be important in validating findings reported in July 2005 from the Orange Farm Intervention Trial in South Africa, funded by the French Agence Nationale de Recherches sur le SIDA (ANRS), which showed a reduction of 60% or more in the risk of acquiring HIV infection among circumcised men.

The interim data from the ongoing Uganda and Kenya trials were reviewed in June 2006 by the Data and Safety Monitoring Board (DSMB), which recommended that the studies continue on the grounds that there were not yet enough data to draw firm conclusions. The DSMB further proposed that an additional interim analysis of data from the two studies take place within the next year.

“The results of the two ongoing trials will help clarify the relationship between male circumcision and risk of HIV in differing contexts, which is key to determining the reproducibility and application of the Orange Farm findings,” noted Dr Kevin De Cock, Director, WHO HIV/AIDS Department. “While we await these important results, UN partners and others are

working to provide coordinated guidance and support to countries to help improve the safety of current male circumcision practices."

An additional trial assessing the impact of male circumcision on the risk of HIV transmission to female partners, led by researchers at Johns Hopkins University, is currently under way in Uganda with results expected in late 2007. The effect of male circumcision on reducing the risk of HIV transmission among men who have sex with men has been studied but has not been the subject of a trial.

Guidance and support efforts now underway

WHO, UNFPA, UNICEF and the UNAIDS Secretariat emphasize that their current policy position has not changed and that they do not currently recommend the promotion of male circumcision for HIV prevention purposes. However, the UN recognizes the importance of anticipating and preparing for possible increased demand for circumcision if the current trials confirm the protective effect of the practice. Recent mathematical modelling based on an assumed reduction of HIV transmission of 60% in circumcised men suggests that, if this level of protection is indeed confirmed and if male circumcision were widely practised, the number of HIV-related infections and deaths could be considerably reduced over a twenty-year period in sub-Saharan Africa.

Countries currently considering how to improve the safety of current services will need to ensure that male circumcision is implemented by appropriately trained practitioners with adequate equipment in hygienic settings, and with close follow-up and post-operative care. Countries should ensure that the procedure is being performed under conditions of informed consent, confidentiality, and counselling tailored to the individual, emphasizing the continuing need for multiple HIV prevention measures.

"Even if further trials show a lower risk of HIV infection in circumcised men, male circumcision will not provide complete protection against HIV infection," said Catherine Hankins, Chief Scientific Adviser, UNAIDS. "Circumcised men can still contract HIV and pass it to their partners. If male circumcision is proven to be effective, it must be considered as just one element of a comprehensive HIV prevention package that includes correct and consistent use of condoms, reductions in the number of sexual partners, delaying onset of sexual relations, and voluntary and confidential counselling and HIV testing to know one's HIV serostatus. Just as combination treatment is more effective than single drug therapy for people with HIV, combination prevention is more effective than reliance on a single HIV prevention method."

Since the reporting of the Orange Farm study findings, the UNAIDS Secretariat, WHO, UNFPA, UNICEF, the World Bank and other partners have been working together to develop a range of guidance documents and practical materials for countries or institutions that choose to improve the safety of and/or scale up male circumcision services, now or in the future.

The UN Work Plan on Male Circumcision, which was developed with financial support from the US National Institutes of Health, the UNAIDS Secretariat, the ANRS and the Bill & Melinda Gates Foundation, includes the development of technical guidance as well as survey methodologies that can help countries to determine their needs and capacity to enhance

services, and help track implementation and changes in sexual behaviour. As part of the UN plan, a number of country stakeholder meetings are also being organized to help countries assess the current status of male circumcision including human rights, ethical and cultural aspects, evaluate clinical capacity, and define knowledge gaps.

While this programme and policy work is ongoing, some high HIV prevalence countries are already working to improve the safety of current male circumcision practices and some are considering whether and how to offer male circumcision in an HIV prevention context. UN agencies emphasize that the final results of the ongoing trials will be essential to determining the efficacy of circumcision in preventing HIV infection in men in differing social and cultural settings. Once the findings of these trials have been announced and reviewed in 2007, WHO, the UNAIDS Secretariat and their partners will define specific policy and programming recommendations.

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All information on WHO events and activities at the XVI International AIDS Conference in Toronto, Canada can be obtained from the webpage: <http://www.who.int/hiv/toronto2006>. All WHO press releases, fact sheets, features and other information can be found on <http://www.who.int>.