

Inside this issue:

Questions and Answers: NIAID-Sponsored Adult Male Circumcision Trials in Kenya and	1
Male Circumcision Should Never Pre-empt Other HIV Prevention Measures	3
Men should seriously consider circumcision	4
A Real-World AIDS Vaccine?	5
Male circumcision 'cuts' HIV risk	6
SAfAIDS comment: Circumcision, a landmark in the fight against HIV?	7

Questions and Answers: NIAID-Sponsored Adult Male Circumcision Trials in Kenya and Uganda

1. Who funded and who conducted the two adult male circumcision trials in Africa?

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), supported two clinical trials, one in Rakai, Uganda, and the other in Kisumu, Kenya, designed to determine whether adult male circumcision is safe and can prevent men from acquiring HIV infection in geographic areas where heterosexual transmission of the virus is most common.

The Ugandan study, led by Drs. Ronald Gray and Maria Wawer of Johns Hopkins Bloomberg School of Public Health and Drs. David Serwadda and Nelson Sewankambo of Makerere University in Kampala, Uganda, enrolled 4,996 men since the trial began in August 2003.

The Kenyan trial, also known as the UNIM trial (Universities of Nairobi, Illinois and Manitoba trial), opened in February 2002, in a collaborative effort between U.S., Canadian and Kenyan researchers. Drs. Robert Bailey, University of Illinois, Chicago, Stephen Moses, University of Manitoba, Jeckoniah Ndinya-Achola, University of Nairobi, and Kwango Agot, UNIM, are funded by NIAID and the Canadian Institute of Health Research. This trial enrolled 2,784 men.

2. What is a Data and Safety Monitoring Board, and how does it monitor this study?

A Data and Safety Monitoring Board (DSMB) is an independent committee composed of clinical research experts, statisticians, ethicists and community representatives. The DSMB re-

views data while a clinical trial is in progress to ensure the safety of participants. The DSMB may recommend that a trial, or part of a trial, be stopped if there are safety concerns or if the trial objectives have either been achieved or are unlikely to be achieved. During the trial, the DSMB looks at analyses that are not available to the investigators or to anyone else.

3. What were the results of the most recent DSMB review of the two circumcision trials?

The NIAID adult male circumcision trials have been under the review of the NIAID Prevention DSMB. On December 12, 2006, the NIAID DSMB reviewed an interim data analysis of the trials and determined the following:

Adult male circumcision performed by trained medical personnel and with appropriate post-surgical follow-up to ensure management of any infections or other problems with wound healing was shown to be safe. Among men in these trials, adult male circumcision reduced the risk of acquiring HIV infection by 48 percent in the Ugandan study and by 53 percent in the Kenyan study. Given these results, both trials will offer men in the control group circumcision. In order to understand the long term impact of adult male circumcision, the studies will continue to measure HIV infection rates and to study the risk-taking behavior and attitudes of participants.

4. What is adult male circumcision and how was it performed in these studies?

Adult male circumcision is a surgical procedure to remove the foreskin (prepuce) of the male

penis. The NIAID-supported trials tested whether there is a decreased risk of HIV infection among men who were circumcised, in which their foreskin has been nearly or completely removed, compared with men who were not circumcised. Both studies performed the circumcision in a surgical room with local anesthesia.

The circumcision procedure used in the Kenyan trial was the foreskin clamp method. The Kenyan trial procedure took about 25 minutes and used stitches to control bleeding and improve wound closure. The circumcision procedure used in the Ugandan trial is known as the sleeve method and takes about 30 minutes. The Ugandan trial used cauterization of the blood vessels to control bleeding and stitches to close the wound. Both methods are commonly used throughout the world.

5. How were the studies designed?

Both trials recruited healthy, HIV-negative uncircumcised men who planned to remain near the study site for the duration of the trial. The trial in Uganda recruited men between 15 and 49 years old; the trial in Kenya recruited men between 18 and 24 years old.

After an initial HIV screening and a medical exam, eligible men were randomly assigned either to receive circumcision immediately or to wait two years before circumcision. All participants were closely followed for two years to collect information about their health, sexual activity, and theirs and their partners' attitudes about circumcision; to counsel participants in HIV pre-

entation and safe sex practices; and to check the HIV status of the volunteer. Participants in the Kenyan study were scheduled for six visits over the two-year follow-up, compared with four visits for the Ugandan trial participants. In addition to the study visits, men enrolled in the Kenyan trial were encouraged to receive all of their outpatient health care at the study clinics, which enabled researchers to collect information on the safety of the procedure and the number of other sexually transmitted diseases the men had during follow-up.

6. What were the primary objectives of the adult male circumcision trials?

The primary objectives of these studies were to determine whether adult male circumcision 1) can be administered safely, and 2) reduce the risk of acquiring HIV infection through heterosexual contact.

7. Why were these studies done?

Previously published studies on male circumcision found a protective effect against HIV acquisition ranging from 40 to 88 percent. However, since male circumcision is closely tied to culture, it was not possible to rule out other cultural factors as the reason for the lower HIV rates in circumcised men. Scientists concluded that there was insufficient evidence from these observational studies to support adult male circumcision as a means of reducing HIV acquisition in men, and therefore, called for randomized controlled trials of adult male circumcision.

8. What other trials have been conducted?

The first randomized controlled trial of adult male circumcision was funded by the French government's research agency, Agence Nationale de Recherches sur la SIDA (ANRS). The trial, ANRS-1265, was conducted in South Africa to test the effect of adult male circumcision on HIV acquisition. Led by Dr. Bertran Avert, the investigators found a 60 percent reduction in HIV acquisition for the men enrolled in the circumcised arm of the trial. (Avert B, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med.* 2005 Nov;2(11):e298. Epub 2005 Oct 25.) There were a total of 69 HIV infections among participants: 20 were among the 1,546 circumcised men and 49 among the 1,582 uncircumcised men.

Despite these results, there was still debate among clinicians, policy makers and the international community over whether these results could be generalized to different populations. These NIAID-sponsored trials provide additional scientific evidence for the role of adult male circumcision in HIV prevention.

9. How could male circumcision prevent HIV infection?

There are several proposed mechanisms for

how male circumcision might reduce a man's risk of HIV infection. The foreskin's inner mucosal surface is more susceptible to HIV because it has more immune cells vulnerable to HIV infection than the external surface. Furthermore, the foreskin acts as a physical barrier, trapping HIV next to the mucosal surface of the penis for a longer period of time. In this moist environment, the virus can also survive longer, potentially increasing the risk of infection. Small tears in the foreskin as a result of intercourse could also promote entry of the virus. After circumcision the penile shaft and glans develops more epithelial keratinization, a process which makes the penis less susceptible to viral invasion.

10. What are possible negative biological and behavioral complications associated with adult male circumcision?

Male circumcision is a surgical procedure with recognized risks. There have been multiple reports of serious complications and adverse events following improperly performed male circumcision, including serious infection, severe loss of blood, mutilation, penile amputation and death. These serious complications are due to poor training of those performing circumcision, lack of appropriate surgical equipment, and lack of patient follow-up.

Furthermore, the procedure requires some time for healing, and during that time there is a break in the epithelial (skin) surface of the penis. This incision site may be a portal for HIV entry and until fully healed, it may increase the risk of HIV infection. For this reason, men in the trials were cautioned to not resume sexual activity until the incision was fully healed and checked by the physician.

As with most prevention strategies, adult male circumcision is not completely effective at preventing HIV transmission. Millions of circumcised men have become infected with HIV through heterosexual exposure to the virus. Men who receive adult male circumcision may perceive that they are at decreased risk for transmission and, therefore, may not maintain other risk reduction strategies. Modest increases in the number of sexual partners could negate the protective effect and increase the rate of HIV transmission in a community. Adult male circumcision will be most effective when integrated into a comprehensive prevention strategy which includes the ABCs (Abstinence, Be Faithful, and Condoms) of HIV prevention.

11. How common is male circumcision in Africa?

Studies have shown that overall, 62 percent of adult males in Africa are circumcised. However, there are significant differences in these rates by region and tribal groups. In particular, male circumcision is strongly tied to religious beliefs. In Southern Africa, where the HIV epidemic is the most severe, rates of male circumcision are less than 20 percent.

12. How acceptable is adult male circumcision in Africa?

Surveys conducted in Africa in both men and women have found that adult male circumcision is acceptable (50 to 86 percent), provided that the procedure is safe, affordable and has minimal side effects or pain. Among the reasons cited include better hygiene, lower sexually transmitted disease rates, more modern/urban appearance, peer pressure and perceived attractiveness to women. However, because of varying religious and cultural norms, not all groups or communities practice adult male circumcision.

13. How might these new findings affect future HIV prevention strategies?

These results indicate that HIV transmission to men could be lowered, though not eradicated, by increased rates of male circumcision.

Adult male circumcision is only one component of a comprehensive prevention strategy. As a partially effective procedure, it can be an important component of a comprehensive prevention strategy that also stresses the ABCs: abstinence and delay of sexual debut, overall partner reduction and reduction in number of concurrent partners and correct and consistent use of condoms. These studies looked only at risk of heterosexual HIV transmission from females to males. The risks associated with other modes of transmission, such as male-to-male and male-to-female sexual transmission, are not addressed, and risks associated with needle sharing are not affected.

14. How will these findings influence other prevention trials already under way?

Other trials and research are under way to evaluate methods and strategies (e.g., microbicides, pre-exposure prophylaxis, vaccines and behavioral interventions) for HIV prevention. These studies are being conducted in a variety of different populations and settings.

These results indicate that adult male circumcision may play an important role in the prevention of heterosexual HIV transmission to males in some areas of the world. In areas where international and country-specific HIV prevention recommendations are adapted to include male circumcision, research trials will need to determine how to ensure that education about, and access, to safe male circumcision is incorporated into comprehensive trial prevention services.

15. Will these results have an effect on policy in Africa and other regions?

United Nations agencies, including the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO), are multinational organizations that guide health ministries and aid organizations in determining how research findings should

be applied to recommendations for and provision of health services in different parts of the world. These agencies will review the data from these studies and develop appropriate policy guidelines. In preparation for the possibility of these findings, WHO and UNAIDS are working with key stakeholders in several countries to host country consultations and conduct needs assessments to help prepare for any change in policy that may result from the findings of these studies. To learn more about the international response to the study findings, visit the WHO website at www.who.int/hiv and the UNAIDS website at www.unaids.org.

16. How will these results affect the U.S. epidemic?

These NIH studies have focused on popu-

lations in Africa, where the infection rate is high and where heterosexual sex is the predominant mode of HIV transmission. In the United States, the majority of adult men are already circumcised. According to the U.S. Centers for Disease Control and Prevention (CDC), in a 1992 survey, 77 percent of men in the United States reported being circumcised. In addition, there is a lower prevalence of HIV in this country, and the men at greatest risk have been those who have sex with other men. The degree of protection that circumcision may afford for men who have sex with men is unknown. For all of these reasons, the study findings will likely have less of an impact in the United States. Information about circumcision is available from the CDC at <http://www.cdc.gov/hiv/resources/factsheets/circumcision.htm>.

17. Are other studies of male circumcision being conducted?

In addition to the NIAID trials in Uganda and Kenya, a randomized trial led by researchers at Johns Hopkins University is studying whether male circumcision reduces male-to-female HIV transmission. (In contrast, the NIAID trials studied whether male circumcision reduces female-to-male transmission.) The Johns Hopkins-led trial, which is supported by a grant from the Bill & Melinda Gates Foundation, is scheduled for completion in 2007.

Source: http://www3.niaid.nih.gov/news/QA/AMC12_QA.htm

Male Circumcision Should Never Pre-Empt Other HIV Prevention Measures, UN Warns

December 14, 2006

United Nations health agencies have given a guarded welcome to United States trials in Africa showing that male circumcision halves the risk of HIV infection in men in heterosexual relations, warning that it should never pre-empt other preventive measures such as the use of condoms.

Proper guidelines "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," they said in a joint statement.

They plan to quickly draw up guidelines after examining the implications, particularly in sub-Saharan Africa and elsewhere with high HIV prevalence and low male circumcision levels, taking into account cultural and human rights aspects and the need to ensure that circumcisions are performed safely by well-trained practitioners in sanitary settings.

"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," they said. "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," they added.

The statement was issued by the UN World Health Organization (WHO), UN Population Fund (UNFPA), UN Children's Fund (UNICEF), the Joint UN Programme on HIV/AIDS (UNAIDS) and World Bank.

Noting that the trials' results will likely heighten interest in male circumcision from governments, non-governmental institutions and the general public, the agencies said they would define specific policy recommendations for promoting

male circumcision after a detailed review of the findings.

The recommendations will take into account cultural and human rights considerations; the risk of complications from the procedure performed in various settings; the potential to undermine existing protective behaviours and strategies; and the fact that the ideal and well-resourced conditions of a randomized trial are often not replicated in other settings.

To support countries or institutions that decide to scale up male circumcision, the agencies are developing technical guidelines on ethical, rights-based, clinical and programmatic approaches.

They are also drawing up 'rapid assessment toolkits' for determining circumcision prevalence and acceptability; identifying key providers; estimating costs; and monitoring numbers of circumcisions performed, their safety, and their potential impact on sexual behaviour.

Source: <http://allafrica.com/stories/200612140405.html>

Men should seriously consider circumcision

Beatrice Tonhodzayi

It is not unheard of. Some men have actually done it and haven't been maimed for life. On the contrary, some of them called in to tell me that they are circumcised and have not had any far-reaching problems as a result.

For those of you who had fears about your performance after the procedure, it might cheer you a bit to know that five brothers called to tell me that they were circumcised.

And the glory of it — they are all HIV negative. Now, before you get excited and pin their HIV negative status on circumcision, we cannot be sure whether they are HIV negative because they were circumcised or they have just been lucky.

While two swore that they were faithful to their wives and have been faithful for the past five years, the other three say they have been naughty from time to time and indulged in unprotected sex not because "vaitemba circumcision" but because they just had to have it unprotected.

When they tested negative, however, they vowed to never be careless again. We are still on the subject of adult male circumcision as something that is increasingly becoming effective at cutting in half men's risk of getting HIV through heterosexual intercourse.

My question last week was if that is the case, should men in this country and region, the epicentre of the pandemic, not start considering it in earnest? Male circumcision is the surgical removal of some or all the foreskin from the male reproductive organ.

This removal reduces the ability of HIV to penetrate the skin of the male reproductive organ. Men with a foreskin are more prone to sexually transmitted infections and several studies now suggest that female partners of circumcised men have a lower risk of cancer of the cervix and re-infections with yeast infections.

It is against this background that my piece last week was calling out to men to consider circumcision along with other known and proven prevention methods like the condom. My thrust was "is it not

time to be open-minded and try anything, anything at all that may assist us to get the greatest treatment of all time — PREVENTION.

And have you given a thought to the hygiene aspect of circumcision? I observed something --- the foreskin at times makes it difficult to really clean oneself up. How many little boys have you seen hopping from one foot to the other saying "my wee itches?" I have a three-year-old son and he used to complain about this problem and I would worry. The granny then suggested that I bath him myself at least three times a week and really ensure that he got cleaned under the foreskin.

He has not complained since and I trained my helper at home to clean him thoroughly as well. Now with a circumcised little boy (had the good fortune of seeing a niece's son who was born in the United States) it's very easy to clean him for everything is out in the open.

Nothing is hidden and as such, he stays dry, unlike the warm moist conditions under the foreskin where bacteria can find a really good home. In addition on the underside of the foreskin are located many immunological cells which are prime targets of HIV. In fact, among some of the responses from readers were some from women who echoed my sentiments that the foreskin hid a lot of things, even sores.

"A man without a foreskin is one without surprises. While his performance is definitely surpassed by one with a foreskin there are many bonuses, chief being that everything is there for the eye to see. There are very few surprises and there is no place for bacteria or gems to hide. "We keep on getting re-infected with yeast infections and other transmissible infections because they find a warm spot to hide under the foreskin," the very vocal 35-year-old Lissa who is based in London said.

Matthius, who e-mailed me all the way from Australia, said a doctor in Marondera had circumcised him in 2002 after suffering from some problems that made him suffer excruciating pain during sexual encounters. This would result in bruising, which made him very vulnerable to infections.

"I got circumcised and would just like to urge my brothers back home and elsewhere in the region that if circumcision can cut the risk of catching HIV even by two percent, it is worth it." "We are really in a tight fix and should consider anything that might help people," he said. Others, of course, wanted to know whether we have in this country, medical practitioners able to perform the procedure.

I asked around and would just like people to know that there are so many medical practitioners who are qualified to conduct the procedure. If you need to get it done, have your general practitioner refer you to someone. I was expecting some of the doctors to write in and let the world know the medical aspect of the procedure but our good doctors did not do so. We still would welcome their input though so that we can supply our readers with the correct information.

While I have opened my mind to male circumcision and am even considering taking my son in for the procedure (for hygienic purposes though I worry about his reaction when he is older, maybe he would want to make the decision, himself)! I would like adult males who decide to have it done to know that circumcision is not a licence for irresponsible sexual behaviour.

A circumcised man still has to behave very responsibly or else they will still risk getting infected with HIV. And be advised: circumcision also works best with other already proven methods of preventing HIV infection so if it is condoms — they still need to be correctly and consistently used. If it's being faithful to one uninfected partner — remain faithful.

Till next time, let's keep talking about it for in talking about Aids we will demystify it and help each other with answers and information.

<http://www.healthdev.org/viewmsg.aspx?msgid=B1D3C82E-C675-4AC5-AC91-8A7120DF6EAA>

A Real-World AIDS Vaccine?

By TINA ROSENBERG, The New York Times
14 January 2007

Last month, scientists invented the AIDS vaccine. Missed it? Perhaps that's because you were still seeking the vaccine fantasy: the magic bullet, the impenetrable shield that finally pitches this disease into the trash bin, the shot that will end not only the AIDS epidemic but our anxiety about the AIDS epidemic as well.

The vaccine thunderbolt didn't strike — and might never. Drearily, the real AIDS vaccine is likely to be imperfect: one more tool in our arsenal, to be used along with condoms and all our other tools. It will most likely avert millions of infections and save millions of lives. But it will not end the Age of AIDS.

The vaccine that arrived last month was not actually a vaccine. It was, instead, a confirmation of what scientists had long suspected: circumcision helps protect men from AIDS infection. For years, AIDS researchers have observed that many African tribes that circumcise boys or young men had lower AIDS rates than those that don't, and that Africa's Muslim nations, where circumcision is near universal, had far fewer AIDS cases than predominantly Christian ones. The first research proof came in 2005, when a study in South Africa was stopped early in the face of evidence that the men who had been randomly assigned to be circumcised were getting 60 percent fewer H.I.V. infections than the men assigned to the control group. Last month, ethics boards halted two similar studies, in Uganda and Kenya, when they found similar results. In both, the circumcised men caught the AIDS virus half as often as the uncircumcised control group.

Circumcision would be given more weight if the world recognized that it is, in fact, the real-world equivalent of an AIDS vaccine. In some ways, it is closer to the fantasy than a real vaccine might be. Vaccine research began in the early 1980s but with little financing or urgency and went nowhere. In 1996, the effort was revived with the creation of the International AIDS Vac-

cine Initiative, and financing has soared in the last five years. But a vaccine has proved elusive. Most vaccines work by mimicking infection, which stimulates the body to make antibodies that kill the disease. But H.I.V. infection generally does not produce those kinds of antibodies. H.I.V. also mutates constantly and comes in many different varieties, factors that further complicate the search for a vaccine.

Many vaccines provide nearly 100 percent protection — after my daughters finish their two doses of the measles, mumps and rubella vaccine, for example, they won't have to think about those diseases again. But that's not on the horizon for AIDS. "Fifty to 60 percent efficacy is what people would feel really good about," says Frances Priddy, the director of efficacy trials with the AIDS vaccine initiative. The best candidates in the vaccine pipeline right now — which won't be ready until 2013 at the earliest — wouldn't keep you from getting H.I.V. They instead would seek to change your body's response to the virus so that if you did get infected, the disease would progress more slowly — or not at all — and you would be less infectious to others.

An efficacy rate of 50 to 60 percent is actually a lot better than it sounds, because of herd immunity. We get AIDS from one another. Every time a person is rendered less infectious, the chance of an uninfected person catching H.I.V. from each sexual contact drops, and in a virtuous circle, the whole community becomes progressively safer. A vaccine of 50 to 60 percent efficacy might come close to wiping out the epidemic in places with low AIDS rates. In high-prevalence areas, it could reduce the epidemic and save millions of lives.

In contrast to a vaccine, circumcision's origins are about as far from the laboratory as you can get; carvings depicting circumcisions have been found in ancient Egyptian temples. But the effects may be very similar to those of a vaccine. So far, we have proof only that circumcision protects the circumcised men. But there are strong indications that it also protects their sexual partners. A trial in Uganda is now test-

ing whether H.I.V.-positive men are less likely to infect their wives if they are circumcised than if they are not.

Together, circumcision and an imperfect vaccine might be enough to stop AIDS. But they will need help from behavior change, microbicides, fighting malaria, treating genital herpes and other interventions we don't even know about yet. That is unsatisfying. The danger does exist that circumcised men will feel invulnerable and throw sexual caution to the winds, a risk that would also exist with an imperfect vaccine. But so far, there is not much evidence of a problem. In the Uganda and Kenya studies, the sexual behavior of the circumcised men was no more risky than that of the others. In the South Africa study, circumcised men did report 25 percent more sexual activity. But the circumcised group as a whole still had 60 percent fewer infections. Certainly one reason that risky behavior did not jump is that the men got counseling as part of the clinical trials. Counseling goes naturally with circumcision; counseling would be harder to include in a vaccine campaign, since one of a vaccine's great advantages is that it can be given assembly-line-style in seconds.

Circumcision is a surgical procedure, however, and in the hands of traditional ritual circumcisers, it has a high rate of infection and mishap. The solution is to train these circumcisers and give them decent tools, and at the same time encourage men to come to clinics. Since men in studies say that cost is the biggest reason they are not circumcised, the operation must be free. Countries will also have to equip these clinics and train counselors and medical circumcisers, who don't have to be doctors.

Research on an AIDS vaccine is more crucial than ever. But we must not let our hope for a thunderbolt prevent us from racing ahead with circumcision now. For the biggest difference between circumcision and a vaccine is this: only one of them exists.

<http://www.healthdev.org/viewmsg.aspx?msgid=90D3068F-882A-46AC-86DF-069FEBF20E6C>

Male circumcision 'cuts' HIV risk

Circumcision can cut the rate of HIV infection in heterosexual men by 50%, results from two African trials show.

The findings are so striking, the US National Institutes of Health decided it would be unethical to continue and stopped the trials early.

It supports a previous South African study, which reported similar results.

Experts said it was a significant breakthrough but could not replace standard methods of preventing infection such as condoms.

These findings are of great interest to public health policy makers who are developing and implementing comprehensive HIV prevention programmes

The two trials of around 8,000 men took place in Uganda and Kenya were due to finish in July and September 2007 respectively.

But after an interim review of the data by the NIH Data and Safety Monitoring Board, it was decided to halt the trials as it was unethical not to offer circumcision in the men who were acting as controls.

The trial in Kenya found a 53% reduction in new HIV infections in heterosexual men who were circumcised while the Ugandan study reported a drop of 48%.

Results last year from a study in 3,280 heterosexual men in South Africa, which was also stopped early, showed a 60% drop in the incidence of new infections in men who had been circumcised.

There are several reasons why circumcision may protect against HIV infection.

Specific cells in the foreskin may be potential targets for HIV infection and also the skin under the foreskin becomes less sensitive and is less likely to bleed reducing risk of infection following circumcision.

When Aids first began to emerge in Africa, researchers noted that men who were circumcised seemed to be less at risk of infection but it was unclear whether this was due to differences in sexual behaviour.

A modelling study done by international Aids experts earlier this year showed that male circumcision could avert about six million HIV infections and three million deaths in sub-Saharan Africa.

A further trial in Uganda to assess the risk of HIV transmission to female partners is due to report in 2008 but the effect among men who have sex with men has not yet been studied.

Dr Kevin De Cock, director of the HIV/Aids department of the World Health Organization told the BBC the results were a "significant scientific advance" but were not a magic bullet and would never replace existing prevention strategies.

"We will have to convene a meeting which we hope will happen quite soon to review the data in more detail and have discussions about the implications.

"This is an intervention that must be embedded with all the other interventions and precautions we have. Men must not consider themselves protected. It's a very important intervention to add to our prevention armamentarium."

Dr De Cock said that countries in Africa who wanted to use this approach would still have to decide what age groups to target and there would

have to be training and hygienic practices in place.

"This is about as good epidemiological data as we can request. There will be many other research questions about implementation but this is very persuasive."

NIH director Dr Elias Zerhouni said: "Male circumcision performed safely in a medical environment complements other HIV prevention strategies and could lessen the burden of HIV/Aids, especially in countries in sub-Saharan Africa where, according to the 2006 estimates from UN-Aids, 2.8 million new infections occurred in a single year."

Dr Jeckoniah Ndinya-Achola, co-principal investigator at the University of Nairobi, Kenya said: "The Ministry of Health of the Kenyan government is already holding discussions about how this can be made available. It will need a certain amount of improvement to existing facilities."

But Tom Elkins, Senior Policy Officer at the National AIDS Trust warned: "There is a real danger in sending out a message that circumcision can protect against HIV. This is not the case and could lead to an increase in unprotected sex.

"There is still a long way to go in providing comprehensive prevention programmes in many countries, and resources should go into normalising the use of condoms, which are the most effective method currently available for preventing HIV."

Source: <http://news.bbc.co.uk/2/hi/health/6176209.stm>

SaFAIDS comment: Circumcision, a landmark in the fight against HIV?

"This is a landmark day in the history of fighting the epidemic."

Robert Bailey, of the University of Illinois at Chicago, who led the study into adult male circumcision in Kisumu, Kenya, made this observation late last year as it became evident that the procedure could offer some protection against HIV transmission.

Prominent researcher into male circumcision and its implications for AIDS prevention, Daniel Halperin, also voiced his satisfaction at the preliminary results. "Circumcision is now the only intervention for the prevention of HIV that has passed the highest standard for clinical trials," he said. "I think it's a pretty historical event."

It might not be the much longed for HIV vaccine, but male circumcision is offering many men, and their partners, new hope in preventing the spread of HIV. With possible HIV reduction rates put at 53% and 48% in the Kenyan and Ugandan trials respectively, the procedure's efficacy in HIV mitigation is almost undoubtable. And the two studies build on earlier tests con-

ducted in South Africa in 2005, which found that male circumcision reduced HIV infection risk in heterosexual men by about 60%.

But this good news must be met with the necessary caution. As the United Nations stated, male circumcision should not replace other proven methods of HIV prevention such as condom use, abstinence, partner reduction and voluntary counseling and testing (VCT). Circumcised men are *not* immune from HIV, as was emphasised by The Executive Director of AIDS Vaccine Advocacy Coalition (AVAC), Mitchell Warren. "The benefits of this new prevention strategy will only be realized if male circumcision is included as a part of a larger package of prevention services," he said in a public release immediately after the latest findings were revealed.

"Ensuring male circumcision becomes an effective AIDS prevention strategy must mean access to safe, sterile, confidential procedures accompanied by clear, culturally-appropriate education, counseling and information for both men and women."

Male circumcision is performed in some African tribes at birth but is more commonly practised in Jewish and Muslim communities either as part of a cleansing rite, or in preparation for puberty or marriage. A Think Tank meeting on HIV prevention in southern Africa, held in Lesotho in May 2006 stated that low levels of male circumcision was one of the key drivers of HIV and AIDS in the region, where rates of male circumcision are much lower than in western and central Africa. Circumcising cultures in West Africa are believed to have HIV infection rates below 5%, while countries such as Botswana and South Africa are reported to have infection rates of over 30%. Studies have shown that just over 60% of African men are circumcised, but with less than 20% of these being in southern Africa, the epicentre of the spread of HIV. As such, male circumcision brings with it many doubts and questions, especially among those for whom it is not a cultural or religious

rite – *does it affect one's sexual prowess, is it painful, and most importantly, is it safe?*

One of the strongest dissenting voices on male circumcision is Doctors Opposing Circumcision (DOC), an international organisation opposed to non-therapeutic circumcision, especially as performed on newborn babies. In a detailed statement issued following the halted African trials, they said that the claims made for male circumcision in mitigating HIV transmission were "exaggerated". The organisation gives diverse reasons for this, including what they term the "cultural bias" of the study, and also the risks, complications and drawbacks involved in the surgical procedure.

Male circumcision is said to have a minimal complication rate when carried out in settings where those who perform the procedure have adequate training and appropriate surgical equipment, and the patient has regular follow-up consultations to ensure proper healing of wounds. Complications range from pain, swelling, damage to the penis, infection, to delayed wound healing. However, serious complications include serious infection, severe loss of blood, mutilation, penile amputation and even death. Sexual satisfaction following circumcision seems to remain largely a matter of personal preference, although some women have said that they found sex with an uncircumcised man less painful and chaffing.

The positive outcome of the recent male circumcision trials is much welcomed in a sector that is constantly looking for good news. The studies however have many more implications that will hopefully be investigated in the near future. These include what safety male circumcision could offer for women, and men who have sex with men, as these studies have only focused on HIV transmission from women-to-men and not men-to-women, or men-to-men.



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