MALE CIRCUMCISION CONSORTIUM

MCC News

MALE CIRCUMCISION CONSORTIUM

May 2013
Issue 45

MCC News

An e-newsletter about male circumcision for HIV prevention in Kenya

In this issue:

Clinician Maurice Onyango explains to a client how the PrePex device works

Photo by Silas Achar/FHI 360

Device study moves to second phase

Men are now enroling in the second phase of a study of the PrePex™ device for performing adult male circumcision after a planned review of the data from the first phase raised no safety concerns.

A committee of independent experts conducted the review and recommended continuing the study.

The device has shown promise in clinical studies conducted in Rwanda and Zimbabwe. But this study, conducted by the Male Circumcision Consortium

(MCC) in collaboration with the National AIDS/STI Control Programme (NASCOP) and the Nyanza Reproductive Health Society (NRHS), is the first to assess the safety and acceptability of PrePex-assisted adult male circumcision in routine clinical settings in Kenya.

"Our study will provide the information that the Ministry of Health (MOH) needs to decide whether to add PrePex to the national programme on voluntary medical male circumcision (VMMC)," says Dr. Peter Cherutich, NASCOP deputy head and head of HIV prevention, who is a co-investigator for the study.

The first phase of the study was designed as a "safety run-in," with an analysis and independent review of the data on the first 50 participants after 42 days of follow-up. Men ages 18 to 49 who sought VMMC services at the UNIM Research and Training Centre run by NRHS in Kisumu and consented to be in the study were circumcised by trained providers using the PrePex device.

Each man was scheduled to return after seven days to have the PrePex device removed and for additional follow-up visits after nine, 14, 28, 35 and 42 days.

Dr. Elijah Odoyo-June of UNIM reports that most of the men returned for all of their follow-up visits. Only two men missed any visits at all, and more than 97 percent of the scheduled visits were completed.

Enrolment in the study has also proceeded smoothly. The first 50 participants were recruited within three weeks.

Now the study is enroling another 375 men at the UNIM Research and Training Centre and at dispensaries or health centres in Rachuonyo where VMMC is provided on specific days by outreach teams.

"Both service-delivery approaches — fixed and outreach — are important components of the Kenyan VMMC programme and will provide essential data on how the device might be integrated into ongoing services," explains co-principal investigator Paul Feldblum of FHI 360.

In addition to getting circumcised, all participants receive the package of HIV prevention services recommended by the Kenyan MOH, including HIV testing

and counseling, screening and treatment for any sexually transmitted infection, condoms and instructions in how to use them, and counseling on HIV-risk reduction and safer sex.

The men participating in the second phase of the study are asked to return after seven days to have the device removed and the circumcision wound assessed, and then for a final assessment 42 days after the procedure. They are encouraged to contact a study clinician or come to the clinic at any time should they have problems or questions related to care of the wound.

The main objective of the study is to assess the safety of PrePex procedure by measuring rates of complications and side effects and comparing them to the rates seen with the conventional surgery.

The researchers will also examine a range of other service delivery issues, such as client satisfaction with the procedure, providers' perceptions of ease of use, return for follow-up visits, time to wound healing, the training required to achieve proficiency in the PrePex procedure and the cost of the procedure. Results are expected by September 2013.

The PrePex device

The PrePex device consists of an elastic mechanism that fits closely around an inner ring, clamping the foreskin and cutting off its blood supply. The foreskin then dries up and is removed after a week.

Use of PrePex dramatically reduces the time needed to perform a male circumcision. The procedure requires no stitches, involves minimal bleeding and can usually be performed without injected anaesthesia. These advantages could make male circumcision more accessible and acceptable to adult and adolescent men. Disadvantages include the need to wear the device for a week and possibly a longer healing period.

Several PrePex studies have been conducted in Rwanda, including a randomised controlled trial that documented the safety of the procedure. A randomised trial has also been completed in Zimbabwe; the results have not yet been published.

The World Health Organization's Technical Advisory Group on Innovations in

Male Circumcision has endorsed the use of PrePex only in Rwanda based on the results of the studies there. The Kenya implementation study will show how well the device performs in a wider variety of settings.

The MCC consists of FHI 360 and the University of Illinois at Chicago, working closely with the NRHS. It is funded by a grant to FHI 360 from the Bill & Melinda Gates Foundation.

Study may help explain male circumcision's protective effect

Randomised clinical trials conducted in Kenya, South Africa and Uganda have shown that getting circumcised reduces a man's chances of becoming infected with HIV by about 60 percent. The research also shows that male circumcision offers protection against genital ulcer disease, which increases the risk of HIV infection. The reasons for these benefits are not well understood.

Now a study published April 16 in *mBio,* the online open-access journal of American Society for Microbiology, suggests that changes in the bacteria living on and around the penis may be partly responsible for male circumcision's protective effect against HIV infection.

Scientists conducted a detailed genetic analysis of the microbial inhabitants of the coronal sulcus (the groove behind the head of the penis) among men who participated in the clinical trial of male circumcision for HIV prevention in Rakai, Uganda. After 12 months, the circumcised men harbored dramatically fewer bacteria that survive in low-oxygen conditions compared to the uncircumcised men.

The authors of the study suspect that in uncircumcised men, these anaerobic bacteria may provoke an inflammatory response that promotes HIV infection. They call for more research to understand how reductions in anaerobic bacteria may contribute to the reduced risk of HIV acquisition provided by male circumcision.

Male circumcision in the news

Ministry upbeat of attaining male cut target to reduce HIV infections
Coastweek, 17-23 May

Stigma keeps Siaya men away from the knife – research
The Star, 8 May

Resources

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations

This guide provides implementing partners with a comprehensive, consistent process for establishing and supporting VMMC services for HIV prevention at the facility or site level. It draws upon numerous documents developed by the Joint United Nations Programme on HIV/AIDS, the World Health Organization and the VMMC Technical Working Group of the President's Emergency Fund for AIDS Relief (PEPFAR). It also builds on the experiences and materials from existing VMMC programs in southern and eastern Africa.

www.malecircumcision.org

Developed by the World Health Organization, AVAC and FHI 360, the Clearinghouse on Male Circumcision for HIV Prevention website is a comprehensive source of information and resources about male circumcision for HIV prevention.

The **Male Circumcision Consortium** works with the Government of Kenya and other partners—including the US President's Emergency Plan for AIDS Relief (PEPFAR), which supports service delivery—to prevent HIV and save lives by expanding access to safe and voluntary male circumcision services. FHI 360 and the University of Illinois at Chicago, working with the Nyanza Reproductive Health Society, are partners in the Consortium, which is funded by a grant to FHI from the Bill & Melinda Gates Foundation.

Please send questions or comments to Silas Achar at: **mccinfo@fhi360.org**; also, please indicate whether you want to continue receiving this e-newsletter regularly.