

# Use of devices for adult male circumcision in public health HIV prevention programmes

Conclusions of the *WHO Technical Advisory Group on Innovations in Male Circumcision*

## EXECUTIVE SUMMARY

World Health Organization, HIV Department  
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### Background

The WHO Global Health Sector Strategy on HIV/AIDS, 2011–2015, strives to reduce new HIV infections. This goal will be achieved only by implementing existing effective prevention technologies with sufficient intensity and scale. In March 2007 WHO and UNAIDS recommended male circumcision as an efficacious intervention for the prevention of heterosexually acquired HIV infection in men. It is recommended that countries with generalized HIV epidemics and a low prevalence of male circumcision progressively expand access to safe voluntary medical male circumcision services<sup>i</sup>.

As countries have begun implementing this intervention, several challenges have become evident, including uncertain client demand and limited human and material resources. Specifically, the number of physicians and surgeons available to perform the procedure is low, and the time and equipment required for the currently recommended standard surgical methods are substantial. Therefore, research is underway to identify innovative methods that are simpler, less resource intensive, usable by non-physician providers, acceptable to clients and providers, and as safe as standard surgical male circumcision. Research on specific devices for adult male circumcision as alternative methods to standard surgical male circumcision has evolved over the past year, and member states and supporting partners have requested guidance regarding use of the new devices.

WHO, through expert consultations, has defined a pathway for the clinical evaluation of male circumcision devices for use in public health programmes for HIV prevention<sup>ii</sup>. The pathway includes an initial efficacy and safety study in the country of intended use, followed by a series of clinical studies consisting of a comparative study and a field study. For WHO global recommendations on use of devices as alternative methods for male circumcision, two series of clinical studies from different countries are required. By the end of 2011, a series of clinical studies was completed in one low-resource country, Rwanda, on one device that causes necrosis of the foreskin over one week through controlled radial compression with an elastic ring after which the device is removed. Safety and efficacy, and comparative studies had been completed on another device that achieves haemostasis by compression of the foreskin between two non-elastic locking rings. The foreskin can be excised immediately after the device has been placed correctly and the device remains in place for one week. Field studies with this device are underway in 2012.

## Objectives, target audience and development of conclusions and recommendations

This Executive Summary is from a report on the conclusions and recommendations of the *WHO Technical Advisory Group on Innovations in Male Circumcision* (TAG) on use of a device as an alternative method to standard adult surgical procedures. The full report will be available soon. The TAG met in January 2012 and the report was developed to advise Member States implementing voluntary medical male circumcision as a HIV prevention intervention in national programmes and supporting partners. Given the data available, the conclusions and recommendations focus on an elastic ring controlled radial compression device. As noted, data on this device were available from one series of clinical studies conducted in Rwanda. Additional data on at least this device and another type of device are expected within the year. The report on the TAG conclusions also identifies additional information needed to guide further research to inform decision-makers and the development of guidance. The exact timing of guidance depends on availability of evidence from studies still in progress.

The report is intended for national public health officials in countries implementing male circumcision for HIV prevention and for policy- and decision-makers, including funders, interested in the potential use of devices as additional methods for male circumcision in resource-limited settings. It may also be of interest to health workers and non-governmental organizations.

To review the data and develop the conclusions, WHO applied the GRADE approach for the development and review of recommendations<sup>iii</sup>. The approach, in brief, includes stating clear questions to be answered and specifying primary outcomes of interest, reviewing the literature, and grading the quality of the evidence for each question and outcome<sup>iv</sup>. Moving “from evidence to recommendation” for each question required consideration of the quality of evidence, the balance of benefits and harms, values and preferences, resource use and feasibility. A separate document with the GRADE tables and evidence summaries will be made available once the study data are in the public domain.

Each participant of the TAG and consultants submitted a Declaration of Interests to the WHO Secretariat. No significant conflicts or potential conflicts of interests were identified that required any invited participant not to attend. One participant had been involved as a clinical researcher on the initial safety research of the device studied in Rwanda. As requested by the Secretariat, he did not contribute to discussions on the implications of the evidence or the formulation of recommendations, but he did provide technical information on the study.

## Key conclusions from the January 2012 meeting of the Technical Advisory Group

The key recommendations of the WHO TAG cover the use of a device as an alternative to standard adult surgical methods and its use by specific types of providers for voluntary male circumcision in public health HIV prevention programmes. Further remarks and information needs are described in the full report.

### I. Use of an elastic ring controlled radial compression device for adult male circumcision

- 1.1** The elastic ring controlled radial compression device for which data were available from one safety, one comparative, and one field study in one country (Rwanda) by the end of 2011 can be used in that same country (Rwanda), subject to approval/endorsement by the national programme, for phased implementation among men 18 years and older with rigorous monitoring for adverse events and side-effects.

It was recommended that the phased implementation include:

- a) active surveillance of the first 1000 clients to identify and record all adverse events and side-effects based on standardized definitions. The active surveillance may change to passive surveillance after the first 1000 clients, if the incidence of events is reassuringly low, as determined by independent review.
  - b) appropriate counselling on sexual abstinence and condom use<sup>1</sup> after male circumcision and before complete healing is always crucial, but it is particularly crucial with use of this device because the healing time is at least one week longer than with standard surgery.
  - c) that, as approximately 10–15% of adult men were not clinically eligible for this device (due to phimosis or narrow opening of the foreskin), access is assured to standard surgical circumcision services. Alternative acceptable and efficient service delivery models for men who are not eligible for this device method should be identified and these models should be pilot-tested for feasibility.
- 1.2** The controlled radial elastic compression ring device for which data were available from one safety, one comparative, and one field study in one country (Rwanda) in 2011 is not yet recommended for use as an alternative method for male circumcision in national programmes outside the country where the first series of studies was conducted.

### II. Use of the elastic ring controlled radial compression device by mid-level providers

In Rwanda where a field study with this device has been completed, physicians and mid-level providers (nurses) who are appropriately trained and deemed competent can perform the placement and removal of the device for men 18 years and older, with careful monitoring during phased implementation in actual practice, and in different types of settings, with active surveillance of the first 1000 clients as indicated above.

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<sup>1</sup> Condom use is also advised after healing since male circumcision only partially reduces the risk of sexual transmission of HIV from women to men. Male circumcision should be considered as part of a combination prevention package.

## Information gaps

Since the device has not been evaluated in men under age 18 years bridging studies must be conducted to establish its performance and safety in younger populations. In addition no systematic follow-up of clients has been done beyond nine weeks and longer-term follow-up of selected clients must be completed to document wound healing and final cosmetic result one year after the procedure. Since there are limited data in men with HIV infection or those with other immuno-compromising co-morbidities such as diabetes, the performance and safety of the device in such clients must be documented. Service delivery models will need to be tested to identify efficient approaches to delivering the entire minimum service package and ensuring access to male circumcision for those men excluded for device-specific contraindications.

Data from independent studies in countries other than Rwanda are necessary before a recommendation can be generalized beyond the country where the initial three studies were conducted. A comparative and a field study to assess the safety, efficacy and acceptability of the device in another country are underway. The TAG encourages the studies to be completed so results would be available during 2012. The TAG recommended that national programmes interested in exploring the potential of devices within voluntary medical male circumcision for HIV prevention public health programmes, in advance of a global recommendation, should not conduct additional comparative studies but prepare in a stepwise manner for possible implementation, including discussing with key stakeholders and conducting preliminary research on acceptability and feasibility.

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- i. New data on male circumcision and HIV prevention: policy and programme implications, WHO and UNAIDS, March 9 2007, ISBN 978 924 159598 8.
  - ii. *Framework for the clinical evaluation of adult devices for male circumcision*. Geneva, World Health Organization, 2012. [version 2012 available soon]
  - iii. Guyatt GH et al. GRADE guidelines: 2. Framing the question and deciding on important outcomes. *Journal of Clinical Epidemiology*, 2011, 64:395–400. <http://www.ncbi.nlm.nih.gov/pubmed/21194891>
  - iv. Balshem H et al. GRADE guidelines: 3. Rating the quality of evidence. *Journal of Clinical Epidemiology*, 2011, 64:401–406. <http://www.ncbi.nlm.nih.gov/pubmed/21208779> (accessed 13 April 2011).