MALE CIRCUMCISION FOR HIV PREVENTION

MEETING REPORT

USE OF DEVICES FOR ADULT MALE CIRCUMCISION FOR HIV PREVENTION IN EAST AND SOUTHERN AFRICA

13–14 NOVEMBER 2013, ENTEBBE, UGANDA

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ACRONYMS

AE	adverse event
AFRO	Regional Office for Africa
AIDS	acquired immunodeficiency syndrome
HIV	human immunodeficiency virus
ISO	International Organization for Standardization
MC	male circumcision
OGAC	Office of the Global AIDS Coordinator
PEPFAR	President's Emergency Plan for AIDS Relief
RCT	randomized controlled trial
STI	sexually transmitted infection
TAG	Technical Advisory Group on Innovations in Male Circumcision
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VMMC	voluntary medical male circumcision
WHO	World Health Organization

1.0 INTRODUCTION

Fourteen countries in east and southern Africa have taken action towards the scale-up of medical male circumcision (MC) for HIV prevention. This followed the 2007 WHO and Joint United Nations Programme on HIV/AIDS (UNAIDS) recommendations that voluntary medical male circumcision (VMMC) be considered as part of a comprehensive HIV prevention package in countries with generalized epidemics. Modelling studies indicate that, in these priority countries, the MC intervention will have the greatest public health impact and provide the largest cost-saving if services are rapidly scaled up. Currently recommended conventional surgical methods for adult MC were described in the WHO/UNAIDS/Jhpiego *Manual for male circumcision under local anaesthesia (2009)*.[1]These conventional surgical methods require considerable time and skill in the context of a limited number of surgically qualified health-care providers. C*onsiderations for implementing models for optimizing the volume and efficiency of male circumcision services* (2010),[2] developed by WHO, outlines options for organizing surgical services to improve the efficiency of surgical service delivery. However, the conventional surgical methods still require substantial resources, which limits efficiency. Innovations (e.g. the use of devices) in this minor surgical procedure may alleviate some of the challenges, and result in an accelerated pace of delivery of VMMC, while maintaining the safety of the procedure.

In line with its mandate, WHO convened a meeting in Entebbe, Uganda, on 13 and 14 November 2013, to:

- inform key stakeholders about the details of a new guideline on the use of devices;
- provide an opportunity to discuss key considerations; and
- identify next steps for potential device use in national programmes.

Participants included ministry of health MC focal points, national staff from nursing or medical services (or both) from 13 of the 14 priority countries, researchers, partners from the President's Emergency Plan for AIDS Relief (PEPFAR) and the Bill & Melinda Gates Foundation, WHO country office MC focal points, and staff from the WHO Regional Office for Africa (AFRO) and WHO Headquarters.

1 http://www.who.int/hiv/pub/malecircumcision/who_mc_local_anaesthesia.pdf
2 http://malecircumcision.org/programs/documents/mc_MOVE_2010_web.pdf

2.0 OBJECTIVES OF THE MEETING

The overall objective of the meeting was to accelerate the delivery of VMMC for HIV prevention in the 14 priority countries in east and southern Africa.

The specific objectives were to:

- share the WHO guidance on use of devices (including the research findings that informed its development);
- provide an update and share findings on continuing and planned research studies, including pilot and bridging studies;
- discuss programme considerations and issues for the introduction and use of devices; and
- discuss key next steps in countries, and the support needed from partners.

3.0 OPENING SESSION

The Coordinator of the WHO Headquarters HIV Department, Key Populations and Innovative Prevention team introduced the speakers at the Opening Session. The Senior Program Officer and Initiative Lead at the Bill & Melinda Gates Foundation applauded the great momentum attained by national VMMC programmes in recent years. She recognized the need for additional MC methods (e.g. devices), and the need to reduce costs and increase demand for VMMC services. She acknowledged the many who have contributed to the devices work including, globally, PEPFAR, the United States National Institutes of Health, and WHO, which has shown true leadership through establishment of the WHO Prequalification for Male Circumcision Devices Programme, and guidance on research (including the WHO *Framework for Clinical Evaluation of Devices for Male Circumcision*[3]).

The Senior Technical Advisor of PEPFAR/Office of the US Global AIDS Coordinator (OGAC) stressed the potential use of MC devices to reach more men in less time – the aim being to maximize reduction of HIV infections. Many questions, however, remain unanswered: Will these devices be acceptable to men? Will they be less expensive? Will programmes embrace them? There is reason for optimism, considering that governments have demonstrated their capacity to embrace and scale up conventional surgical MC as a public health intervention. PEPFAR estimates that over 5 million men have been circumcised in the 14 priority countries up to the end of September 2013. Key to successful introduction and scale-up of MC devices will be stakeholder engagement, creation of demand and communication.

The WHO Uganda National Programme Officer addressed participants on behalf of the WHO Representative, Uganda. He acknowledged the ministries of health in the priority countries, and the numerous partners who have provided technical and financial support to scale up VMMC in the 14 priority countries. The UNAIDS/WHO J*oint Strategic Action Framework to Accelerate the Scale-Up of Voluntary Medical Male Circumcision for HIV Prevention in Eastern and Southern Africa 2012–2016*[4] was developed to better coordinate efforts focusing on seven strategic pillars. These pillars are leadership and advocacy, country implementation, innovations for scale-up, communication, resource mobilization, monitoring and evaluation, and coordination and accountability. This meeting was part of Pillar 3 – innovations for scale-up – and focused on the new WHO *Guideline for the use of devices for adult male circumcision for HIV prevention* (2013).[5] He highlighted key achievements in 2012 conveyed in the WHO summary report on *Progress in scaling up voluntary medical male circumcision for HIV prevention in east and southern Africa*,[6] including the research conducted on the PrePex and ShangRing devices. The report noted that an estimated 3.2 million medical circumcisions among males of all ages were performed in 2012; that is, about 15% of the estimated 20 million MCs needed to achieve 80% coverage among adult men 15–49 years. Of note is that twice as many MCs were performed in 2012 than in 2011, in part thanks to non-physician health professional cadres performing the MC procedures. Pivotal to progress were communication and mobilization strategies to create demand, coordinated technical and financial support from implementation partners, and strengthened reporting systems; these must all be intensified to maximize impact.

The Minister of Health of Uganda emphasized key achievements. He focused on the tremendous progress in scaling up VMMC services in Uganda, which will help to reduce new HIV infections, of which there were about 140 000 in 2012. The number of medical MCs performed in Uganda increased from 21 000 in 2010, to 77 000 in 2011 and 467 000 in 2012. At the time of the meeting in 2013, an impressive 742 000 medical MCs had been performed, thanks to the collaborative efforts of key stakeholders who worked hard to ensure that men accessed this service all over the country. Uganda is one of the few countries where the demand for VMMC services exceeds the supply, and the country's Ministry of Health is working hard to address the supply gap, in part through the introduction and safe use of prequalified MC devices. The Minister of Health commended WHO for its renewed engagement and leadership, and thanked the partners for their commitment and continued technical and financial assistance to scale up VMMC services for adults and adolescents. He committed the support of the Ministry of Health to use all means to prevent HIV infections and to endorse prequalified male MC devices as a method – along with HIV testing and counselling, and a comprehensive package of prevention interventions – to accelerate medical MC service coverage.

(Note: points from the discussions after the presentations in each session are incorporated within the session that is most relevant to the question raised.)

3 http://www.who.int/hiv/pub/malecircumcision/framework/en/

4 http://www.pepfar.gov/documents/organization/178294.pdf

5 http://www.who.int/hiv/pub/malecircumcision/devices_guidelines/en/

6 http://www.malecircumcision.org/country_updates/documents/FINAL%20VMMC%20Progress%20Report%20Jan-Dec%202011%20WHO.pdf

4.0 GUIDELINE OVERVIEW AND CLINICAL EVIDENCE

4.1 Guideline overview

The Focal Point for Male Circumcision for HIV Prevention at WHO Headquarters provided an overview of the new WHO *Guideline for the use of devices for adult male circumcision for HIV prevention* (2013). She described the rigorous process used to assess the clinical evidence and formulate the WHO recommendations. The guideline development process involved the Technical Advisory Group on Innovations in Male Circumcision (TAG), which reviewed the available evidence in January 2013; the Guideline Development Group, which contributed throughout the development of the guideline and recommendations; and the External Review Group, which provided additional inputs to the Guideline Development Group. The TAG had previously classified in situ devices into three categories based on their mechanism of action (collar clamp, elastic collar compression and ligature). Sufficient clinical evidence was available to review two devices: a collar clamp type (the ShangRing) and an elastic collar compression type (PrePex).

The WHO evidence-based recommendation issued in October 2013 was:

WHO prequalified male circumcision devices are efficacious, safe and acceptable as additional methods of male circumcision for HIV prevention among healthy men 18 years and older in high HIV prevalence, resource-limited settings (conditional, moderate quality evidence).

This recommendation applies in settings where:

- the devices are used by health-care providers, including physicians and mid-level providers, who are appropriately trained and competent in the use of the specific device; and
- surgical backup facilities and skills are available, as appropriate to the specific device.

The methodology used to rate the quality of evidence (high, moderate, low or very low) for the priority outcomes (eligibility, successful circumcision, adverse events [AEs], healing time, pain and procedure time) was described. The strength of the recommendation was based on the quality of the evidence, the balance of anticipated benefits and harms, the values and preferences of clients and providers, and a consideration of resource use and costs. The overall quality of the evidence was rated as "moderate", based on a detailed assessment of each outcome (details available in the evidence profile tables in Annex 2 of the guideline[7]). The recommendation was conditional in favour of the intervention, primarily due to concerns about potential harms, in particular following device slippages and displacements. The evidence was reassuring in well-resourced research settings; however, there was insufficient evidence on safety with device use in routine settings. In addition, there was uncertainty about patient acceptability and costs (discussed in later sections).

The current WHO recommendation is limited to men 18 years and older, because no data on safety were available in younger men. A recommendation on device use in adolescents under 18 years will be considered when additional data become available and have been reviewed by the TAG. The WHO recommendation is not made for a specific branded product, but must be used in conjunction with the current list of WHO prequalified devices.[8] The prequalification programme ascertains whether a specific device meets relevant international standards in terms of product specification, manufacturing process and the manufacturer's quality-management system, in addition to being assessed as clinically safe and efficacious by the TAG. The prequalification list is updated as new information becomes available.

The programmatic considerations provided in the guideline were intended to support the implementation of the WHO recommendation. In contrast to the evidence-based recommendation, programmatic considerations were based on insights gained from the randomized controlled trials (RCTs) and field studies, and inputs from the guideline development groups. As further experience is gained and more lessons learnt, it will be important to share these across countries, to maximize the coverage of VMMC and the safe use of in situ devices.

4.2 Illustrated summary of device procedures and wound healing after the procedure

A medical researcher from the Rakai Health Sciences Program, Uganda, described and demonstrated the clinical procedures for the placement and removal after 1 week of the collar clamp ShangRing device and the elastic collar compression PrePex device. The ShangRing requires a sterile field and injection of local anaesthetic at placement, whereas the PrePex requires neither a sterile field nor the injection of local anaesthetic at placement. Suturing is not required with either device.

A medical researcher from the Nyanza Reproductive Health Society, Kenya, described the wound healing processes following MC using an in situ device and by conventional surgical methods. Healing following circumcision with the in situ devices is by secondary (also known as second) intention (i.e. when an acute wound is left open and heals 'on its own') and takes longer than after conventional surgery, where healing is by primary (also known as first) intention (i.e. the skin edges are intentionally brought together with the aid of materials such as sutures).

7 http://www.who.int/hiv/pub/malecircumcision/devices_guidelines/en/

8 http://www.who.int/diagnostics_laboratory/evaluations/prequalification_male_circumcision_devices/en/

4.3 Clinical performance of adult male circumcision devices compared with surgery

The evidence underlying the WHO recommendation and guidance was described. Details of the African clinical studies on the ShangRing and the PrePex reviewed by the TAG are summarized in the January 2013 TAG report,[9] and details of the evaluation of the evidence can be found in Annex 2 of the guideline.[10]

The outcomes evaluated were based on a total of 1983 ShangRing and 2417 PrePex procedures:

- Compared to all men eligible for conventional surgical MC, the proportion of men eligible for the device and in whom the device was successfully placed was high: 98.8% for ShangRing and 92.6% for PrePex.
- Compared to conventional surgery, a high proportion of men were successfully circumcised using a device method: 99.8% for ShangRing and 99.5% for PrePex. Unsuccessful device circumcisions were due to insufficient removal of the foreskin or the need to complete the procedure by a conventional surgical method.
- The frequency of AEs with devices was no higher (and possibly lower) than with conventional surgery. A few AEs required prompt skilled surgical intervention to prevent serious sequelae, and were thus classified as serious AEs, even though they were all properly managed and resolved satisfactorily. The type and category of AE (based on the TAG classification of AEs) varied according to the type of device:
  - With the ShangRing, no serious AEs occurred, moderate AEs occurred in 1.0% of placements and mild AEs in 2.2%. Surgical skills to manage the rare complications arising during or soon after ring placement must be available on-site for the ShangRing device, to prevent potentially serious AEs.
  - With the PrePex, serious AEs occurred in 0.4% of placements, moderate AEs in 0.7% and mild AEs in 0.6%. No permanent impairment occurred; however, device displacements or self-removals (once the ischaemic process had started but was not complete) resulted in swelling, blistering and pain that required prompt referral and surgical intervention. This occurred in about 0.5% of clients.
- Where in situ devices were used, healing took about 1–2 weeks longer on average than with a conventional surgical method.
- Pain varied by type of method, and is a subjective measurement:
  - With the ShangRing, local injectable anaesthesia was required for placement; some pain was reported while wearing the device, and pain during erection was reported as being somewhat higher than at comparable times following surgery.
  - With the PrePex, the greatest pain and discomfort occurred 3–6 hours after placement, and some men reported transient but intense pain when the device was removed. Pain control protocols for the PrePex evolved during initial studies in Rwanda, with all subsequent studies using 5% lidocaine topical anaesthetic cream, applied before placement, and oral analgesics given to patients to take as required after placement and while wearing the device. There appeared to be somewhat less pain due to wearing the PrePex than was reported at comparable times following surgery.
- Total procedure times (including time for placement and removal of the devices) were less than the times required for conventional surgery. For the ShangRing, total procedure time was 10.3 minutes compared to 20.3 minutes for conventional surgery; for the PrePex, total procedure time was 5.7 (standard deviation [SD] 1.4) minutes compared with 19.2 (SD 3.9) minutes for surgery. (Times for conventional surgery differed because the method may differ across the comparative studies; that is, forceps guided or dorsal slit.)

Overall, men reported a high level of satisfaction with the cosmetic result following both types of circumcision: device and conventional surgery. Devices left a neat circumferential wound with no suture marks at 6 weeks. Unpleasant odour associated with the PrePex was reported by some clients and noticed by partners, and was also noticed by providers during device removal; however, odour was not systematically assessed in any of the studies. Although direct comparative data are lacking, the inconvenience associated with the device remaining in situ for 1 week and requiring a second visit for removal did not appear to be a deterrence. In general, it appears that use of a device may reduce the loss of time at work compared to conventional surgery.

A larger proportion of physicians and non-physicians expressed a preference for a device over conventional surgical circumcision. Common advantages reported by providers with the device techniques compared to the conventional procedure were that these techniques are easy to perform and faster, give better cosmetic results, have fewer complications, remove the need for suturing, cause less bleeding, and remove the need for routine injectable anaesthesia (in the case of the PrePex).

9 *WHO Technical Advisory Group on Innovations in Male Circumcision: Evaluation of two adult devices, Meeting report,* Geneva, Switzerland. January 2013 (http://www.who.int/hiv/pub/malecircumcision/tag_devices/en/)

10 *Guideline on the use of devices for adult male circumcision for HIV prevention* (http://www.who.int/hiv/pub/malecircumcision/devices_guidelines/en/)

4.4 Researchers' comments on the adult male circumcision devices

Researchers involved in the various studies of efficacy and safety of the ShangRing and PrePex devices provided additional perspectives. Key comments are summarized by specific device.

Comments on the PrePex device

The Medical Research Center at Rwanda Biomedical Center has undertaken several studies on the PrePex device. Between 8% and 12% of men in the Rwandan studies were not eligible for MC using the PrePex device. The problem of odour is being further investigated.

Research at the International Hospital in Kampala, Uganda, identified several AEs related to the PrePex: bleeding, displacement, odour, voiding difficulties and pain, which peaked at day 2 after device placement. The clinical courses of two cases of device displacements were presented; the cases demonstrated the degree of penile swelling 2 days after device placement, but complete resolution of symptoms occurred following device removal and conventional surgical circumcision. Other events shown were a rare case of pseudo-paraphimosis,[11] in which the device was no longer visible due to an everted and swollen foreskin.

The National Male Circumcision Coordinator, Ministry of Health and Child Care, Zimbabwe, commented on eligibility, AEs and acceptability data in the Zimbabwe PrePex studies. Six per cent of men were not eligible for the device, mainly because of phimosis. In three men, the device could not be used because devices of a sufficiently large size were not available. Overall, less than 1% of clients experienced an AE and, in those cases, client behaviour was considered a contributing factor, particularly relating to device displacement and early removal. The occurrence of unpleasant odour was noted but not systematically documented. Clients in both the device and conventional MC groups were interviewed before circumcision and 2 weeks and 90 days afterwards. Most men expressed a high level of satisfaction with the outcome. They talked about their circumcision to others, particularly to wives and male friends. Men who underwent the device method talked to about twice as many people as the conventional surgery group, perhaps because people are more likely to talk about an innovative procedure rather than a conventional one. Contrary to their expectations, and excluding sexual abstinence, clients reported little impact on activities of daily living at both 2 weeks and 90 days after the procedure. The device method was preferred over conventional surgery by service providers including primary care nurses, general registered nurses and physicians.

11 Phimosis is a condition in which the foreskin cannot be fully retracted over the glans penis

Comments on the ShangRing device

A researcher from University Teaching Hospital in Lusaka, Zambia, commented on AEs reported in the ShangRing studies in Kenya and Zambia. Although no serious AEs were reported from a total of 1434 device placements, the researchers classified two events as "severe": one case of severe postoperative pain and one case of wound dehiscence (i.e. separation of the layers of the wound). Researchers classified 35 AEs as "moderate": these included dehiscence, infections, oedema, cutaneous skin pinches, postoperative pain and insufficient foreskin removal. The "time to removal" study found the optimal time of removal to be 7 days, although there were no safety concerns if the device stayed on longer (in most cases the device detached spontaneously, although partial detachment sometimes occurred and was often painful). The field study included 84 HIV-positive subjects, and there was no difference in the proportion healed by day 42 between the HIV-positive and HIV-negative subjects.

A researcher from the Rakai Health Sciences Program, Uganda, reported on the acceptability of the ShangRing from the perspective of providers. Factors that led providers to prefer the device over the conventional surgical method included: easier to learn and apply, short application time, fewer contraindications and good cosmetic result. Also, the ShangRing was reported to cause less pain on removal than the PrePex device. Reservations that providers had about the device method included: appropriate ring sizes sometimes being unavailable, self-removal may lead to complications, and the additional stress of, and responsibility for, tracking clients for the second visit.

4.5 Update on pilot, bridging and other studies

Overview

An overview was provided of recently completed, ongoing and planned studies related to MC devices. The Bill & Melinda Gates Foundation is funding pilot studies in Kenya, Mozambique, South Africa, Zambia and Zimbabwe; PEPFAR is funding studies in Botswana, Lesotho, Malawi, South Africa, Swaziland and the United Republic of Tanzania. The studies in Botswana, Kenya and Mozambique have been completed, and preliminary results and insights were shared during the session. A bridging study on the use of the ShangRing device among adolescents under 18 years has been completed in Rakai, Uganda, and a study on the use of the PrePex device among adolescents under 18 years is ongoing in Zimbabwe. Special studies on the use of the PrePex device among HIV-positive men are planned in Kenya and Zimbabwe, and odour prevention and management studies on the PrePex device are planned in Swaziland, Uganda and Zambia in 2014. Studies on the use of Accu-Circ for infant circumcision were conducted in Botswana, are ongoing in Zimbabwe and are planned in Kenya. Studies on the use of the Mogen clamp for infant circumcision are ongoing in Kenya and Uganda.

Key insights from completed pilot studies

Provisional reports from the PrePex pilot studies completed in Botswana, Kenya and Mozambique were encouraging, and researchers expressed considerable optimism about future uptake of the method. PrePex device displacements occurred at a rate no higher than in the evidence reviewed by the TAG, and all displacements were successfully managed. Considering that AEs are heavily dependent on client factors, it is essential to undertake good-quality patient education and counselling. Clients can help to prevent AEs by following care instructions and not "meddling" with the device while it is in situ.

The researchers from the pilot study in the Nyanza Reproductive Health Society attributed the few cases of inadequate foreskin removals to errors in use of the devices by the providers. Spontaneous displacements were uncommon, and there was usually indication of meddling by the client in these cases. In the case of the PrePex, the AEs with the most remarkable clinical profiles occurred 36–72 hours after placement. No infections were observed. A long foreskin may contribute to unique complications such as dispersion of urine stream, retained urine, early sloughing and unpleasant odour. Regarding healing time, in the Kenya pilot project, 44% of PrePex wounds were healed by day 42, and 90% by day 56. A pilot study supported by the Ministry of Health in Mozambique reported that about 10% of PrePex wounds were not healed 7 weeks after placement.

Pain was discussed several times during the meeting, and key points are summarized here. With the PrePex device, pain at device placement was characterized as absent or minimal. During the study in Kenya, pain typically occurred on day 2 and 3 after device placement; perhaps more so among clients who did not elevate the penis in order to prevent oedema. Pain at the time of PrePex device removal was reported in all studies. The pilot study in Botswana found that removal pain varied from client to client; pain was always brief, but in some cases it was intense. The Kenya study found that, during the healing period after the device was removed, early sloughing of the resulting scab exposed the raw wound and was also a source of pain.

Odour was reported by several men in most studies. The impression from one investigator was that men with long foreskins were more likely to have problems with odour, but this has not been formally documented.

In the Botswana pilot study, uptake of MC with the PrePex device method seemed to be the same for high and low socioeconomic groups. However, some men seemed to be reluctant to undergo PrePex MC at the time of the study because it was still an "experimental device". Men who had undergone PrePex MC reported the need for more details in the information and education materials, including information on how the device worked; they thought this might be a means to potentially increase uptake. Employed men appeared to find the PrePex method more convenient than surgery; and, despite the pain and odour, clients circumcised using the PrePex were happy to recommend the PrePex method to others.

Key insights from bridging studies

Preliminary findings were shared from a bridging study conducted among adolescents aged 13–17 years in the Rakai Health Sciences Program, Uganda. Adolescents were given a choice between MC with the ShangRing, or conventional surgery using the dorsal slit method. Over 80% of adolescents selected the ShangRing in preference to conventional surgery, stating the following positive perceptions about the ShangRing: requires less time (83%), less painful since no sutures (77%), safer (56%) and faster healing (29%). Those who opted for conventional surgical method (<20%) shared the following negative factors or reservations: no time for the second mandatory visit, parents' refusal, method still experimental, and healing may take longer. Among the 384 adolescents who chose the ShangRing, 50 (13%) had to be converted to a dorsal slit MC; in 47 cases this was because the correct size of device was not available (underscoring the need to have the full range of device sizes available at the service delivery site). In the remaining three cases, the device slipped during placement, probably due to lack of competence by the provider (the events all occurred during the early phase of the study and involved the same provider). Few moderate AEs were reported; those that were reported included three insufficient skin removals (again, these all occurred early in the study) and one wound dehiscence that occurred 1 day after device removal. Wound healing with the ShangRing method took slightly longer than with the dorsal slit method, but appeared to be somewhat faster than in the studies on ShangRing use among adults.

At the time of the meeting, a Zimbabwe PrePex sizing study to enroll 400 adolescents had been initiated. A total of 142 of the targeted 400 procedures had been completed. Among the first 150 adolescents aged 10–17 years had the following distribution of device sizes:

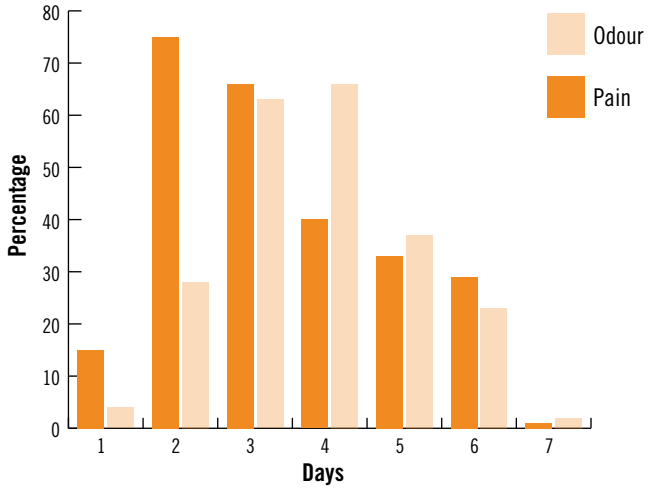
Adolescent device sizes (new sizes)	Adult device sizes (used in studies evaluated for males 18+ years)
<14 – 4%	A (26 mm) – 19%
14 – 17%	B (28 mm) – 23%
16 – 9%	C (30 mm) – 2%
18 – 12%	
20 – 13%	

Uptake had been slow, probably due to the end of the school year and exams. In this study, physicians performed the PrePex device procedures for the first 50 subjects in each of three age groups: 10–12, 13–14 and 15–17 years. There had been no device displacements or self-removals, and the subjective assessment from providers was that outcomes were better than in adults.

Other studies

A study conducted at the International Hospital of Kampala assessed data on odour associated with the use of the PrePex device. The odour peaked at days 3–4 post-placement, as illustrated in Figure 1. The odour was characteristic of anaerobes and it seemed that trapped moisture and urine contributed to it, as did long or thick prepuces; however, these observations all require further investigation.

Figure 1. Percentage of study participants experiencing pain or odour by day after placement of PrePex device, International Hospital of Kampala



The lead investigator in the Rwandan PrePex studies also described research on the management of odour associated with the PrePex device, generally noted at 3–7 days after device placement. More odour was found in those subjects having a long foreskin and poor hygiene, and various options for foreskin hygiene are therefore being explored to mitigate the odour. A small (n=100 men) RCT is planned with three arms:

- control;
- daily cleaning with soap and water; and
- daily injection of a diluted chlorhexidine solution using a syringe (without needle) followed by a clean water rinse.

Smell tests will be performed on days 3, 5 and 7 after placement of the device, by three independent masked assessors (i.e. unaware of which arm subjects are in) using a standardized method involving a "nasal ranger" device. The hypothesis is that odour will be reduced with chlorhexidine but not with soap and water.

Another study in Rwanda is investigating a revised method with the PrePex device, the aim being to increase the proportion of men eligible for the procedure. The clinical intervention consists of making a small incision in the foreskin under local anaesthesia in men with phimosis or a narrow foreskin opening, to allow placement of the device in the usual manner. Preliminary observations indicate that the elastic compression ring is sufficient to prevent any bleeding from the site of the incision.

5.0 KEY PROGRAMMATIC CONSIDERATIONS

5.1 Planning for successful scale-up

The Focal Point on Male Circumcision for HIV Prevention at WHO Headquarters gave an overview of key programmatic considerations for the introduction and use of MC devices in public health HIV programmes, based on insights drawn from studies and working groups. It is anticipated that, over time, more lessons will be learnt from the pilot and other introductory studies. It was emphasized that:

- a country's adoption of a new technology and taking it to scale are two separate processes, each of which requires careful planning;
- a phased approach to implementation is important to:
  - facilitate multiple stakeholder engagement;
  - build a favourable policy environment;
  - test the readiness of the health system to offer MC services that include MC devices, and monitor and report on device safety; and
- monitoring and evaluation activities include active surveillance of the first 1000 device procedures, followed by routine surveillance (or post-market vigilance) once the AE rate is considered acceptable; monitoring is also important for identifying potentially new types of AEs when a new method is used among a large number of men.

5.2 Pre-market approvals and post-market safety monitoring

The Focal Point at the WHO Department of Essential Medicines and Health Products outlined the key elements of pre-market and post-market regulation, both being equally important. Regulators need to find a good balance between ensuring the timely availability of a new technology on one hand, and ensuring its performance and safety on the other. Regulators, manufacturers, importers and distributors, and providers and users all have unique roles in the regulatory process:

- The **regulator** is responsible for licensing manufacturers and distributors in the country, listing medical devices, setting requirements for placing the device on the market and undertaking post-market vigilance.
- The **manufacturer** is responsible for implementing a quality-management system to ensure compliance with quality, safety and performance standards; and establishing procedures for post-market vigilance. This involves adherence to International Organization for Standardization (ISO) standards, continuous feedback on the performance of the device and corrective actions – all communicated through the appropriate channels.
- The **importer** and **distributor** are responsible for storage and transport, maintaining distribution records, interacting with national regulatory authorities and undertaking post-market vigilance.
- The **provider** or **user** is responsible for using the device according to its intended use, educating and counselling the client, and undertaking post-market vigilance.

All stakeholders have a role and responsibilities in post-market vigilance. This is a big challenge for all types of products under surveillance, particularly given the evolving nature of regulatory agencies in countries. Ministries of health have a key role in oversight and reporting. Unless all countries report the AEs that occur, it is not possible to track the ongoing safety of a product – the manufacturer cannot take corrective actions unless events are reported through the appropriate channels. Three factors occurring together trigger reporting of an event:

- the event has occurred;
- the device is associated with the event; and
- the event has led to one of the following outcomes:
  - death of a patient, user or other person;
  - serious injury of a patient, user or other person; or
  - no death or serious injury has occurred, but the event might lead to death or serious injury of a patient, user or other person if the event recurs.

Post-market surveillance has two aspects:

- proactive surveillance – monitoring performance prospectively (as in active surveillance of the first 1000 device procedures); and
- a reactive vigilance system, which comprises the notification of events as they occur.

In group discussion, it was noted that it is important to report both serious events and more minor events, since the latter may contribute to improvements (e.g. in the instructions for use). A standardized list of events, of "reasonable" length, would make the reporting system easier to use. Existing systems should expand to cover VMMC and device post-market vigilance, including the routine monitoring system, the MC task forces who may play a role in safety monitoring, and revision of quality assurance tools to include device aspects.

5.3 Stakeholder engagement

The National HIV Prevention Coordinator at the Ministry of Health and Child Care, Zimbabwe, highlighted the critical role of stakeholder engagement in the successful scale-up of the VMMC programme in Zimbabwe. It is part of Zimbabwean culture to engage stakeholders in planning and implementation of all public health interventions. A national multi-stakeholder meeting was held in 2008 to ensure a broad base of support for the decision to adopt VMMC as an additional HIV prevention intervention within Zimbabwe's HIV Prevention Strategy. The consultative process was not a one-time effort – it continues to the present day and includes technical working groups in the areas of advocacy and demand creation, training and service delivery, and policy and resource mobilization.

Parliamentarians are actively engaged in advocacy work, and the uniformed services assist in VMMC campaigns. Traditional and religious leaders advocate VMMC – to date more than 8000 boys have undergone medical MC as part of their traditional rituals. Celebrities, both male and female, champion VMMC – female celebrities encourage dialogue between women and their partners, promote the benefits of VMMC for women, and encourage women to support their partners during the required days of abstinence. A multi-stakeholder policy visit to Rwanda was organized, for participants to learn about the PrePex method.

From the group discussion, key issues and challenges to address with stakeholders included:

- organization of backup surgical services;
- coordination between procurement, supply and management (including waste) systems;
- prioritization of populations;
- determination of which methods need to be available at which sites;
- implementation of training; and
- safety monitoring.

Also raised for discussion was the question of whether traditional providers would be willing to use a device method. A general consensus was that traditional providers have not yet been engaged regarding devices; however, any provider who uses a device needs to be trained to use it competently. Another question was whether the gender of the provider makes a difference in acceptance of MC. In general, it was thought that this is not a major issue, although in some settings it may affect uptake.

5.4 Phased implementation

The Ministry of Health, Rwanda, has made the most progress in use of the PrePex device, and the Government of Rwanda plans to roll out this device using a phased-implementation approach, starting with a demonstration project: the "35k Pilot Project". The ultimate aim is to circumcise 2 million men. The 35k Pilot Project will begin in January 2014 with the introduction of the PrePex device at a limited number of central health facilities and district hospitals. The primary objective is to assess the safety and efficacy of the PrePex method when performed in routine "naive" settings outside a research setting. A secondary objective is to assess the operational requirements for scaling up services (including human resource requirements, best methods for sensitizing the public and creating demand, and building an optimal AE monitoring system). The PrePex VMMC method will be introduced one facility at a time. Several national training centres are being set up, and providers at each facility will be trained and supervised for a period. Only when a site is operating effectively and independently will the process be repeated at the next facility. This phased approach enables programme managers to scale up services while maintaining a measure of control; it also allows a degree of flexibility as experience accumulates.

5.5 Favourable human resource policies

The National HIV Prevention Officer at the Ministry of Health and Child Care, Zimbabwe, has taken steps to broaden the scopes of practice of registered general nurses and primary care nurses. The aim is to help overcome human resource shortages faced by the VMMC programme, particularly in rural areas, where 70% of the population lives. Steps have included:

- policy visits to Zambia and Kenya to learn how those countries addressed human resource challenges;
- advocacy and negotiations with health professional regulatory bodies, such as the Health Professions Authority (an umbrella body for regulation of health professionals) and the Nursing Council;
- revising the nursing curriculum for different cadres of nurses to incorporate minor surgical procedures such as MC methods; and
- using evidence from the PrePex clinical trials to inform national VMMC policy about which nursing cadres are authorized to perform MC, using which methods and under whose supervision.

Also needed are an evidence-based approach to policy-making, and a clearer process for reassigning tasks and responsibilities to other health professional cadres, particularly in the context of high-impact public health interventions such as VMMC.

The group discussion highlighted several issues: an inventory of the number of health-care providers available and their impact on targets would be useful in planning; existing policies on scopes of practice may need to be revised or broadened; a subregional meeting with medical and nurses regulatory bodies is needed, to advocate for revising the cadres permitted to perform MC with devices and broadening scopes of practice; and training with certification of competence and mentorship are essential to good-quality service. Training would probably be "targeted" to those providers already performing the service; it could be delivered through in-service education and phased training, together with the introduction of a device; this would avoid too many health-care workers being absent at one time.

5.6 Service delivery

WHO AFRO gave an overview of programmatic considerations for service delivery using MC devices including:

- physical facilities, equipment, pharmaceuticals and supplies;
- staff requirements and skills, including device-specific surgical backup requirements and skills;
- training;
- procurement, with the supply chain needing to be capable of handling multiple sizes of devices and accessories for device placement and removal;
- waste management;
- financing considerations; and
- the need for device-specific messaging.

It was emphasized that MC, regardless of method, is part of a comprehensive HIV prevention package that includes informed consent, HIV testing and counselling, prevention education and counselling, sexually transmitted infection (STI) management and condom promotion. Countries will need to develop device-specific clinical guidelines, and to refine and reinvigorate quality standards that build on the existing 10 WHO standards for surgical MC.[12] Finally, multiple modes of service delivery are possible – fixed, mobile and outreach – and the choice of the most appropriate mix of service delivery modes will depend on whether the necessary requirements for device use can be met. It was recommended that, whenever a device is introduced into a new mode of service delivery, an initial pilot project be undertaken before expanding to other sites.

In group discussion it was noted that countries will probably need to establish a policy regarding VMMC service delivery using in situ devices. For example, will the device method generally replace conventional surgical MC, with the latter being restricted to clients who are not eligible for the device method, or will clients have a choice between the two methods? Also discussed was the role of the health-care provider in following up men who have received the device.

5.7 Device-specific skills and training

The National MC Coordinator at the Ministry of Health and Child Care, Zimbabwe, emphasized the importance of training in use of the PrePex, even in settings where physician supervision was assured. In Zimbabwe, proficiency in the PrePex method was generally achieved after completing five or six MC procedures. The decision on supervision depends on the professional cadres. For example, in Zimbabwe, registered general nurses are supervised by physicians, and primary health nurses are supervised by registered general nurses. Surgical backup is required in case AEs should occur, and must be available when the method is rolled out to peripheral sites.

The skills requirements and training for the ShangRing device in Kenya were discussed by the medical research officer of the Nyanza Reproductive Health Society. To perform MC using this device, providers require basic surgical skills, including injection of anaesthetic, maintenance of a sterile field and suturing techniques. In Kenya, only physicians, clinical officers and nurses already trained in conventional surgical MC were offered training to perform ShangRing circumcisions. Conventional surgical MC training comprises 4 days of didactics and 1 day of observed practical (where trainees observe procedures performed by trainers), followed by 5 days during which the trainee assists in two MC procedures and then operates as lead surgeon on 20 MCs. ShangRing training for providers who are proficient in conventional surgical MC lasts 5 days; it comprises 1.5 days of didactics and 3.5 days of practicum, during which trainees must perform three circumcision procedures as an assistant and five procedures as a lead operator before being certified proficient. ShangRing training for providers who are not proficient in conventional surgical MC requires an additional 2 days of training. Since providers also require the knowledge and skills to handle intraoperative complications on-site, at least one member of the team must have these skills. ShangRing procedures require skilled backup similar to that required for conventional surgery.

A WHO urologic surgeon consultant spoke about the management of PrePex device displacements which, in the clinical trials, occurred in about 1 in 200 procedures. He discussed management under three possible clinical scenarios, as outlined below.

Scenario I: PrePex displacement with no adverse clinical signs

This clinical picture usually occurs within 4–6 hours of device placement, any swelling is minimal and distal to the line of placement, and the circumcision marking line is usually still visible. Management consists of repositioning or replacing the device if possible. If the device is displaced due to client interference, then it is advised not to replace it but instead to proceed to surgical MC by an appropriately trained competent provider. Surgical MC by the dorsal slit or sleeve method (described in the WHO/UNAIDS/Jhpiego *Manual for male circumcision under local anaesthesia*[13]) is preferred.

Scenario II: PrePex displacement with oedema

This clinical picture is usually seen within 4–6 hours of placement and before 3–4 days. Oedema may be very pronounced and may be proximal to line of placement. There may also be blistering, ulceration, loss of skin or necrosis. The marking line is usually visible and distinct, but may be distorted. When present, the marking line easily defines the plane of surgical resection. Management comprises surgical MC by the dorsal slit or sleeve

12 http://www.who.int/hiv/pub/malecircumcision/qa_guide/en/ and http://www.who.int/hiv/pub/malecircumcision/qa_toolkit/en/

13 http://www.who.int/hiv/pub/malecircumcision/who_mc_local_anaesthesia.pdf

method within 6–12 hours, performed by a trained competent provider who has the skill to deal with distorted anatomy. Local anaesthesia may not be needed. The forceps guided method is contraindicated. Clinical judgement must prevail regarding management, including referral to a more qualified or experienced provider.

Scenario III: Late displacement with advanced or complete foreskin necrosis

This clinical picture is usually seen 4–5 days after placement. The foreskin is partially or fully necrosed. Management involves excising the necrotic foreskin and the device rings as per normal removal. The wound is likely to be wider than normal (i.e. at 7-day removal) and there may be a delay in healing. Slight bleeding may require one or two sutures. Clinical judgement must prevail regarding management and referral to a more experienced provider.

5.8 Communication programming

The PEPFAR Senior MC Focal Point discussed communication about MC devices, noting that MC devices present an opportunity to inject new energy into VMMC scale-up efforts, and overcome some of the most common barriers (e.g. the prequalified PrePex device could help to overcome the fear of anaesthesia injection, cutting, bleeding and pain). Once the ShangRing device is prequalified, it could expand the choices available to clients. However, differentiating between methods is likely to complicate messaging, and the availability of multiple methods (and multiple sizes) may make meeting client demand more challenging. The appropriate mix of generic versus device-specific VMMC messaging will vary by audience, objective and knowledge levels. Messages need to be targeted to different audiences: policy-makers and decision-makers, providers and programme managers, communities and individuals, and media and journalists. Quality services are critical, as is conveying correct information (including information about the occasional complications that may require referral to qualified surgeons). Journalists may need support to understand and report accurately on MC devices; hence, it will be necessary to convene workshops for journalists.

The AVAC Global Advocacy for HIV Prevention MC Focal Point described the media as a key partner and advocate in VMMC programmes, which needs to be engaged. Hence, AVAC organizes media cafés (or discussion groups) in communities where VMMC is being rolled out, to allow media to be involved in discussions around key concerns with experts. Various questions have arisen through the AVAC managed listserv; for example, Although device methods may be easier and faster, what about odour, displacements and cost? It is important that the VMMC community manage expectations around devices in communities, and advocate for fair and affordable prices.

Jhpiego Headquarters staff presented an animation video clip produced by Jhpiego on the PrePex procedure. The clip will be adapted to different target audiences, including providers, clients before and after the procedure, and communities.

In the group work, client education and counselling were stressed as being critical to safe use of devices. Consistent and standardized messages need to be developed that realistically manage client expectations about eligibility, the procedure itself (e.g. two visits required), wound healing, benefits, risks and symptoms, including pain and odour (in the case of the PrePex device) and their management. Partners need to receive messages to be able to support safe behaviours with a device method. Existing counselling procedures and tools need to be adapted accordingly. To roll out the device it will be important to better understand their acceptability to clients.

5.9 Equipment and supply requirements at delivery sites

The Director of the Zimbabwe Gates MC Partnership Project, and Population Services International discussed medical equipment and supply requirements with devices at VMMC delivery sites; these requirements depend on the device as well as the service delivery model. A key question that will influence equipment and supply requirements is which methods will be offered in a single facility. Each method has unique requirements in terms of sterility of environment and equipment, surgical backup and emergency equipment. The ShangRing device requires a sterile field and instruments; thus, a system for cleaning and sterilization will need to be in place. Emergency resuscitation equipment and supplies are also required for the ShangRing methods, because injectable anaesthetic is used. Although the placement and removal of the PrePex device does not require a sterile field, sterile instruments were used in most clinical studies for removal of this device. Therefore, sterilization equipment for use of the PrePex device unless single-use or disposable removal kits are used.

One question raised in the discussion is whether sterile equipment is required for removal of a PrePex device, or whether high-level disinfection of reusable instruments would suffice. Backup emergency equipment and supplies are not required on a routine basis for the PrePex because no injectable anaesthetic is used; however, the equipment needed to manage AEs will need to be in place at the designated site for management of such events. Referral systems and supply chain management systems must be in place for equipment and consumables. Supplies and equipment for the minimum service package will still need to be available; such a package needs to include facilities that offer client privacy and confidentiality for HIV testing and counselling, STI management and waste management.

5.10 Procurement, supply chain and waste management

The Senior Biomedical Prevention Advisor from the United States Agency for International Development (USAID) discussed supply chain management considerations. Supply chain management is an essential element of a successful programme, and can represent 40–50% of programme costs. A standard commodities list needs to be developed, keeping in mind that the system becomes more complex and costly as more items are added to the list. For example, it would be advisable to harmonize the choice of ibuprofen or acetaminophen as an analgesic on the commodities list rather than listing both. Other considerations include:

- whether to use pre-packaged kits, and single-use or reusable instruments (there are advantages and disadvantages to each);
- importation regulations and warehousing; and
- the shelf life (currently 3 years for the PrePex device, which is an advantage because a better price can be obtained when large quantities are procured).

Multiple sizes and a mix of methods (device method versus conventional surgery) make forecasting complex. Quality control monitoring of supplies is important. The role of USAID supply chain management was discussed, including device procurement and quantification, as well as price negotiations. The issue of inadequate resources for MC waste management, especially in rural areas, was raised and discussed in group work.

5.11 Cost considerations

A consultant from Strategic Development Consultants, South Africa, discussed cost considerations. The chief cost drivers were human resources (clinical and non-clinical) and consumables; in particular, the cost of devices. The key programme elements that need to be costed include service delivery, demand creation, supply chain management, waste management (especially in outreach rural sites), programme management, and monitoring and surveillance. Expansion to new outreach sites may trigger additional costs. Although devices promise potential efficiencies, this will depend on having sufficient demand; therefore, it will be critical to match supply and demand in order to maximize efficiency. Unit costs vary dramatically with throughput and scale. Costs will depend on service delivery models, an appropriate mix of surgical versus device methods, integrated versus dedicated service sites, and use of disposable or reuseable instrument kits. Other considerations include the impact of devices for adolescent services, the willingness to incur higher incremental cost to achieve higher coverage levels, and the triggering of higher costs for related services such as STI management and HIV counselling and testing.

6.0 NEXT STEPS

6.1 Country action planning for the next 12 months

National programmes are at different stages of preparation for introducing and scaling up the use of MC devices as a new method of MC for HIV prevention. This situation was reflected in the key plans that countries have for the next 12 months. Each country planned to introduce and scale up the use of MC devices at a pace that is appropriate to its health system capacity and the resources available. The phased approach described by Rwanda reflects the intent of most countries; it is aimed at not overwhelming the service delivery system and providing sufficient flexibility to "learn as they go".

Currently, pilot studies on safety, acceptability and feasibility of using prequalified devices are planned or under way in most of the 14 VMMC priority countries. The PrePex, in particular, is being tested in a variety of routine service delivery settings, using diverse cadres of health professionals – physician and non-physician – and different levels of the health system. Several countries were also conducting bridging studies to safely extend the use of MC devices to other populations, in particular to adolescents, who make up a large proportion of VMMC clients. Those VMMC programmes that had already completed studies were developing a national strategy to scale up use of prequalified devices in their country.

Countries planned to develop and implement MC devices in consultation with a wide range of stakeholders, and in partnership with technical and funding partners. A number of countries planned stakeholder workshops to disseminate the new WHO guideline, share meeting outcomes and initiate participatory action planning for the introduction of devices. Sharing of results, advocacy and community mobilization processes is planned, to reinforce programme expansion and policy development. Substantial attention was given to establishing policies (e.g. expanding the cadres of health professionals who can use the devices), and technical, programmatic and managerial capacities essential for success.

Countries' plans include activities to ensure that all service delivery requirements will be in place, including assigning roles and responsibilities within the VMMC programme, in-country registration of devices, costing studies, identification of training sites and trainers, logistics, procurement, waste management, quality assurance, safety monitoring and demand creation.

6.2 Key meeting outcomes

The HIV Prevention Officer, WHO AFRO, summarized the key outcomes of the meeting. WHO has issued new guidance and a recommendation on the use of devices for adult MC for HIV prevention. The evidence that informed the recommendation was discussed, and the WHO prequalification for MC devices explained. Introduction of MC devices presents an opportunity to improve the entire package of MC services and programmes, including reaching priority age groups during the catch-up phase for which use of the device is currently recommended (i.e. men 18 years and above). Evidence on use of devices for males under 18 years will probably be available in 2014.

Key programmatic considerations for the introduction and use of devices were addressed. Various presentations helped participants gain insight into the programmatic challenges ahead of scaling up. Pilot studies to date have provided valuable lessons, and further studies will add to the information that needs to be shared across countries. Participants were reminded that, as with any medical intervention, there are benefits and risks to all MC methods, and a balanced perspective is needed. Participants were also reminded that all serious AEs to date have been successfully managed with complete resolution. The currently known risks with the devices can be mitigated through provider training, client selection, education and appropriate surgical backup services. Conventional surgical MC also has its risks, which are addressed by standard operating procedures. Introduction of a new method provides an opportunity to strengthen monitoring and reporting systems, regardless of the MC method.

6.3 The way forward

The Focal Point from WHO Headquarters highlighted the next steps. Countries have proposed specific next steps they will take, which reflect a phased-implementation approach that includes:

- sharing the WHO guidance with relevant colleagues and VMMC technical working groups;
- planning and engaging other key stakeholders – those who can "make or break" the use of the MC devices;
- drawing upon all partners, including WHO, to make maximum use of available resources;
- completing or initiating pilot projects, and using the lessons learnt to develop and refine the services and systems to support device use;

- incorporating plans into strategies and operational planning;
- refining tools for safety monitoring and quality assurance; and
- using the opportunity presented by this new method to strengthen monitoring and evaluation systems.

WHO will provide technical support as requested from countries; develop a short bulletin or policy brief on the recommendation and guideline to facilitate sensitization and advocacy efforts; convene a subregional meeting in 2014 to discuss device use by non-physician cadres, gain support on expanding scopes of work (particularly of nursing cadres), and prepare a statement on MC being performed by nursing cadres; re-inspect the site of the PrePex manufacturer when production moves to a larger scale; and incorporate feedback into the draft WHO complaint form, which is used by the WHO Prequalification Programme as part of post-market surveillance.

Finally, countries will be provided with updates should there be any evolution in clinical management or AEs. A small group will consider issues related to removal of the PrePex device, in relation to sterilization of instruments or high-level disinfection processes. Also, WHO plans to convene the WHO TAG on Innovations in MC during 2014, to review clinical safety data from the pilot studies with adults and data from the bridging studies in adolescents.

7.0 CLOSING SESSION

In closing, the Bill & Melinda Gates Foundation thanked participants for their valuable contributions, and observed that VMMC programmes are entering an exciting new phase of implementation. PEPFAR thanked WHO for the new guidance on the use of MC devices for HIV prevention, and noted that the progress reported by countries over the 2 days of the meeting was very encouraging. More than 5 million MCs have been performed, and MC devices present a remarkable new opportunity to accelerate towards the overall target of 20 million circumcisions. PEPFAR will continue to support countries in implementing this method of MC, provided the device is prequalified by WHO. PEPFAR sees the introduction of MC devices as an opportunity to examine and fix weaknesses in existing VMMC programmes.

WHO's Coordinator of HIV Prevention closed the meeting by saying that the first step was taken in device introduction by sharing and discussing the guideline, and that the next steps will be primarily at the country level. MC devices do not replace conventional surgical MC; rather, they present an additional option for MC, and provide a new impetus to revise and reinvigorate programmes. She remarked that MC was underfunded compared to other interventions in the HIV prevention toolbox, and urged countries to coordinate with the Global Fund Country Coordinating Mechanisms to include MC in national proposals. She reminded participants that the 2013 International Conference on AIDS and STIs in Africa was "around the corner", and presented a real opportunity to emphasize the MC work.

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ANNEX 2: MEETING AGENDA

DAY 1: WEDNESDAY 13 NOVEMBER 2013 Chair: R Baggaley		
08:00 – 08:30	**Registration**	
08:30 – 09:00	**Opening session**	**PRESENTERS/FACILITATORS**
	Welcome remarks	Ministry of Health, Uganda
	Security briefing	WHO
	Introduction of participants Objectives and agenda of the meeting	B Ncube (WHO)
	Remarks by partners	Bill & Melinda Gates Foundation
		PEPFAR
	Remarks by WHO	WR Uganda (WHO)
	Opening remarks	Ministry of Health, Uganda
09:00 – 11:30	**Session I: Guideline overview and clinical evidence**	
09:00 – 09:30	Guideline on the use of devices for adult MC for HIV prevention	J Samuelson (WHO)
09:30 – 10:00	Illustrated summary of device procedures	J Nkale (Uganda)
	Wound healing	E Odoyo-June (Kenya)
	Clinical evaluation of devices	T Farley (WHO Consultant)
10:00 – 10:15	Discussion	
10:15 – 10:45	TEA BREAK	
10:45 – 11:00	Researchers' comments on the PrePex device: • Eligibility • Adverse events • Acceptability	Chair: T Hargreave Panellists: V Mutabazi (Rwanda) M Galukande (Uganda) S Xaba (Zimbabwe)
11:00 – 11:15	Researchers' comments on the ShangRing device: • Eligibility and adverse events • Acceptability by users and clients	Panellists: R Zulu (Zambia) J Nkale (Uganda)
11:15 – 11:30	Discussion	
11:30 – 13:00	**SESSION II: Key programmatic considerations Part I: Planning for successful scale-up, regulation and policy**	**Chair: B Ncube**
11:30 – 11:40	Overview	J Samuelson (WHO)
11:40 – 12:00	Regulatory and safety considerations: • Pre-market approvals • Safety monitoring	I Prat (WHO)
12:00 – 12:15	Discussion	
12:15 – 12:45	Planning for successful adoption and scaling up: • Phased approach to implementation • Stakeholder engagement • Favourable human resource policies	Panellists: V Mutabazi (Rwanda) G Ncube (Zimbabwe) G Ncube (Zimbabwe)
12:45 – 13:00	Discussion	
13:00 – 14:00	LUNCH	

14:00 – 16:00	**Group Work I: Planning for successful scaling up, regulation and policy**	
14:00 – 15:00	Three topics to be discussed in parallel: 1. Pre-market approval and safety monitoring 2. Scopes of practice and use of devices 3. Moving from pilot to national implementation (including stakeholder engagement)	
15:00 – 15:30	TEA/COFFEE BREAK	
15:30 – 16:00	Feedback from groups followed by discussion	Group presenters
16:00 – 17:15	**Session III: Update on pilot, bridging and other studies**	**Chair: E Njeuhmeli**
16:00 – 16:10	Overview of ongoing and planned studies	R Ridzon (Consultant)
16:10 – 16:40	Key insights to date from pilot studies	Panellists: E Odoyo-June (Kenya) C Ntsuape/A Musiige (Botswana) D Loykissoonlal (South Africa) J Come (Mozambique)
16:40 – 17:00	Bridging studies on the use of devices in adolescents under 18 years	S Xaba (Zimbabwe) J Nkale (Uganda)
17:00 – 17:15	Discussion	
19:00	Reception	

DAY 2: THURSDAY 14 NOVEMBER 2013 Chair: A Thomas		
TIME	**ACTIVITY**	**PRESENTERS/FACILITATORS**
08:00 – 08.15	**Recap from Day 1**	**Rapporteur**
08:15 – 10:30	**SESSION IV. Key programmatic considerations Part II –service delivery**	
08:15 – 08:25	Overview of programme considerations: service delivery	B Ncube (WHO)
08:25 – 09:00	Skills, training and surgical backup needs:	Panellists:
	• Skills, training and surgical backup needs for the PrePex	S Xaba (Zimbabwe) V Mutabazi (Rwanda)
	• Skills, training and surgical backup needs for the ShangRing	E Odoyo-June (Kenya)
	• Management of displaced device cases	T Hargreave (WHO TAG co-chair)
09:00 – 09:10	Discussion	
09:10 – 09:30	Communication programming needs Engaging community: an example Animation clip on how to place and remove an elastic collar clamp device	J Reed (PEPFAR) Angelo Kaggwa (AVAC) T Adamu (Jhpiego)
09:30 – 09:40	Discussion	
09:40 – 10:20	Equipment and logistics:	Panellists:
	Equipment and supply requirements at service delivery sites	K Hatzhold (PSI)
	Procurement, supply chain and waste management	E Njeuhmeli (PEPFAR/USAID)
	Cost considerations	C Schutte (South Africa)
10:20 – 10:30	Discussion	
10:30 -11:00	TEA/COFFEE BREAK	
11:00 – 12:30	**GROUP WORK II**	
11:00 – 12:00	Four topics to be discussed in parallel: 1. Device-specific skills and training 2. Client education and counselling 3. Communication programming 4. Procurement, supply chain and waste management	
12:00 -13:00	LUNCH	
13:00 – 13:30	Feedback from groups followed by discussion	Group presenters
13:30 – 16:30	**SESSION V. Next steps**	**Chair: R Baggaley**
13:30 – 13:50	Partners' areas of support	Bill & Melinda Gates Foundation PEPFAR

13:50 – 16:30	**GROUP WORK III**	
13:50 – 15:00	Countries meet to identify key actions for the next 12 months	
15:00 – 15:30	**Report feedback**	**Group presenters**
15:30 – 16.00	TEA/COFFEE BREAK	
16:00 – 16:30	Summary of key points Next steps and way forward	B Ncube (WHO) J Samuelson (WHO)
16:30 – 17:00	**CLOSING**	
	Remarks	Bill & Melinda Gates Foundation
		PEPFAR
		WHO
	Closing remarks	WR Uganda (WHO)
END OF MEETING		

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