

# MEETING THE DEMAND FOR MALE CIRCUMCISION

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REPORT OF

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Written on behalf of all presenters, panelists and discussants  
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DEPARTMENT OF PREVENTION AND COMMUNITY HEALTH

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## EXECUTIVE SUMMARY

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### BACKGROUND

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Adult male circumcision is the first biomedical intervention for prevention of sexually transmitted HIV infection in adults with proven efficacy, in this case for heterosexual acquisition of infection among men. UNAIDS and WHO have issued recommendations for its implementation as part of a comprehensive HIV prevention intervention package, however scale-up of male circumcision faces challenges in many countries. One reason for this is the additional burden on the health care system, particularly on surgical services in the public sector. To achieve the maximum public health impact, programs that are scaled up should target the appropriate groups, employ cost-effective surgical methods and ensure an adequate supply of expertise and surgical materials.

The Forum for Collaborative HIV Research, in collaboration with the Bill and Melinda Gates Foundation, WHO and UNAIDS, organized the workshop “Meeting the Demand for Male Circumcision” in Kampala in March 2008. The meeting was attended by a broad spectrum of stakeholders involved in implementation of male circumcision, including academic researchers, bi- and multilateral organizations, implementing organizations, representatives from national male circumcision task forces, and health care providers including nurses, surgeons and urologists.

### MEETING OBJECTIVES

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The goal of the meeting was to focus on three main topics identified in previous meetings and pertinent to the scale-up of male circumcision:

- 1) To assess technical innovations for male circumcision that can facilitate the surgical procedure
- 2) To examine the role of demand forecasting for program planning and implementation
- 3) To determine the utility of kits of surgical consumables for male circumcision surgery and to examine overall supply chain considerations.

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## I. TECHNICAL INNOVATIONS FOR MALE CIRCUMCISION SURGERY

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Approaches to simplify the male circumcision procedure include surgical device assisted circumcision and non-device solutions for anesthesia, hemostasis, and wound closure.

Surgical devices have the potential to reduce the complexity and duration of the male circumcision procedure; however there is still insufficient independent data on their safety in adults, although approximately 20 devices are currently available worldwide. The existing devices can be categorized by their method of hemostasis into crush, clamp or ligature devices. Data from a first independent study of a clamp device was presented at the meeting, with the results cautioning against the use of this particular device in young adults. Newer concepts for surgical devices were presented for discussion, including an advanced necrosing style clamp and a temporary clamp with guided closure, however these concepts need to be developed further. Eventually, it is hoped that surgical devices can further improve the cost-effectiveness of male circumcision, particularly if they allow task shifting from surgeons to lower cadre health care workers.

Non-device innovation for the surgical procedures for local anesthesia, hemostasis and closure can reduce both discomfort and the skill level required to perform the surgery. Although several interesting options exist, all still require further clinical testing to

determine their applicability in the settings where they will be utilized, with special consideration required for stability and efficacy in warmer climates.

**Recommendations:**

*1. Prioritization of User Needs*

The user needs of each individual stakeholder were ranked in order of importance as follows:

**A. Patient**

1. Good pain control
2. Ability to quickly resume work (low return visits needed)
3. Simple post-operative instructions

**B. Administration (Ministries of Health)**

1. Effective control of HIV (method effectively removes enough foreskin)
2. Rapid uptake
3. Procedure does not disrupt clinic workflow

**C. Clinic**

1. Reliable hemostasis (and low rate of adverse events in general)
2. Easy to use and train – promotes/facilitates “task shifting”
3. Reliable to replicate over multiple patients

*2. User Requirements and Clamp Features/Benefits to Meet Requirements*

User requirements at the patient, clinician and supplier levels were described as follows:

User	Requirement	Description
<b>Patient</b>	HIV Protection	Removal of key foreskin regions most susceptible to HIV transmission
	Post-op Recovery	Healing time, comfort, duration, etc. of post-operative recovery phase. Cut quality is expected to impact this factor.

	Patient Acceptance	Desirability of procedure from a patient perspective; includes “cut tightness” (choice of loose or tight), pain and comfort during procedure, nature and severity of adverse events, scarring, sexual function and satisfaction. Current feeling is necrosing clamp would be preferred, and that guided closure would improve patient acceptance.
<b>Clinician</b>	Cut Speed (where applicable)	Time for clinician to perform the removal step.
	Ease of Use	Requirements for clinician experience and training, as well as device simplicity.
	Wound Closure (where applicable)	Requirements for sutures, need for follow-up visit for suture removal, strength of closure, and related issues. Necrosing clamp is regarded as best option right now, with guided closure (e.g. clamped while suturing) and improvement over conventional suturing.
	Procedure Time	Time with attending clinician to perform the full procedure.
	Consistency	Ability for procedure to be reproducible and repeatable regardless of clinician or subject. Improved cutting is expected to have leverage here.
	Safety	Device failure modes, including infection from aseptic conditions, injury to the glans and potential exposure of the medical staff to HIV.  Demonstrated efficacy of procedure in clinical trials. Need for surgical backup, remote or on site.
<b>Supplier</b>	Packaging and Distribution	Weight, size, number of stock-keeping units (SKUs) and other features related to getting the kit to where it needs to be used in a way that it can be used. Includes storage limitations (e.g. if a controlled ambient temperature is needed to maintain shelf life).
	Sizeability	Ability to fit geometrical size requirements, and other physiological differences, between infant, prepubescent, and adult populations.
	Cost	Cost per user, capital costs, distribution costs, potential for reimbursement, etc.
	Field Usability	Factors that influence use of the device in remote areas, including durability, disposability, power requirements, and auto destruct (reuse prevention) features.



Potential features and benefits to meet user requirements were also identified, again at the patient, clinician and supplier levels:

User, Requirements	Potential Features/Benefits to Meet Requirements
<p><b>Patient</b></p> <ul style="list-style-type: none"> <li>• HIV Protection</li> <li>• Post-op Recovery</li> <li>• Patient Acceptance</li> </ul>	<p><b>Control of how much foreskin is removed</b> – Maximum HIV protection</p> <p><b>Minimal to no bleeding</b> – Clamping prevents bleeding, only blood is from foreskin</p> <p><b>Protective Guard</b> – A cover for cutting area and foreskin to protect staff/patient</p> <p><b>Small Clamping Band</b> – Provides user with better post op experience</p> <p><b>Light Weight</b> - Provides user with better post op experience</p> <p><b>Operation completed at end of visit</b> – Cut and closed</p> <p><b>Control of how much foreskin is removed</b> – Maximum HIV protection</p>
<p><b>Clinician</b></p> <ul style="list-style-type: none"> <li>• Cut Speed</li> <li>• Ease of Use</li> <li>• Wound Closure</li> <li>• Procedure Time</li> <li>• Consistency</li> <li>• Safety</li> </ul>	<p><b>Designed for use by lower cadre staff</b> – Guided procedure</p> <p><b>Faster Operation</b> – the surgeon can supervise more cases done by other staff</p> <p><b>Disposable</b> – No need to autoclave device</p> <p><b>Auto-Cut</b> – Same cut every time, no sharps near patient or staff</p> <p><b>No scalpel required</b> – No sharp device required</p> <p><b>Consistent results</b> – Not operator dependent (first cut of the day same as last)</p> <p><b>Interlocks</b> – Ensures operations happen in proper sequence</p> <p><b>Auto-destruct</b> – Prevents reuse of device</p> <p><b>Protective Guard</b> – Cover for cutting area and foreskin to protect staff/patient</p> <p><b>Glans Protection</b> – Hard protective tube is always in place during device operation</p>
<p><b>Supplier</b></p> <ul style="list-style-type: none"> <li>• Packaging and Distribution</li> <li>• Sizeability</li> <li>• Cost</li> </ul>	<p><b>One Circumcision Kit fits all Adults</b> – Helps reduce supply line issues.</p> <p><b>Pre-Sterilized</b> – No sterilization required in the field.</p> <p><b>Requires no electricity</b> – No external power source required.</p> <p><b>One Circumcision Kit fits all</b> – <i>(Disposable Only)</i> Helps reduce supply line issues.</p>

<ul style="list-style-type: none"> <li>Field Usability</li> </ul>	<p><b>Pre-Sterilized – (<i>Disposable Only</i>)</b> No sterilization required in the field.</p> <p><b>Estimated Cost</b> – 15 – 20 USD for disposable. Durable version would be more.</p> <p><b>No need to re-supply Durable Model</b> – Designed to last many years.</p>
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### 3. Identification of Barriers to Acceptance

Main barriers to device acceptance and strategies to overcome these are listed here:

Barriers to Device Acceptance	Strategy or Actions to Overcome
Bias from clinical community - Expectation of large number of side effects - Need to provide training identical to surgical approach to deal with side effects - Extra training, supervision and monitoring burden on doctors and clinical officers	Develop and execute a robust trial to demonstrate proof of safety when used by target user AND good patient acceptance
Potential for adverse events to present well after the procedure	Use clinical proof that AE profile is at least as safe as surgical male circumcision
Patient acceptance of necrosing clamp staying on for several days is not good	Conduct patient outreach and educate on the outcomes with device  Design to minimize/optimize the time device must stay on.
Unclear regulatory pathway	Clarify individual country requirements and follow broadest possible pathway to satisfy individual country regulation
Long and potentially unreliable (off-continent) supply chain	Design most robust supply chain possible. Investigate the opportunity to develop and implement African manufacturing strategy (could be an industrial development project or not-for-profit corporation)
Potential for unauthorized and/or untrained use	Implement surveillance and security measures on supply chain  Implement fail-safes in device design  Establish a low price of procedure and advertise the

	quality and outcome benefits to patients to remove incentive for unauthorized use.
Potential of counterfeit devices	See above Investigate the opportunities for authentication and/or certification for products and packaging
Assurance of necrosed, compressed, scarred results is effective, safe and robust	Determine minimum effective dimensions for tissue post-operatively and validate the result obtained with production devices – standard medical device product validation protocols
Cost	Design device to be minimum cost (current rough order of magnitude (ROM) materials cost <2.00 USD) <ul style="list-style-type: none"> <li>- Minimize procedure cost (task shift)</li> <li>- Minimize program costs</li> </ul> Establish national tender pricing and eliminate or minimize commercial sales
Patient perceptions - time to return to sexual activity - discomfort post-op (weight, constriction, etc) - time to return to daily activity (work)	Demonstrate equivalence to surgical male circumcision Minimize the physical size/weight of clamp as much as possible Minimize time off
Assurance of removal of sufficient amount of foreskin to assure protective effect	Define minimum acceptable standard from current procedures and use this as definitive device design specification (3mm max tissue cuff proximal to corona – TBC)
Clamps currently associated with high infection rates	Design to minimize opportunity for infection
Damage to penis from mispositioned, misplaced or poorly clamped device Prevent torquing organ during placement or cutting – potentially irreversible damage to penis Risk of damage to frenulum and sexual function	Provide positioning features or guides Provide reversible lock for adjustment Make multi-step place/adjust/lock/cut process to minimize locking incorrect position Design cutting function and pathway to avoid damage to frenulum

Consistency of training	Comprehensive training (and train-the-trainer) programs to be rolled out to all users (consider a certification program?)
Patient anatomy variable make device difficult or dangerous to use	Identify and quantify as broad an anatomical variation as possible as a design specification  Develop a clear physical examination decision process so that user can quickly escalate non-conforming anatomy or physical anomalies
Requires a more comprehensive physical exam	See above  Enhance training for all users at all levels
Device design may not be appropriate for a large enough target population to make it cost-effective	See above  Minimize or eliminate adjustments  Conduct complete cost-effectiveness review prior to beginning scale-up to production quantities

### **Next Steps – Technical innovations**

- The two groups contracted by the Gates Foundation to develop recommendations for a prospective device will use the information and feedback gained during the meeting to produce more detailed device specifications that can then be demonstrated to providers. Alternative methods to assist male circumcision surgery, e.g. for wound closure, suture and local anesthesia, will also be considered.
- As most currently available devices are suboptimal for the purpose of adult male circumcision, only a limited number of candidate clamps would be shortlisted to undergo more thorough review by a clinician team and subsequently enter clinical testing:
  - a. The only clamps currently available in adult sizes include the Sunathrone clamp, SmartKlamp and TaraKlamp. The SmartKlamp is the only FDA approved clamp; data currently available on the TaraKlamp suggests it is suboptimal for this purpose.

- b. Testing of available devices by independent clinician investigators, e.g. to perform a case series of 30-40 surgeries, was recommended to document information beyond that available from the manufacturers. The importance of publishing any available data was highlighted. Clinicians present confirmed their willingness to participate in clinical testing of selected devices:
- In Uganda, testing could be possible in an urban setting where participants can be closely monitored.
  - Professional societies, including the African Gulf Society for Sexual Medicine (AGSSM) and the International Society for Sexual Medicine (ISSM) also expressed willingness to test surgical devices outside of the U.S. In general, US-centered studies were perceived as problematic, as indications for circumcision are very different in the US, and the resulting smaller numbers of patients would require multi-centre trials more difficult to conduct.
- Further clarification on the pathway for regulatory approval should be obtained in parallel to the development of initial clinical protocols. Consensus needs to be established among regulators, policy makers, clinicians and program managers on the minimum testing requirements for surgical male circumcision devices, including the type of study design (e.g. case series or randomized trial). A meeting will be convened by WHO later in 2008 for this purpose.

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## II. DEMAND FORECASTING

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Demand forecasting estimates effective market demand for efficient allocation of resources in programs. Main principles developed in 2006 by the Center for Global Development (CGD) specify that demand forecasting should facilitate decision making for the customer; occur within a relevant process and context; and utilize appropriate methodology and data. In the field of male circumcision, the data required to generate

demand forecasts remains scarce at present. Data from acceptability studies of male circumcision in various countries in sub-Saharan Africa have been the main source for estimating demand. An initial rough model was presented utilizing data from acceptability studies as well as demographic data, pegging demand within a wide range of between 24 and 56 million men; such models will need to be refined and updated with country-level data as this becomes available.

Issues related to availability of human resources to provide male circumcision services were briefly touched on at the meeting. The existing severe shortage of health care workers will necessitate task shifting in order to meet the expected demand for male circumcision services, with surgeons training and certifying health care workers to perform high quality procedures; this should also include appropriate training for traditional circumcisers. Assistance from abroad remains a controversial issue; members of various professional societies (International Society for Sexual Medicine, American Urological Association, US National Medical Association, African Gulf Society for Sexual Medicine) have expressed willingness to volunteer or be deployed to assist in short-term service delivery. Such work will be contingent on invitations from individual countries.

### **Recommendations**

1. The rationale for demand forecasting for male circumcision is as follows:
  - Document demand for the purposes of policy making
  - Budget for staff, supplies, facilities, communications, etc.
  - Establish baseline models that can be tracked and made more accurate over time
  - Prepare the environment, e.g., identify bottlenecks to enable mobilization of resources
  - Develop scenarios, e.g., to address pent up demand, and impact of “conditioning”
  - Inject a note of realism into planning

The timeframe for demand forecasts varies, from short-term ordering and annual budgeting to informing long-term capacity development.

2. Demand forecasting was seen as less useful if aggregate demand is greater than supply; when forecasts are unreliable because of heavy dependence on how programs are executed or through the influence of outside factors (e.g. lack of political will); or if there is not enough data available to draw meaningful conclusions. The forecasting exercise should not interfere with the delivery of valuable programs.
3. The main customers for demand forecasting were identified as follows:
  - Political leadership: to establish the call to action
  - Donors, ministries, implementers: to inform budgeting
  - Supply chain management and technical assistance groups: to inform planning
4. Data to be collected to inform demand estimation should include demographic and social data:
  - Impact on demand of:
    - ⇒ Service location
    - ⇒ Quality
    - ⇒ Community location
    - ⇒ Opinion leader view
    - ⇒ Perception of benefits
    - ⇒ Leader country experience
  - Acceptability of infant circumcision in cultures that practice male circumcision as rite of passage
  - Demand for traditional circumcision
  - Urban/rural population breakdown

- Population by age
  - Circumcision % by age
  - HIV prevalence by age and male circumcision status
  - Impact of offering testing on acceptability of male circumcision
  - Price elasticity of demand
  - Willingness to travel
  - Target risk group size/characteristics/demand
5. Participants recommended the development of a demand forecasting toolkit that could be incorporated into existing toolkits, such as the UNAIDS decision makers' program planning toolkit currently under development or situation analysis toolkits.

#### **Next Steps – Demand Forecasting**

- A grid will be developed to classify data needs; this should include:
  - the importance or ranking of each parameter
  - model sensitivity
  - considerations on ease of collection for the data required, and existence and availability of data from other sources.

A core working group will focus on developing a framework for data collection and how this data will inform decision making, as well as assessing how much data is already available from countries for each portion of the grid. Opportunities for data collection will be identified, particularly in the context of ongoing and new programs or research studies. The data collected should serve to capture both the current or baseline conditions and ultimately support data collection at the national level. It can also serve to strengthen existing tools through input of real data.



- Factors affecting acceptability of male circumcision at the policy level should be further explored to identify specific data necessary to support advocacy. Demand forecasting can thus play an important role in driving policy.
- Male circumcision demand forecasting should be added to existing decision makers and situation analysis tools developed by WHO, even if initially based on rough estimates. It was requested that these tools be reviewed to ensure that they adequately address demand estimation, as opposed to being focused primarily around need.
- There was a general call to document and publish results of any ongoing research so that experiences can be shared.

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### III. KITS AND SUPPLY CHAINS

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As pilot male circumcision programs are already underway, one of the biggest and most time-consuming challenges is to obtain sufficient, high quality surgical supplies and equipment. Procurement of supplies may occur either at the national or international level; while international procurement has the potential for greater cost reduction, national level procurement is better adapted to local conditions and strengthening of existing supply chains. Policy makers and program planners can decide to supply items required for the male circumcision procedure individually or consider supplying them in standardized kits; similarly, it is possible to use existing or separate supply chains to deliver these supplies. Grouping consumables into *kits* for a single male circumcision procedure at a set cost is one approach to ensure high quality products regardless of setting and to simplify ordering of supplies. Similarly, standardized *modules* of reusable instruments and other equipment could be provided to facilities as needed. The final strategy adopted should reflect local conditions, and can be developed based on a procurement strategy matrix.

**Recommendations:**

1. Procurement and kit assembly

Procurement of supplies can occur either at the national or international level; while international procurement has the potential to achieve greater reduction in costs through negotiations with suppliers, national procurement would be more adapted to local conditions and has the potential to further strengthen national supply chain systems. While no final recommendation could be made on the process to be adopted for supply procurement, it was agreed that packaging of kits should occur at the national level where possible, ideally in the form of income-generating projects for local groups.

2. Kit contents and monitoring of distribution

Male circumcision supplies can be provided in the form of *kits*, containing consumables for a single male circumcision procedure; and *modules*, containing reusable clinic supplies, instruments and equipment.

International HIV treatment and family planning programs provide good examples for successful procurement activities. However supplies for male circumcision are not male circumcision-specific but rather belong to the category of general surgical supplies that are not limited to use in male circumcision alone. This presents additional challenges to be considered in the monitoring of distribution, particularly when male circumcision-specific supplies are provided to surgical centers in the public sector that have been largely under prioritized for funding in the past, with the potential for use of supplies beyond male circumcision services.

3. Private sector involvement

In order to maximize available services to meet male circumcision demand in the near future, mechanisms to involve the private sector, including faith-based health facilities, need to be explored to alleviate the anticipated burden on surgical services in the public

sector. A client-driven voucher system was recommended that could be used to support the provision of both consumables and male circumcision services in general. This would give more access to private providers and provide quality assurance mechanisms for the conduct of procedures in these settings.

The role of various stakeholders including national ministries of health and international donors needs to be further defined. In the short term, it is likely that individual programs with funding for male circumcision services will have to move ahead with individual procurement systems. However, the long-term goal should be to establish procurement systems at the national level, as has been achieved with HIV treatment programs such as PEPFAR.

#### **Next Steps – Kits and Supply Chains**

- National level: Countries with male circumcision task forces should include a point person or subcommittee to prioritize supply chain issues, so that this component of programs is planned prospectively. This subcommittee will convene a group to identify the contents of kits and/or modules. The components of kits will vary, depending on local preferences for supplies and method of male circumcision surgery. Input on the content of kits should be gained from mid-level providers who will be performing the male circumcision procedure.
- International level: An international task force with supply chain expertise should be formed to advance this agenda. This group could also address the issue of prequalification of supplies and instruments to avoid distribution of substandard supplies; UNFPA should be involved in these efforts. At the international level there are additional opportunities for price negotiations, provided larger numbers are being procured.
- Links should be established between supply chain groups, demand forecasting experts and programs near implementation.

## INTRODUCTION

Adult male circumcision is the first and thus far only proven efficacious biomedical intervention for the prevention of sexually transmitted HIV infection in adults – in this case, of sexually acquired HIV infection among men. Unfortunately, proven efficacy and effectiveness do not immediately translate into policy, nor do supportive policies translate quickly into program implementation. For example, the efficacy and effectiveness of antiretroviral drugs to prevent perinatally acquired HIV infection in infants has been clearly demonstrated, the data available for over a decade; the intervention is arguably simpler to implement than adult male circumcision, and supportive policies were adopted worldwide, yet uptake had reached a bare 23% on the global scale by 2006 [1]. Successful uptake of male circumcision by programs and communities will require proactive planning, resourcing and support in order for the potential impact on the epidemic to become evident.

Following the release of the data from the three randomized trials of adult male circumcision [2-4], UNAIDS and WHO released recommendations for the implementation of male circumcision as a prevention intervention [5]. Several countries have also adopted policies endorsing adult male circumcision. However, scale-up of adult male circumcision will likely be challenging for many countries. There are two main reasons for this. First, the procedure has social, cultural and religious meaning associated with it. Implementing male circumcision in places where it is traditionally performed by different ethnic groups, or where it has not been practiced at all, may be complicated. Second, the introduction of a surgical procedure in under-resourced settings may put undue strain on the health system, requiring many more health workers than are available. This meeting was called to explore innovations to support implementation of male circumcision that could reduce additional burdens on the health systems.

The *Meeting the Demand for Male Circumcision: an assessment of what is needed* workshop<sup>1</sup> in Kampala fits under the umbrella of the Forum's project on Biomedical Interventions for the Prevention of HIV Infection, initiated in September 2006 [6] and is in line with recommendations made at that meeting.

This meeting also fits into the context of a series of WHO and UNAIDS meetings on male circumcision<sup>2</sup>, starting with the workplan and action planning that took place as the evidence began to emerge from the randomized clinical trials in 2005; through national and regional consultations in 2006; global technical consultations on programming, social science perspectives, integrations of adolescent sexual and reproductive health; to the March 2007 WHO/UNAIDS International Technical Consultation which recognized and endorsed male circumcision as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men [5]. Additional meetings since then have included Eastern and Southern Africa Consultation on Safe Male Circumcision (May 2007, Harare), Operations Research Priorities (Nairobi, June 2007), Situation Analysis and Certification and Quality Assurance for Male Circumcision Services.

Parallel efforts have focused on mathematical modeling of the potential impact of male circumcision at the public health level in different regions<sup>3</sup>. In November 2005, the framework for modeling studies was set by a group of experts who met in Geneva to discuss evidence, data needs, questions to address in modeling, as well as methodologies most appropriate for public health impact modeling. Two years later, in November 2007,

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<sup>1</sup> Meeting materials including individual presentations and additional resources are available online: <http://hivforum.org/projects/Male%20Circ.html>

<sup>2</sup> See presentation by Tim Farley, <http://hivforum.org/projects/Male%20Circ.html>

<sup>3</sup> See presentation by Cate Hankins, <http://hivforum.org/projects/Male%20Circ.html>

experts met again in Stellenbosch, this time to review and compare the results of various public health impact models. A further meeting in March 2008 compared further developments of the models and a consensus statement from that meeting will be published shortly.

This meeting was organized to address three specific topics identified in previous meetings and pertinent to the scale-up of adult male circumcision: 1) the potential utility of surgical devices to facilitate the male circumcision procedure (reducing the amount of time and/or expertise required without jeopardizing safety); 2) the utility of supplies kits in supporting program implementation; and 3) the role of demand forecasting in program planning.

## BACKGROUND

With 6800 new HIV infections daily, the need for prevention interventions to reduce HIV transmission is clear and urgent [7]. Behavior change interventions (e.g. reducing the number of partners, increasing the age of initiation of sexual activity, increasing condom use), routinization of HIV diagnosis and expanded access to care, and socio-political leadership may have contributed to reducing incidence of infection in some regions; however, clearly these have not been sufficient to control the epidemic. Broadly implementable biomedical interventions such as vaccines will not be available in the near future; other modalities such as microbicides and Pre-Exposure Prophylaxis (PrEP) are still in research phases. It is hoped that these interventions will prove to be efficacious and provide a range of interventions for women and men. Current attention is focused on the scale-up of adult male circumcision.

The mechanism of action of male circumcision for reducing acquisition of HIV infection by men during heterosexual sex is biologically based. The working hypothesis is that the removal of the foreskin significantly reduces the number of target cells available for the uptake of HIV infection [8, 9]. In addition, male circumcision may contribute to lower incidence of other sexually transmitted infections and provide benefit to women by lowering the risk for HPV infection and cervical cancer. The evidence in support of male circumcision in the HIV prevention arena comes from decades worth of epidemiological research [10], and three randomized clinical trials conducted in Africa [2-4] clearly demonstrating a 50-60% reduction of infection risk among HIV uninfected men. Several research questions remain unanswered, including the impact of male circumcision on transmission of HIV from men to women, and from men to men for men who have sex with men. Although the impact of male circumcision in reducing infection risk is significant, it does not provide absolute protection, and should be viewed as part of a comprehensive package of HIV prevention interventions. Importantly, combining

interventions can achieve synergy – where each intervention increases the other’s effect in reducing transmission<sup>4</sup>. To maximize the benefits and make the best use of precious resources, each intervention needs to be directed effectively – i.e. at the appropriate group. [11, 12]

Mathematical models investigating the potential public health impact of male circumcision indicate a potential direct effect of up to 30% reduction of HIV infection in male populations over 10 years, with an indirect effect on female populations estimated at 15% reduction (Stellenbosch 2007 meeting report, in preparation). The impact and cost-effectiveness will be dependent on who is targeted for male circumcision (e.g. 20-34 year olds vs. 15-24 year olds, with the former contributing more impact in the first 20 years, whereas the latter show a slower but more lasting effect) and the pace of the scale-up.

Between demonstration of efficacy and effective program uptake, there are knowledge gaps regarding approaches to successful implementation and scale-up of an intervention [13]. Challenges in implementation of adult male circumcision are many, including those from the patient perspective, the practitioner/implementer’s perspective and the health system perspective<sup>5</sup>. Patients are frequently from the rural setting, affected by issues such as poor hygiene and lack of water. They are likely to be from poor socio-economic status with a low level (or no) formal education. Transport and communication facilities are poor, and there is a high prevalence of use of traditional healers. Patient expectations include good pain control, few post-operative visits, simple/clear post-operative instructions and the ability to return to routine activities sooner rather than later.

<sup>4</sup> See conference presentation by Peter White (<http://hivforum.org/projects/Male%20Circ.html>)

<sup>5</sup> See conference presentation by Stephen Watya (<http://hivforum.org/projects/Male%20Circ.html>)



From the practitioner's perspective, the procedure should be easy to perform, be safe, and be highly replicable when performed by trained providers. The health system infrastructure challenges are great. They include the existence of few surgical facilities that meet the required standards for safety and quality; difficulties with the ability to manage complications and follow-up, maintenance of a regular supply of surgical materials, all in the face of competing demands for the surgical facilities. From the administrator's perspective, male circumcision programs should facilitate rapid uptake, while not affecting routine provision of health care, should be affordable and of course, effective in HIV prevention.

Thus, to maximize the public health impact of scaling up efforts, careful attention needs to be paid to targeting the right groups (which necessitates that demand be present in these groups), to finding the most cost-effective surgical method (a discussion of which includes the potential utility of surgical devices) and to ensuring an adequate supply of expertise and surgical materials. These considerations provide the rationale for the three topics which were the subject of this meeting.

## A. OVERVIEW AND CURRENT STATUS

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### I. TECHNICAL INNOVATIONS FOR MALE CIRCUMCISION SURGERY

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Commonly applied methods for adult male circumcision surgery include the forceps guided method, the dorsal slit method and the sleeve method [14]. Potential improvements to male circumcision surgery should address ease of use by a range of providers, patient comfort and duration of procedure while maintaining safety, surgical quality and cost effectiveness. Approaches include optimizing surgical device-assisted circumcision (which mimic the forceps guided surgical method) as well as non-device solutions to facilitate the procedure.

#### ***Surgical devices for male circumcision***

##### 1. Landscape of surgical devices for male circumcision<sup>6</sup>

Over 20 surgical devices for male circumcision have been identified, produced in a variety of countries. Main practical features of a device are to protect the glans during the procedure, position the foreskin to remove a controlled amount of tissue and to minimize blood loss. Surgical devices should be sterile, easy to use, associated with a low adverse events rate and achieve an acceptable cosmetic result. The ideal device will reduce the duration and complexity of the male circumcision procedure, and allow the surgery to be performed by mid-level healthcare providers. Devices should also be associated with a low overall cost; cost savings can be expected in terms of procedure costs when

<sup>6</sup> See meeting presentation by Reade Harpham, <http://hivforum.org/projects/Male%20Circ.html>

comparing surgical devices to other surgical methods, although costs for additional training, counseling, etc. need to also be considered.

The devices currently available can be categorized based on the method of hemostasis, as either crush, clamp or ligature devices. Clamp and ligature devices are designed to achieve necrosis and thus need to be worn for several days. A comparison overview of each type of device is shown in the table below (adapted from R. Harpham, representing Battelle):

<b>Type of device</b>	<b>Examples</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b><i>Crush</i></b>	Gomco clamp, Mogen clamp	<ul style="list-style-type: none"> <li>-Does not need to stay on the patient</li> <li>-Works well with infants</li> <li>-Sutures are not typically required for infants</li> </ul>	<ul style="list-style-type: none"> <li>-Only crushes the tissue, may not always prevent bleeding in adults</li> <li>-No information on adult use</li> </ul>
<b><i>Clamp</i></b>	Ali's Klamp, Ismail clamp, Sunathrone clamp, TaraKlamp, SmartKlamp,	<ul style="list-style-type: none"> <li>-Perceived ease of use - no knots or sutures</li> <li>-Reliable hemostasis</li> </ul>	<ul style="list-style-type: none"> <li>-Must be worn from 3 to 12 days, depending on device</li> <li>-Can be uncomfortable due to size</li> <li>-Patient may experience pain due to difficulty during removal</li> <li>-Potential for complications if swelling or erection occurs.</li> </ul>
<b><i>Ligature</i></b>	Plastibell, Circ-Ring	<ul style="list-style-type: none"> <li>-Small size when compared with clamps</li> <li>-Potentially less discomfort for patient</li> <li>-Reliable hemostasis</li> </ul>	<ul style="list-style-type: none"> <li>-High potential for self-use error (Circ-Ring)</li> <li>-Can be difficult to hold in place while tying ligature</li> <li>-Must be worn from 3 to 7 days, depending on device</li> <li>-Little information regarding use on adults</li> <li>-Potential for complications if swelling or erection occurs</li> <li>-Requires proper technique to reduce complications</li> <li>-Clinic must stock multiple sizes</li> </ul>

## 2. Performance data on existing surgical devices

Performance data for existing devices is generally lacking, and available data typically originates from the manufacturers. The suitability of the existing devices for adult male circumcision has yet to be established; many were developed for pediatric or pre-

adolescent circumcision. As a result, there is an urgent need for clinical data on the utility and performance of existing surgical devices, ideally to be obtained in the settings where adult male circumcision programs are to be established.

Bertran Auvert presented data from a first independent study of the TaraKlamp, a device developed in Malaysia. Previously, an unpublished report from Thailand had shown a high rate of adverse events (32%) with use of the TaraKlamp in adults, compared to a much lower rate (1%) in patients circumcised with the traditional surgery. However, results published from tests of the device in children showed good outcomes in terms of safety, pain and cosmetic result [15, 16]. The results of the study from South Africa caution against the use of the TaraKlamp in young adults, and confirm the need for descriptive studies to characterize existing male circumcision devices.

### 3. Technical innovations for surgical devices

Additional new concepts for surgical devices solutions were presented by PA Associates for discussion<sup>7</sup>, including an advanced necrosing style clamp and a temporary clamp with guided closure, however, these approaches will require provider input to develop further.

### *Non-device innovations for male circumcision surgery*

Alternative methods presented by JHPIEGO include innovations in procedures for anesthesia, hemostasis and closure<sup>8</sup>. These can contribute to reducing discomfort and the skill level required to perform the procedure.

<sup>7</sup> See presentation by Don Walsh & John Gola, <http://hivforum.org/projects/Male%20Circ.html>

<sup>8</sup> See presentation by Kristin Chrouser, <http://hivforum.org/projects/Male%20Circ.html>

## 1. Anesthesia

The need for injections to administer local anesthesia is a possible deterrent for use of services. It is also challenging to novice providers, with potential for complications. Alternatives to ring or dorsal block via injection include topical anesthetic agents, formulated as creams or gels that could be applied in condoms prior to the procedure, or as patches. These approaches require clinical testing to determine whether they will be appropriate to meet the requirements for male circumcision surgery and how they perform compared to anesthesia administered by injection.

## 2. Hemostasis and Closure

Successful hemostasis requires careful patient selection and use of appropriate intraoperative techniques. Postoperatively, hemostasis is maintained through preventive measures and timely management of postoperative complications. Various advanced technologies are available, such as medical glues/sealants, absorbable staples and impregnated dressings, which could be evaluated for use routinely or in case of complications, also taking cost considerations into account. However, these technologies also still need to be tested to determine their stability particularly in warmer climates; for example, tapes and adhesives adhere poorly and cannot be stored in environments with higher temperatures. Many of these materials would thus require adaptation for use in different settings in sub-Saharan Africa.

### *Cost considerations*

There is strong evidence supporting the cost-effectiveness of male circumcision, with the cost per HIV infection averted significantly lower than that of HIV care and treatment [17]. However, there are constraints in both funding and in the availability of human resources, requiring a high level of efficiency for optimal use of the available resources.

A draft framework to assess the cost of male circumcision surgery was presented by James Kahn<sup>9</sup>, which calculated the total estimated cost per circumcision at 40-50 USD (including counseling, pre and post op visits, supplies, etc. and assuming that a surgeon/assistant pair performs between 10 and 15 circumcisions daily). Based on the salary and work time assumptions of the preliminary model, this corresponds to a core cost of surgical health care worker time of between 8 USD (15 circumcisions daily) and 12 USD (10 circumcisions daily). The cost of newborn male circumcision is generally estimated to be about a third of adult male circumcision.

It is hoped that surgical devices could serve to lower costs compared to traditional surgical methods, particularly if they present opportunities for task shifting from surgeons to lower cadre health care providers to perform the circumcision procedure.

<sup>9</sup> See presentation by James Kahn, <http://hivforum.org/projects/Male%20Circ.html>

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## II. DEMAND FORECASTING

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The purpose of demand forecasting is to estimate effective market demand, i.e. product needs that will result in actual orders, in order to assist with efficient allocation of resources. Demand forecasting should not be confused with needs estimation, demand creation or target setting tools. The Center for Global Development (CGD) convened a Global Health Forecasting Working Group in 2006, which outlined main principles of demand forecasting [18]:

1. Customer focused: to help customers make decisions
2. Process and context-focused: to make the forecast relevant in the overall market and policy environment
3. Methodology- and data-focused: to select the right methods and effectively incorporate qualitative and quantitative information.

Demand forecasts require input of an assortment of data (qualitative and quantitative) to determine adoption rates, levers of engagement, downside risk, etc. Challenges exist in domains such as male circumcision where there is a scarcity of published data available to inform forecasts<sup>10</sup>.

Studies have been conducted to determine the acceptability of and barriers to uptake of male circumcision in various countries in sub-Saharan Africa. Kawango Agot<sup>11</sup> presented a review of 13 acceptability studies conducted in nine countries between 1991 and 2006 finding willingness among men to be circumcised ranging between 25 and 87% (median: 65%); similarly, willingness among women for circumcision of their partner ranged

<sup>10</sup> See presentation by Philip Baciaz, <http://hivforum.org/projects/Male%20Circ.html>

<sup>11</sup> See presentation by Kawango Agot, <http://hivforum.org/projects/Male%20Circ.html>

between 47 and 79% (median: 69%). Facilitators of male circumcision included penile hygiene, protection from sexually transmitted infections, acceptability by other ethnic groups, enhanced sexual pleasure and aesthetic appearance. Main barriers included pain, cost, time off work, and cultural/religious reasons.

There is a need for additional data beyond acceptability studies to strengthen demand forecasting models. An initial model developed by the Clinton Foundation<sup>12</sup> to estimate demand incorporates demographic information and data available from acceptability studies as a first step in the demand forecasting process. These rough estimates peg demand within a wide range of between 24 and 56 million men; such models need to be updated with data as new evidence from programs becomes available. This again demonstrates the need to document and publish research data to inform implementation efforts. Only rough estimates can be generated initially; more refined forecasts will require national-level assessments of male circumcision policy. While some data exists to estimate the impact of targeting certain groups for male circumcision (e.g. based on age), there is little data on the impact of cost or distance to services on demand.

### **Human resource considerations**

The severe and ubiquitous shortage of health care workers in sub-Saharan Africa necessitates task shifting in order to be able to offer male circumcision services, even if these will still be insufficient to meet demand. Surgeons should train, certify and supervise health care workers to conduct high quality male circumcision. Countries have differing laws governing who can perform male circumcision procedures; nurses can provide male circumcision services if they are certified in the procedure in some countries, and not in others. Traditional circumcisers also play an important role, and should be trained in infection control procedures, achieving hemostasis and referring

<sup>12</sup> See presentation by Jessica Fast, <http://hivforum.org/projects/Male%20Circ.html>



cases with complications (UNAIDS has developed a best practices guideline for collaborating with traditional healers for HIV prevention and care in sub-Saharan Africa[19]).

Short-term assistance from abroad is a controversial topic; while some countries prefer to focus on mid- to long-term solutions for health system strengthening and resolution of human resource crises, others are open to the concept of inviting foreign providers to conduct surgeries over limited periods of time. In some countries, this has already been implemented for other diseases, e.g. for cataract surgeries in India. Financing for such short-term programs may be unclear, but volunteers from various urological, surgical and medical societies (including the International Society for Sexual Medicine, the American Urological Association and the US National Medical Association) have expressed interest in assisting with short-term service delivery on invitation.

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### III. KITS AND SUPPLY CHAINS

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Pilot circumcision programs are already underway; Mary Stopes International is running a program in Kenya<sup>13</sup>, where mid-level providers performed over 2,500 male circumcision procedures between May and December 2007, with an average of 20-25 procedures performed per day by one to two providers. Early lessons learned from this program underscore the need to train providers in wound care and treatment of complications (observed here at an estimated rate of <2%/month), and showed that providing all aspects of the procedure in addition to HIV counseling and testing was challenging in terms of time, staff and resources, particularly in the setting of mobile services.

#### **Grouping supplies in standardized kits and modules**

One of the biggest challenges is ensuring that sites have sufficient and high quality supplies and equipment. Local medical suppliers may not often have access to all necessary items and have difficulty sourcing internationally. Much valuable time is spent trying to solve supply issues. Kits that group consumables required for a single male circumcision procedure, ideally at a set cost, have the potential to support scale-up by ensuring high quality products regardless of healthcare setting and simplifying ordering of supplies. This is particularly important in facilities without equipment for sterilization and with general scarcity of supplies.

Several kit approaches are in development. A kit containing various consumables required for forceps guided circumcision, costing approximately 17 USD, was recently developed and tested in South Africa for this purpose, with good results showing

<sup>13</sup> See presentation by Michael Oyah & Heidi Quinn, <http://hivforum.org/projects/Male%20Circ.html>

equivalence to the optimal use of conventional instruments and consumables [20]. Initial experiences with the development of kits by PSI in Zambia<sup>14</sup> show that packaging and shipping comprises up to a quarter of kit costs. Opportunities for cheaper packaging and assembly of kits need to be explored.

In addition to kits that contain consumables for a single procedure, standardized but flexible “modules” of reusable instruments, equipment and infection control supplies can be provided separately, particularly to high volume health care facilities.

### **Supply chain considerations**

Desired outcomes for supply chains include uninterrupted product supply reaching the intended recipients, and secure, agile supply chains with minimal waste or leakage that can accommodate unpredictable use of products. Experience of the USAID | DELIVER and SCMS Projects with supply chains in sub-Saharan Africa underscores the many challenges faced, including poor storage facilities, weak transport, problematic customs, diversion of products, inadequate training<sup>15</sup>.

Decisions faced by policy makers and program planners include whether to utilize standardized kits/modules or to supply items individually, as well as selection of items and kit contents. The choice of supply chain also needs to be determined; supplies for male circumcision could be integrated into existing supply chains or delivered separately. Procurement sourcing and the strategy adopted should reflect local conditions. Use of kits will require longer planning, and add time and cost. However, while simply adding volume to existing quantities of routine items is likely to be most cost effective, it is also

<sup>14</sup> See presentation by Steve Gesuale, <http://hivforum.org/projects/Male%20Circ.html>

<sup>15</sup> See presentation by Yasmin Chandani & David Jamieson, <http://hivforum.org/projects/Male%20Circ.html>

more likely to result in program delays if stock outs occur. To inform programming decisions and achieve effective supply management, a procurement strategy matrix [21] can be employed, ranking supplies by importance and complexity of supply market, thus identifying strategic items, bottleneck items, leverage and non-critical items specific to male circumcision programs.

## **B. RECOMMENDATIONS AND NEXT STEPS**

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Breakout sessions were held for participants to discuss the three focus areas: 1) technical innovations for surgery; 2) demand forecasting; 3) supplies and kits, and then develop recommendations for the way forward and formulate next steps.

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### **I. TECHNICAL INNOVATIONS FOR MALE CIRCUMCISION SURGERY**

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Battelle and PA Consulting Group are both contracted to investigate and develop device solutions for adult male circumcision. Three separate group consultations were held to ascertain and prioritize user needs, device features and barriers to entry for potential device solutions.

#### *1. User Needs Assessment – Forced Choice Exercise (developed by Battelle)*

##### Background:

The “user needs” breakout group focused on gathering the latent user needs of each of the stakeholder groups in male circumcision. Each of these stakeholders has specific wants and needs that they feel are the most important. However, in order to move the device concepts forward, the group must come to a consensus on which needs are the most important. The “user needs” were derived from Steven Watya’s presentation “Meeting the demand for male circumcision: an assessment for what is needed”

##### Process:

While not very scientific, the forced choice method was a relevant way to achieve consensus from the groups in the short time available. Each group (G1-G3) was asked to review the needs from the specific viewpoint (patient, administrator, and clinic) and rank which one was most important. The participants were encouraged to discuss the ranking

among the group but in the end had to all agree on the ranking. To offset any bias, the results of each group were kept confidential. The assumption was made that the cost of the device would be acceptable and could be fully absorbed into the cost of the procedure.

### Results:

The results for the patient and clinic needs were exactly the same across all three groups. The only variation was found in the administration, which could potentially be a result of the cultural differences of the participants and their respective Ministries of Health. The final results, in order of importance are shown in the text box.

### Conclusions:

While each stakeholder had their own specific needs, when discussed as a group a consensus was quickly reached. The groups unanimously agreed with respect to the patients and clinic's viewpoints, and varied slightly on the MOH viewpoints. These conclusions are a great first step in understanding the specific requirements for a device solution, but will require more research to define the specifics of each (i.e. what does "easy to train" mean and how can it be tested?)

## *2. User Requirements and Clamp Features/Benefits to meet requirements (PA Consulting)*

### RANKING OF USER NEEDS

#### **Patient**

1. Good pain control
2. Ability to quickly resume work (low return visits needed)
3. Simple post-operative instructions

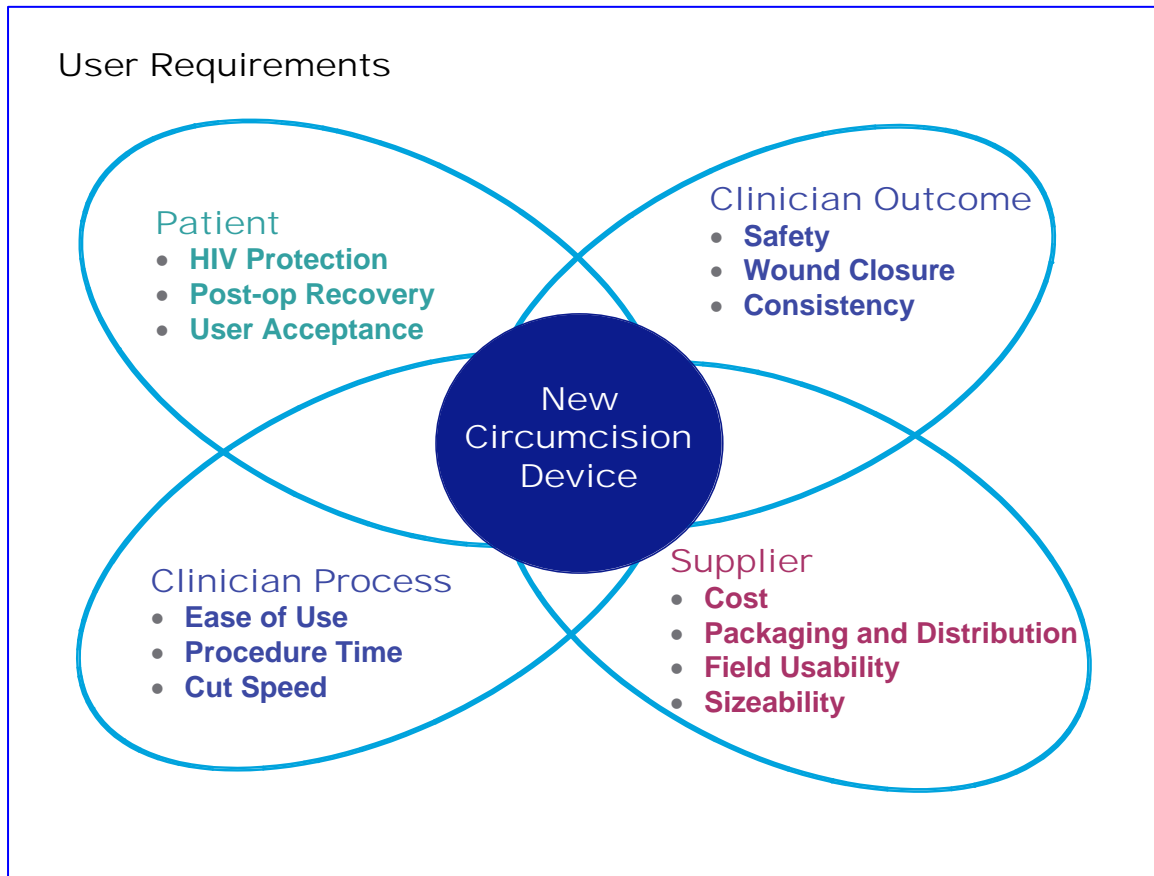
#### **Administration (Ministries of Health)**

1. Effective control of HIV (method effectively removes enough foreskin)
2. Rapid uptake
3. Procedure does not disrupt clinic workflow

#### **Clinic**

1. Reliable hemostasis (and low rate of adverse events in general)
2. Easy to use and train – promotes/facilitates "task shifting"
3. Reliable to replicate over multiple patients

User requirements of a new circumcision device are summarized in the figure below:



User requirements at the patient, clinician and supplier levels were described. A summary is provided here.

User	Requirement	Description
Patient	HIV Protection	Removal of key foreskin regions most susceptible to HIV transmission <i>Does this device facilitate best HIV protection?</i>
	Post-op Recovery	Healing time, comfort, duration, etc. of post-operative recovery phase. Cut quality is expected to impact this factor. <i>Does this device improve post-op recovery?</i>

	Patient Acceptance	Desirability of procedure from a patient perspective; includes “cut tightness” (choice of loose or tight), pain and comfort during procedure, nature and severity of adverse events, scarring, sexual function and satisfaction. Current feeling is necrosing clamp would be preferred, and that guided closure would improve patient acceptance.  <i>Will patients recognize the added value from this device?</i>
<b>Clinician</b>	Cut Speed  (where applicable)	Time for clinician to perform the removal step.  <i>Does this device speed up the foreskin removal step?</i>
	Ease of Use	Requirements for clinician experience and training, as well as device simplicity.  <i>Does this device simplify the procedure and/or allow for use by less skilled clinicians?</i>
	Wound Closure  (where applicable)	Requirements for sutures, need for follow-up visit for suture removal, strength of closure, and related issues. Necrosing clamp is regarded as best option right now, with guided closure (e.g. clamped while suturing) and improvement over conventional suturing.  <i>Does this device improve wound closure?</i>
	Procedure Time	Time with attending clinician to perform the full procedure.  <i>Does this device increase patient throughput for the clinician?</i>
	Consistency	Ability for procedure to be reproducible and repeatable regardless of clinician or subject. Improved cutting is expected to have leverage here.  <i>Does this device improve reproducibility?</i>
	Safety	Device failure modes, including infection from aseptic conditions, injury to the glans and potential exposure of the medical staff to HIV.  Demonstrated efficacy of procedure in clinical trials. Need for surgical backup, remote or on site.  <i>Does this device improve safety?</i>



<b>Supplier</b>	Packaging and Distribution	Weight, size, number of stock-keeping units (SKUs) and other features related to getting the kit to where it needs to be used in a way that it can be used. Includes storage limitations (e.g. if a controlled ambient temperature is needed to maintain shelf life).  <i>Does this device impact packaging and distribution?</i>
	Sizeability	Ability to fit geometrical size requirements, and other physiological differences, between infant, prepubescent, and adult populations.  <i>Does this device eliminate the need for sizing or reduce the number of sizes required?</i>
	Cost	Cost per user, capital costs, distribution costs, potential for reimbursement, etc.  <i>What is the cost impact from moving to this device?</i>
	Field Usability	Factors that influence use of the device in remote areas, including durability, disposability, power requirements, and auto destruct (reuse prevention) features.  <i>Does this device change the field usability of current approaches?</i>

Potential features and benefits to meet user requirements were also identified, again at the patient, clinician and supplier levels:

User, Requirements	Potential Features/Benefits to Meet Requirements
<b>Patient</b> <ul style="list-style-type: none"> <li>• HIV Protection</li> <li>• Post-op Recovery</li> <li>• Patient Acceptance</li> </ul>	<p><b>Control of how much foreskin is removed</b> – Maximum HIV protection</p> <p><b>Minimal to no bleeding</b> – Clamping prevents bleeding, only blood is from foreskin</p> <p><b>Protective Guard</b> – A cover for cutting area and foreskin to protect staff/patient</p> <p><b>Small Clamping Band</b> – Provides user with better post op experience</p> <p><b>Light Weight</b> - Provides user with better post op experience</p> <p><b>Operation completed at end of visit</b> – Cut and closed</p> <p><b>Control of how much foreskin is removed</b> – Maximum HIV protection</p>

<p><b>Clinician</b></p> <ul style="list-style-type: none"> <li>• Cut Speed</li> <li>• Ease of Use</li> <li>• Wound Closure</li> <li>• Procedure Time</li> <li>• Consistency</li> <li>• Safety</li> </ul>	<p><b>Designed for use by lower cadre staff</b> – Guided procedure</p> <p><b>Faster Operation</b> – the surgeon can supervise more cases done by other staff</p> <p><b>Disposable</b> – No need to autoclave device</p> <p><b>Auto-Cut</b> – Same cut every time, no sharps near patient or staff</p> <p><b>No scalpel required</b> – No sharp device required</p> <p><b>Consistent results</b> – Not operator dependent (first cut of the day same as last)</p> <p><b>Interlocks</b> – Ensures operations happen in proper sequence</p> <p><b>Auto-destruct</b> – Prevents reuse of device</p> <p><b>Protective Guard</b> – Cover for cutting area and foreskin to protect staff/patient</p> <p><b>Glans Protection</b> – Hard protective tube is always in place during device operation</p>
<p><b>Supplier</b></p> <ul style="list-style-type: none"> <li>• Packaging and Distribution</li> <li>• Sizeability</li> <li>• Cost</li> <li>• Field Usability</li> </ul>	<p><b>One Circumcision Kit fits all Adults</b> – Helps reduce supply line issues</p> <p><b>Pre-Sterilized</b> – No sterilization required in the field</p> <p><b>Requires no electricity</b> – No external power source required</p> <p><b>One Circumcision Kit fits all</b> – <i>(Disposable Only)</i> Helps reduce supply line issues</p> <p><b>Pre-Sterilized</b> – <i>(Disposable Only)</i> No sterilization required in the field</p> <p><b>Estimated Cost</b> – 15 – 20 USD for disposable. Durable version would be more</p> <p><b>No need to re-supply Durable Model</b> – Designed to last many years</p>

### 3. Identifying Barriers to Acceptance (PA Consulting)

Assumption: That a safe and effective device is developed for mid-level or low-level medical practitioner use.

Main barriers to device acceptance and strategies required to overcome these are listed in the table below.

Barriers to Device Acceptance	Strategy or Actions to Overcome
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<p>Bias from clinical community</p> <ul style="list-style-type: none"> <li>- Expectation of large number of side effects</li> <li>- Need to provide training identical to surgical approach to deal with side effects</li> <li>- Extra training, supervision and monitoring burden on doctors and clinical officers</li> </ul>	<p>Develop and execute a robust trial to demonstrate proof of safety when used by target user AND good patient acceptance</p>
<p>Potential for adverse events to present well after the procedure</p>	<p>Use clinical proof that AE profile is at least as safe as surgical male circumcision</p>
<p>Patient acceptance of necrosing clamp staying on for several days is not good</p>	<p>Conduct patient outreach and educate on the outcomes with device</p> <p>Design to minimize/optimize the time device must stay on.</p>
<p>Unclear regulatory pathway</p>	<p>Clarify individual country requirements and follow broadest possible pathway to satisfy individual country regulation</p>
<p>Long and potentially unreliable (off-continent) supply chain</p>	<p>Design most robust supply chain possible.</p> <p>Investigate the opportunity to develop and implement African manufacturing strategy (could be an industrial development project or not-for-profit corporation)</p>
<p>Potential for unauthorized and/or untrained use</p>	<p>Implement surveillance and security measures on supply chain</p> <p>Implement fail-safes in device design</p> <p>Establish a low price of procedure and advertise the quality and outcome benefits to patients to remove incentive for unauthorized use.</p>
<p>Potential of counterfeit devices</p>	<p>See above</p> <p>Investigate the opportunities for authentication and/or certification for products and packaging</p>
<p>Assurance of necrosed, compressed, scarred results is effective, safe and robust</p>	<p>Determine minimum effective dimensions for tissue post-operatively and validate the result obtained with production devices – standard medical device product validation protocols</p>

Cost	<p>Design device to be minimum cost (current rough order of magnitude (ROM) materials cost &lt;2.00 USD)</p> <ul style="list-style-type: none"> <li>- Minimize procedure cost (task shift)</li> <li>- Minimize program costs</li> </ul> <p>Establish national tender pricing and eliminate or minimize commercial sales</p>
<p>Patient perceptions</p> <ul style="list-style-type: none"> <li>- time to return to sexual activity</li> <li>- discomfort post-op (weight, constriction, etc)</li> <li>- time to return to daily activity (work)</li> </ul>	<p>Demonstrate equivalence to surgical male circumcision</p> <p>Minimize the physical size/weight of clamp as much as possible</p> <p>Minimize time off</p>
Assurance of removal of sufficient amount of foreskin to assure protective effect	Define minimum acceptable standard from current procedures and use this as definitive device design specification (3mm max tissue cuff proximal to corona – TBC)
Clamps currently associated with high infection rates	Design to minimize opportunity for infection
<p>Damage to penis from mispositioned, misplaced or poorly clamped device</p> <p>Prevent torquing organ during placement or cutting – potentially irreversible damage to penis</p> <p>Risk of damage to frenulum and sexual function</p>	<p>Provide positioning features or guides</p> <p>Provide reversible lock for adjustment</p> <p>Make multi-step place/adjust/lock/cut process to minimize locking incorrect position</p> <p>Design cutting function and pathway to avoid damage to frenulum</p>
Consistency of training	Comprehensive training (and train-the-trainer) programs to be rolled out to all users (consider a certification program?)
Patient anatomy variable make device difficult or dangerous to use	<p>Identify and quantify as broad an anatomical variation as possible as a design specification</p> <p>Develop a clear physical examination decision process so that user can quickly escalate non-conforming anatomy or physical anomalies</p>
Requires a more comprehensive physical exam	See above

	Enhance training for all users at all levels
Device design may not be appropriate for a large enough target population to make it cost-effective	See above Minimize or eliminate adjustments Conduct complete cost-effectiveness review prior to beginning scale-up to production quantities

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**Next Steps – Technical innovations:**

- The two groups contracted by the Gates Foundation to develop recommendations for a prospective device will use the information and feedback gained during the meeting to produce more detailed device specifications that can then be demonstrated to providers. Alternative methods to assist male circumcision surgery, e.g. for wound closure, suture and local anesthesia, will also be considered.
- As most currently available devices are suboptimal for the purpose of adult male circumcision, only a limited number of candidate clamps would be shortlisted to undergo more thorough review by a clinician team and subsequently enter clinical testing:
  - The only clamps currently available in adult sizes include the Sunathrone clamp, SmartKlamp and TaraKlamp. The SmartKlamp is the only FDA approved clamp; data currently available on the TaraKlamp suggests it is suboptimal for this purpose.
  - Testing of available devices by independent clinician investigators, e.g. to perform a case series of 30-40 surgeries, was recommended to document information beyond that available from the manufacturers. The importance of publishing any available data was highlighted. Clinicians present confirmed their willingness to participate in clinical testing of selected devices:
    - In Uganda testing could be possible in an urban setting where participants can be closely monitored.
    - Professional societies, including the African Gulf Society for Sexual Medicine (AGSSM) and the International Society for Sexual Medicine (ISSM) also expressed willingness to test surgical devices outside of the U.S. In general, US-centered studies were perceived as problematic, as indications for circumcision are very different in the

US, and the resulting smaller numbers of patients would require multi-centre trials more difficult to conduct.

- Further clarification on the pathway for regulatory approval should be obtained in parallel to the development of initial clinical protocols. Consensus needs to be established among regulators, policy makers, clinicians and program managers on the minimum testing requirements for surgical male circumcision devices, including the type of study design (e.g. case series or randomized trial). A meeting will be convened by WHO later in 2008 for this purpose.

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## II. DEMAND FORECASTING

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The objective of the session was to identify the value of demand forecasting for male circumcision, discuss application of forecasting principles to male circumcision and highlight data to be captured in research and programs to inform demand forecasts. In addition, participants had a broad range of expectations for the discussions (see text box). Main questions addressed in the session are outlined below.

### GOALS OF PARTICIPANTS IN DEMAND BREAKOUT SESSION:

- Learn from experience of other countries: for Uganda, and others
- Document lessons learned from demand forecasting for other programs
- Determine data to capture
- Disaggregate discussion to a useful level
- Understand size and shape of pent up demand
- Quantify the synergies and redundancies
- Incorporate demand forecasting into broader prevention strategies
- Select the best methods for demand forecasting
- Perform risk analysis and demand analysis
- Provide persuasive data for policy makers
- Discuss methodologies to go from need to demand

### 1. Why is demand forecasting important for male circumcision programs?

The following points provide rationale for demand forecasting in male circumcision:

- Document demand for the purposes of policy making
- Budget for staff, supplies, facilities, communications, etc.
- Establish baseline models that can be tracked and made more accurate over time
- Prepare the environment, e.g., identify bottlenecks to enable mobilization of resources
- Develop scenarios, e.g., to address pent up demand, and impact of “conditioning”
- Inject a note of realism into planning

The timeframe for demand forecasts varies, from short-term ordering and annual budgeting to informing long-term capacity development.



## 2. When is forecasting of demand not valuable?

Demand forecasting was seen as less useful if aggregate demand is greater than supply; when forecasts are unreliable because of heavy dependence on how programs are executed or through the influence of outside factors (e.g. lack of political will); or if there is not enough data available to draw meaningful conclusions. The forecasting exercise should not interfere with the delivery of valuable programs.

## 3. Who are the main customers for demand forecasting in male circumcision?

- Political leadership: to establish the call to action
- Donors, ministries, implementers: to inform budgeting
- Supply chain management and technical assistance groups: to inform planning

## 4. What data needs to be collected to inform demand forecasting?

Discussions highlighted the need to define data to be collected during programs to inform and improve demand estimation. This includes data on demographics and social attitudes to adult male circumcision (e.g. among opinion leaders, traditional circumcisers, women) specific to each setting and

### SUGGESTED DATA FOR COLLECTION:

- Impact on demand of:
  - ⇒ Service location
  - ⇒ Quality
  - ⇒ Community location
  - ⇒ Opinion leader view
  - ⇒ Perception of benefits
  - ⇒ Leader country experience
- Acceptability of infant circumcision in cultures that practice male circumcision as rite of passage
- Demand for traditional circumcision
- Urban/rural population breakdown
- Population by age
- Circumcision % by age
- HIV prevalence by age and male circumcision status
- Impact of offering testing on acceptability of male circumcision
- Price elasticity of demand
- Willingness to travel
- Target risk group size/characteristics/demand

epidemic (see text box).

Participants recommended the development of a demand forecasting toolkit that could be incorporated into existing toolkits, such as the UNAIDS decision makers' program planning toolkit currently under development or situation analysis toolkits.

Additional questions raised included which sector of the population to target for demand, e.g. to focus on reaching core transmitters or discordant couples, and how to strike the balance when combining male circumcision and other prevention interventions to achieve synergy rather than duplicating efforts. Finally, the quality of any implemented program for male circumcision will affect demand for male circumcision services, underlining the importance of avoiding early missteps as services are established.

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## Next Steps – Demand Forecasting:

- A grid will be developed to classify data needs; this should include:
  - The importance or ranking of each parameter
  - Model sensitivity
  - Considerations on ease of collection for the data required, along with existence and availability of data from other sources.

A core working group will focus on developing a framework for data collection and how this data will inform decision making, as well as assessing how much data is already available from countries for each portion of the grid. Opportunities for data collection will be identified, particularly in the context of ongoing and new programs or research studies. The data collected should serve to capture both the current or baseline conditions and ultimately support data collection at the national level. It can also serve to strengthen existing tools through input of real data.

- Factors affecting acceptability of male circumcision at the policy level should be further explored to identify specific data necessary to support advocacy. Demand forecasting can thus play an important role in driving policy.
- Male circumcision demand forecasting should be added to existing decision making and situation analysis tools developed by WHO, even if initially based on rough estimates. It was requested that these tools be reviewed to ensure that they adequately address demand estimation, as opposed to being focused primarily on need.
- There was a general call to document and publish results of any ongoing research so that experiences can be shared.

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### III. KITS AND SUPPLY CHAINS

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The objectives of the group session on kits and supply chain activities were 1) to discuss different approaches to supply procurement and assembly of kits for male circumcision supplies; 2) outline the process for deciding on kit contents and monitoring of supply distribution; and 3) develop mechanisms to exploit the private sector supply chain.

#### 1. Procurement and kit assembly

Procurement of supplies can occur either at the national or international level; while international procurement has the potential to achieve greater reduction in costs through negotiations with suppliers, national procurement would be more adapted to local conditions and has the potential to further strengthen national supply chain systems. While no final recommendation could be made on the process to be adopted for supply procurement, it was agreed that packaging of kits should occur at the national level where possible, ideally in the form of income-generating projects for local groups.

#### 2. Kit contents and monitoring of distribution

Male circumcision supplies can be provided in the form of *kits*, containing consumables for a single male circumcision procedure; and *modules*, containing reusable clinic supplies, instruments and equipment.

International HIV treatment and family planning programs provide good examples for successful procurement activities. However supplies for male circumcision are not male circumcision-specific but rather belong to the category of general surgical supplies that are not limited to use in male circumcision alone. This presents additional challenges to be considered in the monitoring of distribution, particularly when male circumcision-specific supplies are provided to surgical centers in the public sector that have been

largely under prioritized for funding in the past, with the potential for use of supplies beyond male circumcision services.

### 3. Private sector involvement

In order to maximize available services to meet male circumcision demand in the near future, mechanisms to involve the private sector, including faith-based health facilities, need to be explored to alleviate the anticipated burden on surgical services in the public sector. A client-driven voucher system was recommended that could be used to support the provision of both consumables and male circumcision services in general. This would give more access to private providers and provide quality assurance mechanisms for the conduct of procedures in these settings.

The role of various stakeholders including national ministries of health and international donors needs to be further defined. In the short term, it is likely that individual programs with funding for male circumcision services will have to move ahead with individual procurement systems. However, the long-term goal should be to establish procurement systems at the national level, as has been achieved with HIV treatment programs such as PEPFAR.

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**Next Steps – Kits and Supply Chains:**

- National level: Countries with male circumcision task forces should include a point person or subcommittee to prioritize supply chain issues, so that this component of programs is planned prospectively. This subcommittee will convene a group to identify the contents of kits and/or modules. The components of kits will vary, depending on local preferences for supplies and method of male circumcision surgery. Input on the content of kits should be gained from mid-level providers who will be performing the male circumcision.
- International level: An international task force with supply chain expertise should be formed to advance this agenda. This group could also address the issue of prequalification of supplies and instruments to avoid distribution of substandard supplies; UNFPA should be involved in these efforts. At the international level there are additional opportunities for price negotiations, provided larger numbers are being procured.
- Links should be established between supply chain groups and demand forecasting experts and programs near implementation.

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