



**World Health
Organization**

HIV/AIDS Department

MALE CIRCUMCISION and HIV PREVENTION

Operations Research Implications

REPORT OF AN INTERNATIONAL CONSULTATION

21-22 JUNE 2007, NAIROBI, KENYA

**Male Circumcision and HIV Prevention:
Operations Research Implications**

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Executive Summary

A multidisciplinary group of 26 individuals experienced with the operational aspects of adolescent and adult male circumcision services in sub-Saharan Africa met 21-22 June 2007 to discuss operational aspects of adolescent and adult male circumcision programmes and to identify research priorities for the next 12 months. Consensus of the meeting was that, in the context of the failure of HIV prevention efforts in sub-Saharan Africa to more successfully end the epidemic, the March 2007 endorsement of male circumcision as an additional means of HIV prevention by United Nations co-sponsors and by attendees from health ministries and health care agencies in sub-Saharan Africa at the 5-7 May Eastern and Southern Africa Consultation on Safe Male Circumcision and HIV Prevention provided a unique opportunity for large-scale successful HIV prevention not previously possible. The year 2008 is seen as pivotal in the acceptance of scale-up as an HIV prevention strategy and the beginning of male circumcision programmes. As countries make individual decisions about adoption of male circumcision for HIV prevention, countries choosing to adopt this strategy will need to formulate goals and targets, and scale-up ways to meet them. In doing so, countries will face funding decisions and, while desirable to not shift funding from other prevention programmes to male circumcision, sentiment at the meeting was that some cost-shifting would be acceptable, as male circumcision provides a predictable, proven intervention method. During scale-up, operational research (OR), which was not previously possible because of the lack of programmes, will become vital to identify effective and efficient means of recruiting patients and delivering services--OR should be a formal part of every country operational plan. At individual programme level, whether formal OR is done or just programme delivery, however, all efforts at service delivery should be evaluated and their operations and results documented and disseminated.

The need for initial situation analysis, upon which programme can be based, was clearly identified. Whom to target for services, whether by age or organization (the military being a group potentially easily accessible), with what messaging, and how to avoid stigma (men who may or may not get circumcised, results of HIV testing) were identified as important--the use of champions has been helpful in similar campaigns. Multiple approaches to delivery of service--location, type of surgery, supplies--will undoubtedly be used and no one approach can now be favoured, although task-shifting in probably every service locale must be explored. Surgical kits will likely be important, and the use of a single source to deal with suppliers, much as WHO does for antiretrovirals, was recommended for exploration. How to work with private medical services was debated, with incentives being a frequently mentioned topic. For this, but also other health care scale-up issues, not ignoring existing literature was stressed as we should learn from already existing resources, e.g., the WHO ExpandNet system for scaling up health care services. The potential value of the "essential package" and "expanded package" of services were discussed, and experience in delivery of the each is very much needed, with piggy-backing of male circumcision services onto existing service delivery encouraged for efficiency.

Although not explicitly discussed at the meeting, sustainability of male circumcision programmes were debated and the value of neonatal circumcision as a viable, long-term strategy to achieving high rates of male circumcision recognized.

A prioritization process, asking what OR issues must be started or completed in the next 12 months, was conducted with 22 issues identified. The issues that rated most highly were, in order of priority:

1. Study task-shifting, with feasibility, safety and acceptability of non-physicians to perform surgery;
2. Determine effective and cost-effective models of delivering mc services, and compare their advantages and disadvantages;
3. Determining the approach to counseling (couple or individual), and content of messages and numbers of sessions, that decrease risk compensation following surgery and lessen sexual activity immediately following surgery;
4. Determine the acceptability and feasibility of neonatal circumcision;
5. Building mutually agreeable linkages of traditional circumcisers with the formal health care system to provide culturally appropriate mc in a safe environment, and to learn lessons from traditional circumcisers.

Despite identifying priorities, the group felt it was too early to form a formally-accepted OR agenda. Rather, countries, implementers and implementers should begin to scale up services in varying ways. A meeting in another year could bring together programmes that have been evaluating and instituting programme to share experiences and determine renewed priorities.

Overview of meeting

The conclusions of an international consultation March 2007 that: 1. Male circumcision should now be recognized as an efficacious intervention for HIV prevention, and; 2. Promoting male circumcision (mc) should be recognized as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men, provided a unparalleled opportunity for HIV prevention. 68% of all HIV incidence occurs in sub-Saharan Africa (UNAIDS, 2007), where the association of low prevalences of mc and high prevalences of HIV has been convincingly shown. And, it is here that each of the three randomized controlled trials (RCTs) investigating the effect of mc on HIV incidence has been conducted. When analyzed together, these trials show an approximately 60% protective effect of mc on acquisition of HIV by men who have been circumcised as adults. The research evidence that male circumcision is efficacious in reducing sexual transmission of HIV from women to men is compelling.

The challenge now is in implementing a strategy of mc for HIV prevention in selected parts of the world. This challenge will be one of both policy and implementation. Policy is required because mc is different than other population-scale HIV prevention measures, all of which rely on behaviour change; mc requires surgical services and to make a meaningful impact on the HIV epidemic will require a national approach to delivering safe mc services, with significant public health care institution investment, coordination with the private health care sector, national certification of health care providers, and coordination with traditional circumcisers to provide safe mc services. Once policy is adopted, then countries can move to implementation.

But, other than endorsing mc as an effective HIV prevention strategy, what approaches towards introducing services should governments adopt--what policy will provide the best services to the most people at the cheapest price? And, how can these approaches be implemented?

OBJECTIVES

The meeting had two objectives:

1. To review different models of male circumcision service delivery, identifying challenges encountered in implementation and implications for operational research (OR);
2. To review priority areas for OR and to identify key questions that need to be answered.

The meeting had two desired outcomes:

1. To identify OR implications and challenges in differing models of mc service scale-up;
2. To develop a prioritized list of OR questions that need to be answered or at least addressed in the next 12 months.

CONDUCT OF THE MEETING

The meeting was divided, by day, into two meeting approaches. The first day discussed methods of service delivery that have been or are being conducted, and focused on "lessons learned" and "challenges," and implications of programmes for OR. Included in the subject of service delivery were the vertical programmes of the three randomized controlled trials (RCTs) from South Africa, Kenya and Uganda; integrated programmes from Zambia and Swaziland; innovative programmes from Swaziland (Circumcision Saturday), and Kenya (work of faith-based medical institutions with traditional circumcisers); plans for introducing services by two nongovernmental organizations, Family Health International and Population Council, the potential role of neonatal circumcision in "scale-up" efforts; and, resource issues (The Constella assessment of resource needs/health system capability in three countries, the potential role of pre-packaged surgical kits, and a model of assessing efficiency of circumcision services). Throughout the day, key OR issues were identified and placed on cards arranged on one wall. At the conclusion of the day, there was a summary of the day's discussions, and presentation and discussion of the key issues that had been captured.

The morning of the second day consisted of group work, with the attendees divided into five working groups. The charge to each of four of the working groups was to identify the 5-7 OR projects that we must have either begun or finished by July 2008, 12 months away. The fifth working group focused on "What is the role of economics in OR of mc?" In the afternoon, the working groups reported to the entire meeting with their results, there were questions for clarification posed to each group (if needed) and open discussion of all groups followed. The thoughts of each group were captured on cards and if there were ideas different than the "running tally" of cards, then these ideas were added to the running tally. The running tally was presented to the group to ensure that all important issues were tallied and prioritization was done by allowing each person five votes, to be distributed as (s)he wished.

The meeting was closed by reports and discussion from two funding agencies, The Gates Foundation and PEPFAR, followed by a discussion of how funding and implementing agencies could work together.

The agenda is provided (Appendix 1) as is the List of Participants (Appendix 2).

Introduction

WHAT HAS BEEN DONE IN THE PAST FOR PRIORITIZATION OF OR (GEORGE SCHMID)

This meeting is not the first to address OR aspects of mc. In 2000, the Population Council convened a meeting to discuss operational aspects of male circumcision (<http://www.popcouncil.org/pdfs/circumcision.pdf>). In May 2006, the Gates Foundation also convened a meeting ([link?--could not find](#)). In 2000, however, no mc programmes were operational in sub-Saharan Africa and in 2006, only the three randomized trials had substantive information to discuss. Nevertheless, in both meetings, important issues were identified and a complete understanding of OR for mc in sub-Saharan Africa requires reading these documents as well as pertinent articles that have appeared in the peer-reviewed medical literature.

WHAT IS OR?

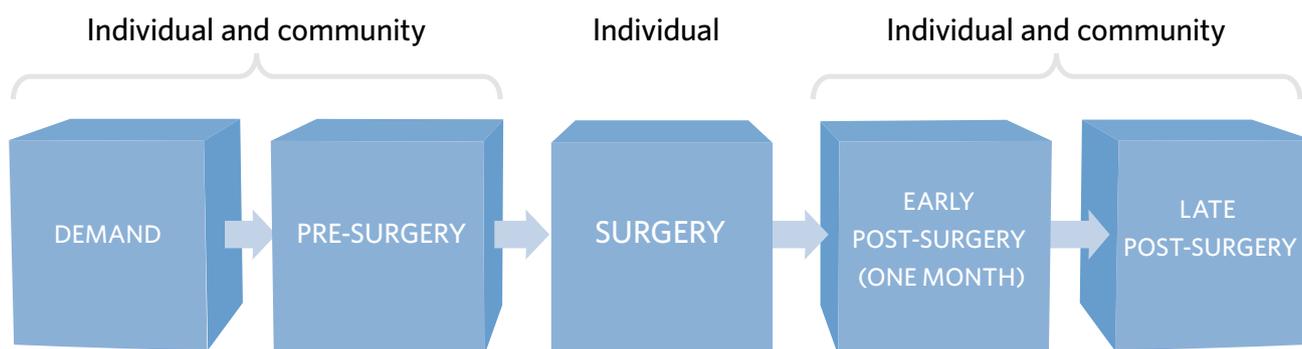
Varying definitions of OR exist, as well as approaches to OR. OR, which arose out of a need to manage logistics during World War II, is often--in the business interpretation of OR--used to analyze and improve throughput by the use of flow analysis and modeling. Others, however, interpret OR broadly and in more of an epidemiologic sense, e.g., "it identifies problems that limit program quality, efficiency and effectiveness, or, determines which alternative service delivery strategy would yield the best results." This latter interpretation includes both "diagnostic" approaches, meant to identify problems that limit program quality, efficiency and effectiveness, and, investigations that determine which alternative service delivery strategy would yield the best results.

Two frameworks for discussing OR were presented, one during this presentation and the second during the presentation from Mike Welsh, Family Health International. The frameworks provide a structure to methodically and systematically consider aspects of mc programmes and associated OR. Noted was the fact that OR requires that programmes be in existence, whether under construction or in operation. Thus, only now, as mc is recognized as a means of preventing HIV infection, can OR for mc begin to be studied.

FRAMEWORK #1.

A possible framework for viewing OR in the context of mc was presented. The framework outlined five steps leading to the scaling up of mc services (Figure 1).

FIGURE 1.



This framework has five phases, which sequentially depict the process of achieving successful volumes of safe mc at community and individual level, and depicts supply and demand functions. The framework is intended to logically “deconstruct” the process of circumcision, with community and individual needs, allowing systematic thinking towards OR needs. Within each phase, examples of possible topics for OR would include:

1. Demand

- Determination of, and effectiveness of, communication strategies to enhance demand for mc;
- Determination of influence of cost of mc on demand;
- Determination of the type of mc “package” (i.e., the bundled range of services) and its influence on demand (such as providing only mc, or providing mc and additional services, e.g., contraceptive counseling);

2. Pre-surgery

- Access (location, type of service, type of facility);
- HIV testing and its relationship to acceptance of mc or prioritization of services for HIV-negatives;
- Type of counseling and its effectiveness in varying areas, e.g., understanding surgery, understanding effectiveness of HIV prevention afforded by mc;
- Task-shifting of varying pre-surgical tasks, e.g., counseling, physical exam;

3. Surgery

- Type of surgical approach;
- Task-shifting of surgical tasks;
- Type and quality of surgical theatre;
- Type and packaging of surgical commodities;

4. Post-surgery (shortly after surgery, e.g., one month)

- Type of counseling and its effectiveness in varying areas, e.g., return rates, maintenance or adoption of safer sex practices;
- Task-shifting for post-surgical follow-up or counseling;
- Success of referral for “expanded package” of services;
- Number of visits;

5. Post-surgery (late, e.g., after one month)

- Type and effectiveness of “expanded package” of services;
- Evaluation of mc services by customers;
- Effect on sex practices;
- Means of monitoring and evaluation.

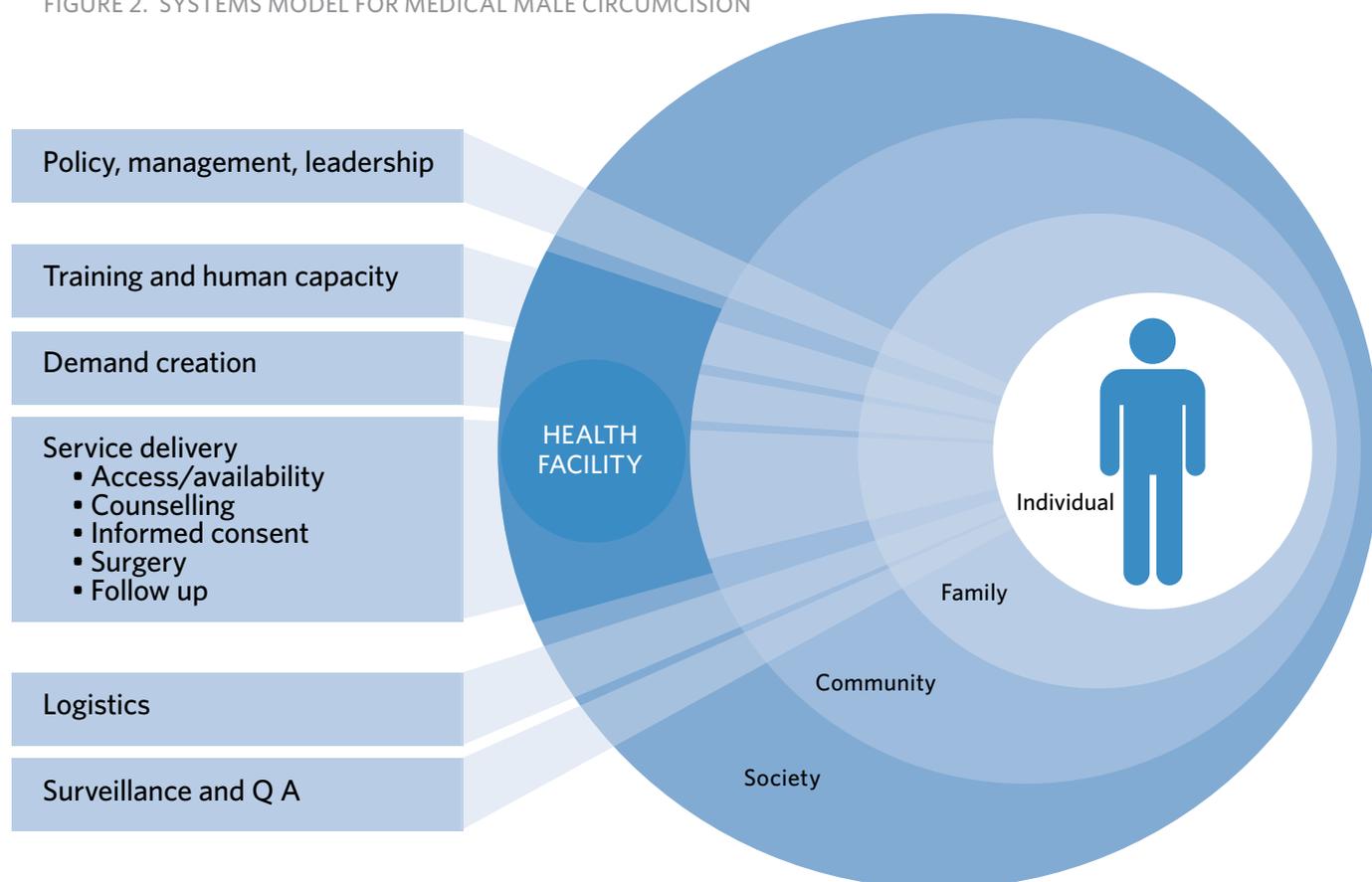
FRAMEWORK #2. (MIKE WELSH)

A second possible framework for viewing OR in the context of *scaling-up* mc was presented (Figure 2). This framework provided a different aspect of OR than the first model, in that it went beyond pure OR into a broader approach to understanding scale-up, for example, by including policy issues. The framework was presented in the context of needing to understand health systems and how to incorporate mc into thinking about how health systems are structured.

The presentation began with a brief review of how we are beginning scale-up efforts. **What** is being scaled up is either the “minimum package” of services or the “expanded package” of services. **How** it is being scaled up at this time is based on three models: 1) centres of excellence; 2) integration into existing services; 3) special events--more models, of course, may follow. The progression of scale-up, defined as “the deliberate transfer of innovations to large scale public sector/private sector health systems” will follow the traditional path of determining efficacy of the intervention, followed by determining effectiveness in practice situations, followed by improving efficiency in practice situations and, finally, expansion of the best and most efficient models of delivery of care.

The systems model framework for viewing OR was divided into six compartments:

FIGURE 2. SYSTEMS MODEL FOR MEDICAL MALE CIRCUMCISION



Adapted from: Strategies for an expanded and comprehensive response to a national HIV/AIDS epidemic, FHI, 2001

1. **Policy, management and leadership.** The primary question of this compartment is: What policy and leadership change will facilitate scale up at national, province, district and local facility levels?
2. **Training and human capacity.** The primary question of this compartment is: What is the relative cost-effectiveness of different service providers (e.g., doctors, clinical officers, nurses) on specific mc outcomes? This large question has multiple parts, e.g., ability of individual providers to deliver care, how efficient are each, how to train the providers, what outcomes will be measured, etc.
3. **Demand creation.** The primary questions of this compartment are: Would circumcision of key leaders stimulate acceptance of mc in communities? Can mass media in local languages stimulate a desired mc outcome?
4. **Service delivery.** The primary questions of this compartment are: What is the population level impact of mc and does mc lead to behavioral disinhibition? What changes, if any, occur in traditional circumcising communities as well as in noncircumcising communities as mc is adopted uniformly (e.g., stigmatization, condom use)? What are the relative merits of alternative surgical techniques (e.g., dorsal slit vs guided forceps method) and their safety outcomes? What is the effectiveness of specific communication tools for communicating relative protection of MC? What is the relative cost effectiveness of different service models for reaching rural populations (e.g., mobile clinics, MC camps/days)? What impact does MC scale up have on other HIV prevention services, or other health services? How price sensitive will circumcision be? Would incentives increase acceptance in specific situations? How can we most effectively reach neonates (e.g., antenatal care clinics vs. immunization programmes)? How best can we integrate mc within expanding networks of VCT or CCC centers?
5. **Logistics.** The primary question of this compartment is: What supplies are needed, and how should they be packaged (e.g., do we need special service packages of surgical supplies for mc, for example, a kit for single-use for individual circumcisions?)?
6. **Surveillance and quality assurance.** The primary questions of this compartment are: How do we establish active and passive surveillance systems? How can we adapt health care management and information services (HMIS) to track adverse events throughout scale up in centers of excellence and other service venues? How do we assure prompt feedback and links with supervisory and management systems to monitor mc practices and outcomes? How do we adapt behaviour surveillance systems (BSS) and demographic and health surveys (DHS) to monitor behaviors post mc.

Practical points and discussion:

- In considering scale-up of male circumcision, we should not ignore the existing enormous volume of literature on scale-up, although scale-up has been conducted for reasons other than male circumcision. Even WHO (and partners), through WHO/ExpandNet (<http://www.expandnet.net/guide.htm>), has provided guidance on how to develop sustainable scale-up of health service interventions. This latter project has showed the importance of three factors when scaling-up:
 1. Local leadership, including “champions.” Such leadership must be at both national and local levels;
 2. Vision (a view reinforced by extensive British literature)—one must have the imagination to envision what scaled-up, high quality programmes “look like”;
 3. A research agenda. This agenda might be formed, depending on the issue, at an international level (or similar “high” level), but ultimately the research agenda must be brought to local level, while being informed by the international agenda.
- For task-shifting, an operational research issue that is seemingly well accepted for mc, multicentre protocols will be needed;
- For successful scale-up, there should be interest at multiple levels. For instance, a family might be thinking of circumcision for a son, and there should be simultaneous community interest and information, and health care facility interest/information/capability, to provide information, reinforce tentative decisions, and provide services. Information flow could, of course, work in other directions (e.g., community interest informs parents); the key is multiple levels of interest and advocacy;
- We should consider the effects on traditional circumcising communities of scale-up in nontraditional circumcising communities;
- Once projects to scale up are underway, only then can we evaluate, fine-tune, and conduct OR.

Discussion: There was agreement that a structured means of addressing OR needs was useful, that both frameworks identified many of the same needs, that both approaches provided a useful framework, and that the second approach extended traditional limits of OR but that this was useful for thinking about overall scale-up. Both frameworks provided a means of systematically thinking about scale-up, with subsequent identification of research needs, and that as plans and implementation of scale-up occurred, OR needs would be further identified or refined. There was agreement that there should not be a research agenda drawn up at this time, just as means of scaling up services are being explored. Rather, as scale-up occurred, it would be important to be creative in thinking about how to incorporate mc into health systems.

REPORT FROM EASTERN AND SOUTHERN AFRICA CONSULTATION ON SAFE MALE CIRCUMCISION AND HIV PREVENTION, HARARE (CHIWENI CHIMBWETE)

In March 2007, UNAIDS recommended mc as an additional means of HIV prevention. In 5-7 May, the Eastern and Southern Africa Consultation on Safe Male Circumcision and HIV Prevention meeting was held in Harare. The meeting was attended by 65 participants, ministries of health, faith-based organizations, non-governmental organizations, UN agencies and development partners. Noticed at that meeting was that, in the two-month time span between the meetings, a considerable evolution of thinking about mc had occurred. Male circumcision was being recognized and considered as a serious HIV prevention strategy and at the Harare meeting mc was strongly endorsed as an HIV prevention strategy. The meeting made it clear that current resources were limited and that innovative approaches to scale up, e.g., use of task-shifting, would be needed. Similarly, the cultural (and surgical) importance of traditional circumcision was recognized and participants emphasized that traditional circumcision leaders must be engaged to determine how best to scale-up mc in areas where traditional circumcision is practiced. The meeting was clear that efforts to scale up mc should not take resources away from other HIV prevention programmes nor other health care services. There was little discussion of neonatal circumcision but one concern raised was that UNAIDS seemed to be endorsing neonatal circumcision even though the three RCTs addressed only adult circumcision. A general approach to adopting mc for HIV prevention purposes in eastern and southern Africa was drawn up, and countries devised road maps for their individual countries. These road maps included: 1) briefing country leaders (ministries of health, political and other stakeholders) on mc and the results of the meeting; 2) develop policy guidance on who should be circumcised, how, and by whom; 3) engage national stakeholders and, in particular, traditional circumcising communities and traditional circumcisers, and if needed develop national task forces; 4) integrate mc into existing HIV prevention strategies; 5) develop cost estimates for mc scale-up; 6) undertake resource mobilization (see report, Harare meeting). It was agreed to meet again in February 2008 to measure progress.

Discussion: The question arose of whether mc could be integrated into sexual and reproductive health (SRH) programmes, as opposed to just HIV programmes. Amid support for this, a caution was raised that this may be difficult and that simply integrating mc into mainstream health services might be difficult enough.

OR Implications of Different Models of Service Delivery: Vertical Services

THE THREE RANDOMIZED CONTROLLED TRIALS (RCTS)

Prior to the meeting, representatives of the three RCTs were requested to prepare for presentation at the meeting a review of the major operational hurdles they faced in conducting their trials, the solutions they found to those hurdles, and recommend principal areas for OR as scale-up left the research setting and entered mainstream health care services.

ORANGE FARM SOUTH AFRICA TRIAL (DIRK TALJAARD AND BERTRAN AUVERT)

The trial: Recruitment was an initial hurdle. A variety of means of recruitment were used: word-of-mouth, community campaigns, door-to-door information-giving, use of the general practitioners who provided circumcision services, and informal meetings. Word-of-mouth was thought to have been the most effective means, centered around men who had been circumcised recruiting other men, while community campaigns and door-to-door giving of information also seemed effective.

The Orange Farm trial was unique among the three RCTs because all circumcisions were performed by three general practitioners with established practices in the community, and this approach worked well. Thus, this approach can be a model for South Africa and also in other countries where efforts to scale-up mc will include the private sector. There was an initial start-up workshop to standardize surgical approaches (forceps-guided method, because this was felt to be the easiest method, done in conjunction with the University of Witwatersrand Department of Urology), surgery was performed in the private offices of the doctors, and follow-up was done there also. The doctors provided follow-up and emergency care (if needed) with a doctor being on call 24 hours-a-day, and a toll-free number was supplied for participants. Adverse events were judged and recorded by the general practitioners. Doctors were paid for each mc performed. This approach, as opposed to hiring doctors (and other staff) full-time to perform mc, was chosen for several reasons: 1) it fit into the South African health system approach to elective surgery (the public sector does not pay for male circumcision except for medical indications); 2) it was thought to likely be the most efficient and cost-effective.

It was thought to be efficient and cost-effective for several reasons. First, no overhead costs needed to be paid. Second, if there were slack periods there would be no need to pay for doctor or nursing staff when no operations were being performed. If, however, there were consistent demand, the Orange Farm team felt that hiring a dedicated surgical team would likely be the most cost-effective, and the cost of mc was higher in this trial than the others; 3) the surgery was the responsibility of the general practitioner; 4) the general practitioners use their own equipment and have an existing system of instrument and waste disposal because they perform other surgeries. The approach had several disadvantages: 1) the trial had more limited control over the doctors and the surgical procedure than if the surgical procedure had been a fully-integrated part of the trial; 2) there was more limited control over times to schedule mc (although most men received mc within 3 days of randomization); 3) monitoring and evaluation provided challenges, and may have been more difficult than if the surgical procedure and follow-up had been fully integrated into the trial.

Enrolment of participants occurred before surgery, however, and not at the doctors' offices. There was an initial information visit followed by, if the participant wished, an enrolment visit. At this latter visit, participants were administered a behavioural base-line questionnaire, a physical exam and biomedical testing, counseling about the operation and safer sex practices, and informed consent was obtained and patients were randomized. Initially, group counseling was designed but men preferred one-to-one counseling, which was subsequently implemented.

The adverse events rate was reported in the RCT report and was 3.8%.

Specific challenges that the trial faced which would likely be shared by at least some other interventions were:

1. Enrollment (see above);
2. Means of communication of information itself about mc, and ensuring that the information distributed by both those organizing mc and others is correct;
3. That persons understand both communications messages, and counseling, correctly;
4. That risk compensation be monitored and, if detected, means of eliminating it instituted.

Scaling-up mc: The investigators in Orange Farm trial are hoping to implement a city-wide scale-up of mc in the Orange Farm community. There are multiple reasons for doing so, but two are to learn lessons about how to implement large-scale scale-up, and to measure the impact on HIV incidence of scale-up on a large scale. In considering the lessons learned from the RCT and applying them to a city-wide scale-up, or even a country-wide scale in the Republic of South Africa, the investigators have identified issues they feel will be important to overcome:

- There would need to be a national, or city, situation analysis (identified as important, also, at the Harare meeting) of such factors as current practices and safety of circumcision, prevalence of circumcision, knowledge about mc and its relationship to HIV infection, and acceptability. Noted was that we do not know what it will take to do mc on a large scale and we should be prepared, even with a situation analysis, to look for surprises, e.g., we do not know what acceptability will be even with a situation analysis. We also do not know the amount of funding that will be needed.
- It was felt important to begin scale-up on a smaller level and learn lessons, rather than a national level, where we have absolutely no experience.
- Simplification of the surgical process will be needed. There will need to be task-shifting, with reasonably short periods of training. Ideally, new means of mc will be identified, which do not require sutures and which are bloodless.
- The difficulty of instituting routine, high-quality counseling, surgery and post-operative care, and in particular monitoring and evaluation, into the practices of private physicians was emphasized.
- An important point was that mc should be free to patients, particularly if done by general practitioners. While cost has been repeatedly identified in acceptability studies as an important obstacle to patients obtaining mc (the cost that general practitioners charge to patients in South Africa is about US\$60), to allow doctors to insert fees which might be of varying cost will create obstacles to patients obtaining mc and confusion for patients. Knowing that mc is free at all (participating) general practitioners' offices will be simple and equitable.
- Transport of patients will need to be arranged.

The magnitude of scale-up needed in South Africa was addressed. The population of South Africa is about 50,000,000 with about 19,000,000 adolescent or adult males. If one assumed all were candidates for circumcision and the cost of circumcision was US\$60, then US\$1.1 billion would be needed. Assuming, simplistically, that circumcision of all men would be accomplished and needed over 10 years, this would be 2,000,000 men circumcised each year at a cost of US\$110 million. Since, in South Africa, mc is not provided in the public sector, all circumcisions in this model would be done by general practitioners. There are about 9,000 general practitioners in South Africa. Assuming all participated in mc, each general practitioner would need to do about 220 circumcisions per year or, about one per working day. If one wanted to proceed faster, over five years, then each general practitioner would need to perform 440 circumcisions per year, or, about two per working day. Either scenario is not insurmountable.

Communication in any national scale-up will be of vital importance. Initially, communication needs to be directed at national leaders, e.g., political leaders, medical/nursing professional leaders, civil society leaders, community leaders. For the general public, in South Africa, existing channels of communication exist that might be used, e.g., Soul City. Needed to be addressed in such communications will be men who are and are not circumcised, women, parents (because neonatal circumcision and circumcision of adolescents may be done, and general practitioners can perform circumcision on males of all ages).

Discussion: One point raised was that, with a system based on payment for services, health authorities must guard against paying for services that might not even be delivered.

KISUMU, KENYA TRIAL (BOB BAILEY)

This report concentrated on the surgical procedure and means of enhancing efficiency and lessening the adverse event rate. The Kenya trial used the forceps-guided technique. There were 24 adverse events occurring in 23 individuals out of 1,334 procedures with a procedure-related adverse event rate (1.7%); of these, 21 adverse events were believed related to the procedure (1.6%). Adverse events were evaluated as severe, moderate and mild and, of the 21, 11 (0.8%) were moderate and 13 (0.9%) mild. The most common events were infection or bleeding (N=9), bleeding (N=5), and delayed healing (N=5), with wound disruption (N=3), anesthetic reaction (N=1) and erectile dysfunction (N=1) of lesser importance--all but the erectile dysfunction resolved quickly with no sequelae.

Four clinicians performed surgery and there were no statistically significant differences in the adverse event rate among them (1.0%, 1.7%, 2.3%, 2.7%; $p=0.24$). Adverse event rates declined with experience: 3.8% for procedures 1-100, 2.1% for procedures 101-200, 0.7% for procedures 201-300, 0.3% for procedures 301-400, and 0.7% for procedures subsequent to 400 ($p<0.001$). Viewed another way, of 27 adverse events experienced (the 27 includes circumcisions done subsequent to the trial), 23 occurred in the clinicians' first 200 circumcisions. Thus, while the overall adverse event rate was low (1.7%), once individuals become trained and proficient, the rates become quite low, and low for all clinicians.

Important lessons were learned:

- Training in anaesthesia was important. Clinicians wanted to use more anesthesia than was necessary to limit what they perceive to be the minimum amount needed to control pain, and it is important to limit the amount that is used;
- Although some men might be judged to be at higher risk of post-surgical infection, prophylactic antibiotics were not found to be of help in reducing adverse events and their prescription should be avoided;
- Surgically, attention should be paid to optimal wound apposition and closure, with use of 4-0 chromic sutures after placement of the initial anchoring sutures, and there should be limited residual prepuce, <1 cm;
- Clear, written, post-surgical instructions are important. Men should be told to void frequently post-surgery, especially before bed; men should wear tight underwear to hold the penis pointed upward (to avoid swelling); and the taking of analgesics (panadol) before bed lessens discomfort.

Surgery became faster as surgical teams became more experienced. The median duration of surgery was 28 minutes (range, 14-63 minutes). The median time for surgery decreased, however, from 38 minutes for the first 100 procedures to 29 for procedures 200-500, and to 21 minutes for the final 75 procedures ($p<0.001$).

Results of surgery were good (although at least 10% of men resumed sexual activity earlier than instructed). 87% of men were evaluated 30 days following surgery (10% reporting having had sex) and 76% 90 days following surgery (65% reporting have had sex). After 30 days, all men had resumed normal activities (median, one day after surgery; range, 0-21 days) and 99% of employed men had resumed work, 83% within 3 days, 93% one week, and 98% two weeks). 99% of men were pleased with the results. Of the 65% of men resuming sex by 90 days, 45% of female partners expressed an opinion about the operation and, of these, 92% were very satisfied, 5% somewhat satisfied, 3% somewhat dissatisfied, and 0.3% dissatisfied.

Following the conclusion of the trial, training occurred to enhance the ability to meet demand and circumcise controls. Four trainees and 67 patients were evaluated. Lessons from this scale-up effort were:

- Clinicians are unfamiliar with consent issues, and special attention must be paid to this process;
- A model of a penis might be helpful to teach proper anaesthesia administration, but models are expensive (about US\$1,000);
- A desire to limit the number of sutures used to two (saving time and suture, which is expensive);
- The ability to alter the follow-up period, which was 3 and 7 days post-operatively in the RCT, to an initial visit at 7 days. The advantage of this is that the time is easy to remember, and the principal adverse event outside the immediate post-operative period (when bleeding might occur) is infection, which does not become manifest until 5-12 days post-operatively). However, a disadvantage is that patients must remember to remove the dressing themselves 3 days post-operatively. Currently, men are routinely provided with a 3% tube of topical tetracycline to apply to the wound at this time but its effectiveness is uncertain;
- Nurses are eager to perform mc. Per their own self-assessment, they will need special training.

Additional observations from the RCT or follow-up training included:

- The demand for circumcision in the Kenya trial was high, with an estimated four times as many men seeking circumcision as could be accommodated. However, men may be unprepared for the routine offer of HIV testing, which is part of the "standard package" of mc. Linking mc to voluntary counseling and testing (VCT) sites may be a logical thing to do;
- Learning how to limit adverse event rates will be important. The 1.7% rate experienced in the trial is considerably lower than experienced in practice outside the study situation. Indeed, in a 2005 study in Bungoma, the adverse event rate was 10.8% in public facilities (12/111 procedures), 22.5% in private facilities (78/346 procedures), and 34.3% in traditional circumcision rites (146/426 procedures). One approach to this might be to do a case study of adverse events to learn why they occur, e.g., poor technique, poor materials? An important aspect of such a study will be the study of suture technique and the amount of suture, i.e., there is the desire to lessen the amount of suture material used because of cost, but if such an attempt leads to higher adverse event rates then this approach may not be advisable;

- An evaluation of the capability of health care facilities in Kisumu District and Suma District found many health care facilities currently inadequately supplied to perform safe mc. Sterilization equipment was often missing or not functional, and many were lacking expendables (e.g., gloves, suture, anaesthetic);
- An evaluation of the capability of doctors, clinical officers and nurses in these same districts also found that many thought they themselves needed further training (Table 1).

TABLE 1. SELF-ASSESSED NEED FOR TRAINING IN MALE CIRCUMCISION

Category of Professional	Kisumu District	Suba District
Doctor	5/21 (24%)	1/3 (33%)
Clinical Officer	15/26 (58%)	14/16 (88%)
Nurse	16/18 (89%)	16/18 (89%)

- Whom to target for mc? Standard 8 students would be ideal, as they are very easy to reach. Girls who might participate in aspects of mc scale-up could be accessed at SRH sites. To scale-up mc targeting Standard 8 students, and given the number of health care facilities that could do mc in areas of Kenya where mc is not traditional would require 300 mc per facility per year, an achievable number.
- The potential demand for mc in each district was also assessed to determine feasibility of meeting that demand (Table 2).

TABLE 2. ESTIMATES OF NEED FOR MALE CIRCUMCISION, BY DISTRICT, AND NUMBER NEEDED PER HEALTH CARE FACILITY TO MEET THAT NEED, KENYA, 2007

	Number of mc	Number of mc/ health care facility, annual	Mean number of mc/ health care facility per week (52 weeks)
Kisumu District			
Upper estimate	33,612	5,600	108
Lower estimate	14,273	2,350	45
13-15 year-old's*	6,900	300	6
Suba District			
Upper estimate	94,463	4,100	79
Lower estimate	33,398	1,452	28
13-15 year-old's*	1,800	300	6

*Assume 80% will accept circumcision

RAKAI UGANDA TRIAL (STEPHEN WATYA AND GODFREY KIGOZI)

The protocol used in the trial, ranging from HIV testing to follow-up, was briefly reviewed, with the remainder of the presentation focusing on challenges encountered in the trial and some of the approaches used to meet those challenges. The presentation was divided into issues encountered in three parts: the trial, post-trial period, and scale-up:

Trial

- **Lack of understanding about circumcision.** There was a need to provide accurate information to populations and individuals about both male circumcision and what was intended by the trial providing service for mc. For instance, a theme that needed to be countered was that mc was a means of "Islamizing" men, because mc was seen as being closely associated with the Muslim faith, or, that mc improved sexual prowess. There was also lack of understanding of trial procedures and consent issues. The first step in addressing these general issues was to realize that they occurred. They were then overcome by addressing them with accurate information, sometimes presented with unusual venues, including drama, films, and village meetings.
- **Impersonation to get circumcision rapidly.** Circumcision was popular and some men did not wish to wait to be screened, enrolled and then receive circumcision. Circumcision was provided to 91% of men within two weeks of enrolment (median, two days). But, some men wished immediate surgery and had means of knowing that others were scheduled for surgery. They would present themselves for surgery as though they were the person who had been tested for HIV and enrolled. Thus, accurate identification of men being circumcised became necessary. The problem was overcome by working with community leaders to provide accurate information of the procedures needed for the trial, and use of photo identification.

- **False-positive rapid HIV-tests.** During the trial, rapid HIV tests were initially used to screen for infection but it became apparent that there were false-positive HIV tests (paper reference). The problem was overcome by testing all participants by two ELISA tests with confirmatory Western blot for positives.
- **Surgery.** Nurses and doctors were initially trained in male circumcision and associated care. Importantly, re-training was found to be necessary and the health care staff acknowledged and appreciated the need for and provision of this training. There was widespread belief among health care staff and participants in the need for and benefit of prophylactic antimicrobials, and this needed to be countered in both groups. There was belief that pain following surgery would be more severe than it is, and health care personnel needed to be dissuaded from providing strong non-steroidal and opiate analgesics. Panadol was found to be an effective means of pain relief.
- **Post-operative follow-up.** Traveling long distances to have surgery, and moving house following surgery, proved challenges to follow-up. In response, passive follow-up was supplemented by creation of follow-up sites ("hubs") in communities located far away from the surgical sites and by active follow-up at the individual house level. These sites also performed follow-up for study purposes, e.g., HIV testing at 6 months. Clear patient education proved important, for such things as pain management or dressings of the wound. For example, there was the common belief that the wound needed to be covered at all times until healed, or that daily dressing changes were needed. Patients had unreasonable expectations about the responsibility of the study for health care, and some patients assumed that any health problem that occurred following surgery was the responsibility of the programme--education about exactly what was the responsibility of the mc surgical programme and what was not proved important.
- **Importance of regular team meetings.** There were continual questions about such things as diagnosis of adverse events, possibly overtreatment with analgesics or antimicrobials, and regular team meetings to discuss such issues was important. Again, the concept of continual training and retraining became important and was viewed as beneficial by staff.
- **Misconceptions, post-operatively.** Health care staff must look for misconceptions and, when found, address them. For instance, in Rakai, misconceptions and dangers to good care were: urine is good for wound healing, vaginal fluid is good for wound healing, local application of herbs is good for wound healing, curiosity about the wound (leading to opening of dressings with touching/feeling, or, application of above fluids, etc), and that the first sex post-operatively should be with a non-regular partner.

Post-trial, after results were known and controls being circumcised

- **Political commitment.** Political leaders, to initiate and maintain support for mc for HIV prevention purposes, needed to be continually briefed on the importance of mc to HIV prevention and the results of the ongoing trial, and their ongoing support needed to be reaffirmed;
- **Possible harm to women if HIV-positive men are circumcised.** Men who are HIV-positive but wish circumcision must be fully counselled on the current data that show circumcision does not lessen risk of HIV transmission;
- **Surge in demand.** The results of the trial resulted in an increased demand, in excess of the capacity to provide services. In response, a Center of Excellence to provide and train for services was proposed; funding for it was approved by PEPFAR;
- **Competition of mc services with other services at the health care facility level.** With the introduction and scale-up of mc services within health care facilities with fixed and limited capacity, there is proving to be competition for space and resources. No particular solution has been found.

Scale-up issues, based on experience in the trial

- **How to screen for STIs?** Is a simple visual inspection sufficient, or should laboratory evaluation be done?
- **Who should be circumcised?** Questions increasingly being asked are who should be prioritized for surgery, e.g., adolescents, all adult males, children. Policy needs to be made.
- **Consent/assent.** The creation of appropriate, clear and understandable information and documents, that are administered in a uniform and clear way, is important.
- **Task-shifting.** Whether nurses or midwives should be trained to perform mc is under discussion.
- **How should follow-up be done?** The issues about follow-up found in the trial will be of increased importance as scale-up is implemented and solutions, appropriate to the community, must be found.
- **Type of surgery and operative care.** The Rakai trial used the sleeve method, but which method of mc might be preferable, if any, should be investigated. Similarly, the entire surgical process such as types of dressings, type of anesthesia, etc, all should be investigated for effectiveness and cost-savings.
- **Situation analysis of health care facilities.** The capacity of the current health care facilities must be done. Currently, in Uganda there are three levels (1,2, 3) of health care facilities. Health clinics, type 1, do not have surgical capacity, but whether they can be fitted to do so is uncertain, and whether type 2 can reliably be used is uncertain.

Discussion of RCTs: Many comments were made following the presentations from the three RCTs.

- There was little mention of approaches to counseling, and the importance of determining the best approaches to counseling--about procedures and especially to prevent risk compensation--were raised several times;
- The community needs to be considered in scaling up services, and empowered, as it is the community that will respond, or not, to accepting mc;
- The role of traditional circumcision, and traditional circumcisers, must be considered;
- The degree of precision for removing the foreskin must be discussed or ascertained. This could be important because too much residual foreskin may reduce the preventive effect of mc;
- JHPIEGO is working with a commercial company to devise a model of a penis upon which surgical training can be performed; the model was field tested in Lusaka in early June;
- The issue of how many surgeries are needed to be performed by a trainee before they are competent was asked. Dr. Groeneveld replied five or six. Whether one method or another might be best suited for training individuals who are not surgeons or who have little surgical experience was raised in different parts of the discussion, as was the need to devise an appropriate training approach for persons with no surgical skills, e.g., nurses;
- If having sex too early after surgery is a risk factor for HIV acquisition, we should understand why men do this. Another comment suggested that men agree, perhaps by signing a letter of commitment, not to have sex until sex is approved by the surgical team. Perhaps women partners might participate in assisting men to not have sex;
- Whether, if HIV-positive men will be circumcised, there is any difference in outcome by HIV viral load or stage of HIV infection was asked;
- Since mc is common in West Africa, we should review practices there and learn from those;
- The importance of quality assurance of the surgical process was raised.

OR Implications of Different Models of Service Delivery: Integrated Services

ZAMBIA (KASONDE BOWA)

The University Teaching Hospital (UTH) in Lusaka has operated a male circumcision service for three years. It has not been a service that has fully integrated HIV testing nor strong counseling and follow-up into its programme, concentrating mostly on delivering the service of mc. It is now, however, planning to broaden into a service that offers the full “basic package” of services and expand its role into being a center of excellence. The plans for doing this were principally discussed.

Within Zambia, the UTH clinic has been supplemented by three additional sites (two private, one government hospital), done in conjunction with external NGO partners, e.g., JHPIEGO, PSI. The results of the effort were mixed in terms of success of sustainability, with logistics and supply issues being the principal determinant of failure. External partners plan to expand services at these and other sites.

The UTH clinic currently uses VCT for HIV testing, performs counseling about mc, has done training three times for mc (having trained 50 providers), and has circumcised about 1,500 men. There is currently a waiting list of about one month for mc. Noting that there is no definition of what a center of excellence is, the clinic plans to become a center of excellence, plans to expand capability in four ways: 1) counseling; 2) VCT; 3) the circumcision procedure itself and follow-up; 4) training. It will increase its volume from 50-80 circumcisions per month to 200 per month. It will increase its counseling capability to include individual and group sessions, with one each provided to clients. Training will increase to hopefully 12 trainees per 3-4 months, and these trainees will become the principal means of spreading care from the center of excellence to elsewhere in Zambia.

There are constraints to developing the center. First, there are space (the operating room currently used is shared with the urology department, which needs it for other types of surgeries), financial support, and staffing limitations. Second, to become a centre, funding will be needed. Third, the need for ways to increase surgical ability other than just on patients would be welcomed (see reference to surgical model, above), so that when practitioners are being trained, they are more adept than pure novices. Fourth, whether the center should concentrate on “teaching” a vertical approach to service delivery, or a horizontal one is not clear, and at the Harare meeting, the conference was divided on which approach might be best.

Discussion

- How to coordinate HIV testing? Currently, the LTH programme gives persons requesting circumcision an appointment for HIV testing at a VCT site, but does not require results of HIV testing for circumcision. The problem with this is that persons may not get the test or, alternately, if the person wants the test now but you cannot provide it, he may lose motivation to seek it. When counseling and HIV testing is combined at the same visit, one gets better uptake of HIV testing.
- Counseling for HIV testing can be “task shifted” as is done in Kenya, where a video provides information on HIV and testing. Subsequently, a counsellor or doctor can provide further information.
- The current time for an operation at UTH is 20-25 minutes, with some surgeons performing surgery more rapidly than others. Different ways to speed surgery were suggested, e.g., have one surgeon alternate tables, or operating rooms, and “task-shift” specific tasks. Thus, the penile nerve block is put in by a nonsurgeon, and after anaesthesia is assured, the surgeon performs the circumcision, then leaves dressing to nonsurgeon staff. However, the surgeon should give instructions (oral, written) to the patient, as this has been found to markedly improve adherence to post-surgical care. With this methodology, an Israeli team has found surgery takes 13-17 minutes from the time the penile block is in place.
- Noted to be absent from presentations was information on long-term effectiveness of counseling to prevent risk compensation.

NEONATAL CIRCUMCISION

No presentation on neonatal circumcision was made. Rather, the time on the agenda was left to free discussion on the issue. While UNAIDS has made recommendations only for circumcision of adolescent and adult males, since this is the group that will immediately benefit for HIV prevention, that neonatal circumcision is considerably easier to do surgically than surgery later is causing discussion of the issue even though HIV prevention impact will not be seen until 15 or more years into the future.

- In Swaziland, surgery on children from one week of age to 15 years of age requires general anesthesia, which can be dangerous and might currently be thought of as a specialized field. No neonate currently in Swaziland gets circumcised neonatally. The Swazi feeling was to be in favour of a programme in neonatal circumcision but to recognize the problems it might present—there are no “obstacles, only hurdles.”
- The human rights issues need to be considered, since neonates cannot speak for themselves and benefit of HIV prevention will accrue to adults—a legitimate concern.
- The anticircumcision movement is vocal and can be strident in its opposition, and this group could prove to be an obstacle.
- Prevention must be prioritized and we in the HIV field are leaving prevention behind in the wake of treatment. We must agitate more for prevention. Circumcision of neonates is a legitimate means of HIV prevention and we should give parents honest information and then let them decide on behalf of their children.
- Conversely, UTH has experienced some problems circumcising children using sedation. Partly as a result of this but also for human rights and clarity of counseling, their target age is 10-35 years.
- The Israeli team, with the experience of circumcising neonates routinely at 8 days of age in the Jewish religion, has noted three things. First, that neonatal circumcision brings a big benefit in terms of less resource use. Individuals can easily be trained to do neonatal circumcision, whereas circumcision of adolescents and adults is more difficult. Second, that circumcision of neonates can be done safely. Third, that we can look at neonatal circumcision as an opportunity to enroll parents in SRH services as their neonates are being circumcised.
- Neonatal circumcision is more readily accepted in societies where traditional circumcision is not practiced.

KENYA AND AMERICAN CDC PLANS FOR SCALE-UP (BECKY BUNNELL AND JONATHAN MERMIN)

- Kenya has set up an overall task force for mc, with subgroups to be formed for important individual parts, e.g., monitoring and evaluation or quality assurance. At the moment, things are rather disjointed and an attempt at a unifying approach is just forming, e.g., a task force is in place but there is no Kenya policy yet.
- Plans are to target two districts, but CDC will focus on Nyanza. There it will begin an “AFFIA 2” programme and, in Suba District, partner with the Institute of Tropical Medicine and the team that conducted the Kisumu trial. HIV testing to identify those most likely to benefit will be assisted by an existing, novel door-to-door HIV testing programme that has already tested 10,000 individuals. Mass media work will be supported by PEPFAR, the National AIDS Commission and the Ministry of Health.
- A “phase IV study” is planned that will look at the comprehensive implementation of a basket of prevention measures, including mc. For the latter, some innovative measures such as fixed vs. mobile mc services will be tested. The ability to measure impact on HIV incidence is already in place, as there is surveillance using HIV testing conducted triannually already, although the singular contribution of mc to any measured decline in HIV incidence may be difficult to ascertain amid the multiple prevention measures being implemented. There will be in the package a specific focus on discordant couples, where impact of mc may be more readily measurable.
- Another project will investigate integration of traditional circumcision into the formal health care system. The Kemri Research Institute and the Ministry of Health will, in XX (where 80% of men are circumcised, with an absolute percentage of 75% by traditional circumcision), pair traditional circumcisers with the formal health care system and have the traditional circumcisers bring prevention messages to youth, as well as incorporate the traditional circumcisers into a monitoring system for adverse events. The project is at an early stage and details are lacking.

ZAMBIA AND POPULATION SERVICES INTERNATIONAL (STEVE GESUALE)

- PSI is working with two private clinics (one very well-appointed, and the other more “typical”--crowded and informal), the UTH programme, and VCT services to bring mc services into the VCT site. Each has benefits and challenges (Table 3). The VCT services are, in particular, very desirous of working with mc programmes to incorporate mc into their prevention package and even deliver services.

TABLE 3. BENEFITS AND CHALLENGES OF DELIVERING MC SERVICES IN THREE SETTINGS, ZAMBIA

Site	Benefits	Challenges
Teaching Hospital (public)	Experienced in mc	Lack of VCT experience
	Well-known by public	Oriented toward surgery with need to enlarge scope
	Eager for training	Lack of supplies
Two private clinics	Adequate supplies	Less willing to devote time for training
	Strong operational systems	Danger of quantity over quality
	Experienced staff	Lack of VCT experience
VCT Center	Counseling, and VCT, experience	Build theatre, supply materials
	Eager for training	Need for emergency back-up
	Non-medical setting	Non-medical setting

- Cost of services varies greatly. In the public sector, mc is US\$2.50, while it is US\$80-100 in the private sector, and patients do not understand why there is this difference. By supplying materials without cost, PSI believes it can get prices in the private sector to about US\$12.
- Initial indications are that some men prefer the non-medical setting of the VCT center
- Three sets of patient education materials are being developed and will be evaluated: 1) a simple brochure for persons interested in mc; 2) a flip chart for counseling; 3) a booklet for post-operative care. A caution expressed by counsellors is the need to not overwhelm the patient with information, and there will be a need to balance the need to deliver essential information with time limitations.
- To be evaluated at the sites are: client satisfaction, client return rates (2, 7, 30 days), adverse events, post-operative sexual behaviour, cost of service, cost to client.
- Also being developed with a firm in the Netherlands is a surgical circumcision kit. The programme has already worked with developing such a kit, and has learned lessons, e.g., .more suture, more gauze, more lignocaine are necessary.

SWAZILAND (ADAM GROENVELD)

- Within the public sector, mc has been performed for about two years at one clinic, and three special one-day events (“Circumcision Saturday”) have been held. Israeli doctors are planning to donate time to assist in training. An NGO, the Family Life Association of Swaziland, has also performed mc for about two years. Overall, there is demand but not on a large scale, perhaps because no media campaigns have started.
- A Task Force headed by the Deputy Director of Health, Ministry of Health, has been formed. Swaziland will concentrate on 15-25 year-olds, and a policy and guidelines are being drawn up, with standardization--surgery, forms, etc--being a vital guiding principle.
- Swaziland has determined that only doctors will perform adult mc. Training of doctors has begun, but “certification” and determining when doctors are competent has proven to be politically tricky, as doctors feel that if they have a medical license, that is all the certification they need to perform mc.
- In considering scale-up, it is thought that a doctor can perform 10 circumcisions in an average day although this could be increased by task shifting and use of multiple operating beds per surgeon. To bring services to the country and circumcise all adult males, about 5 full-time mc centers would be needed and doctors would need to be imported.
- VCT has been integrated into services, and is proving acceptable to patients, but the time needed to perform VCT has slowed service delivery.

CATHOLIC MEDICAL MISSION BOARD (FAITH BASED ORGANIZATION), KENYA (SALVADOR DE LA TORRE)

The Catholic Medical Mission Board of Kenya is working with faith based organizations (FBOs) and traditional circumcisers in an attempt to continue the culture and cultural importance of traditional circumcision but with the operation itself being conducted in a formal medical setting. The Board is working with mission hospitals in areas where traditional circumcision is practiced. A meeting on male circumcision and faith based organizations, for eastern and southern Africa, was held in early June.

Circumcision might be seen as a danger, protection and a teaching opportunity. A danger because unsafe circumcision practices could occur with morbidity and even HIV infection; protection because it is widely reported in Kenya mass media that mc protects against HIV infection and demand for mc in FBO settings is increasing, and; a teaching opportunity because mc may allow teaching about sexual and reproductive health, risk reduction, and the “enhanced package” (e.g., discussion about responsible alcohol use or responsible gender relationships). These opportunities are particularly possible because boys see mc as a turning point in their lives and are eager to learn about sexual and reproductive health, HIV risk reduction, responsible adult behaviour and how to balance tribal values with modern life. Since peers are often a source of information for boys, the programme offers to all boys similar, accurate, information, leading to a knowledge base of accurate information within a community. And, parents are involved in the process because they must sign a consent form for surgery (and may otherwise participate--see below). Parents have been particularly pleased with the programme because the programme tells boys things that parents themselves are reluctant to state, or, that the programme has more and better information than the parents can supply.

More than 30 FBOs offer mc in Kenya and there is no standardized curriculum. Themes of these programmes, however, include: safe surgical circumcision, several days of teaching about issues above, some FBOs encourage girls to participate in teaching, parents are often involved pre- and post-circumcision (for example, one model has parents receive two pre-surgery counseling sessions and a third two months following circumcision. Occasionally, parents are asked to attend VCT), programmes are supported by the community, and, there is a focus on family and community values.

The size and structure of the programmes vary, most commonly in size of the programme. Of 24 programmes surveyed, 14 serve <100 boys per year, 8 serve several hundred boys or more, and, 2 serve >1,000 boys per year. Classes occur over 5-7 days, typically with 50-70 boys per class. The age served is 15-17 years. In 2006, about 12,000 boys were circumcised in the FBO programmes, about 4% of the estimated 300,000 boys circumcised in Kenya that year. The cost for the mc is about US\$18, and parents pay this.

An important, controversial, aspect of the programmes is that traditional circumcisers are not part of the surgical part of the programme. Salvador believes that they should be. However, exactly how to include them, and the effectiveness of such inclusion on an overall mc programme, is unknown as operational research has not been performed.

A number of additional operational challenges have been identified in the FBO programmes:

- A very high demand for circumcision in November/December, the time when circumcision traditionally occurs (occasioned, in part, by school holidays), which leads in part to the following challenge;
- A lack of resource ability and infrastructure to meet big surges in demand. The most that have been circumcised is 500 boys over a two-day period, with surgical teams working two very long days;
- A lack of leadership and, if there is leadership, organizational skills. Noted has been that without these, these programmes will not work;
- Lack of guidance and protocols for how to structure programmes;
- Varying types of programmes, none of which have been evaluated for quality or content, nor for outcome;
- No system to monitor the programmes in place nor quality assure them;
- Lack of record keeping of programmes;
- Lack of ability to follow-up participants, many of whom are “lost to follow-up,” and there is no long-term follow-up of boys who participate in the programme.

Discussion of Kenya, Zambia, Swaziland and FBO: It was suggested that for the curricula of the FBO, rather than trying to develop guidelines or standardize curricula now, that we evaluate existing programmes, determine what is “good” and what is not, develop a couple of model curricula from that information, and then evaluate these.

The issue of poor follow-up following mc was discussed. Having patients attend for three follow-up visits can be onerous for the patients and outside the study situation is seldom achieved. In Swaziland, it has been found that patients attending for

the second post-operative visit are always ones who come for the first post-operative visit--thus, if patients do not attend the first follow-up visit, it seems likely they will attend no visit. On the one hand, one opinion expressed was that this is acceptable and understandable, as if patients are doing well, they will not return. On the other hand, it makes counseling, monitoring and effectiveness efforts difficult.

Mentioned again was the issue of what criteria should be used to screen for STIs.

Helpful would be guidance on the quantities of supplies needed, and not just supplies for each circumcision (such as a circumcision kit) but also other supplies, e.g., surgical gowns.

What messages should be delivered to HIV-positive men is uncertain and need to be developed. Certainly included are the concept that such men will not benefit from HIV protection for themselves, and there might be reasons not to be circumcised, i.e., risk of complications.

How many patients can be circumcised by one clinician in a day was again discussed, in light of the Swaziland, Zambia and Israeli estimates. In Kenya, doctors or clinical officers can do 25-30 a day, and the reason for this high number is thought due to the fact that mc is fee-for-service, and the monetary incentive for the practitioners is important. In a later discussion, however, the surgeon was not thought to be the rate-limiting step but, rather, the set-up for the patient on the operating table.

Will men accept women performing circumcisions? In the FBO experience, there was some reluctance on the part of some males, but when told that if one is to be circumcised and a women doctor must do the operation, there is acceptance.

Whether leadership itself can be a subject of research was discussed, and consensus was that this was a legitimate and important area of research. For example, "champions" have been found to be important in other scale-up efforts, and we should know their potential value in mc scale-up.

POPULATION COUNCIL (JOHANNES VAN DAMME)

In 2000, the Population Council convened a meeting to discuss operational research for mc (van Dam J, Anastasi MC. Male Circumcision and HIV Prevention: Directions for Future Research). The meeting was convened in part to develop an awareness in the global HIV community of the need for research on mc and, also, to enhance funding for mc. However, without sufficient controlled data showing the effectiveness of mc for HIV prevention, funders still did not wish to fund operational research for mc. This has now changed. The discussion in this meeting has identified a number of OR issues, and many of these are similar to those identified in 2000. Now, however, these ideas can be tested. It would be ideal to meet regularly to determine progress in identifying, and testing, OR ideas.

Operational research can now be done, because we are starting to conceive and conduct programmes. These programmes should be founded on formative research following situation analysis. Even if, however, programmes do not do OR (but, rather, simply deliver services), we need to carefully document how these programmes are conducted and their outcomes.

An area of relative need in mc scale-up is in social science. We need to concentrate on clients, as how well we understand them will help determine communications strategies and means of scale-up. For instance, what are the desires of clients regarding mc, why are they seeking mc, where do they prefer to get mc services? Understanding these issues will also inform counseling to prevent risk compensation, determine the most appropriate messages, and how often and how to deliver them.

The Population Council will team up with Marie Stopes International and propose to study communities--the health care structure and the individuals within them. The studies will seek to identify the social science issues in the above paragraph, and also best means of providing services. The latter will involve fixed vs. mobile clinics, working with men and male health issues, with the latter even possibly delivered in women's health clinics.

Discussion: Added to the group of men for whom OR studies are needed is the military.

Stigma must be an area to be addressed, particularly if mc is targeted at or prioritized for men who are HIV-negative. In noncircumcising communities, will men who are HIV-positive and subsequently not circumcised be stigmatized? What about men who are HIV-negative, or of unknown HIV status, who do not choose to seek circumcision? Will women preferentially seek men who are circumcised?

THREE-COUNTRY COSTING EXERCISE (GAYLE MARTIN; UPDATED NOVEMBER)

The United States Health Policy Initiative has studied the cost of mc, and the impact implications of scale-up of mc on HIV incidence, in Lesotho, Swaziland and Zambia, and attempted to place these services within the current social, cultural and policy context in which scale-up would occur.

The study costed circumcision of adolescents and adults, and measured direct and indirect costs (using the new terminology for "indirect cost," which would currently be called by the United States government, the sponsor of the study, facility and administration--"F and A"--cost, which includes things like facility cost, cost of administration, cost of utilities, etc). Four facilities, from urban/rural sites as well as referral hospitals and sites with less sophisticated facilities in each country were selected for in-depth study, and the costs of mc at each site determined. Included in the analysis was the cost of treatment of adverse events.

Costs per circumcision were reasonably similar among countries, and ranged from about US\$55 per circumcision in Lesotho to about US\$48 per circumcision in Zambia. More than 75% of the costs were for the surgical procedure, with the remainder for counseling, HIV testing, follow-up visits, etc. Direct costs were found not to vary widely among facilities and cost was not sensitive to such items as use of prophylactic or therapeutic antimicrobials, commodity costs, adverse events, changes of dressings, etc. Indirect costs varied more widely among facilities and the cost of circumcision was sensitive to indirect costs, with the level of facility being related to costs.

Scale-up was quite affordable. Assuming that one set moderate circumcision prevalence scale-up targets by 2015 (Lesotho, current 0% to a goal of 50%; Swaziland, current 15% to 58%; Zambia, current 17% to 57%), the annual cost of circumcision was, respectively, US\$1.5 million, US\$0.6, and US\$7.9 million with cumulative costs of scale-up, assuming scale-up occurred 2008-2020, were: Lesotho (US\$20 million); Swaziland (US\$7.8 million), Zambia (US\$102 million). To achieve scale-up, the number of circumcisions needed per day was also quite achievable: Lesotho (N=114), Swaziland (N=47), Zambia (N=461).

The impact evaluation examined, in each country, varying levels of achieved mc by 2015 using four levels of risk among men, and assumed a 60% reduction in HIV transmission by mc. To avert one HIV infection, the numbers needed to treat (NNT) number of circumcisions needed to be done to avoid one HIV infection--and associated cost per HIV infection averted were: Lesotho, 6.1 (US\$292); Swaziland, 4.1 (\$176); Zambia, 8.0 (\$313). Interestingly, when modeling how quickly scale-up occurred, the more rapid scale-up occurred, the more HIV infections were averted even if the same goal was achieved by 2020 (this makes sense, as if one circumcised more men early, then these men would be protected, not acquire HIV, and not spread HIV). And, the cost per infection averted would be less with rapid scale up. This insight adds impetus to scaling-up services quickly.

Among issues important to scale-up are:

- How to work with private practice to avoid artificially costs of surgery when there is high demand? One might use a voucher system, where the government gives vouchers to patients to redeem, but a danger with this system is that private practice might prioritize quantity over quality of service. Noted, however, is that there is considerable information on incentivizing private practice and this literature should not be ignored;
- This study did not, and does not plan to, study neonatal circumcision.

CIRCUMCISION SURGICAL PACK (STEVE GESUALE)

PSI has worked on designing a surgical kit with all-disposable items (with surgical instruments not included). They had difficulty finding a supplier who was able to supply such an item, and settled on a Dutch firm (Figure 3).

FIGURE 3. MALE CIRCUMCISION KIT (PSI).



The cost of the kit is US\$5.60. This price might be lowered, as \$0.90 of this is for shipping and packaging (labour included), and this seems high. After use of the kit in practice, changes are anticipated for version two (Figure 3). For example, the kit currently contains three days of panadol, but more is needed because painful morning erections begin soon after surgery. The type and numbers of pairs of gloves proved an unanticipated obstacle, as the size of glove is important to the surgeon and with a kit one must supply appropriately-sized gloves. And, if the kit is to supply gloves for the assistant, one does not know these sizes, either. Currently, the kit contains one pair of big and one pair of little gloves, but this may not be a sufficient number for both surgeon and assistant(s).

Development of the surgical kit has been, in part, a reaction to previous lessons learned. Materials not in kit form were supplied in appropriate numbers to several sites performing mc, but there was significant diversion of material to other purposes. As a result, materials were not available for mc and mc ceased. The lesson learned was that “when there were no supplies, there were no circumcisions.”

It was recommended that someone, perhaps at WHO, be assigned to work with suppliers, much as there are dedicated staff to work with suppliers of ART medications. Who this would be is uncertain. The Clinton Foundation is going to begin work on a similar package in several months.

THE UN WORKPLAN, HUMAN RIGHTS ISSUES, AND WORKING TOGETHER (CATHERINE HANKINS)

This presentation consisted of two major themes: 1) the two UN Work Plans for Male Circumcision (UNAIDS web site); and, 2) the legal/ethical/human rights aspects of male circumcision (http://data.unaids.org/pub/Manual/2007/070613_humanrightsethicallegalguidance_en.pdf).

The first UN Male Circumcision Workplan, the “readiness” workplan, of August 2005-August 2007, prepared for the possibility that the three randomised controlled trials would find male circumcision effective for reducing the risk of HIV acquisition in men. Thus, the workplan focused on developing a framework to support policy-making at international, regional and national levels and on developing programmatic tools to assist countries deciding to explore or adopt male circumcision for HIV prevention. A secondary focus was to explore means of making existing male circumcision practices safer. International, regional, and country stakeholder consultations were held and reports and recommendations prepared. Two meetings of modellers were convened to compare assumptions and models of potential impact, assess cost-effectiveness and the factors influencing it, and gather information to inform decision-makers. Products included a surgical manual to be used for training in safe male circumcision procedures, including associated counselling; a situation analysis toolkit; certification and standard setting; and legal/ethical/human rights. .

The second UN Male Circumcision Workplan, which commenced in September 2007, is assisting countries to make evidence-informed policy and programme decisions to improve availability, accessibility, and safety of male circumcision and reproductive health services. To achieve this, resource estimations have been made by UNAIDS. Within selected sub-Saharan African countries that could gain the biggest benefit from mc (those with areas of “low” levels of male circumcision together with “high” HIV prevalence), a goal of 80% of 15-24 year-old men being circumcised was used to estimate resource needs to achieve a prevalence of male circumcision that would have a significant impact on the HIV epidemic. Three scenarios were examined, depending upon rapidity of scale-up and the year in which one wished to achieve this goal. Resource needs are quite achievable when viewed against current funding levels for HIV prevention, with annual expenditures for male circumcision being in the range of US\$60-160 million (with 950,000-2.5 million circumcisions being done in 2010). The UNAIDS estimates conducted with The Futures Institute suggest that, within all monies needed for prevention to achieve universal access to prevention, male circumcision would consume a small proportion yet contribute significantly to overall HIV prevention effects. Where monies would come from would depend upon donor aid and on the capacity and willingness of countries to contribute domestic funding. Resource tracking figures for 2004 show that, excluding The Global Fund and monies spent for research, the United States donated 49.6%, with the UK being the second-largest contributor at 20.5% of total direct bilateral donor commitments to recipient countries for AIDS.

The UNAIDS role in operations research for male circumcision scale-up is simply to foster operations research via identification of priorities, methodologies, funding sources, partnerships and synergies with monitoring and evaluation, and to work with countries/funding/implementing partners to address priority questions. For the latter, the UNAIDS Legal, Ethical and Human Rights Guidance document addresses issues, including informed consent, that must be considered as countries implement programmes to scale up male circumcision.

THE GATES FOUNDATION (AMY WELTON)

The Gates Foundation has funded the UNAIDS Work Plan but no programmes in country implementing mc, pending decisions on the efficacy of mc for HIV prevention, a decision reached at the March 2007 UNAIDS Conference (web site). Now that mc has been endorsed as an effective prevention strategy for HIV prevention, The Gates Foundation will be actively considering further steps toward supporting programme and OR within countries, ideally with other donors. Within the next few weeks, The Gates Foundation will be developing their policies and guidelines towards mc and presenting this to the leadership of The Gates Foundation for consideration.

Within The Gates Foundation, mc is seen as a potentially very effective HIV prevention strategy and a Strategic Intervention Team has formed to address mc. The represents varying disciplines, such as advocacy, communications, prevention, health systems and product development. Subsequent to the development and acceptance of the policy, The Foundation will be open to consideration of funding for mc. Talking informally with the Foundation about potential ideas before submitting a formal concept paper would be ideal.

PEPFAR (CAROLINE RYAN)

The United States government through the President's Emergency Plan For AIDS Relief (PEPFAR), committed to donating US\$15 billion over five years, is on track to doing and even exceeding this figure, with a recent increase of funding to US\$30 billion being requested by the United States government. PEPFAR works in 15 "focus countries," chosen because about one-half of all HIV infections occur there. All but three are in sub-Saharan Africa and support of mc activities by PEPFAR, as PEPFAR is doing, could have a considerable influence on HIV infection.

PEPFAR is poised to fund mc programmes and public health evaluations (the PEPFAR equivalent of OR). Monies in 2007 and before could address assessment work but, as with The Gates Foundation, without international agreement that mc is an effective prevention strategy for HIV, funding of service delivery was not allowed. In 2008, this will change.

In April, 2007, \$15 million was put aside in "Plus-up Funding" for selected sub-Saharan Africa countries, with Zambia (\$8 million) and Kenya (\$5 million) having the most money available. Country Operating Programmes (COPs) will be formulated in July 2007 with funding available in April 2008, and the "Plus-up Funding" can provide a bridge for activities until the 2008 COP money is available. For instance, restrictions do not allow PEPFAR to construct buildings (remodelling is acceptable), and partnering with other donors without such restrictions may be a feasible way to build infrastructure for mc programmes.

PEPFAR's approach will be to develop a prevention package and not one focused solely on mc service. Public health evaluation will need to investigate the value of varying approaches to the package and how to integrate it into health care programmes. On the important issue of traditional circumcisers, there are no restrictions on working with them and, indeed, PEPFAR believes they are important and will investigate means of working with traditional circumcisers. There also are no age restrictions on funding so that mc services can be for neonates, children or adults.

Working Groups

Five working groups of 7-8 people each were formed, with four formed of multidisciplinary members and the fifth formed principally of individuals trained or interested in economics. The working groups addressed the question of: "Within 12 months, what 5-7 OR issues must we have started or completed?" Studies could be of three types: 1) Problem identification and exploration (for example, we know that working with traditional circumcisers is important but we do not know how to do it); 2) an intervention study (for example, we know that pre- and post-surgical risk reduction counseling is important and we have some information on what is effective, so we do an intervention study comparing two ways of counseling); 3) costing/cost-effectiveness (for example, a country wishes to scale up mc but does not know the costs involved or how the costs will be distributed, so we estimate the cost of the programme and to what "cost centers" those costs will need to be allocated). Groups were encouraged to think broadly and systematically, using the frameworks previously presented, but projects themselves could be broad or narrow. Groups were encouraged to use, for consistency and comparison purposes, a Cochrane Collaboration format for reporting their work, with a single sentence containing the intervention, the purpose, and the target group, e.g., "counseling strategies to lessen risk compensation among men having mc."

All groups found the range of potential topics to be vast. Two groups adhered to the instructions for limiting the number of OR projects to 5-7, although none chose to use the suggested Cochrane Collaboration format, sometimes including in one statement multiple interventions, for multiple purposes, and targeting multiple groups. Among the groups, there was expected repetition of ideas, and different ways of presenting similar thoughts. For clarity of presentation, the concepts of the four non-economic working groups are presented together and the economic working group separately. Where an idea was clearly enunciated by more than one group, the number of groups identifying that priority is in parentheses, e.g., (2).

GROUPS 1-4

Basic, non-operational research (since basic, non-operational research was explicitly stated prior to the exercise not to be part of OR, the following ideas were provided by one or two groups even though acknowledging that they were outside the scope of the group exercises):

- Determining the impact of mc on male to female transmission of HIV;
- Determining the population impact of mc on HIV and STI incidence and prevalence, but also other areas, e.g., sexual behaviour, attitudes of women (2);
- Identifying simpler, faster, cheaper and bloodless circumcision techniques (2);
- Determining the time-protection relationship of HIV following circumcision, i.e., when after mc are men more or less susceptible to acquiring HIV, and by how much? (2);
- Evaluating the acceptability and feasibility of newborn MC in Eastern and Southern Africa (2);

Needs assessment

- Perform situation analyses in countries, or appropriate regions of countries, and tailor scale-up efforts on the basis of those findings (2)
- Develop and apply models for impact, costing, advocacy and planning for policy-makers;
- Identifying the determinants--demographic, behavioural, supply--of demand/uptake of male circumcision and, once identified, what messages effectively motivate men who are choosing not to have circumcision to seek circumcision. One group suggested setting a target, e.g., 80% of adult males circumcised, and then determining the determinants of uptake needed to achieve that level and, once 80% coverage was achieved, determining the impact on HIV incidence/prevalence (see below) (2);
- Understanding how to enhance community interaction with the health systems to enhance mc, including the potential roles of stigma and traditional circumcisers (the emphasis of this topic was on "understanding the community");

Service delivery models

- Determining the effectiveness of differing means of HIV testing, e.g., on-site vs VCT, individual counseling vs. group;
- Determining if stigma occurs with mc scale-up, e.g., if HIV-positive men are excluded and, if it occurs, how to deal with it;
- Determining the roles of differing types of health care providers--traditional, government, private, FBO, NGO--and their varying levels of ability of delivering care to providing successful access to all priority target groups;
- To assess the advantages and disadvantages (e.g., equity, utilization, provision of service, ability to quality assure) of different service delivery models (e.g., fixed site services, mobile services, camp services, VCT-based, special events) to different target groups (e.g., neonatal, adolescent, adult) to deliver quality service (e.g., measured by numbers circumcised, adverse events, cost per circumcision, number of providers needed) by location and ethnicity (4);
- To assess the feasibility and synergies of linking mc services with other established services (e.g., family and child health,

maternal health, VCT, STI, and HIV prevention) (2);

- Feasibility, safety and acceptability for non-physicians to perform MC. This should include differing levels of non-physicians, with an evaluation of the type of training needed, and the outcomes to include adverse events, client satisfaction, and ability to scale-up services because of the task-shifting (3);
- After using formative research to explore the effectiveness and safety of traditional circumcision, implement differing models of collaboration with traditional circumcisers; measure safety and acceptance by the community and the traditional circumcisers of these models;
- vWhat are the most effective, and cost-effective, means of providing post-surgical follow-up to achieve good surgical outcome? For example, training patients to recognize adverse events so that patients, and not health care providers at follow-up visits, may be used to detect adverse events, or, a single follow-up visit at 7 days with the patient providing dressing change before that.;

Surveillance/monitoring and evaluation

- Developing monitoring and evaluation systems for mc programmes within national programmes;
- Developing quality assurance guidance and programmes, with standards, for mc programmes. This quality assurance should focus on surgical services but consider other aspects of the programme, also, e.g., HIV testing or counseling. Can a standardized approach with teaching curricula be devised?;
- Assess the population impact of scale-up of mc services on HIV incidence/prevalence (male and female), STI rates, and sexual behaviour (2);

Sexual behaviour

- Study the degree of sexual activity at the individual and population level, and their determinants (whether individual, community, or as a result of mc), as mc programmes are scaled up;
- What is the most appropriate package of counseling and communication (individual, couples and community) to minimize risk compensation, and ensure post-surgical abstinence (2)?

GROUP 5

This group concentrated on economics but, since economics must be applied to practice, the group considered many scale-up issues as did preceding groups and considered the economic consequences of them. As with the other groups, far more than 5-7 issues were identified and the suggested Cochrane format was not followed.

The group found a logical sequence to their thinking, and identified five domains for study, with time frames for beginning/completing them, with all but the last, cost-effectiveness, beginning or completing within 12 months:

1. Financing¹;
2. Pricing²;
3. Modelled resources/costs¹;
4. Empirical measurement of resources/costs²;
5. Cost-effectiveness.

1=some projects finish in 12 months 2=some projects start within 12 months

1. Financing. The initial funding needs, total and by country, should be determined with an estimation of the funding mix needed, international vs domestic contribution. Determining the domestic contribution will require study, as it may be difficult to assign value to the contributions that countries will make, e.g., infrastructure, indirect costs. But, such a measurement is needed so countries can rightfully be seen to be making (significant) contribution to the scale-up effort;

2. Pricing. The current prices of services, by type/completeness of service and service delivery setting, should be determined within the context of the country in which those services will be delivered, as the existent pricing and health care context will differ by country. For example, prices for the surgical procedure or the “basic package” or the “expanded package” will need to be priced, as well as whether delivered in the public or private sector. Elasticity of demand, differentiated by income level, will be useful to determine in pre-marketing surveys. Such data will help inform the level of demand and also ways that demand might be influenced. If parts of the package are important for public health reasons but perhaps deemed by the individual not so important for him, e.g., post-operative visits for counseling, the value of incentives for selected services (such as counseling) may be determined. The pros and cons of use of vouchers for payment in the private sector was discussed, with the major con argument being a potential low quality of service, but with a pro argument being that if the voucher covers the entire cost of circumcision surgery, it is in the interest of the provider to have a low complication rate.

3. Modelled resources/costs. Needed is a toolkit to allow decision makers within countries to, within the HIV epidemiologic and circumcision status context of their own countries, assess costs of services, overall resources needed, and the impact of scaling up services on HIV incidence. Such a toolkit would allow individual countries to understand their country's, or perhaps individual regions', resource needs (current prevalence of circumcision, HIV incidence/prevalence), how to distribute resources, and how to assess the benefit of scale-up. The toolkit and its associated modeling would allow the input of specific cost items, e.g., costs of delivering mc services, and allow the modelling of impact depending on various factors, e.g., which age groups to target, circumcision and HIV prevalences, speed of scale-up. The cost savings of averted HIV cases in the model would add important information for policy- and decision-makers, who must weigh the cost and benefit of scale-up decisions.

4. Empirical measurement of resources/costs. In the previous model, one could input guessestimated figures or figures derived elsewhere, e.g., cost of male circumcision. Once, however, services are available within a country, determining actual costs will allow more accurate modelling. Thus, all scale-up costs should be continually monitored and the sources of funding for them noted, so that realistic estimations and accounting of resource allocation made. Efficiencies of scale-up on unit costs should be considered. Outcome data, e.g., frequency of adverse events (and their costs) should be simultaneously measured. Countries considering adult and neonatal circumcision should model both approaches. Public/private costs should be calculated. The effect of positive and negative externalities on the health system by mc scale-up should be considered. The use of vouchers in the private system (see above) can be considered. The effect on sexual behaviour of multiple follow-up visits can be determined, costed, and their value evaluated. If desired, costs to patients may be determined and modelled (see 3, above).

Differing approaches to modeling may be used. For example, on a local level, the detailed facility costing approach of the Cornell group can provide precise measurement of resource need and use, and efficiencies of scale calculated.

5. Cost-effectiveness. Cost-effectiveness of scale-up should be made using the empirically-derived data. An evaluation and estimation of cases of HIV averted as a result of scale-up should be planned for (the estimation should include any cases of HIV thought to be acquired by risk compensation) and the cost-effectiveness of scale-up should such estimations.

6. Discussion of Group 5's report: Ways of financing scale-up were discussed. While assumed is domestic financing with, at least initially, international financing, how the domestic financing will occur is uncertain. Some will be "in-kind" financing, where, for example, indirect costs are given. Some domestic monies will be needed, however, and shifting of monies from other HIV (or even other disease prevention and control priorities may be needed). General sentiment was that some cost-shifting from other HIV prevention programmes would be reasonable and ethical because mc is a well-proven and cost-effective intervention, while other programmes from which funding may be taken do not have such a solid evidence base or cost-effectiveness. Individuals may be reasonably asked to contribute some funding, and even communities may consider use of community funds, as lowered HIV rates will benefit communities.

Identification of OR Priorities and Prioritization

A prioritization process was conducted to determine the issues that had most support. First, a list of OR topics was generated, based upon the results of the working groups. Disparate ways of phrasing similar thoughts from the working groups were collated until 22 topics were identified. Second, each member of the meeting was given 5 votes to distribute among the 22 topics. Third, the priority of topics was determined based upon the number of votes given to each topic. The results were, in order of priority with number of votes in parentheses:

1. Study task-shifting, with feasibility, safety and acceptability of non-physicians to perform surgery (19);
2. Determine effective and cost-effective models of delivering mc services, and compare their advantages and disadvantages (18);
3. Determine the approach to counseling (couple or individual), and content of messages and numbers of sessions, that decrease risk compensation following surgery and lessen sexual activity immediately following surgery (18);
4. Determine the acceptability and feasibility of newborn circumcision (15);
5. Build mutually agreeable linkages of traditional circumcisers with the formal health care system to provide culturally appropriate mc in a safe environment, and to learn lessons from traditional circumcisers (14);
6. Determine sexual behaviour and its determinants following mc, and determination of successful strategies--behavioural counseling or otherwise--to limit risk compensation following mc (11);
7. Conduct needs assessment, including attitudes towards mc, role of traditional circumcisers, demand, target groups (8);
8. Identify and then create useful linkages/synergies/integration of differing models of service delivery with other non-male circumcision programmes, perhaps differentiated by differing target groups, e.g., adolescent males (7);
9. Assist policy makers, using models or other approaches, to make informed policy and programme decisions about mc (7);
10. Modeling resource and costs with a toolkit to help decision makers make scale-up decisions about mc (6);
11. Find effective and cost-effective strategies of providing post-mc follow-up (5);
12. Determine how much funding will be needed, and from where it will come, for scale-up activities (5);
13. Develop surveillance, monitoring and evaluation, and quality assurance systems (4);
14. Determine determinants--behavioural, demographic, pricing--of uptake of mc (4);
15. Assess the capacity to scale-up mc within countries (4);
16. Determine the population impact on HIV of scale-up (4) (few votes because not possible in the next 12 months)
17. Study the community context of mc, and how to learn from the community about mc and attitudes toward it, how to respond to community concerns, and how to benefit from community resources (3);
18. Understand the current context of pricing and the elasticity of demand (2);
19. Determine how to incorporate, and enhance acceptance of, HIV testing in mc services without increasing stigma (3);
20. Determine empirically the costs and resources needed for scale-up, including descriptive studies and comparisons of alternative models of service delivery (3);
21. Develop and test a bloodless male circumcision method (2) (few votes because not possible in the next 12 months and not strictly OR);
22. Determine cost-effectiveness of approaches to mc and its associated basic or expanded package (0) (no votes because not possible to do this in the next 12 months).

Conclusion

The group concluded that a subsequent meeting in about one year would be worthwhile to review OR experiences and what has been learned, and reset priorities.

Appendix 1 – Agenda

Purpose and Objectives

A two day meeting is being convened to bring together individuals and groups working in different areas of male circumcision to deliberate on operations research (OR) priorities now that WHO/UNAIDS recommends that male circumcision (MC) be considered as an additional HIV prevention strategy. The meeting's discussions will focus on sub-Saharan Africa.

The meeting will build on a number of other meetings and initiatives including; an informal OR meeting in January 2006, the Gates Foundation OR meeting of May 2006, the UNAIDS Nairobi Regional Meeting of November 2006, the Strategies and Approaches for MC Programming meeting of December 2006, the MC and Adolescent SRH meeting of February 2007, the Policy and Programme meeting of March 2007, and other sources of guidance, e.g., Population Council report of 2001.

Specific Objectives

1. To review different models of male circumcision service delivery, identifying challenges encountered in implementation and implications for OR;
2. To review priority areas for operations research and to identify the key questions that need to be answered.

Expected Outcomes

Operations research implications and challenges in differing models of male circumcision services scale up identified; Prioritized list of OR questions developed.

Day 1 21 June 2007 Chair: Dorothy Mbori Ngacha		
TIME	TOPIC	PRESENTER
08:50 – 09:40	OPENING SESSION	
	Registration	
	Welcome and introductions	Cate Hankins
	Review of meeting objectives, expected outcomes and agenda	Tim Farley
	Review of previous OR meetings and selected documents	George Schmid
	Feedback from the Harare meeting sub-Regional Meeting	Chiweni Chimbwete
SESSION 1	OR IMPLICATIONS OF DIFFERENT MODELS OF SERVICE DELIVERY: VERTICAL SERVICES	
09:40– 09:55	Orange Farm trial presentation	Orange Farm Team (Dirk Taljaard, Bertran Auvert)
10:05 – 10:30	Kisumu trial presentation	Kisumu Team (Bob Bailey)
TEA BREAK		
11:05: - 11:10	Welcome remarks on behalf of WHO	Rex Mpazanje, on behalf of David Okello
11:10- 11:35	Rakai trial presentation	Rakai Team (Stephen Watya)
11:35 - 11:50	Discussion of the three trials and identification of important areas for OR	
SESSION 2	OR IMPLICATIONS OF DIFFERENT MODELS OF SERVICE DELIVERY: INTEGRATED SERVICES	
11:50 – 12:00	U of Lusaka Clinic/Centre of Excellence	Kasonde Bowa
12:00 – 12:15	Discussion of clinic-based approaches, and identification of important areas for OR	
12:15 – 12:30	Neonatal circumcision – discussion of priority and OR needs	George Schmid
12:30 – 13:50	LUNCH	

SESSION 3		
OR IMPLICATIONS OF DIFFERENT MODELS OF SERVICE DELIVERY		
13:50 – 14:10	OR plans in Suba District, Nyanza Province	Becky Bunnell, Peter Cherutich, Doug Shaffer
14:10 – 14:25	PSI – social marketing	Steve Gesuale
14:25 – 14:45	Circumcision Saturdays, public and private clinics	Adam Groeneveld
14:45 – 15:05	Kenya mission hospitals/traditional healers	Salvador de la Torre
15:05 – 15:30	Discussion of different models of service delivery, and identification of important areas for OR	
15:30 – 16:00	TEA BREAK	
SESSION 4		
PROPOSED RESEARCH MODELS		
16:00 – 16:20	FHI: Scaling up MC—a research framework and priorities	Mike Welsh
16:20 – 16:30	Pop Council: plans and OR thoughts	Johannes van Dam
16:30 – 16:35	Discussion of novel approaches and identification of important areas for OR	
SESSION 5		
RESOURCE (MONEY/TIME/CLINIC FLOW) ESTIMATIONS		
16:35 – 17:00	Constella three-country costing exercise	Gayle Martin
17:00 – 17:10	Circumcision surgical pack	Steve Gesuale
17:10 – 17:20	Resource estimates	Eric Hollingsworth
SESSION 6		
CRITICAL ISSUES FOR OR-- SUMMING UP THE DAY		
17:25 – 18:35	Closing summarization	Bruce Dick
18:00 – 19:00	Reception	

Day 2 22 June 2007 Chair: Johannes Van Damme		
TIME	TOPIC	PRESENTER
Review of Day 1		
08:30 – 09:30	Introduction to Group Work	
SESSION 5		
IDENTIFYING QUESTIONS		
09:30 – 12:00	Group work (four groups discussed general research priorities, one group concentrated on costing issues)	
10:00 – 10:30	TEA BREAK	
10:30 – 12:30	Report back from groups	
12:30 – 14:10	Lunch	
14:10 – 14:40	Report back from groups	
	Discussion	
14:40 – 15:00	Prioritization of the important issues	Bruce Dick
15:00 – 15:30	COFFEE	
15:30 – 15:45	Review of research priorities	Bruce Dick
15:45 – 16:05	Gates Foundation	Amy Welton
16:05 – 16:25	PEPFAR	Caroline Ryan
16:25 – 17:10	Roles of UN agencies, technical agencies, PEPFAR and other funders in OR and scale-up	Cate Hankins
17:10 – 17:15	Close	

Appendix 2

List of Participants

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