

STRENGTHENING MALE CIRCUMCISION IN ZAMBIA

END-OF-PROJECT REPORT

FEBRUARY 2005



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ABBREVIATIONS AND ACRONYMS

AE	Adverse event
AIDS	Acquired immunodeficiency syndrome
CBoH	Central Board of Health
DHMT	District Health Management Team
GA	General anesthesia
HIV	Human immunodeficiency virus
JHU	Johns Hopkins University
MC	Male circumcision
MOH	Ministry of Health
NW	Northwest
STI	Sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNIM	Universities of Nairobi, Illinois and Manitoba
USAID	United States Agency for International Development
UTH	University Teaching Hospital
VCT	Voluntary counseling and testing

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EXECUTIVE SUMMARY

The United States Agency for International Development funded JHPIEGO and AIDSMark (Population Services International) to improve the quality and accessibility of comprehensive male circumcision (MC) services in Zambia to meet existing demand, and to develop experience and tools that would enable scale-up of these services in the future. Specifically, JHPIEGO aimed to achieve this by:

- Strengthening existing MC services in areas with unmet need (traditionally MC practicing areas, such as NW province, and urban areas such as Lusaka and the Copperbelt provinces, where there is evidence of unmet need)
- Exploring alternative approaches to make high-quality, comprehensive MC services more accessible in the public and private sectors (specifically in localities where need exists, i.e., pockets of demand; with traditional as well as medical practitioners)

Between May 2003 and January 2005, JHPIEGO initiated activities to strengthen MC services in Zambia. By the end of the project, the following activities had been conducted:

- An initial stakeholders' meeting with MC providers from different groups (public, private and traditional practitioners from urban areas with existing demand and traditionally circumcising areas)
- A study on the acceptability of MC in Zambia
- Formation of an MC technical working group
- MC site assessments at three service sites in Kampala, namely the University Teaching Hospital, George Clinic and Chainama Health Centre
- Site strengthening for MC at the selected sites
- Development of standardized training materials for male reproductive health and MC
- Development of a variety of patient education materials on MC and other male reproductive health issues
- Study tour of the Universities of Nairobi, Illinois and Manitoba (UNIM) MC project in Kisumu, Kenya
- One-day MC health education event
- MC and reproductive health training course for 18 health care providers from seven provinces
- Data collection and analysis of the socio-demographic characteristics of the MC clients
- Data collection and analysis of adverse events occurring at and following MC

In May 2003, JHPIEGO supported a meeting of MC stakeholders to examine the evidence linking MC with a reduced prevalence of HIV infection. During this meeting, participants reviewed the international data and perspectives on MC and HIV infection and concluded that there is very strong observational evidence suggesting that MC has a protective effect against HIV transmission and acquisition. While taking note of the need to await the results of ongoing

randomized controlled trials in South Africa, Kenya and Uganda, the group felt that there was a need to move ahead with strengthening existing traditional and medical MC services in Zambia.

An acceptability and feasibility study of MC conducted in Zambia by Mainza D. Lukobo¹ concluded as follows:

- Circumcision is embedded in a complex web of cultural and religious issues in Zambia. Many study participants felt that MC was a Luvale and Lunda cultural tradition or Moslem and Chawa religious practice.
- There were indications that MC was becoming widespread in Zambia, particularly among the younger generation.
- The HIV pandemic has also been changing people's attitudes and making them more receptive to prevention interventions that can protect them from HIV. Hence, nearly all the participants expressed a willingness to get their sons circumcised, in order to reduce the risk of sexually transmitted infections and HIV.
- Fear of impotence was recognized as a potential barrier to MC. This is closely related to the experience of the circumciser. For this reason, **nearly all respondents preferred an experienced medical doctor to perform the circumcision at a health facility**. A few still preferred a traditional surgeon (*chikeji*) because they felt that he could keep secrets (confidentiality) and also teach them some cultural practices.

A site assessment conducted at the Urology Clinic of the University Teaching Hospital (UTH), the Chainama Health Centre and George Clinic, all in Lusaka, showed that there was an unmet need for MC at the three selected facilities, but that shortage of equipment, consumable surgical supplies and low staff motivation were barriers to voluntary MC services. All three facilities lacked dedicated space for counseling clients in privacy and with assured confidentiality. There were also significant gaps in infection prevention practices at all three sites.

In order to motivate the key MC health workers at the three selected sites, a study tour of the UNIM Male Circumcision Research Project at Kisumu, Kenya, was conducted in August 2004. The primary purpose of this trip was to showcase a high-performing MC site in Kenya prior to the MC standardization workshop scheduled for 28 August to 3 September 2004 in Lusaka, Zambia.

A MC and reproductive health education event was held for members of the public and invited MC workshop participants at the UTH on Saturday, 28 August 2004. The agenda included an overview of MC and HIV/AIDS, sexually transmitted infections (STIs), adult and civic responsibilities, smoking, alcoholism and drug abuse, MC and religion, the role of men in gender issues and male contraception. Participants were generally convinced about the need to embrace MC pending the final outcome of the ongoing randomized controlled trials looking at the relationship between MC and HIV infection in Uganda, Kenya and South Africa.

A MC and reproductive health standardization workshop was held at the Fairview Hotel, Lusaka, from 27 August to 3 September 2004. There were 18 participants from nine health facilities

¹ Mainza D. Lukobo, Doctor of Public Health Candidate, University Of Illinois at Chicago, mlukob1@uic.edu.

nationwide. The participants included six medical officers, five clinical officers and seven nurse/midwives. As much as possible, team training was encouraged. Hence, a medical or clinical officer and a nurse/midwife represented each center. In the participants' true/false knowledge assessment exercise, mean scores increased significantly from 67.5% in the precourse to 89% in the midcourse assessment. The range of scores narrowed in the midcourse questionnaire when compared to the precourse assessment. Furthermore, 77.7% of participants scored more than 85%, compared to only 15% in the precourse assessment.

During the training, participants used learning guides for clinical skills acquisition during role plays. Skills assessed included counseling, provision of health education, client assessment, pain relief and MC technique. Only designated medical and clinical officers were trained in the MC procedure itself. The nurses learned to counsel clients and to prepare for and assist at surgery.

An analysis of client record forms showed that most of the patients (57%) lived in areas of high density. Children under the age of 15 years made up 55.2% of the MC clients. This explains why most of them were single (85.1%) and had never been treated for sexually transmitted infections or ever used the condom. Over 90% were Christians and had come to the service site through self or parental referral. The remaining 9.1% were referred from voluntary counseling and testing centers. Three tribes constituted two-thirds of the clientele. They were the Bemba (25.1%), the Nyanja (21.5%) and the Luvale (21.5%).

The primary indication for MC in 83.9% of clients was social or religious reasons while phimosis, paraphimosis and erectile pain were indications for 11.4%, 1.9% and 2.8% of clients respectively. Only 35% were sexually active and 14.3% had fathered children. The prevalence of chronic medical conditions was quite low, namely hypertension (0.9%), diabetes mellitus (1.9%) and HIV infection (1.4%). Physical examination of the penis revealed normal findings in 96.6% of clients.

With regard to adverse events associated with MC, about half of the clients experienced mild pain during the procedure while 41.6% had no pain. Mild to moderate bleeding occurred in one-third of patients while six patients (3.2%) experienced anesthesia-related adverse events. In another six patients (3.2%), excessive skin was removed. This may explain the slight damage to the penis also seen in 3.2% of patients. No other significant complications were noted during surgery.

In conclusion, there was an unmet need for MC in Zambia. This need is likely to increase in the short term because of increasing awareness about the relationship between STI/HIV infection and lack of MC. Most clients have expressed a preference for MC instead of traditional circumcision because of safety concerns. However, as shown in the project, adult MC in modern health institutions is not completely free of adverse events, especially when performed by poorly trained health care workers. Therefore, great attention must be paid to the quality of training of male circumcisers. JHPIEGO's competency-based approach provides a direction for achieving high-quality training. Lessons learned from this project indicate that the following interventions are essential for quality MC services:

- Provision of dedicated space for client counseling and assessment in order to ensure privacy and confidentiality.

- Provision of numerous packs of surgical equipment for MC (number will depend on daily client load at the service site; usually five to six clients).
- Provision of surgical consumables (sutures, gauze, gloves and personal protective wear, chlorine solution, anesthetic solutions etc.).
- Provision of space for postoperative recovery, giving of postoperative instructions in privacy and postoperative reviews at the eighth day and 1-month followup visits.
- Competency-based training of health care workers (team training involving the physician, nurse assistant and reproductive health counselor is recommended). The training should teach a standardized MC technique with special attention to the application of effective and safe local anesthesia. In Zambia where stakeholders opted to provide MC in the context of male reproductive health, counselors should also be trained to discuss other male reproductive health topics. The service sites should also store and provide condoms.
- Staff motivation initiatives are crucial to the success of the project. Frankly speaking, health care workers often demand monetary compensation for abandoning private practice and other revenue-yielding activities in favor of long MC surgical lists.
- The provision of free services has also proved to be most welcome to parents contemplating MC for their children.

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1.0. BACKGROUND

1.1. Global

The effect of male circumcision (MC) on the risk of HIV infection—and the practice’s impact on the spread of HIV across different populations—has, for years, been the subject of interest to epidemiologists and other researchers. Numerous studies have noted a decreased risk of infection in circumcised men as well as continued low HIV prevalence rates in populations that traditionally practice MC. HIV/AIDS and reproductive health professionals have become increasingly interested in MC, and the U.S. Agency for International Development (USAID) has been supporting preliminary activities to investigate MC as a potential tool in the fight against HIV/AIDS².

As reviewed in *The Lancet* in 1999, more than 35 studies from 10 countries, mostly from Africa but also India, the United States and other countries, have found a significant association, from two- to eight-fold greater HIV risk, due to lack of male circumcision (MC)³. These studies include eight cohort studies, most recently by Johns Hopkins researchers in Rakai, Uganda⁴, who analyzed risk factors for HIV infection in married couples in which only one partner was initially infected. Among 137 uncircumcised, uninfected men at baseline, 40 seroconverted during the 2-year study. Among the 50 circumcised men (including 14 non-Muslims), **none** became infected during the same period, regardless of their female partners’ viral load levels.

A systematic review and meta-analysis conducted by the London School of Hygiene and Tropical Medicine⁵, after controlling for potentially confounding socio-cultural, religious or other factors, found a **significant association between lack of MC and HIV infection in all 15 (adjusted) African studies**. MC was associated with a 58% decrease in risk for men in the general population and a 71% decrease among higher-risk men. (A recent meta-analysis of the estimated HIV risk reduction from treatment for sexually transmitted infections [STIs] was 22%.)

An extensive UNAIDS multi-site study by leading European researchers investigated numerous behavioral and other potential factors for the large disparities in HIV prevalence across different African regions⁶. Lack of MC (and genital herpes, which is more common in uncircumcised men) emerged as the principal determinant for the pervasive, continuing differences in HIV rates found in sub-Saharan Africa.

As the *Lancet* study found, most countries in West Africa (except Côte d’Ivoire and Burkina Faso, which are the only two West African countries with significant numbers of uncircumcised

² USAID. Bureau for Global Health.

³ hivinsite.ucsf.edu/InSite.jsp?doc=2098.4613.

⁴ *N Engl J Med* 2000; 342: 921–929.

⁵ *AIDS* 2000; 14: 2361–2370.

⁶ *AIDS* 2001; 15: S15–30.

men) continue to report HIV levels under 5%, and in many cases below 2–3%, despite the presence of other classic risk factors for heterosexual HIV (multiple sexual partnering, low condom use, prevalence of other STIs, etc.). Prevalence in the South and Southeast Asian countries where nearly all men are circumcised (Philippines, Indonesia, Pakistan, Bangladesh) remains extremely low, despite similar HIV/STI risk factors found elsewhere in the region.

The search for a biological explanation for the increased risk of HIV infection among uncircumcised men has revealed that the inner foreskin is much less keratinized than other genital mucosa, so its numerous Langerhans and other immune cell targets are unusually susceptible to HIV infection. In an *in vitro* study, viral uptake in this tissue was seven times more efficient than in cervical tissue⁷.

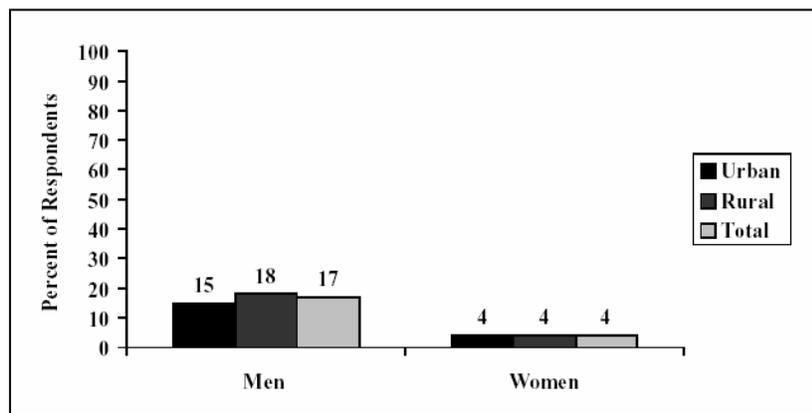
In addition to the highly vascularized foreskin mucosa being prone to tearing or bleeding during intercourse (especially with the “dry sex” practices particularly common in Southern Africa), ulcerative STIs like HSV-2, chancroid and syphilis, which further facilitate HIV infection, are more prevalent in uncircumcised men.

1.2. Zambia

Not much has been published on the relationship between MC and HIV prevalence in Zambia. One study that explored the role of MC in the spread of HIV infection in four urban populations in sub-Saharan Africa found that in Cotonou (Republic of Benin) and in Yaoundé (Cameroon), two low HIV prevalence cities, 99% of men were circumcised. In contrast, in Kisumu (Kenya) and Ndola (Zambia), where HIV prevalence rates exceeded 25%, the rate of MC was only 27.5% and 9% respectively⁸.

The Zambia 2000 Sexual Behaviour Survey showed that the prevalence of MC in Zambia is about 16.9% (15.3% in the urban areas and 17.8% in the rural areas; see **Figure 1** below)⁹. Most circumcisions are performed in the Northwest province of the country where the HIV seroprevalence is lowest (see **Figure 2** below).

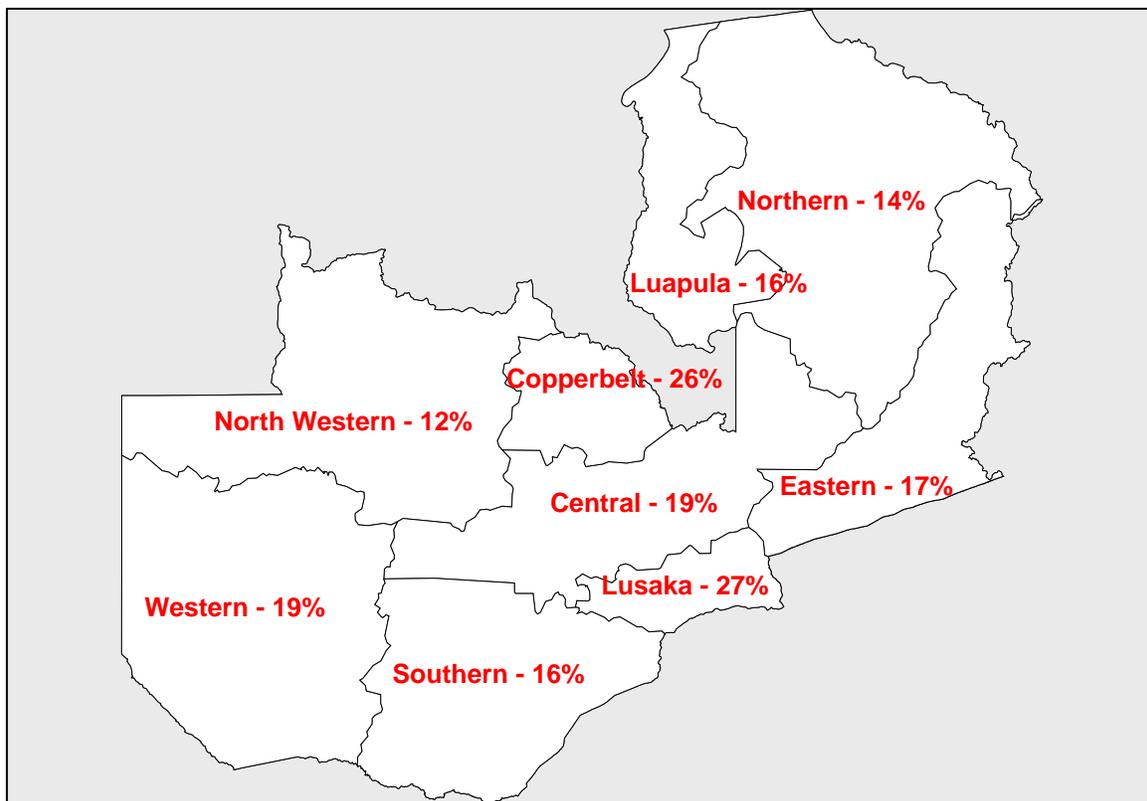
Figure 1. Percentage of Zambian Respondents Who Reported Being Circumcised



⁷ kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=11427_

⁸ Auvert B, Buve A, Lagarde E, Kahindo M, Chege J, Rutenberg N, Musonda R, Laourou M, Akam E, and Weiss HA. 2001. Male circumcision and HIV infection in four cities in sub-Saharan Africa. *AIDS*. Aug; 15 Suppl 4: S31–40.

Figure 2. HIV Prevalence: Zambia 1998 Sentinel Sites¹⁰



1.3. The Zambia Male Circumcision Project

USAID has funded JHPIEGO and AIDSMark (Population Services International) to improve the quality and accessibility of comprehensive MC services in Zambia, and develop experience and tools that would enable scale-up of these services in the future. Specifically, JHPIEGO aimed to achieve this by:

- Exploring alternative approaches to make high-quality, comprehensive MC services more accessible in the public and private sectors (specifically in localities where need exists, i.e., pockets of demand; with traditional as well as medical practitioners)
- Developing and testing tools and approaches required to strengthen MC services
- Strengthening existing MC services in areas with unmet need (traditionally MC practicing areas, such as NW province, and urban areas such as Lusaka and the Copperbelt provinces, where there is evidence of unmet need)

2.0. ASSESSMENT OF EXISTING SERVICES

Several activities were conducted to explore the unmet need for MC services, identify gaps in the quality of existing MC services at selected clinical sites, and make recommendations for strengthening such sites. These included the following:

⁹ Zambia Sexual Behaviour Survey. 2000.

¹⁰ Steve Hodgins, USAID Zambia, 2002.

- An initial stakeholders' meeting with MC providers from different groups (public, private and traditional practitioners from urban areas with existing demand and traditionally circumcising areas)
- A study on the acceptability of MC in Zambia
- MC site assessment at specific facilities identified for strengthening

2.1. National Stakeholders' Meeting on Strengthening Male Circumcision Services in Zambia

JHPIEGO's Regional HIV/AIDS Advisor ('Dipo Otolorin), Country Director (Rick Hughes) and USAID Senior Technical Advisor (Steve Hodgins) facilitated a 2-day meeting on *Strengthening of Male Circumcision in Zambia*. During this meeting, participants reviewed the international data and perspectives on MC and HIV infection and concluded that there is very strong observational evidence suggesting that MC has a protective effect against HIV transmission and acquisition. While taking note of the need to await the results of ongoing randomized controlled trials in South Africa, Kenya and Uganda, the group felt that there was a need to move ahead with strengthening existing traditional and medical MC services in Zambia.

Participants also reviewed the profile of current MC services in Zambia, including services in the private and traditional sectors of the country. The group noted the following:

- Most MCs are currently being performed around the age of 7 years (7–10 years), even though the procedure is sometimes carried out among adults whose wives have demanded it.
- Most MCs performed at the University Teaching hospital were medically indicated (e.g., for phimosis, paraphimosis, genital warts, diabetes mellitus, and condom allergies).
- Though there were frequent demands for **voluntary** MC at the University Teaching Hospital (UTH), the surgeons generally treated such requests as low priority.
- Waiting lists for such voluntary procedures may sometimes be as long as 4 months.
- MCs in the UTH attract fees as low as K5,000 (\$1) but clients are often given a shopping list to buy their own medical supplies.
- MC services in the private sector, on the other hand, cost as much as K250,000–750,000 (\$50–150).
- For traditional MCs, payment is usually in kind (chicken, beer, maize, etc.) and is not fixed. In camp settings, parents are required to bring food items for their children and for the



Figure 3. MC Stakeholders Working in Small Group
(Photo by 'Dipo Otolorin)

traditional circumcisers. An “MC organizer,” who may charge up to K150,000 (\$30), runs the post-MC “civil education” classes, in addition to arranging the traditional MCs in camp settings.

- Participants also noted the lack of national policies, guidelines and protocols in Zambia to guide MC services. There were likewise no standards or systems for record keeping or reporting of cases or of complications related to MC services.
- Most clinicians use scissors or surgical knives to perform the circumcision under local or general anesthesia (GA). GA is preferred for children under the age of 12 years. The use of devices like the Gomco, Mogen, Plastibell or similar devices was virtually non-existent.
- Traditional circumcisers also use only the knife to excise the foreskin. They use herb poultices to reduce and manage the bleeding, and the healing occurs over an extended period of time while the boys are in the “camp” setting (for as long as 1 month).
- It was noted that some traditional circumcisers were using lignocaine injection for pain relief (a skill learned from the some missionary doctors).
- The general consensus was that there was a trend toward a preference of medical MC services even in traditionally practicing areas; however, there were still those who preferred the traditional methods and felt that enduring the traditional procedure was an important part of showing one’s manhood.
- The disposal of the excised foreskin was an issue of some concern. In the traditional setting, the foreskin is handed over to the father of the client who will secretly dispose of it to prevent witches from having access to it and making the boy impotent or infertile in future. In the hospital settings, parents are given the option of disposing of the foreskin by themselves or allowing the hospital staff to discreetly do so on their behalf.
- While traditional MCs conducted in camps are associated with a range of adult and sexual education, MCs performed in clinics generally do not offer additional reproductive or sexual health services (e.g., HIV/AIDS counseling, family planning, etc.).
- The strong consensus among providers was that the complication rates experienced, both in traditional settings and clinical settings, was extremely low. Providers from referral sites where one would expect such complications to be treated confirmed that they saw few complications.

After reaching consensus on the need to strengthen existing MC services in Zambia, the group suggested the following next steps:

- Advocacy for MC:
 - Development of an MC orientation package for clinicians and another for lay persons (e.g., church and community leaders, politicians and nongovernmental organizations).
 - Development of a simple MC Fact Sheet to be circulated widely.
 - Enlisting of journalists to post feature articles on MC in the national newspapers.
 - Support of radio and television discussions about the role of MC in HIV/AIDS and STIs.
- Development of national guidelines for traditional MC and medical MC.
- Use of MC as an entry point to increased involvement of men (young and old) in reproductive health by strengthening counseling processes for MC, in or outside camp settings. Such counseling and health education sessions should include information on

benefits and risks of MC, informed choice, informed consent, HIV/AIDS acquisition and transmission, family planning and STIs. Where the client is underage, the parents or guardians should be included in the counseling.

2.2. Acceptability Study

An acceptability and feasibility study of MC conducted in Zambia by Mainza D. Lukobo¹¹ concluded as follows:

- Circumcision is embedded in a complex web of cultural and religious issues in Zambia. Many study participants felt that MC was a Luvale and Lunda cultural tradition or Moslem and Chawa religious practice. Others felt that accepting MC is like adopting another culture. This view could be a potential barrier to the acceptability of MC in Zambia.
- There were indications that MC was becoming widespread in Zambia, particularly among the younger generation. Some young men felt that if it was true that MC reduces the chances of contracting sexually transmitted infections, particularly HIV, they would be willing to get circumcised. The researcher however cautioned that disinhibition will need to be addressed as many of the young men will have the misconception that circumcision will fully protect them from STIs, including HIV.
- The HIV pandemic has also been changing people's attitudes and making them more receptive of prevention interventions that can protect them from HIV. Nearly all the participants expressed a willingness to get their sons circumcised, in order to reduce the risk of STIs and HIV, given the rising incidence of these diseases in their communities.
- Because MC is considered more of a cultural tradition than a health issue, tribal chiefs, their advisers and the community need to be involved in the formulation of a policy on MC in order to enhance its acceptability.
- Fear of impotence was recognized as a potential barrier to MC. This is closely related to the experience of the circumciser. Most participants feared that if an inexperienced person performs the circumcision procedure, they or their son's ability to reproduce might be affected. For this reason, nearly all respondents preferred an experienced medical doctor to perform the circumcision at a health facility. A few still preferred a traditional surgeon (*chikeji*) because they felt that he could keep secrets (confidentiality) and also teach them some cultural practices.
- A lack of basic information about MC was another identified barrier to the acceptability of MC in Zambia. Most of the participants expressed a "fear of the unknown" about the procedure. Some felt that their sons could be dismembered or even die. This type of misconception can be partly attributed to the secrecy that has historically been associated with the traditional Lunda circumcision camps, *mukanda*. Going to *mukanda* is like being accepted into an exclusive, members-only club with its own strict rules and vows to secrecy. Nobody is allowed to talk about what goes on in the camps during *mukanda*. It is so exclusive that a trespasser or intruder who dares to enter to find out what is going on is forcibly circumcised and initiated into the group. Only circumcised men are allowed to enter the camps during *mukanda*. Furthermore, reports of infections or death during *mukanda* have not been uncommon. However, nearly all the **participants agreed that if they were**

¹¹ Mainza D. Lukobo, Doctor of Public Health Candidate, University Of Illinois at Chicago, mlukob1@uic.edu.

educated about the benefits and risks of MC, they would be willing to get themselves and their sons circumcised.

- Most participants felt that MC should be done before puberty before a boy starts engaging in sexual activities.
- The most important reasons given for the acceptance of MC in Zambia are reduction of STIs and increased genital hygiene. Participants were of the opinion that MC reduced a man's and woman's chances of contracting a STI because of the removal of the foreskin, which tears and gets bruised during sex and harbors genital fluids, dirt and bacteria. They also said that circumcision makes it easier to clean the penis and maintain hygiene.
- Promotion of MC in health facilities in Zambia would clearly strain the existing health services. Safety, in terms of training health professionals in MC techniques, and provision of supplies, instruments, equipment and space urgently need to be addressed. An inventory of supplies at the health centers visited showed that they had most of the instruments needed for a safe circumcision. However, this equipment was also being used for other medical procedures. Therefore, separate sets would be required for MC procedures.
- The cost of the supplies was another major issue. In Zambezi, patients were asked to provide some of the supplies, which could cost more than K37,500 (\$8.30) per person. This was considered to be rather expensive for most of the potential clients and will probably affect acceptability and reduce demand. Nearly all participants in the focus groups expressed the view that MC services should either be offered free of charge or for less than K10,000 (\$2.50).

2.3. Site Assessment

A site assessment was conducted at the Urology Clinic of the UTH, the Chainama Health Centre and George Clinic, all in Lusaka. All three facilities lacked dedicated space for counseling clients in privacy and with assured confidentiality. The dedicated space for surgical procedures at the UTH needed renovation.

Similarly, there were gross shortages of surgical instruments as well as shortage of a variety of surgical consumables (gloves, suture materials, needles and syringes, local anesthetics etc.). There were significant gaps in infection prevention practices at all three sites, especially with regard to decontamination of soiled instruments prior to cleaning, wiping of the operating table with chlorine solution in between cases, and utilization of personal protective wear.

Staffing was generally inadequate and/or irregular. At the UTH and George Clinic, MCs were usually performed for medical reasons only, while voluntary MCs were put on the waiting list that lasted an average of 4 months. The MC service at the Chainama Health Centre was more active despite the inadequacy of the operating room, which doubled as an ad hoc consulting room and minor procedures room.

Record keeping practices were very poor. Sometimes all that was written on the client's card was "For MC." Registers of minor surgical procedures, however, were kept and these contained some information on age, indication for and type of procedure performed, and name of surgeon. Records of complications were generally not available as very little was written down at followup visits. It was therefore not possible to determine complication rates at these sites, even though discussions with the surgeons indicated that complications were very rare.

An exploration of staff motivation indicated that staff were generally not inclined to attend to non-emergency cases such as voluntary MC. Staff interviewed at the sites saw the establishment of an MC service as additional work that should be accompanied by some form of remuneration. Alternatively, they suggested that additional staff should be hired to perform voluntary MCs.

2.4. Assessment Conclusions and Next Steps

The assessment revealed that there was an unmet need for MC in the three selected facilities, but that shortages of equipment and consumable surgical supplies and low staff motivation were barriers to voluntary MC services. In order to move the project forward, the following next steps were identified:

- Form a technical working group.
- Develop standard guidelines for a comprehensive MC/male reproductive health service.
- Develop tools required for implementation of package (e.g., training package, record keeping tools, and simple information, education and communication materials for patients).
- Arrange a study tour of the Kisumu (Kenya) MC research facility for four local MC champions at the three selected Zambian sites. This will serve to motivate the service providers as well as help the skills standardization process for the Zambia program.
- Strengthen selected sites to test the learning resource package and materials and feasibility of implementing MC services.
- Organize an MC sensitization event.
- Train a team of MC providers from each of the nine provinces in Zambia.
- Conduct followup visits to selected trained providers.
- Analyze patient records from services provided after training.
- Write a final report of lessons learned.

3.0. IMPLEMENTATION

3.1. Meeting of Male Circumcision Technical Working Group

A meeting of MC stakeholders was held in September 2003. Participants later evolved into the Male Circumcision Technical Working Group. The purpose of the meeting was to develop an action plan for strengthening MC and reproductive health services at UTH and other selected urban health centers.

JHPIEGO's Regional HIV/AIDS Advisor, 'Dipo Otolorin, Killian Like (Program Manager) and Rick Hughes (Country Director) participated in the 2-day technical meeting on MC in Lusaka. The meeting was held at the inservice department of the UTH, Lusaka. Eighteen Zambian participants and two Haitian physicians (Dr. Jean-Robert Brutus and Dr. Jean Boisrond), who were on a study tour to Zambia, attended the meeting. Participants worked in two groups (see **Figure 4**) to look at key issues for an MC Standards and Guidelines document for Zambia. The following are some of the decisions reached:

An MC service in Zambia should target children (aged 7–10 years) and young adults, even though older adults may also take advantage of services when available.

- MC should be provided in the context of male reproductive health services, which should include reproductive health education, counseling and services (family planning, gender, STI screening and treatment, voluntary counseling and testing [VCT] for HIV, role of men in safe motherhood), civic education (where it is normally integrated with MC), other life skills and referrals for infertility evaluation, sexual dysfunction and other urological problems.
- Clinicians (medical officers and clinical officers) should perform the procedures while nurse/midwives, counselors and peer educators should conduct the education and counseling sessions.
- Community leaders or traditional circumcisers may be invited to assist with civic education classes (where this is considered to be an important tradition in the community). The group recognized that traditional circumcisers will remain operative even in the absence of specific legislation about their role.
- The group felt that MC services should be provided in hospitals, health centers/clinics and health posts. Where feasible, MC outreaches/mobile camps can also be organized to take advantage of the “rites of passage to adulthood” ceremonies in some localities.
- Children over 18 years may give consent in their own recognition while parental consent should be sought for children under 18 years of age. Irrespective of parental consent, the consent of the child under 18 years should also be obtained.
- In addition to addressing medical topics, educational sessions should address the problems of MC myths and misconceptions; especially the fear that excised foreskins can be used for witchcraft.
- With regard to supervision of services, the group felt that the District Health Management teams (DHMTs), teaching hospitals and supervisors of mission hospitals should have oversight over established public and private MC services.



Figure 4. MC Technical Working Group Members Working in Two Groups (Photo by ‘Dipo Otolorin)

- A proper record system should be established at all service sites. Data to be collected should include name, age, marital status of client, location, physical state of the penis pre-circumcision, type of MC procedure done, adverse events (classified according to the Kisumu criteria), visiting schedules and referral information (why and to where).
- Client assessment for MC should include sexual history, past medical and surgical history, drug history including history of allergies to the local anesthetic drugs, sexual and STI history, and partner notification status. Thereafter, physical examination should document client's vital signs, nutritional status, presence of lymph node enlargement, genital discharges, ulcers and/or rash.
- Service sites should have adequate dedicated space for counseling, surgery and postoperative recovery.
- The list of instruments and consumable medical supplies from the Kisumu MC project was adopted for Zambia (except for the addition of a pair of McIndoe's scissors which is the instrument commonly used by clinicians in Zambia to excise the foreskin). It was recommended that instruments should be pre-packed and sterilized ready for use.
- In order to make MC service sites male-friendly, services should be offered every working day, rather than on a limited number of days per week.
- The staff to be deployed or hired to run an MC service should include a surgeon (medical or clinical officer), an MC coordinator, trained nurses and counselor/peer educators. At the UTH, resident doctors may rotate through the unit to perform MC as part of their surgical training. Whenever appropriate, traditional circumcisers may also be brought in for training to improve their knowledge and skills.
- The consensus surgical technique to be used is the dorsal slit excision method under a dorsal penile nerve and ring block of local anesthesia. Clients may receive preoperative sedation as needed.
- Postoperatively, clients should be observed for 1 hour before discharge and should return for a first review at 5–7 days and for a second review at 1 month.
- Every client should have both written and oral postoperative instructions.
- Adverse events or complications should be recorded and classified (using the Kisumu criteria).

The Technical Working Group also spent some time to consider the implications of developing an MC learning resource package for Zambia. Following an overview of course design by 'Dipo Otolorin, the group worked agreed that the learning resource package should consist of three documents, the MC **reference manual**, a **trainer's guide** and a **participant's handbook**. The reference manual should have the following modules on the following topics:

- Overview of MC (including information on local practices in Zambia)
- Anatomy and pathophysiology of the penis
- Male reproductive health needs
- Education and counseling for MC (including informed consent)
- Facility requirements for MC
- Client assessment for MC
- Preoperative management for MC
- Anesthesia for MC

- Surgical MC technique (dorsal slit method)
- Record keeping for MC
- Identification and management of MC complications
- Infection prevention

The group decided that the service to be established in the Urology Clinic at the UTH should be named the “Male Circumcision and Reproductive Health Clinic.” The group also recommended that services at the Chainama Health Centre be strengthened.

3.2. Site Strengthening

The three MC sites were strengthened. At the **UTH**, the dedicated space identified was partitioned to create a counseling space, a recovery room and a narrow waiting area. The space was also renovated and equipped with furniture (tables, chairs, benches, recovery beds and beddings) (see **Figures 5–8** below). Basic surgical equipment and consumable supplies were also provided, including a new operating table, autoclave and floor lamp. Focal MC staff were identified and oriented to the MC program while patient record forms, MC register and adverse events forms were printed and provided.

At the **Chainama Health Centre** and the **George Clinic**, basic surgical equipment and consumable medical supplies were provided while patient record forms, MC register, adverse events forms and postoperative instructions supplied. Focal persons for MC were also identified.

In order to motivate the focal MC champions identified and to standardize key clinical and infection prevention procedures at the sites, a study tour of the Universities of Nairobi, Illinois and Manitoba (UNIM) MC and HIV research project in Kisumu, Kenya, was conducted in August 2004.

Table 1. Male Circumcision Site Assessment Findings in Lusaka

ASSESSMENT PARAMETER	UTH (UROLOGY CLINIC)	GEORGE CLINIC	CHAINAMA HEALTH CENTRE
	✓ =Satisfactory or Adequate X=Not Satisfactory or Inadequate NA=Not Applicable		
Dedicated space for surgery	X	✓	✓
Dedicated space for counseling	X	X	X
Dedicated space for client examination	✓	✓	✓
Dedicated space for reception/records	✓	✓	✓
MC surgical instruments	X	X	X
Dedicated autoclave/Boiler	X	X ¹²	✓
Surgical lamp	X	✓	✓
Sutures	X	X	X
Gloves	X	X	X
Lotions for infection prevention	X	X	X
Surgical drapes and linen	X	X	X
Patient record forms ¹³	X	X	X
1% or 2% lignocaine	X	X	X
Gauze and cotton swabs	X	X	X
Infection prevention practices	X	X	X
Recordkeeping practices	X	X	X
Surgical technique in line with recommended procedure	✓	X	X
Number of surgeons available for MC	>5	1	1
Number of nurses available for MC	2	1 ¹⁴	1 ¹³
MC service statistics (Feb.–June 2004)			
February	2	8	13
March	2	5	18
April	1	4	11
May	0	6	10
June	4	2	18
July	9	4	14
TOTAL	18	29	84

¹² Sterilization done offsite

¹³ Virtually all sites use exercise books bought by patients

¹⁴ Available on and off

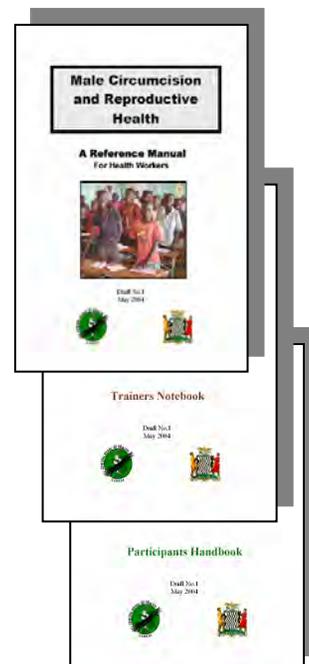


3.3. Development of Standard Guidelines for a Comprehensive Male Circumcision/Male Reproductive Health Service

Even though the MOH/CBoH representatives were convinced of the need to develop standards and guidelines for the practice of MC in the country, this activity was yet to be implemented at the end of the project.

With the assistance of JHPIEGO, the MC technical working group developed a standardized learning resource package for MC in the context of male reproductive health. The package included the following:

- A reference manual entitled *Male Circumcision and Reproductive Health: A reference manual for health professionals*
- Trainer's Notebook
- Participant's Handbook
- Presentation Graphics
- Patient education materials (flyers) covering the following topics:
 - MC
 - HIV/AIDS
 - STIs
 - Male family planning methods
 - Vasectomy
 - Substance abuse



Participants and facilitators at the first MC training activity conducted in September 2004 subsequently reviewed these draft materials.

3.4. Study Tour of Kisumu Male Circumcision Project

In order to motivate the key MC health workers at the three selected sites, a study tour of the Kisumu Male Circumcision (UNIM-University of Nairobi, Illinois and Manitoba) Research Project was conducted in August 2004. The primary purpose of this trip was to showcase a high-performing MC site in Kenya prior to the MC standardization workshop scheduled for 28 August–3 September 2004 in Lusaka, Zambia.

The specific objectives of the visit were to:

1. Observe the client flow including registration, counseling, client assessment and MC procedures at the UNIM project.
2. Observe the technique of pain relief for adult MC.
3. Observe the techniques used for adult MC.
4. Observe infection prevention procedures.
5. Discuss postoperative schedules and postoperative instructions at the UNIM project.

During the study tour, the team noted the user-friendliness of the facility (friendliness of the staff, assurance of privacy and confidentiality, use of male counselors and circumcisers, ongoing television education programs), the motivation of the clients and staff alike and the meticulous attention paid to record keeping and provision of services according to established standards. While acknowledging the excellent set-up at the Kisumu site, however, the team regretted that their own institutions were constrained by limited service space as well as staff shortage.

Another lesson learned at the Kisumu project were client and staff motivation. The team noted that the UNIM project was not part of the public service but was set up by donor agencies in collaboration with the University of Nairobi. Hence, salaries and benefits were outside the public service and were considered to be adequate to motivate all the staff to give their best. In contrast, they regarded a lack of monetary incentives in Zambia as a constraint to scale-up of MC services, which are currently limited to a couple of hours per day, 2–3 days a week.

3.5. A Male Circumcision and Reproductive Health Education Event

A MC and reproductive health education event was held for members of the public and invited MC workshop participants at the UTH on Saturday, 28 August 2004. The agenda included an overview of MC and HIV/AIDS, STIs, adult and civic responsibilities, smoking, alcoholism and drug abuse, MC and religion, the role of men in gender issues and male contraception. Clinicians, and religious and civic leaders made presentations. Participants were generally convinced about the need to embrace MC pending the final outcome of the ongoing randomized controlled trials looking at the relationship between MC and HIV infection in Uganda, Kenya and South Africa.

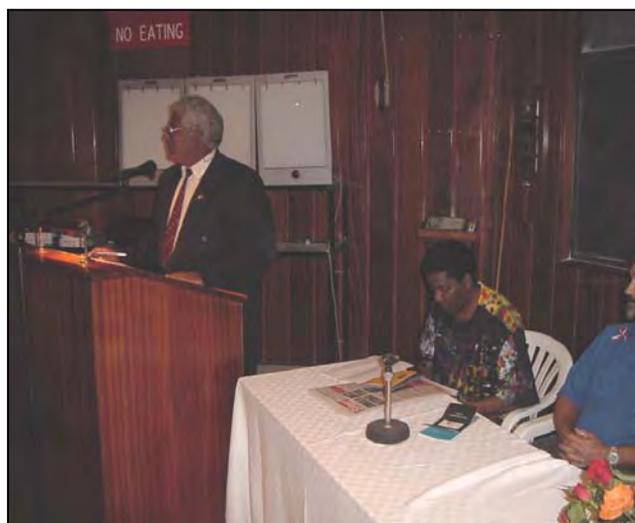


Figure 7. Managing Director of the UTH Dr. Lambart addressing participants at the MC Public Event.

Patient education leaflets were distributed to all participants at the MC public event. Participants were also informed of the upcoming MC week scheduled for the three selected sites.

3.6. Male Circumcision and Reproductive Health Standardization Workshop

A MC and reproductive health standardization workshop was held at the Fairview Hotel, Lusaka from 27 August–3 September 2004. There were 18 participants from nine health facilities nationwide. The participants included six medical officers, five clinical officers and seven nurse/midwives. As much as possible, team training was encouraged. Hence, a medical or clinical officer and a nurse/midwife represented each center. Participants came from the following health facilities:

- Macha Mission Hospital
- Senanga District Hospital
- Kabwe General Hospital
- Chipata General Hospital
- Kasama General Hospital
- University Teaching Hospital
- Kafue General Hospital
- Ndola General Hospital
- George Clinic in Lusaka.



Figure 8. Participants at MC and Male Reproductive Health Standardization Workshop, Lusaka, Zambia

The goals of the MC and reproductive health standardization workshop included the following:

- To influence in a positive way the attitudes of participants to MC.
- To reach consensus on the standard techniques for pain relief and technique for MC procedures in Zambia.
- To provide participants with knowledge and skills needed to provide other male reproductive health services.
- To provide the participants with the knowledge and skills needed to establish or improve infection prevention practices at their health facilities.

The learning objectives included the following:

- Describe an overview of MC.
- Describe male reproductive anatomy, disorders of the penis and testes.
- Identify male reproductive health needs.
- Provide male reproductive health education.
- Demonstrate counseling of clients for MC.
- Assess clients for male reproductive health services, including MC.
- Provide pain relief for MC.
- Demonstrate the standard method of MC in Zambia.
- Identify and manage adverse events resulting from MC.
- Prevent infection in the health care setting.
- Manage a male reproductive health clinic.

The training methods used during the workshop included illustrated lectures, small group discussions, role plays, case studies, clinical demonstrations in the operating rooms, coaching and guided practice activities.

The following methods were used to evaluate the workshop:

- Precourse knowledge questionnaire (True/False format)
- Midcourse knowledge questionnaires (a True/False format and a multiple choice question format)
- Learning guides and checklist
- End-of-workshop evaluation

In the participants' true/false knowledge assessment exercise, mean scores increased significantly from 67.5% in the precourse to 89% in the midcourse assessment. The range of scores narrowed in the midcourse questionnaire when compared to the precourse assessment. Furthermore, 77.7% of participants scored more than 85%, compared to only 15% in the precourse assessment.

During the training, participants used learning guides for clinical skills acquisition during role plays. Skills assessed included counseling, provision of health education, client assessment, pain relief and MC technique. Only designated medical and clinical officers were trained in the MC procedure itself. The nurses learned to counsel clients and to prepare for and assist at surgery.

In the end-of-course participant evaluation, 88.9% of participants felt confident that they could provide quality MC and male reproductive health services for clients in their facilities, while 100% of participants agreed that the workshop had made them more skillful for their work.

At the end of the workshop, participants worked in teams to identify gaps in their current MC practices and to suggest solutions to be implemented in the near future. Problems identified included:

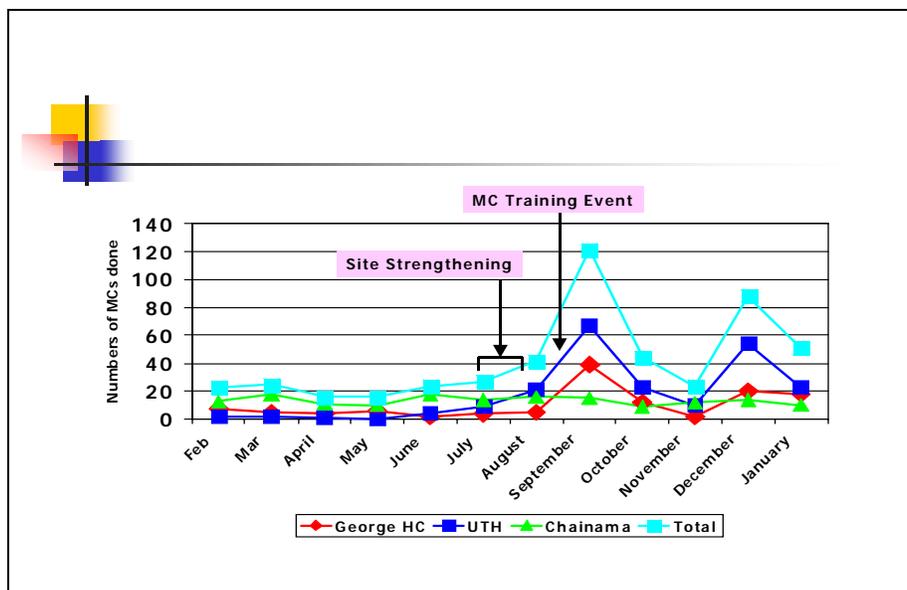
- Lack of a dedicated space for MC and male reproductive health services. Where a procedure room exists, participants were concerned about inadequate space for counseling, client assessment, postoperative recovery and record keeping.
- Lack of or inadequate surgical instruments for multiple MC procedures.
- Inadequate, irregular or inconsistent supply of consumable materials such as sutures, gloves and other personal protective wear and infection prevention materials.
- Inadequate awareness about MC and male reproductive health among health care providers and the community.
- Shortage of staff.
- Lack of incentives to motivate existing staff.

Participants proposed interventions that varied from construction of dedicated MC and male reproductive health facilities, renting of buildings to provide user-friendly services, renovation of available space (if one exists), procurement or donation of surgical instruments and consumable medical supplies, payment of allowances to staff to compensate them for overtime duties in the area of male reproductive health and circumcision (including when sessions are held on Saturdays for working clients), organization of MC orientation workshops for health workers, training of more health workers to provide quality male reproductive health services, improvement in infection prevention practices and employment of additional staff (either as full-time or as part-time staff).

3.7. Provision of Male Circumcision Services

Figure 9 below shows the MC service statistics at the three selected sites before and after the MC standardization workshop. It can be seen that the number of MC procedures done at UTH and George Clinic increased significantly after the training event. At the time of the training event, clients were scheduled and a “Male Reproductive Health / Male Circumcision Week” was sponsored during which fees were subsidized and for a limited period of time staff were supported to handle MC cases in off hours (e.g., on Saturdays).

Figure 9. Number of MCs Performed at Three Lusaka Sites, February–December 2004



However, the numbers dropped significantly again in October and November when clinicians were expected to carry on with MC services within their normal service provision. Unresolved interpersonal problems at the Chainama Health Centre slowed down the services and adversely affected subsequent data collection. The lack of staff to assist the trained clinicians at George Clinic had an impact on their ability to clear their waiting list, and the lack of additional motivational support for clinicians also had a negative impact on the delivery of services. In December, when additional support was provided to the sites (e.g., for clinicians to provide services on Saturdays, etc.), they were again able to increase the number of procedures performed.

3.8. Profile of Male Circumcision Clients at Two Selected Service Sites

Table 2 below summarizes selected socio-demographic characteristics of some clients coming for MC at the two service sites (UTH and George Clinic). It can be seen that most of the patients (57%) lived in areas of high density. Children under the age of 15 years made up 55.2% of the MC clients. This explains why most of them were single (85.1%) and had never been treated for sexually transmitted infections or ever used the condom. Over 90% were Christians and had come to the service site through self or parental referral. The remaining 9.1% were referred from VCT centers. Three tribes constituted two-thirds of the clientele. They are the Bemba (25.1%), the Nyanja (21.5%) and the Luvale (21.5%).

Table 3 summarizes selected clinical characteristics of the clients. The primary indication for MC in 83.9% of clients was social or religious while phimosis, paraphimosis and erectile pain were indications for 11.4%, 1.9% and 2.8% of clients respectively. Only 35% were sexually active and 14.3% had fathered children. The prevalence of chronic medical conditions was quite low, namely hypertension (0.9%), diabetes mellitus (1.9%) and HIV infection (1.4%). Physical examination of the penis revealed normal findings in 96.6% of clients. Table 3 shows a statistically significant relationship between sexual activity and contraceptive use.

Focus group discussions with a group of clients and clients' parents waiting for MC procedures at the UTH and George Clinic revealed that most clients were not seeking the procedure because of information linking the absence of circumcision with a higher prevalence of HIV infection. Rather, most were doing so because of a desire to have better penile hygiene or to follow their ethnic or religious traditions.

Table 4 shows sexual activity by contraceptive use. **Table 5** shows that the duration of surgery was less than 30 minutes in 85.1% of procedures.

Table 2. Profile of Male Circumcision Clients at Two Service Sites in Lusaka, Zambia

SOCIO-DEMOGRAPHIC CHARACTERISTIC	NUMBER	PERCENTAGE
Residence	(N=173)	(100%)
Low Density	32	18.5%
Medium Density	42	24.3%
High Density	99	57.2%
Age	(N=230)	(100%)
0–5 Years	58	25.2%
5–14 Years	69	30.0%
15–35 Years	92	40.0%
Above 35 Years	11	4.8%
Marital Status	(N=222)	(100%)
Single	189	85.1%
Married	31	14.0%
Divorced	2	0.9%
Tribe	(N=223)	(100%)
Bemba	56	25.1%
Nyanja	48	21.5%
Tonga	18	8.1%
Lozi	10	4.5%
Kaonde	9	4.0%
Lunda	16	7.2%
Luvale	48	21.5%
Foreigner	18	8.1%
Religion	(N=219)	(100%)
1=Christian	201	91.8%
2=Moslem	12	5.5%
3=Other	6	2.7%
Patient Referral	(N=219)	(100%)
Self or by parent	199	90.9%
From VCT center	20	9.1%

Table 3. Selected Clinical Information on MC Clients

CHARACTERISTIC	NUMBER	PERCENTAGE
Primary indication for male circumcision	(N=211)	(100%)
Social/Religious	177	83.9%
Phimosis	24	11.4%
Paraphimosis	4	1.9%
Erectile pain	6	2.8%
Recurrent balanitis	0	0.0%
Preputial neoplasm	0	0.0%
Is client sexually active?	(N=220)	(100%)
Yes	77	35%
No	143	65%
Has client fathered any children?	(N=224)	(100%)
Yes	32	14.3%
No	192	85.7%
Has client ever been treated for STIs?	(N=222)	(100%)
Yes	7	3.2%
No	215	96.8%
Previous contraceptive use	(N=216)	(100%)
None	184	85.2%
Condoms	32	14.8%
Past medical history		
Hypertension	2	0.9%
Diabetes	4	1.9%
HIV positive	3	1.4%
Physical examination of penis	(N=174)	(100%)
Normal	168	96.6%
Abnormal	6	3.4%

Table 4. Cross-Tabulation of Sexual Activity by Contraceptive Use

SEXUALLY ACTIVE	PREVIOUS CONTRACEPTIVE USE		TOTAL
	None	Condoms	
Yes	43	30	73 (34.1%)
No	139	2	141 (65.9%)
Total	182 (85%)	32 (15%)	214 (100%)

*Chi-square with Yates correction=56.46 ($P < 0.00000000$)

Table 5. Duration of Surgical Procedure

DURATION OF OPERATION	NUMBER (N=188)	PERCENTAGE (100%)
Less than 15 minutes	4	2.1%
15 to 30 minutes	156	83.0%
31 to 45 minutes	22	11.7%
45–60 minutes	6	3.2%

3.9. Adverse Events during Male Circumcision Procedures at Two Service Sites

Table 6 below summarizes the adverse events that were seen during MC procedures performed at two sites. These adverse events (AEs) are reported according to the AE classification shown in **Appendix A**.

Table 6. Adverse Events during Surgery

ADVERSE EVENT	NUMBER	PERCENTAGE
Pain experience	(190)	(100%)
None	79	41.6%
Mild	102	53.7%
Moderate	8	4.2%
Severe	1	0.5%
Bleeding	(N=190)	(100%)
None	134	70.5%
Mild	53	27.9%
Moderate	3	1.6%
Severe	0	0.0%
Anesthetic-related event	(N=190)	(100%)
None	184	96.8%
Mild	6	3.2%
Moderate	0	0.0%
Severe	0	0.0%
Excessive skin removed	(N=190)	(100%)
None	184	96.8%
Mild	6	3.2%
Moderate	0	0.0%
Severe	0	0.0%
Damage to penis	(N=190)	(N=190)
None	183	96.3%
Mild	6	3.2%
Moderate	1	0.5%
Severe	0	0.0%

About half of the clients experienced mild pain during the procedure, while 41.6% had no pain. Mild to moderate bleeding occurred in one-third of patients, while six patients (3.2%) experienced anesthesia related adverse events. In another six patients (3.2%), excessive skin was removed. This may explain the slight damage to the penis also seen in 3.2% of patients. No other significant complications were noted during surgery.

In general, patients were scheduled for the first postoperative visit at 8 days and final review at 1 month. **Table 7** below summarizes the adverse events recorded during visits that occurred within 1 month after surgery. These adverse events included mild penile pain in 31.5%, mild bleeding in

1.6% and insufficient skin removed in 0.5%. Others include mild damage to the penis in 9.8%, mild swelling and hematoma in 10.3%, mild postoperative infection in 11.9% and delayed wound healing in 1.6%. The cosmetic appearance of the penis was judged to be satisfactory in 95.1% of procedures, while four patients (2.2%) reported urinary voiding problems.

Table 7: Adverse Events Seen at Followup Visits within One Month of Surgery

ADVERSE EVENT	AT <1 MONTH FOLLOWUP	
	NUMBER	PERCENTAGE
Pain experience	(184)	(100%)
None	125	67.9%
Mild	58	31.5%
Moderate	1	0.5%
Severe	0	0.0%
Bleeding	(185)	(100%)
None	181	97.8%
Mild	3	1.6%
Moderate	1	0.5%
Severe	0	0.0%
Insufficient skin removed	1	0.5%
Excessive skin removed	(190)	(100%)
None	190	100%
Damage to penis	(184)	(100%)
None	166	90.2%
Mild	18	9.8%
Swelling/hematoma <1 month post-surgery	(N=185)	(100%)
None	165	89.2%
Mild	19	10.3%
Moderate	1	0.5%
Severe	0	0.0%
Infection <1 month post-surgery	(N=185)	(100%)
None	161	87%
Mild	22	11.9%
Moderate	2	1.1%
Severe	0	0.0%
Delayed wound healing <1 month post-surgery	(N=185)	(100%)
None	182	98.4%
Mild	3	1.6%
Cosmetic appearance of penis <1 month post-surgery	(N=185)	(100%)
Satisfactory	176	95.1%
Mildly unsatisfactory	9	4.9%
Problems with voiding <1 month post-surgery	(N=185)	(100%)
None	181	97.8%
Mild	4	2.2%

4.0. CONCLUSIONS AND RECOMMENDATIONS

In conclusion, there is an unmet need for MC in Zambia. This need is likely to increase in the short-term because of increasing awareness about the relationship between STI/HIV infection and lack of MC. Most clients have expressed a preference for medical circumcision as against traditional circumcision because of safety concerns. However, as shown in the project, adult MC in modern health institutions is not completely free of adverse events, especially when performed by poorly trained health care workers. Therefore, great attention must be paid to the quality of the training of male circumcisers. JHPIEGO's competency-based approach provides a direction for achieving high-quality training. Lessons learned from this project indicate that the following interventions are essential for high-quality MC services:

- Provision of dedicated space for client counseling and assessment in order to ensure privacy and confidentiality.
- Provision of numerous packs of surgical equipment for MC (number will depend on daily client load at the service site; usually 5–6).
- Provision of surgical consumables (sutures, gauze, gloves and personal protective wear, chlorine solution, anesthetic solutions, etc.).
- Provision of space for postoperative recovery, giving of postoperative instructions in privacy and postoperative reviews at the eighth day and 1-month followup visits.
- Competency-based training of health care workers (team training involving the physician, nurse assistant and reproductive health counselor is recommended). The training should teach a standardized MC technique with special attention to the application of effective and safe local anesthesia. In Zambia, where stakeholders opted to provide MC in the context of male reproductive health, counselors should also be trained to discuss other male reproductive health topics. The service sites should also store and provide condoms.
- Staff motivation initiatives are crucial to the success of the project. Frankly speaking, health care workers often demand monetary compensation for abandoning private practice and other revenue-yielding activities in favor of long MC surgical lists.
- The provision of free services has also proved to be most welcome to parents contemplating MC for their children.
- Further research is recommended to compare the surgical outcome of the Plastibell MC device with that of the standard surgical excision method used in most sites in Zambia.

APPENDIX A

CLASSIFICATION OF CIRCUMCISION ADVERSE EVENTS

ADVERSE EVENTS¹⁸

An adverse event (AE) can be defined as *any untoward medical occurrence in a participant and that does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the beginning of the treatment (i.e., male circumcision).*

Adverse events can be characterized as:

- Mild,
- Moderate,
- Severe, or
- Death.

Adverse events can also be classified as:

- Not related,
- Possibly related,
- Probably related, or
- Definitely related to the circumcision procedure.

The following table lists adverse events that are related to the circumcision procedure, according to the time that they will be ascertained, and provides definitions of severity. If death occurs as a consequence of an adverse event, this will be noted and recorded as well.

¹⁸ *Adapted from:* Bailey, B et al. Randomized Controlled Trial of Male Circumcision in Kisumu, Kenya.

Table A. Classification of Adverse Events Resulting from Male Circumcision Procedures

TYPE OF ADVERSE EVENT	DESCRIPTION OF TYPE OF ADVERSE EVENT	SEVERITY
A. DURING SURGERY		
Pain	3 or 4 on pain scale	Mild
	5 or 6 on pain scale	Moderate
	7 on pain scale	Severe
Excessive bleeding	More bleeding than usual, but easily controlled	Mild
	Bleeding that requires pressure dressing to control	Moderate
	Blood transfusion or transfer to another facility for management required	Severe
Anesthetic-related event	Palpitations, vaso-vagal reaction or emesis	Mild
	Reaction to anesthetic requiring medical treatment in study clinic but not transfer to another facility	Moderate
	Anaphylaxis or any reaction requiring transfer to another facility	Severe
Excessive skin removed	Adds time or material needs to the procedure, but does not result in any discernable adverse condition	Mild
	Skin is tight, but additional operative work not necessary	Moderate
	Requires re-operation or transfer to another facility to correct the problem	Severe
Damage to the penis	Mild bruising or abrasion, not requiring treatment	Mild
	Bruise or abrasion to the glans or shaft of the penis requiring pressure dressing or additional surgery to control	Moderate
	Portion or all of the glans or shaft of the penis severed	Severe
B. <FIRST MONTH POST-SURGERY		
Pain	3 or 4 on pain scale	Mild
	5 or 6 on pain scale	Moderate
	7 on pain scale	Severe
Excessive bleeding	Dressing soaked through with blood at a routine followup visit	Mild
	Bleeding that requires a special return to the clinic for medical attention	Moderate
	Bleeding that requires surgical re-exploration to control	Severe
Excessive skin removed	Client concerned, but there is no discernable abnormality	Mild
	Skin is tight, but additional operative work not necessary	Moderate
	Requires re-operation or transfer to another facility to correct the problem	Severe
Insufficient skin removed	Prepuce partially covers the glans only when extended	Mild
	Prepuce still partially covers the glans and re-operation is required to correct	Moderate
	Not applicable	Severe
Swelling/Hematoma	More swelling than usual, but no significant discomfort	Mild
	Significant tenderness and discomfort, but surgical re-exploration not required	Moderate
	Surgical re-exploration required to correct	Severe
Damage to the penis	Mild bruising or abrasion, not requiring treatment	Mild
	Bruise or abrasion to the glans or shaft of the penis requiring pressure dressing or additional surgery to control	Moderate
	Portion or all of the glans or shaft of the penis severed	Severe
Infection	Erythema more than one cm beyond incision line	Mild
	Purulent discharge from the wound	Moderate
	Cellulitis or wound necrosis	Severe

TYPE OF ADVERSE EVENT	DESCRIPTION OF TYPE OF ADVERSE EVENT	SEVERITY
Delayed wound healing	Healing takes longer than usual, but no extra treatment necessary	Mild
	Additional non-operative treatment required	Moderate
	Requires re-operation to correct	Severe
Appearance	Client concerned, but no discernable abnormality	Mild
	Significant wound disruption or scarring, but does not require re-operation	Moderate
	Requires re-operation to correct	Severe
Problems with voiding	Transient complaint that resolves without treatment	Mild
	Requires a special return to the clinic, but no additional treatment required	Moderate
	Requires referral to another facility for management	Severe
C. ONE MONTH OR MORE POST-SURGERY		
Infection	Erythema more than 1 cm beyond incision line	Mild
	Purulent discharge from the wound	Moderate
	Cellulitis or wound necrosis	Severe
Delayed wound healing	Healing takes longer than usual, but no extra treatment necessary	Mild
	Additional non-operative treatment required	Moderate
	Requires re-operation to correct	Severe
Appearance	Client concerned, but no discernable abnormality	Mild
	Significant scarring or other cosmetic problem, but does not require re-operation	Moderate
	Requires re-operation to correct	Severe
Excessive skin removed	Client concerned, but there is no discernable abnormality	Mild
	Skin is tight, but additional operative work not necessary	Moderate
	Requires re-operation or transfer to another facility to correct the problem	Severe
Insufficient skin removed	Prepuce partially covers the glans only when extended	Mild
	Prepuce still partially covers the glans and re-operation is required to correct	Moderate
	Not applicable	Severe
Torsion of penis	Torsion is observable, but does not cause pain or discomfort.	Mild
	Causes mild pain or discomfort, but additional operative work not necessary	Moderate
	Requires re-operation or transfer to another facility to correct the problem	Severe
Erectile dysfunction	Client reports occasional inability to have an erection	Mild
	Client reports frequent inability to have an erection	Moderate
	Client reports complete or near complete inability to have erections	Severe
Psycho-behavioral problems	Client reports mild dissatisfaction with the circumcision, but no significant psycho-behavioral consequences	Mild
	Client reports significant dissatisfaction with the circumcision, but no significant psycho-behavioral consequences	Moderate
	Significant depression or other psychological problems attributed by the client to the circumcision	Severe

Appropriate medical care for adverse events should be provided to all clients, as well as surgical care if required. If referral for medical or surgical complications is required, it should be made to the referral hospital.

Adverse events that are not or may not be related to the circumcision procedure should also be recorded. Severity should be judged as follows:

Mild: Transient or minimal symptoms; did not appreciably affect activity.

Moderate: Notable symptoms requiring modification of activity, but not resulting in loss of work or cancellation of social activities.

Severe: Incapacitating symptoms, requiring bed rest and/or resulting in loss of work or cancellation of social activities, and/or significant intervention therapy, including hospitalization.

As the intervention is a surgical procedure, it will usually be obvious whether an adverse event is related or unrelated to the procedure. The following definitions should be used:

Definitely related: A clear complication of surgery has occurred either during or after surgery.

Probably related: A complication has occurred during or after surgery that is most likely explained by the circumcision procedure, but could possibly be explained by other causes.

Possibly related: A complication has occurred during or after surgery that might be explained by the circumcision procedure, but could equally or more likely be explained by other causes.

Not related: An adverse event has occurred that is clearly explained by a cause other than the circumcision procedure.

Determinations of adverse events, their severity and their relationship to the circumcision procedure should be made by the attending physician or clinical officer, and confirmed by the specialist in charge of the clinic.

Reporting Adverse Events

All deaths and AEs categorized as severe should be reported to the urologist within 24 hours. The relationship of the AE should be specified as definitely, probably, possibly or not related to study procedures. The Medical Officer, in consultation with the urologist, should determine the occurrence and type of AE, its severity and its relationship to the circumcision procedure. A summary of how the severity and relationship was determined should be provided to the urologist.

Aggregate reports of all AEs should be collated and submitted monthly and semi-annually. AEs will be delineated by type, number of days from surgery (day of surgery being Day 0), level of severity (mild, moderate, severe, death) and relationship to the circumcision procedures. AEs should also be listed by date and type to detect any patterns in timing of AE. For example, if a cluster of infections is detected, a review of infection control procedures may be warranted.

Summary

Operative complications of male circumcision can include excessive bleeding, sepsis, unsatisfactory cosmetic effect, urinary obstruction, urinary fistulae, lacerations of the penile or scrotal skin and injury to the glans.

Non-operative complications may include anaphylactic reaction to the local anesthetic drug.

Circumcision complications can be avoided by attention to asepsis, performing adequate but not excessive excision of the inner and outer preputial layers, providing adequate hemostasis and paying attention to cosmesis.

AEs can be classified according to their severity and according to their relationship with the circumcision procedure.

Circumcision complications like excessive bleeding should receive immediate attention in order to prevent hemorrhagic shock. Where necessary, clients may be referred to the referral hospital after emergency procedures for the initial control of bleeding have been instituted.