A STUDY OF THE OUTCOME OF NEONATAL MALE CIRCUMCISION USING GOMCO, MOGEN AND PLASTIBELL NEONATAL DEVICES AMONG TRAINED PROVIDERS IN ZAMBIA

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CERTIFICATE OF APPROVAL

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ABSTRACT

Background

Male circumcision (MC) is the surgical removal of the foreskin in males. Observational studies have shown a correlation between MC and HIV prevalence, such that in areas with high MC prevalence (> 80%), HIV prevalence is generally lower (<10%) (Bailey et al, 2007). Subsequently, three well-designed randomized controlled trials have found MC to have a vaccine-level protective benefit in preventing HIV transmission through heterosexual intercourse (50-60% reduction in risk among males) (Bailey et al2007). In view of these findings, WHO and UNAIDS estimate that over 5.7 million HIV infections could be prevented by 2026 with scale up of male circumcision. Thus, WHO has recommended MC as an important prevention strategy in high HIV prevalence settings, and services are being scaled up widely in Southern Africa (WHO/UNAIDS 2007). Neonatal male circumcision is seen as a cheaper and more cost effective method of circumcision and the Zambian government plans that by the year 2020, 80% of all new born boys will be circumcised (Zambia National Male Circumcision policy 2009).Zambia will be one of the few countries using doctors, nurses, midwives and clinical officers to offer services, and we attempted to ascertain, if they are all given the same training, will they all produce surgically acceptable circumcisions. WHO recommends 3 devices for performing NMC; we looked at these devices among the aforementioned cadres and see if they produce surgically acceptable procedures among them.

Objectives: To determine whether an acceptable surgical outcome can be achieved by any trained service provider using three NMC devices (Gomco, Plastibell, and Mogen).

Method: This was a descriptive prospective study conducted on infants who were circumcised by the "Feasibility and Acceptability of Neonatal male circumcision study". They came for review at 6 weeks post op and were examined a scoring system; looking at exposure of coronal Sulcus, maintenance of penile symmetry, and distance of wound from corona. The results were then analyzed.

Results: More than 75% of our sample size had surgically acceptable male circumcisions, according to our criteria. The Gomco produced the most acceptable circumcisions with 94.1%. There was no clear difference in outcome among the different types of providers.

Conclusion: We conclude that NMC can produce a surgically acceptable outcome whichever device used, but more so with a Gomco device. The health care professionals trained to do not have to have any previous surgical training, as long as they are adequately trained and supervised; we determine that NMC, as implemented in a clinical setting in Zambia, is a safe procedure, resulting in a surgically acceptable outcome.

DEDICATION

For Bo Sepiso and Bo Inonge. Dad and Mum, my boy and girl. All that I ever do, I do it thanks to you.

ACKNOWLEDGEMENTS

This has been a very difficult paper to write and I quite frankly could never have gotten it done without the dedication of my supervisors. Dr Bowa and Dr Elizabeth Stringer I cannot thank you enough for all the assistance you have given me in writing this paper.

To my dear wife Mutinta, I thank you for pushing me to get this work done.

To the staff of the Neonatal male circumcision study you facilitated this work, Emily Waters, Bridgette Mugisa, and Lucy Milambo I am forever in your debt. I must thank the staff of the Fogarty International Clinical Scholars program and the support staff at Centre for infectious disease research in Zambia, CIDRZ, in particular Dr Ben Chi, Dr Jeffrey Stringer and Mark Giganti.

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LIST OF ABBREVIATIONS

AIDS - Acquired Immunodeficiency Syndrome

HIV - Human Immunodeficiency Virus

MC - Male Circumcision

NMC - Neonatal Male Circumcision

WHO - World Health Organization

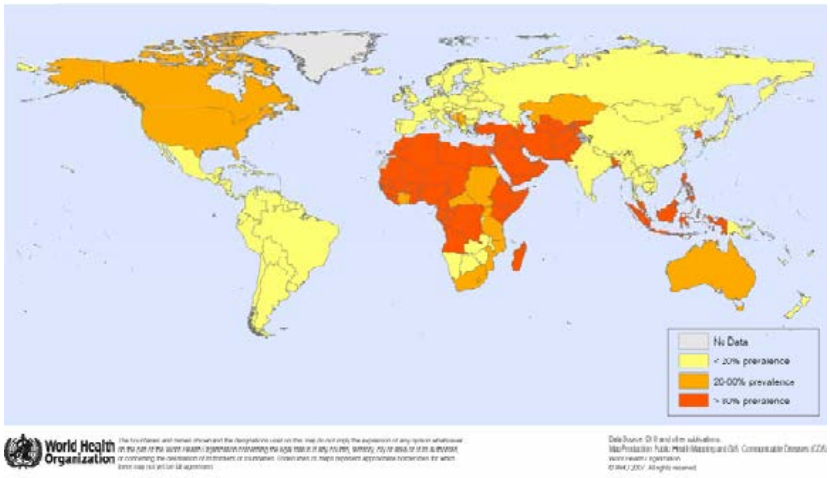
INTRODUCTION

History and Prevalence

Male Circumcision is the surgical removal of the foreskin (prepuce). This is an ancient procedure and is considered to be among the oldest surgical procedures ever performed. Mummified remains have been seen to be circumcised as far back as 2345-2181 BC (W. Dunsmuir 1999). There are many reasons that circumcision has traditionally been performed. For most it is a rite of passage to manhood as well as a means of improving hygiene.

Egyptian priests were circumcised as an encouragement to forsake sinful pleasures. Some Pharaohs were also circumcised.

Figure 1. World Circumcision Prevalence



As shown in Figure 1, the prevalence of MC varies dramatically across the globe. In countries within Southern Africa, such as Zambia and Zimbabwe, the prevalence is less than 15 % (Halperin 1999), whereas in the United States, circumcision is the most frequently- performed surgical procedure performed on males, with approximately 1 million circumcisions performed per year (Laumann et al, 1997).

In 1992, the prevalence of circumcised men in the US was estimated to be 77%. (2) One study found that between 1987 and 1996, 37% of newborn males were circumcised during newborn hospitalization. (3) Circumcision rates in the US are shown to differ among racial and ethnic groups. This may be attributed to the different religious beliefs among them; for example, Jewish

and Muslim males are routinely circumcised as infants, in accordance with their religion. (2) The ethnic distribution of circumcised males in North America varies from as low as 52% in blacks in the South, to as high as 89% in whites in the North Central part of the country (Laumann et al, 1997).

Circumcision rates vary dramatically across Africa, much like they do across the globe. In Africa, circumcision is most common in East and West Africa. The age at which males are circumcised also varies across Africa; neonatal circumcision is common in West Africa, whereas in East, Central and Southern Africa, the average age at circumcision is in the late teens. (K.Peltzer et al).

Neonatal Male Circumcision

Neonatal male circumcision is circumcision that is performed within the first month of a male infant's life. NMC is not widely performed in sub Saharan Africa or Zambia. In West Africa, however, traditional circumcision is done on 90% of neonates. It is most commonly done using a forceps-guided method, in which the foreskin is clamped with a straight artery forceps, and then cut. In developed countries, several different device methods are used, because they are cheap, easy to use and produce good results.

LITERATURE REVIEW

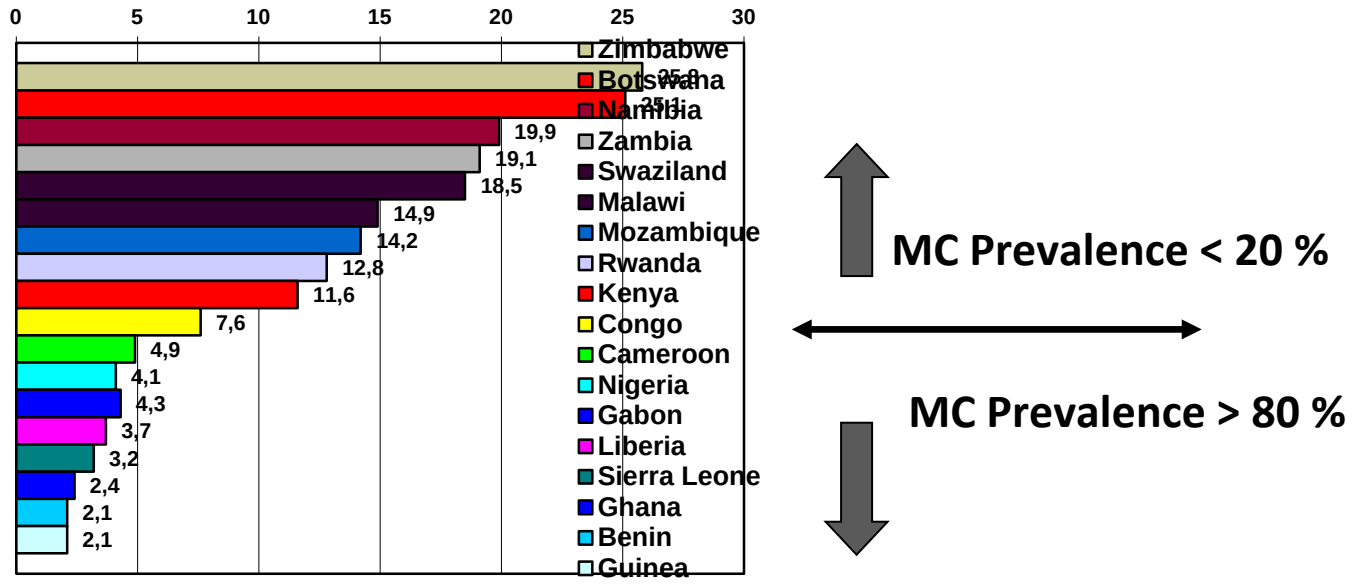
HIV and Male Circumcision

There are currently 26 million adults infected with HIV worldwide. In 1986, Arthur Fink, a urologist in California, proposed that MC might reduce HIV transmission (Fink 1986)

In the 1990s, Caldwell and Caldwell noted that geographical areas with low MC prevalence overlapped with regions of high HIV prevalence (Cadwell 1996). In their 1999 review of epidemiological data, Halperin and Bailey found a strong geographical correlation between HIV prevalence and MC rates (Figure 2).

Figure 2 HIV and MC Prevalence – Africa

(Adapted from Halperin & Bailey, *Lancet* 1999)



In a meta-analysis of over 38 observational studies, Helen Weiss found that MC had a protective effect of 50%. (Weiss 2000)

Given this observational evidence, three randomized controlled studies were conducted in sub-Saharan Africa; these were in Kisumu, Kenya, Rakai district, Uganda, and Orange farm, South

Africa. These studies found a reduction in female-to-male sexual transmission of HIV by 51-60% to 60% among circumcised adult males, which approximates vaccine-level protection rates (Bailey 2007, Gray 2007). Based on the findings from these randomized controlled trials, WHO and UNAIDS estimate that 5.7 million HIV infections could be prevented with the scale up of MC.

In 2007, WHO issued a policy statement supporting the scale-up of MC services for adolescents and young adults. In the same statement, neonatal male circumcision was suggested as a potential long-term strategy for curbing the HIV pandemic in Africa, and was described as a "simpler and less risky procedure" than circumcision of older boys and men.

(Baily et al *Lancet* 2007)

In Zambia, MC rates are estimated at 16% (Bowa et al 2006). Most male circumcisions are done as part of the cultural tradition, in Northwestern province, among the Lunda, Chokwe's, Luvale and Mbundas (ZDHS 2000). These circumcisions are done during tribal initiation ceremonies and the boys are generally adolescents. For these tribes circumcision is a rite of passage to manhood. An example of such a ceremony is the "Mukanda" ceremony, which is done during winter. Another religious/ethnic group in Zambia among whom circumcision is common is the Moslems, who make up less than 5% of the total population of the country. Moslems circumcise for religious reasons, preferably at birth, although Moslem boys may be circumcised at any age. There is also a small Jewish population in Zambia, making up less than 1% of the overall population. Religious circumcisions of Jewish boys are generally performed on the 8^{th} day of life.

Of the adult circumcisions done in Zambia, a 2006 study found that 1-2 % were performed in hospitals for medical indications such as phimosis, while 90 % were done for traditional and 5-8% were done for religious reasons (Bowa, 2006).

The current focus of the Zambian circumcision program is to capture adults in the age group most vulnerable to the disease (15-39 while also trying to reach children below the age of 14, who will enter the vulnerable age group in the next few years. The Zambia Demographic Health Survey shows that the average age of sexual debut among young men in Zambia is 18. Most boys below the age of 12 are HIV negative, except for a small proportion that have had vertical

transmission from infected mothers (Zambia Demographic Health Survey {ZDHS} 2000). Preadolescent circumcision thus provides protection for young boys from HIV acquisition when they are most at risk in the teen years.

While scaling up circumcision programs for preadolescent and adult men may be a key strategy for decreasing HIV transmission in the short-term, circumcision of infants has several advantages over circumcision of older boys and men, making it an important long-term prevention opportunity.

Advantages of Neonatal Male Circumcision

There are several advantages to performing MC during the neonatal period using a device method, as compared to circumcising at a later age. First, the procedure can be done using local anesthesia, which incurs less risk than performing the operation under general anesthesia. An audit of Department of Surgery records from July 2008 showed that 100% of the 44 paedatric circumcisions (those done on patients aged 0-15) were performed under general anesthesia, by paediatric surgeons. Second, device-assisted NMC makes use of crushing techniques to achieve haemostatis, and thus rarely requires sutures. This means that less surgical skill is required to perform the procedure, and healing time is generally faster than in older children and adults (in neonates, the circumcision site is generally well-healed after one week, versus the six-week healing time in adults). This also amounts to less lost time at work, as adult men that are circumcised may need 3 to 5 days away from work to recuperate, whereas this is not a factor with neonates.

In addition to being a simpler surgical procedure with faster healing time, some of the health benefits of NMC may be experienced by the infant immediately, including a reduced risk of urinary tract infections (UTI) during the first year of life, and reduced risk of phimosis. In 1985 Wiswell, Smith and Bass reviewed a cohort of 5261 infants born at an army hospital and found a higher incidence rate of UTI among the uncircumcised male infants (4.12%) as compared to those who were circumcised (0.21%). Circumcision during the neonatal period also ensures that the protective benefits of the procedure are in place upon sexual debut; thus, a male who is

circumcised during infancy will experience a lower risk of contracting HIV and certain STIs throughout his high-risk teen and early adult years.

Other advantages of neonatal circumcision compared to adult circumcision include the faster procedure time. In neonates, circumcision can be performed in less than 10 minutes, whereas in adults the procedure often lasts 30 minutes if there are no complications. Finally, NMC is much cheaper than AMC (Adult Male Circumcision). The Futures Group cost AMC in the sub-Saharan region at 69 US dollars per MC, while the cost of NMC is estimated at about 10USD per MC. Another study found that post neonatal circumcision was 10 times more expensive than neonatal circumcision (Schoen et al, 2006).

Neonatal Male Circumcision Techniques

There are three common techniques recommended by WHO for neonatal male circumcision: Gomco technique; the Plastibell technique; and the Mogen clamp. Choice of technique in the US is typically based on provider preference; each of the three has relative benefits and drawbacks.

Gomco

The Gomco technique employs a reusable metal surgical device which uses a bell to protect the glans of the penis during surgery. Of the three common NMC methods, the Gomco may require the most surgical skill to avoid bleeding complications, and is the technique that takes longest to perform.

Plastibell

In the Plastibell technique, a small plastic bell is used to demarcate the surgical incision and is left in place for up to one week following the procedure. Less technical skill may be required to perform this technique, a potentially important factor in a setting where health professionals other than doctors may be performing the procedure. In addition, this instrument is disposable so

does not require sterilization. As a drawback, the foreign body at the surgical site may predispose an infant to infection.

Mogen clamp

The Mogen clamp is an NMC method that has been widely used in North America, but is less common in Africa. Like the Gomco method, the Mogen procedure uses a reusable device for crushing the foreskin. This method is typically faster than the Gomco procedure; however, minor damage to the glans of the penis is a small risk factor because there is no bell to protect the glans.

Dorsal Slit

The method most commonly used for MC (including for circumcision of infants under general anesthesia) in Zambia is the dorsal slit technique. This procedure differs from the aforementioned techniques, in that it relies on individually finding and ligating all bleeders (rather than on the crushing of vessels) to achieve haemostatis. It is thus a more time consuming procedure, which requires more surgical skill than the device-guided methods, especially in a neonate.

Complications of Neonatal Male Circumcision

Although neonatal circumcision is generally thought to be safer and easier to perform than adult circumcision, it is not entirely without complications. In the United States, where the procedure is normally performed by a physician (paediatricians, obstetricians, and general practitioners), the complication rate is estimated be less than 1-2% (Kaplan GW. 1983). In a study of 5882 neonatal circumcisions over a ten year period, with Gomco and Plastibell devices, a complication rate of 0.2 % was found (William).

As previously discussed, circumcision within the neonatal period does routinely take place in some African communities, mainly for religious and cultural reasons. The complication rate for

MC done by traditional practitioners is typically much higher than the 1-2% seen in the US for clinical NMC; one study in Kenya found that in some communities where traditional circumcision is practiced, the complication rate may be as high as 40% (Okeke et al).

Complications typically associated with the NMC procedure include hemorrhage and infection, which are common risks of any surgical procedure. Cosmetic problems (such as the removal of too little or too much skin, the occurrence of torsion, or adhesions) are among the other possible complications.

Haemorrhage

Bleeding is the most common complication resulting from NMC, and may occur either intra-operatively or post operatively. Nonetheless, when the procedure is done using a device such as the Gomco or Plastibell, the risk of bleeding is minimal, ranging from 1 % to 1.07%. (Gee, W. F., et al 1976).

Whether bleeding may be related to the skill of the provider has not been established.

Infection

Infection, which can vary from minor infection at the incision line, to necrotizing fasciitis and septicaemia, is another potential complication of NMC. (J. R. Woodside 1980). Infection rates of NMC as practiced in the US may be as low as 1%, while those seen in older boys may be as high as 10 % (Fraser et al 1968). In Tanzania, NMC with the plastibell has an infection rate of less than 1% (Manji K. 1999)

The other complications are rare, and complication rates have not been established.

Penile Torsion

This occurs due to poor technique on the part of the provider when there is malalignment of the meatus and frenulum.

Excessive removal of skin

Depending on the extent of the skin removed this may lead to buried penis or a poor cosmetic result that the parents may not be happy with. If excess skin is excised from the shaft and a proper amount of inner preputial epithelium is excised, the resultant penis may be foreshortened and require skin grafting at a later date.

Removal of too little skin

This may lead for the need for recircumcision later in life. Redundant residual prepuce becomes stretched or elongated, producing a mushroom-like widening of the distal shaft and preputial skin. In this event, the normal dorsal slit method would be inadequate for revision. (Redman J.F. 1995)

Adhesions

As the glans and the foreskin develop together, then separate by apoptosis of the cells between them, at the time of circumcision they are usually still attached to each other.

While separating some of the adhesions one may damage the glans, as a result of the premature separation of the glans from the foreskin. These adhesions may form skin bridges later in life that may make erections painful.

Furthermore if inadequate amounts of foreskin are removed, these adhesions may attach the remaining foreskin to the glans, giving the child a look of an uncircumcised penis.

NMC Pilot Program

In November 2008, CIDRZ and surgeons, and obstetricians from the Departments of Surgery and Urology at UTH jointly launched a pilot neonatal circumcision pilot program at the UTH Adult Infectious Disease Centre. Two experts from the United States were brought to Zambia to train a group of nine doctors in Gomco, Mogen, and Plastibell NMC techniques. The training program consisted of several didactic lectures, a video demonstrating the procedure, practice on models of neonatal genitalia, and ongoing supervision. Upon achieving competency in all three NMC techniques, the medical officers were invited to help staff the UTH NMC pilot clinic. Working at the clinic entails circumcising infants, reviewing infants at follow up visits, managing any complications and supervising new provider trainees. As of December 2010, over 700 infants had been circumcised as part of the NMC pilot program.

Study of Feasibility, Acceptability, and Safety of NMC in Lusaka

In October 2009, CIDRZ began enrolling participants in a research study to evaluate the feasibility, acceptability, and safety of NMC in Lusaka, using Gomco, Mogen and Plastibell methods. As part of this study, 15-20 providers, including medical officers, clinical officers and nurses are expected to be trained in the three above-mentioned NMC techniques. Training occurs in small cohorts of 2-3 trainees, over a period of approximately 6-12 weeks per cohort. During their training, each trainee completes at least 10 supervised procedures in each of the three circumcision methods (for a total of 30 procedures). Supervision is provided by the medical officers who were trained as part of the NMC pilot program. To allow providers to gain competence in one method before being introduced to another, the methods are taught sequentially. Trainees are evaluated after every five procedures of one type.

To be included in the parent research study, at least one parent of legal guardian of the infants to be circumcised must complete an informed consent process with a study nurse or other staff member prior to the procedure. The informed consent process addresses risks and benefits of circumcision, gives details about study participation, and provides parents an opportunity to have their questions answered. In addition, infants must meet the following eligibility criteria:

Inclusion criteria:

- Male infants who are in the first day of life and less than 4 weeks of age were considered for circumcision
- Gestational age >37 weeks at birth

Exclusion criteria:

- Any current illness
- Abnormality of urethra or penile shaft such as hypospadias
- Local infection defined as redness, swelling, or a purulent discharge from the infant penis
- Greater than four weeks of age

STUDY JUSTIFICATION

It is expected that many countries where MC prevalence is low will want to promote NMC as part of their scale up of MC for HIV prevention. In Zambia, for example, the Ministry of Health recently adopted a goal to have 80% of newborn boys circumcised within the first month of life by the year 2020 (Zambia National Male Circumcision policy 2009).

In order to ensure the safe scale up of NMC in Zambia, it is important to understand the potential pitfalls of the different device-guided methods that may be adopted, as used within the Zambian health care setting. Trainers and providers need to be made aware of the most common problems or complications, so that they may prevent them from occurring or treat them effectively, and maintain delivery at the highest possible standard. This study will inform the scale-up of national NMC programs in Zambia and other countries in Africa, particularly on the use of NMC devices.

In addition to decisions about which devices to use for scale up, the shortage of medical doctors in Zambia will need to be addressed. Whether or not NMC can be safely done by other types of providers (such as midwives and clinical officers) is not known. Thus, the current study will test the use of different NMC techniques among different types of providers, to determine whether all can consistently produce a surgically-acceptable result.

RESEARCH QUESTION

Does device-guided NMC, using Gomco, Mogen, or Plastibell, produce a surgically- acceptable NMC in the hands of service provider of different skill levels, within a clinical setting in Zambia?

HYPOTHESIS

Neonatal male circumcision, using the Gomco, Plastibell, or Mogen technique, produces a safe and acceptable surgical outcome in the hands of any trained service provider, regardless of the device used and type of provider.

OBJECTIVES

General Objectives

1. To determine whether an acceptable surgical outcome can be achieved by any trained service provider using three NMC devices (Gomco, Plastibell, and Mogen).

Specific Objectives

1. To determine if the Plastibell, Gomco and Mogen clamp techniques consistently produce a cosmetic result in which an adequate amount of foreskin is removed, the coronal sulcus is exposed completely, and penile symmetry is maintained
2. To determine whether any trained service provider can perform NMC safely with an acceptable surgical outcome based on standard criteria

METHODOLOGY

This study assessed the surgical acceptability of circumcisions performed by different types of providers, using 3 standard NMC devices (Gomco, Mogen and Plastibell). The primary outcome of the study was to determine whether the NMC devices produce a surgically-acceptable outcome, as was evaluated 6 weeks postoperatively. The secondary outcome was to determine whether there is a difference in the surgical outcome between providers with different surgical skills.

Participant Selection

Participants for this study were drawn from a parent research study on the feasibility, acceptability, and safety of NMC, also ongoing at UTH and Matero Reference Clinic. From June 2010 to December 2010, clients that returned for review following the parent NMC study were reviewed and assessed using a questionnaire.

Inclusion Criteria for the Study on Surgical Acceptability of NMC

Patients were recruited from the NMC feasibility study. To be included in the study, patients must have undergone NMC through the NMC feasibility study, at least 6 weeks prior to assessment. Furthermore, a parent must be willing to bring the baby back to the clinic for evaluation, and sign an informed consent form. Parents of all infants circumcised as part of the pilot program or feasibility study will be invited to participate in this study, until the desired sample size is reached.

Data was collected over a 3 month period, where the infants were assessed using the aforementioned tools.

Sample Size

We reviewed 100 infants who underwent neonatal male circumcision at least 6 weeks previously. At the age of 6 weeks, the circumcision site was expected to have completely healed. This is a sample of convenience looking at the rate at which children are circumcised in the clinic and the duration that has been given for data collection, we wanted to see more infants however the parent study ended, and we did not have the resources to continue.

Study Site

The study sites were those in which the NMC feasibility study was taking place: University Teaching Hospital outpatient NMC clinic (at the Adult Infectious Disease Centre), Kanyama clinic and Matero Reference clinic.

Infant Follow Up and Evaluations

All infants circumcised as part of the research study received a patient file, and were seen for follow up visits at least once after the procedure (all infants were seen at one week following the procedure; study participants and any infants with complications were also seen at six weeks following the procedure, and thereafter, if indicated). Health history and details about the circumcision procedure and follow up visits (including information about any complications observed during or after the procedure) were recorded on standardized forms and kept in patient files.

All mothers who consented had their baby examined at least 6 weeks after circumcision, and a questionnaire was administered. A standard data sheet captured the clinical assessment information.

When complication's occurred, a photograph was taken (with the mothers consent).

Primary Outcome

The NMC was considered to be surgically acceptable when the following were present after circumcision:

1. The coronal sulcus was visible with the penis at rest
2. The meatus, the frenulum and the scrotal raphe were symmetrical.
3. The parent was satisfied with the cosmetic outcome of the procedure.
4. No other complications noted

This meant that the device performed a precise circumcision and the results can be easily replicated in the hands of different health workers. Based on the above the outcome was graded as acceptable (if all 2 or more are met) or unacceptable (if less than 2 are met).

Secondary Outcome

This was to assess whether there was any difference between the outcomes of the circumcisions versus the type of procedure performed. This was also analyzed based on type of provider who performed the procedure.

To avoid bias, the providers were given codes at the time of data collection; we will not be able to tell what type of provider did which procedures.

The occurrence of complications was compared against the type of device that was used and the provider who carried out the procedure and this information was analyzed.

Data Management and Analysis

All data was being stored in Epi info version 4.0. Standard descriptive data, including means and medians, was be used to show data spread and central tendencies. The overall percentage of surgically acceptable outcomes was calculated for all NMC devices combined. A Chi-Squared

test was also be used to detect statistically significant differences in surgically acceptable outcomes between providers with and without surgical training.

Ethical Considerations

Since neonates were the subject of the study Informed Consent from both parents or when not possible at least one parent was sought.

Mothers whose children underwent the procedure were seen when their children came for 6 week review and were asked to participate in the study.

It also needs mentioning that though this procedure is new in Zambia, it is not new in North America, where they have been using these techniques for over 40 years.

The providers all received standard training and the project paid for the costs of any complications that were found and needed correcting. Two consultant urologists were available to help resolve any complications that arose. Standard NMC guidelines indicated low complication rates with all NMC devices the study used. Standard protocols were used to avoid any complications.

The clients benefited from the large pool of expertise, brought together to run this pilot project. Clients benefited as when any problem arose, as a result of the NMC, the study assisted them to notice it and also help them resolve it.

No personal Identifiers were used in the data collection forms. All data was coded and password locked. All information obtained remains confidential.

All standard ethical requirements in keeping with the most recent version of the Helsinki convention on ethical medical research were adhered to at all times. The local Ethics committee approval was sought before commencing the study.

RESULTS

Table 1: FREQUENCY: TYPE OF PROVIDER

Type of provider 1 Surgically trained doctor 2 Non surgically trained doctor 3 Other nurse, CO. midwife	Frequency	Percent	Cum Percent	
1	45	45.0%	45.0%	
2	19	19.0%	64.0%	
3	36	36.0%	100.0%	
Total	100	100.0%	100.0%	

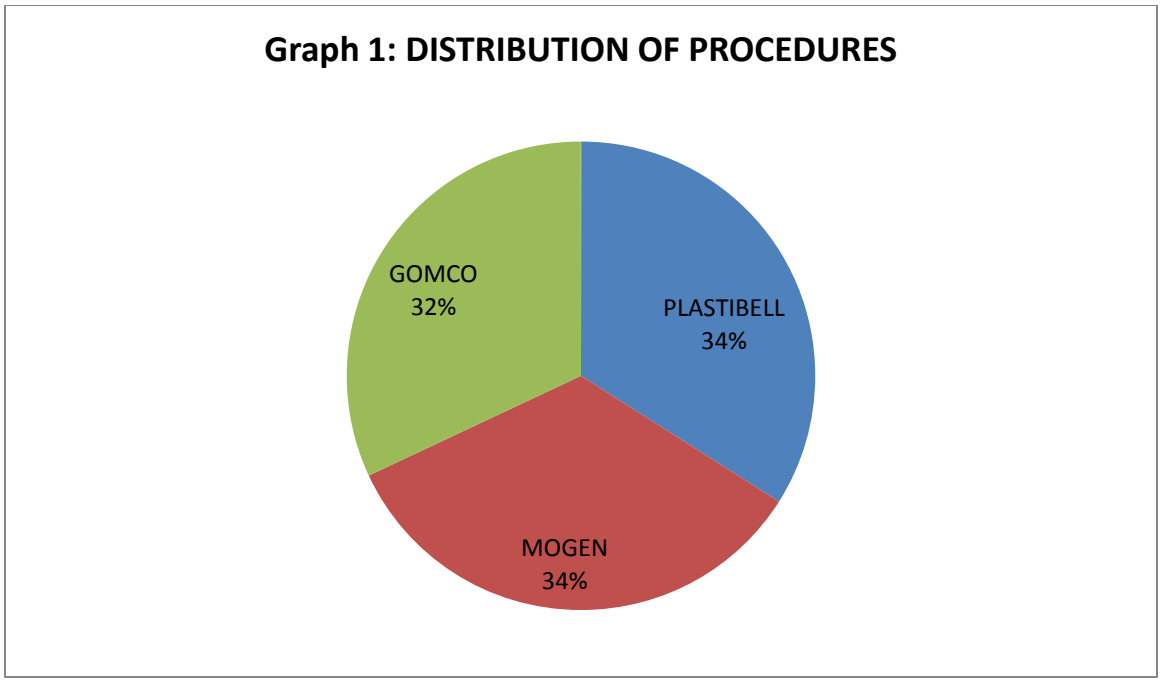
95% Conf Limits

1 35.0% 55.3%

2 11.8% 28.1%

3 26.6% 46.2%

This table shows that the majority of procedures were done performed by the surgically trained doctors. There were two surgically trained doctors that performed in the study.



Graph 2: FREQUENCY OF DIFFERENT VARIABLES

The majority of patients (74%) had a visible coronal Sulcus following circumcision.

In the vast majority (79%), penile symmetry was maintained.

In 64% of the procedures, the distance between the incision and the coronal sulcus was less than 5mm indicating that not too much shaft skin was taken and not too much inner prepuce skin was left behind.

Table 2: Frequency: Other complications

Other complication	Frequency	Percent	Cum Percent	
1	6	100.0%	100.0%	
Total	6	100.0%	100.0%	

95% Conf Limits

1 100.0% 100.0%

Only 6 of these patients had any other complication, and in all of them presented with post-operative bleeding that ranged from immediately post op to within hours after the procedure.

Table 3:Frequency: A line through the shaft of the penis and one drawn through the centre of the urethral meatus are parallel to each other

A line through the shaft of the penis and one drawn through the centre of the urethral meatus are parallel to each other	Frequency	Percent	Cum Percent	
1	91	91.0%	91.0%	
2	9	9.0%	100.0%	
Total	100	100.0%	100.0%	

95% Conf Limits

1	83.6%	95.8%
2	4.2%	16.4%

The majority of the patients (91%), had a penis where a line drawn through the shaft of the penis and urethra were symmetrical, indicating that there was no post circumcision

Table 4: Frequency: Is the Circumcision surgically acceptable

Is the circumcision surgically acceptable	Frequency	Percent	Cum Percent	
1	78	78.0%	78.0%	
2	22	22.0%	100.0%	
Total	100	100.0%	100.0%	

95% Conf Limits

1 68.6% 85.7%

2 14.3% 31.4%

TABLE 5: COSMETIC OUTCOMES VS PROVIDER

	Surgeon		Doctor		Nurse, CO		Total		P value
	N	**Value**	**N**	**Value**	**N**	**Value**	**N**	**Value**	
Coronal sulcus visible at rest									**0.27**
Yes	31	69%	13	68%	30	83%	74		
No	14	31%	6	32%	6	17%	26		
Meatus, frenulum, and scrotal raphe symmetrical									**0.3198**
Yes	36	46%	17	22%	26	33%	79		
No	9	43%	2	10%	10	48%	21		
Distance between incision line and coronal sulcus less than 5 mm									**0.6697**
Yes	30	47%	13	30%	21	33%	64		
No	15	42%	6	36%	15	42%	36		

Of the 64 procedures, that had an incision line less than 5mm from the coronal Sulcus, the majority of them were performed with the Gomco circumcision device. Of the procedures that had an incision line more than 5 mm away from the coronal Sulcus, the majority were performed with a plastibell, 50 %, with the Mogen following not far behind with 38.9%.

Of the three techniques of circumcision, the Gomco was most accurate in that the Coronal Sulcus was visible in the vast majority of patients (43.2%), with the Plastibell not far behind with (40.5%).

TABLE 6: COSMETIC OUTCOME VS METHOD

	Mogen		Gomco		Plastibell		Total		P value
	N	**Value**	**N**	**Value**	**N**	**Value**		**N**	0.0001
Coronal sulcus visible at rest									
Yes	12	16%	32	43%	30	40%	74	32	
No	20	77%	2	8%	4	15%	26	2	
Meatus, frenulum, and scrotal raphe symmetrical									0.7624
Yes	24	30%	27	35%	28	35%	79	27	
No	8	38%	7	33%	6	29%	21	7	
Distance between incision line and coronal sulcus less than 5 mm									0.0010
Yes	18	28%	30	47%	16	25%	64	30	
No	14	4%	4	11%	18	50%	36	4	

From this data set we are able to see that of the three devices, the Plastibell, 35.4%, closely followed by the Gomco (were the best devices at maintaining penile symmetry.

The surgically trained doctors had an incision line closest to the Coronal Sulcus (46.9%), with the non-surgically trained doctor having the fewest no of cases of having an incision more than 5mm.

TABLE 7: Type of Procedure Vs Is the Circumcision surgically acceptable

IS THE CIRCUMCISION SURGICALLY ACCEPTABLE			
Type of procedure 1 :Plastibell 2 Gomco 3 Mogen	**1**	**2**	**TOTAL**
1	28	6	34
Row %	82.4	17.6	100.0
Col %	35.9	27.3	34.0
2	33	1	34
Row %	97.1	2.9	100.0
Col %	42.3	4.5	34.0
3	17	15	32
Row %	53.1	46.9	100.0
Col %	21.8	68.2	32.0
TOTAL	78	22	100
Row %	**78.0**	22.0	100.0
Col %	100.0	100.0	100.0

Single Table Analysis

Chi-square	**df**	**Probability**
19.1112	2	0.0001

78% of the procedures produced a surgically acceptable result. The Gomco clamp had the highest number of surgically acceptable results and had the fewest unacceptable results.

DISCUSSION

From this study we were able to see that the circumcisions were performed by different providers, including Surgeons, one medical officer, and three nurses. What is seen is that the surgeons performed the bulk of the procedures, what would have been a better situation would have been to have had all the subgroups perform the same number of procedures, however this was not possible. All providers were being trained in NMC and none of them were experienced providers of NMC.

In terms of procedures, the number of procedures and types of procedures was not equal, between Gomco, Mogen and Plastibell.

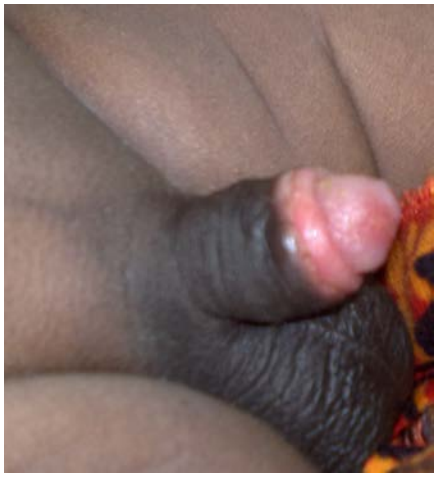


Figure 3: Neonates penis with insufficient skin removed and the coronal Sulcus not visible with the penis at rest.

The purpose of circumcision is to excise the prepuce from the penis. While it is not essential to excise all the skin, some parents may desire the infant undergo “re-circumcision” increasing both cost and morbidity. For example Muslim clients insist no trace of foreskin be left on the penis.

At present no international criteria is available to suggest whether a procedure is acceptable or not, thus while our criteria is a good starting point more work is required in this area.

The association of minor anatomic variations of the newborn genitalia in patients with minor circumcision complications has been previously examined and a study showed that, subtle anatomic variations may be associated with a higher incidence of circumcision complications. (Mayer et al 2003). This may be important as to the decision where the incision should be made and may be partly responsible for the difficulty as to where the incision should be. These anatomical variations may also define the device used for circumcision.

In the vast majority of procedures, 74%, the circumcising device removed sufficient skin.
The gomco was most efficient at this with 94.1 % of procedures done with the gomco leaving the coronal sulcus visible.
This may be due to the design of the gomco clamp; the bell sits on the edge of the corona, ensuring the correct amount of skin is excised.

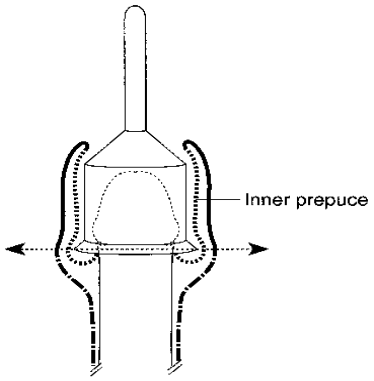


Figure 4: Cross section of Gomco during a circumcision

Of the procedures that **did not** have the coronal sulcus visible, the vast majority 76.9% were performed with a Mogen clamp. This may have been attributed to this device not having a bell to protect the gland and the provider not being guided as well as to where the incision should be. However this was not the case with all Mogen procedures, and we believe that with more practice and better marking techniques the Mogen clamp can be as efficient as the other procedures.

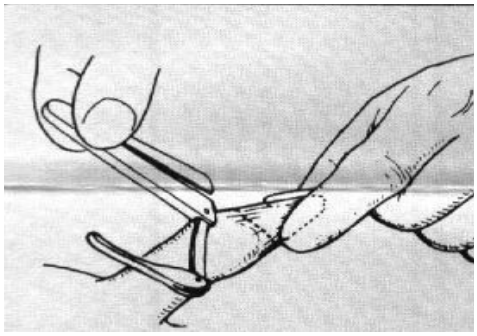


Figure 5: Mogen Circumcision

As for the distance from the coronal sulcus to the incision line, this proves the precision of the device, as well as how much of the inner layer of the foreskin was left. Of all the 100 procedures, 64 of them had an incision line less than 5mm from the corona of the glans. Of these procedures 30 (46.9%) were performed with a Gomco clamp. The Plastibell was least efficient at this accounting for 50% of the procedures that had an incision line that was over 5mm from the corona.

This implies that the procedure with the highest possibility of taking an excessive amount of skin and accidentally denuding the penis is the plastibell. Not all procedures done with the plastibell showed this and it is possible that the plastibell has a steeper learning curve than the other procedures, but one is sufficiently trained on using the correct size device and removing the correct amount of skin this would improve.
When we look at the distance left at circumcision and assess this with reference to the providers, we see that the chi square was less than 5 showing that there was no statistical difference between the respective groups.

In the individual variables, Gomco seemed to have scored better in all the different subgroups.
For maintenance of penile symmetry, 79% of the procedures maintained penile symmetry. Of these procedures, the Plastibell device was the most efficient with 35.4%, though the difference was minimal with the rest of the procedures accounting for 34.2 % (Gomco) and 30.4% (Mogen), respectively. The data on penile symmetry has one flaw, in that this study did not take into account the possibility that some of these infants may have had some degree of natural

penile torsion and chordae.
As regards to penile symmetry and providers, the cases were almost evenly divided between the providers with surgical training and the other providers (nurses, midwives). The chi square was less than 5 and is not valid for these procedures, implying that the difference is so minimal it's too close to tell with them accounting for 42.9% and 47.6% respectively.

Neonatal circumcision with devices produces a surgically acceptable result, according to classification the set forth by the author. Of all the procedures done, 78% of them were surgically acceptable by the set criteria. This may need to be looked at more clearly, as we don't have any data as to how effective classical circumcision using the dorsal slit method would be and this could be an area for further research directly comparing circumcision with devices and classical circumcision. One flaw in this data is that we did not ask the parents satisfaction with the procedure, and this classification may be harsh.
The Gomco device proved to be responsible for the most surgically acceptable circumcisions (42.4%).

For all variables set forth, no clear distinction was seen between those done by surgically trained doctors, Non surgically trained doctors and Other providers. From this we are able to infer that all categories of medical providers can be trained to do NMC safely as long as there is adequate supervision.

STUDY LIMITATIONS

One main limiting factor for this study was the sample size. Using epi info the sample size was calculated at 194 participants. This was not achieved for two reasons; the researcher had to leave Lusaka to go and do a surgical posting in Chingola as part of his academic requirements for school. The other reason was that the parent study finished its data collection, and we did not have the funds to continue seeing the patients.

Another limitation with the study was the proportions of the providers. As you can see from Table 1, most of the procedures were performed by the surgically trained doctors. Ideally, we would have preferred for all the groups, surgically trained, non-surgically trained and other cadres, to have performed equal no's of procedures. This would have given more validity to our findings.

One other limitation to this study was that although we looked whether the results were surgically acceptable according to our criteria, we never looked at whether any of these procedures needed to be revised, and if so, what would be the threshold at which further intervention would be needed. This would be important, because if revision was to be required, who would do it, and where would it be done? These children that were surgically unacceptable would need to be further evaluated and then appropriate treatment, whether a wait and see approach or immediate revision, would be applied.

One last limitation was that our study used trainees that had just learnt and not yet mastered the procedure. Limited data is known about how long it takes to master a circumcision, and trainees should still operate supervised until they attain competence.

CONCLUSION

1. Neonatal Male Circumcision (NMC) with devices can achieve a surgically acceptable result if the procedure is done by a well-trained provider, however the standard for surgical acceptability varies as no international criteria exists, so although we found some procedures unacceptable, they may be deemed acceptable by others.

2. Results are good in the hands of different health care providers, regardless of whether they have previous surgical training or not, and regardless of level of medical training, however these trainees should have adequate training and supervision.
   However the duration these providers were followed as well as the number of different cadres was not sufficient in this study to allow a definitive conclusion to be made.

3. The Gomco clamp produces a more surgically acceptable result, however with good training and supervision, NMC can be performed safely and effectively using all three methods recommended by WHO.

RECOMMENDATIONS

1. Neonatal male circumcision should be rolled out and all health professionals should become providers, as long as they are well trained and supervised during the initial period following training.
2. Very little is known about the outcomes of Neonatal circumcision in this region and more studies using a higher sample size and a better distribution of health professionals need to be done.
3. All three devices can give a surgically acceptable circumcision. The Gomco gives a marginally better surgical outcome, however the devices have similar complication rates therefore other factors, such as cost and reusability, may be looked into when government chooses which of the devices to use for national scale up.

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APPENDIX

QUESTIONNAIRE

Questionnaire Number: _____ Date form completed: ____/____/____ (dd/mm/yy)

Participant ID number: _____Participant Initials (First-Last): _____
Provider:

Who performed the procedure? ☐

1. Surgically trained doctor
2. Non-surgically trained doctor
3. Clinical officer of midwife

Does the circumcision conform to the following?

1. Is the coronal sulcus is visible with the penis at rest ☐

   1= Yes

   2= No

2. Are the meatus , frenulum and scrotal raphe symmetrical ☐

   1= Yes

   2= No

3. Is the distance between the incision line and the ring of the coronal sulcus, less than 5mm? ☐

   1= Yes

   2= No

4. A line through the shaft of the penis and one drawn through the centre of the urethral meatus are parallel to each other ☐

   1= Yes

   2= No

BLEEDING

1. Was there bleeding from the surgical site that required intervention? ☐

1 = Yes

2 = No → *if no, please go to question 2*

a. Timing of onset of bleeding: ☐

1 = <u>immediately</u> post-circumcision

Time of onset: ___:___ (24-hour clock, hh:mm)

2 = Later on the same day/date of the procedure (<u>not</u> immediately)

Time of onset: ___:___ (24-hour clock, hh:mm)

3 = Later, NOT on the same day/date of the procedure

Date: ____/____/____ (dd/mm/yy)

b. Severity:

Lowest Blood Pressure recorded: ☐☐☐/☐☐☐

Date of measurement: ____/____/____ (dd/mm/yy)

Heart rate: ☐☐☐ beats/minute

Date of measurement: ____/____/____ (dd/mm/yy)

c. The required intervention(s) were (indicate all that apply):

☐, ☐, ☐, ☐, ☐

1 = Local pressure

Duration required to control: ☐☐ minutes

2 = Pressure dressing

3 = Sutures

Number of sutures: ☐☐

Person who sutured: _____

4 = IV fluids (not blood products)

5 = Blood products transfusion

☐☐ cc of packed red blood cells transfused

Date(s) (dd/mm/yy) _____/_____/_____

6 = Other intervention *(please specify)*: _____

_____

_____

d. Infant weight ☐☐☐☐ (grams)

2. Other issues related to bleeding not listed above: _____

_____

_____

INFECTION

3. Was there any sign/symptom of infection potentially related to the circumcision procedure as determined by the study staff? ☐

1 = Seen by study staff and YES

If yes, please describe appearance of surgical site and surrounding area in space provided for narrative.

2 = Seen by study staff and NO → *if no, please go to question 3*

3 = Participants were seen elsewhere for related complaints

a. Date of onset: ____/____/____ (dd/mm/yy)

b. Date of resolution : ____/____/____ (dd/mm/yy)

c. Location: ☐

1 = Local infection, erythema limited to penis

2 = Local infection, but erythema extends to soft tissues beyond penis

3 = Local infection, erythema limited to penis *with purulence*

4= Local infection, but erythema extends to soft tissues beyond penis *with purulence*

5 = Local + systemic infection *(for example, fever or hypotension in addition to evidence of local surgical site infection)*

6 = Signs + symptoms of systemic infection without specific local signs or infection noted

d. Did the infant experience shock/hypotension from an infection thought to be related to the circumcision procedure? ☐

1 = Yes

2 = No

3 = Possibly

e. Temperature: ☐☐.☐ Degrees C

Date of measurement: ____/____/____ (dd/mm/yy)

f. Were antibiotics prescribed? ☐

1 = Yes, Intravenous antibiotics

Name of antibiotic(s): _____

_____

2 = Yes, Oral antibiotic(s)

Name of antibiotic(s): _____

_____

3 = Yes, topical antibiotic(s)

Name of antibiotic (s); _____

_____

4 = Combination of antibiotics

Name of antibiotic(s): _____

_____

_____

_____

5 = Yes, but unsure which type of antibiotics

6 = No

3h. Was a procedure necessary to treat the infection? (e.g., incision, drainage, debridement): ☐

1 = Yes

If yes, please detail procedure in space provided for.

2 = No

8. Were there any other complications or events not noted above? ☐

1 = Yes

If yes, please detail the problem, dates of onset and resolution, and the medical attention (with dates and location of treatment) required in space provided .

A STUDY OF THE SURGICAL OUTCOMES OF NEONATAL MALE CIRCUMCISION USING 3 DEVICES AMONG TRAINED PROVIDERS

Investigator:

Dr. David Linyama

Supervisors: Dr. Elizabeth Stringer and Dr. Kasonde Bowa

NEONATAL MALE CIRCUMCISION STUDY

Consent for Evaluation of the Surgical Outcome

1. PURPOSE OF THE STUDY AND EXPLANATION OF PROCEDURES:

We are asking you and your baby to be in a research study because he has been circumcised at an outpatient neonatal male circumcision (NMC) clinic at University Teaching Hospital or Matero Reference Clinic. In this study we are trying to learn whether the NMC procedure, as performed in a clinical setting in Lusaka, Zambia, using one of three different common NMC devices, consistently produces a surgically acceptable result. About 125 infants will be circumcised as part in this study.

Although NMC is common in some parts of the world, it is new in Zambia. The results of this study will be used in helping to decide how best to scale up NMC in Zambia, and in training new providers of NMC.

If you agree to be in the study, your son will be evaluated one time, at least 6 weeks after his circumcision.

Before you decide if you want your son to be in the study, you need to know its purpose, the possible risks and benefits, and what is expected of you. Then, you can decide whether or not you want him to be in the study. This process is called informed consent. This consent form gives you information about the study. If you agree for your son to take part in the study, you will be asked to sign this consent form. You will be offered a copy to keep. You may choose to read this consent or have the consent read to you.

It is important that you know certain things:

- Taking part in the study is entirely voluntary. It is up to you to decide whether or not you and your son will be in the study.
- You may decide not to take part or to leave the study at any time.

Study Procedures

After you agree to be in the study, you will come back to the NMC outpatient clinic for one more visit. Your son will be examined by a trained doctor, who will assess the circumcision result, using a standard form. The doctor may also request to take a photograph of your son's circumcised penis. The photograph will be labeled with a number only, not a name. This picture may be shown to other doctors if a second opinion is needed.

If you have questions or concerns at any time during the study please let us know.

2. RISKS or DISCOMFORTS:

There are no known risks and discomforts associated with this study.

3. POTENTIAL BENEFITS:

If a problem is noted, then we will arrange that a specialist sees your son and assists him to have it rectified. Information learned from this study will be used to help in the training of new circumcision providers, and may be used by the Ministry of Health as they help scale up NMC in Zambia.

4. ALTERNATIVES TO PARTICIPATION:

This study is entirely voluntary. Your decision about whether or not you and your son will be in the study will not affect the care that you or your son receives.

5. CONFIDENTIALITY:

If you agree for you and your son to be in the study, you agree to allow the information we collect to be used for scientific purposes. We will not use any names of participants when we publish or share results of the study. Your records and your son's records will be kept confidential. However, your doctor and their staff, and study personnel will be able to look at

your medical records and have access to confidential information that identifies you by name. Information that could identify you or your son by name may also be shared with the Zambian Research Ethics Committee. No information about you or your son will be given out to anyone besides study staff without your written permission.

6. COSTS TO YOU:

There are no costs to you for participating in this study.

7. REIMBURSEMENT:

You will be reimbursed 20,000 kwacha for transport for coming to the study clinic.

8. PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS:

If you ever have questions about this study or in case you have any problems because of participation in this study, you should contact:

Dr. David Linyama, M.D.

Department of Surgery

University Teaching Hospital

0966 458 223

If you ever have questions about your rights as a research subject you may call:

Dr. E.M. Nkandu

Chair, Research and Ethics Committee

Department of Physiotherapy

Lusaka, Zambia

Tel: 256-027

12. LEGAL RIGHTS

You are not giving up any of your legal rights by signing this informed consent document.

13. <u>STATEMENT OF CONSENT:</u>

You will be offered a copy of this informed consent

If you have read the informed consent or had it read and explained to you and you voluntarily agree to join this study, please sign your name or make your mark below. If there is any part of this form that is unclear to you, be sure to ask questions about it. Do not sign until you get answers to all your questions. By signing this consent form you agree for you and your son to join the study.

I agree for my son and I to join this study.

_____	_____	_____
Participant's Name (print)	Participant's Signature or mark	Date

Participant has stated that she is:

____ Literate and can sign her name

____ Illiterate and cannot sign her name

I have observed the participant sign or make her mark above.

_____	_____	_____
Witness' Name (print)	Witness' Signature	Date

I have explained the purpose of this study to the participant. She had the form read to her, was given the chance to ask questions, accepted the answers, and signed to enroll in the study.

_____	_____	_____
Study Staff’s Name (print)	Study Staff’s Signature	Date

Note: This consent form with original signatures must be retained on file by the principal investigator. A copy must be given to the volunteer.