**A REVIEW OF MALE MEDICAL CIRCUMCISION**

**RECORDS IN KWA-ZULU NATAL**

**PROGRESS REPORT**

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# ACRONYMS, ABBREVIATIONS AND GLOSSARY

**Acronyms and abbreviations**

ART Anti-retroviral Therapy

ARV Anti-retroviral

CDT Conventional Dissection Technique

DoH Department of Health

FG Forceps Guided

HAART Highly Active Anti-Retroviral Therapy

HST Health Systems Trust

KZN Kwa-Zulu Natal

LA Local Anaesthetic

MDG Millennium Development Goal

MMC Male Medical Circumcision

OTP Office of the Premier, KZN

RCT Randomized Controlled Trial

TCD TaraKLamp Circumcision Device

ST SEED Trust

UKZN University of Kwa-Zulu Natal

**Glossary of male circumcision terms**

This glossary, which can be referenced at http://www.circlist.com/glossarymale/m-glossary.html lists and briefly explains abbreviations, acronyms, medical terms and suffixes relating to male sexual anatomy and male circumcision. Links within this link are connect to more detailed explanations, drawings and photographs.

**Acylophiliac (alternatively acucullophiliac)**

Greek for 'lover of the acorn' - acorn being a slang term for the Glans Penis. The language of Ancient Greece had two words for acorn, akulos and balanos. Both occur in circumcision terminology.

**Adhesion**

The uniting of two skin surfaces, especially the union of the opposing surface of the interior foreskin and the glans of the penis in the uncircumcised.

**Anterior**

Towards the front. The opposite of Anterior is Posterior.

**Aposthia**

The condition of having been born without a foreskin, apparently ready-circumcised.

**Balanitis (alternatively Balanoposthitis)**

Inflammation of the glans penis (the tip of the penis). It has been shown that uncircumcised males have a higher incidence of penile inflammatory disorders; circumcision almost completely eliminates these problems.

**Balanus**

Synonymous with Glans Penis.

**Buck's Fascia**

Part of the inner structure of the penis. It is the Buck's Fascia that holds the innermost components of the phallus in place, not the shaft skin. It is important that the Buck's Fascia is not cut during the circumcision procedure.

**Buried Penis**

A minor congenital defect attributable to a short suspensory ligament within the abdomen; causes the shaft of the penis to withdraw into the body. Considered by some to be a contra-indication to neonatal circumcision.

**BXO**

Balanitis Xerotica Obliterans. An auto-immune form of Balanitis. For more detail, follow the link from Balanitis (above).

**Chancroid**

A venereal disease no longer common in the West but quite prevalent in Africa. Several studies have shown a correlation between chancroid and increased susceptibility to heterosexual transmission of HIV/AIDS. This is unsurprising given that the condition produces ulceration of the genitals, providing an additional portal of entry for the virus. Thus the condition can no longer be considered benign, as was previously the case.

**Chordee**

Abnormal curvature of the penis, sometimes only evident when at least partially erect. In severe cases, considered to be a contra-indication to neonatal circumcision.

**Circumcise**

To perform circumcision.

**Circumcised**

The state of having undergone circumcision, i.e. (in the male) the personal condition of having had one's prepuce removed surgically.

**Circumcision clamp**

A metal or plastic device used to hold the foreskin in the required position during the circumcision precedure whilst simultaneously protecting the glans from damage by the scalpel.

**Circumcision (male)**

The surgical procedure in which the sleeve of skin (called the prepuce or foreskin) that covers the glans (head) of the penis is removed. From the Latin *circum* (around) and *caedo* (to cut).

**Circumcision scar**

The scar resulting from the fusion of shaft skin and inner foreskin during the healing process following circumcision. The scar tissue may differ in pigmentation and/or texture from the surrounding skin. Scarring is usually minor and the difference between inner and outer foreskin pigmentation is often more obvious than the actual circumcision scar.

**Congenital defect**

A birth defect - a foetal malformation - that is not (or primarily not) genetic in origin.

**Contra-Indication**

There are a number of birth defects (some congenital, some genetic) which suggest that circumcision should not be performed on a boy suffering from one or more of these problems. These medical conditions are termed 'contra-indications' to neonatal circumcision.

**Corona**

The flared ridge at the back of the glans, forming the prominent posterior border of the glans penis.

**Cryptorchidism**

The medical term for undescended testicle(s). The condition can be "unilateral" (only one testicle affected, more commonly the right side, the other being normal) or "bilateral" (both sides affected). Bilateral cryptorchidism is regarded as a contra-indication to neonatal circumcision because it can indicate an intersex condition.

**Dartos**

Dartos tissue is normally found only in the scrotum and is the tissue responsible for reacting to temperature change, contracting when cold and stretching when warm so as to regulate the temperature of the testes.

**Distal**

An anatomical term meaning "relatively further away from [whatever]". In the context of circumcision, used to describe which way round a circumcision clamp should be applied; the distal face of the clamp being the side farthest away from the abdomen of the patient. The opposite of Distal is Proximal.

**Dorsal**

An anatomical term meaning 'on the upper surface'. (Think of a Dorsal Fin on a fish.) When used in the phrase *dorsal slit* it refers to an incision made through the top surface of the foreskin. In some societies such a cut is all that is done by way of 'circumcision'. More commonly it is the first stage in a more conventional circumcision and is done to facilitate insertion of a circumcision clamp. The opposite of Dorsal is Ventral.

**Elective surgery**

Surgery done as a matter of choice rather than of necessity.

**EMLATM Cream**

A widely available topical anaesthetic, obtainable without prescription in many countries. It contains two active ingredients, lidocaine and prilocaine. Each gram of cream contains 25 mg of lidocaine and 25 mg of prilocaine.

**Epidemiology**

The study of epidemics. Currently a 'hot topic' when discussing circumcision, on account of the link between circumcision and HIV infection rates. Applied Epidemiology :  Medical and Social policy deriving from discoveries made through epidemiology.

**Epispadias**

A rare congenital defect in boys. The urethra opens onto the top side of the penis instead of at the tip of the glans, resulting in urine (and, from puberty, semen) being discharged from an abnormal position. Epispadias is a strict contra-indication to neonatal circumcision.

**Erogenous (as, for example, in Erogenous zone)**

Particularly sensitive to physical sexual stimulation.

**Flaccid**

The normal, relaxed state of the penis, indicating that the male is not sexually aroused. The opposite of Erect.

**Forceps**

A surgical instrument designed to hold and grip tissue. In circumcision sometimes used to grip the foreskin and guide the scalpel.

**Foreskin**

See Prepuce.

**Frenar or Frenular band**

Elastic tissue at the tip of the foreskin (between the inner and outer foreskin) that helps contract the tip of the foreskin causing it to remain positioned over the glans.

**Frenectomy**

Removal of any frenum/frenulum. In the context of circumcision: Removal of the frenum/frenulum that connects the ventral aspect of the glans to the inner foreskin.

**Frenoplasty**

Correction of an abnormally attached frenum by surgically repositioning it.

**Frenotomy**

Surgical division of any frenum or frenulum.

**Frenulum**

1) Literal meaning - a small frenum. 2) An elastic web of mucous tissue under the glans penis that connects to the inner foreskin and helps contract the prepuce over the glans. Optionally, it can removed during circumcision - whether or not that is done is one of the "style options". Sometimes referred to as the "Frenum".

**Frenum**

1) A narrow web or fold of mucous membrane passing from a fixed to a more movable part, serving to check undue movement of the movable part. 2) An anatomical structure resembling such a fold.

**Frenulum Breve (Alternatively 'Frenum Breve')**

The condition in which the frenulum of the penis is short, with consequent restriction of the movement of the prepuce. The frenulum should be sufficiently long and supple to permit full retraction of the foreskin, so that it lays smoothly back on the shaft of the erect penis. Frenulum Breve often results in tearing of the frenulum during sexual activity. Healing is complicated due to the moist condition of the area. Such a tear results in scar tissue which is less flexible after the incident, making further tears more likely. The condition is easily treated by circumcision in a style that includes removal of the frenulum.

**Genetic defect**

A physical defect or medical condition that is inherited, e.g. Haemophilia.

**Glans Penis**

The head or crown of the penis, made up of highly sensitive tissue.

**Haemophilia**

An inhertited medical condition; the sufferer's blood does not clot properly due to a genetic defect. (Women carry the defective gene without showing the symptoms of haemophilia. It is a classic example of an "X-linked recessive" genetic defect and propagates within the population accordingly.) Any surgery on a haemophiliac, including circumcision, can result in considerable loss of blood and appropriate precautions must be taken.

**High**

One of the terms used to define the style of a circumcision. See 'Style'.

**Hooded Prepuce**

Incomplete circumferential formation of foreskin with a dorsal component (the dorsal hood) present but an absent or incomplete ventral portion. Typically seen in boys with hypospadias or isolated chordee. In the rare condition of epispadias, the hooded portion may be ventral. Although perhaps thought of as physically unattractive, the condition is rarely troublesome. Surgical correction of hypospadias and the much rarer condition epispadias both require the harvesting of the foreskin as donor tissue for the repair process. In other cases of hooded prepuce the uneven cosmetic appearance can easily be corrected by elective circumcision.

**Hypospadias**

A congenital defect, fairly common in boys. The urethra opens onto the under side of the penis instead of at the tip of the glans, resulting in urine (and, from puberty, semen) being discharged from an abnormal position. Hypospadias is always to be regarded as contra-indicating neonatal circumcision.

**Informed consent**

The legal condition whereby a person can be said to have given consent based upon a clear appreciation and understanding of the facts, implications and future consequences of an action. In order to give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts at the time consent is given. In cases where an individual is considered unable to give informed consent, another person is generally authorized to give consent on his behalf, e.g. the parent(s) or legal guardian(s) of a child.

**Intersex**

Discrepancy between physical genitalia and EITHER the gender norm OR the individual's karyotype. Intersex states are always to be regarded as contra-indicating neonatal circumcision.

**Karyotype**

The characteristic chromosome complement of a species. In the context of human gender, "XX" is genetically female whilst "XY" is genetically male.

**Loose**

One of the terms used to define the style of a circumcision. See 'Style'.

**Low**

One of the terms used to define the style of a circumcision. See 'Style'.

**Masturbation**

Physical stimulation bringing about sexual arousal, not involving intercourse. Can be done alone or mutually. Mutual masturbation is surprisingly common amongst pubescent boys as they experiment with their sexuality.

**Meatus**

See Urinary meatus.

**Meatal Stenosis**

An abnormally narrow meatus. This condition can be caused by severing or crushing of the frenal artery during infant circumcision, although this is extremely rare. More frequently it is caused by ulceration of the meatus resulting from contact with stale urine. If the ulcer is properly cared for (usually just by applying Vaseline or other barrier ointment) it heals with no such problem, but if it is neglected it can lead to stenosis. For this reason it is recommended that circumcision is either carried out soon after birth, when the urine is very dilute, or deferred until the child is out of diapers.

**Micropenis**

A congenital defect which may be the most obvious indication of a more pervasive Intersex condition. Neonatal circumcision should be deferred pending specialist evaluation of both the cause and the extent of incomplete masculinisation.

**Orchidometer**

A device for measuring the size of testicles and thus assessing developmental progress, particularly at puberty.

**Overhang**

The portion of the foreskin that extends beyond the tip of the glans. Sometimes known as redundant prepuce.

**Paraphimosis**

Painful constriction of the glans penis by a phimotic foreskin which has been retracted behind the corona and got stuck. In severe cases this can constitute a clinical emergency, due to possible strangulation of the blood supply to the glans.

**Pearly Penile Papules**

In essence these are swollen hair follicles without the hair, located on the corona and found in approximately 30% of men at some time in their adult lives. They are benign and do not warrant treatment, but to the naked eye can be confused with genital warts. Being located on the glans, they are unaffected by circumcision. Worth discussing with your doctor if you have them, to ensure that they really are benign papules and not something more serious.

**Penoscrotal Web**

A web of non-mucous tissue stretching from the scrotal raphe to the undeneath of the penis, giving the appearance of a short penis and a deformed scrotum. This can occur naturally or be caused by an overly aggressive circumcision, especially in infancy. Corrected by a surgical procedure known as scrotal z-plasty.

**Peritomy**

MMC is defined as the surgical removal of the major part or all of the inner prepuce, also known as peritomy

**Phimosis**

Narrowness of the opening of the prepuce (foreskin), preventing it being drawn back over the glans. This condition is readily corrected by circumcision.

**Phimotic**

Pertaining to phimosis.

**Posterior**

Towards the rear. The opposite of Posterior is Anterior.

**Posthitis**

Inflammation of the prepuce (the foreskin of the penis). Do not confuse with balanitis, which is inflammation of the glans. For more detail, follow the link from Balanitis (above).

**Prepuce (Male)**

The free fold of skin that covers, more or less completely, the glans penis of an uncircumcised male. Synonyms: Foreskin, Preputium. During circumcision, most or all of the prepuce is removed.

**Prophylactic**

Some thing done to prevent disease before it occurs; preventative treatment. (Associated noun: Prophylaxis.) In a sense, the opposite of therapeutic.

**Proximal**

An anatomical term meaning "relatively closer to [whatever]". In the context of circumcision, used to describe which way round a circumcision clamp should be applied; the proximal face of the clamp being the side closest to the abdomen of the patient. The opposite of Proximal is Distal.

**Preputiotomy**

Incision of the prepuce; for example to make a dorsal slit.

**Raphe**

The line of union of any two continguous, bilaterally symmetrical structures. In the context of the male genitalia, the Raphe runs down the underneath of the penis in one continous line from the tip of the foreskin, down the shaft, down the center of the scrotum and between the legs to the anus.

**Recircumcision**

A second or subsequent circumcision of someone who has already been circumcised. Fairly rare, it is sometimes done to tighten a circumcision that has, over time, become loose.

**Redundant Prepuce**

A foreskin that more than covers the glans when the penis is flaccid. Colloquially known as "Overhang".

**RIC**

Literally, "Routine Infant Circumcision". Refers to the custom of routinely circumcising newborn boys for reasons of culture rather than religion or medical necessity, especially in North America.

**Shaft skin**

The part of the penile sheath that covers the shaft from the abdomen to the foreskin or circumcision scar. Highly mobile with respect to the underlying structures, being separated from them by the Buck's Fascia.

**Skin Bridges**

Natural, discontinuous adhering or uniting of two skin surfaces, especially where unintended. In the context of male circumcision, skin bridges can form between the corona and the circumcision scar during the healing process. Easily corrected by minor surgery.

**Smegma**

The secretion of a sebaceous gland, producing a cheesy substance that collects between the glans penis and the foreskin of the uncircumcised penis.

**Style**

To accurately describe an existing circumcision (or indicate just what's wanted in respect of a forthcoming one), it is necessary to specify four parameters: The High/Low variable, the Loose/Tight variable, whether the frenulum was - or is to be - removed and whether the cut was - or is to be - perpendicular to the shaft of the penis or parallel to the rim of the glans.

**Sulcus**

The groove or furrow between the glans and the shaft of the penis.

**Suture**

A surgical stitch. Suture material is designed to be very strong whilst being tolerated well by the body. There are two types of suture material: a self-dissolving ("soluble") one which lasts about a week and a non-soluble type, which has to be removed by the doctor and is used where the stitch needs to hold for longer periods.

**Tanner Stages**

A method for describing and classifying the progress of puberty.

**Therapeutic**

Something done to cure disease after it occurs; healing treatment. (Associated noun: Therapy.) In a sense, the opposite of prophylactic.

**Thrombocytopenia**

Thrombocytopenia is the term for a reduced platelet (thrombocyte) count in the blood. It happens when platelets are lost from the circulation faster than they can be replaced from the bone marrow where they are made. This condition is a contra-indication to neonatal circumcision.

**Tight**

One of the terms used to define the style of a circumcision. See 'Style'.

**Topical**

(As in "topical ointment"). Applied to the external surface. Example: EMLATM Cream. This word often fools auto-translators; they are liable to wrongly interpret it as meaning "On topic, something up-to-the-minute and in the news".

**UMDNS**

Universal Medical Device Nomenclature SystemTM, a standard international nomenclature and computer coding system for medical devices.

**Urethra**

The tube through the penis in which urine and semen flow. (Do not confuse with the similar-sounding Ureter, the ducts connecting the kidneys to the bladder.)

**Urinary meatus**

The opening of the urethra at the tip of the penis where urine and semen exit the body of the male.

**Venereal**

Pertaining to love and sex; literally "of Venus" (the Roman Goddess of Love).

**Ventral**

An anatomical term meaning 'on the lower surface' or under side of [whatever]. The opposite of Ventral is Dorsal.

**Z-plasty**

A surgical technique used to correct an unacceptable penoscrotal web.

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# EXECUTIVE SUMMARY

# This report is a provisional progress statement on a study carried out in fulfilment of the proposal submitted to the KwaZulu-Natal (KZN) Male Medical Circumcision (MMC) Steering Committee on 24 October 2010.

# The primary objective for the study has been to assess whether there is any significant increase in adverse events in the use of the TaraKLamp Circumcision Device (TCD), the technique primarily used in the KZN mass male circumcision programme,as compared to the published standards such as those obtained in randomised control trials or the “Roll-out model” of 1.8% described by Lissouba et al using the conventional FG technique.

# There is considerable controversy at the moment about the use of the TaraKLamp in adults. In resolving the dispute for the benefit of the community for which it is intended, it is important to emphasize that working from scientific evidence is important at all times. This includes both learning from previous experience such as the randomised controlled trials reported on in the literature review section of the document or the actual experience of practitioners in the field.

There are limitations in this review. It is being done very hurriedly on a limited budget. Because of the controversy, the process of getting permission to undertake the study has been delayed and even the MMC Steering Group convened to oversee the study is being reconstituted and has not given its final approval for the commencement. As a result the research team has been constrained in working within a somewhat narrower framework than initially envisaged on a slightly expanded approach to the thesis topic of Dr MJ Titus. Nevertheless the research team has worked closely with Dr MA Quazi and the MMC surgical outreach team at the Northdale Hospital. This has enabled the researchers to gain good insight into how the MMC programme is currently being implemented in a wide range of sites including urban, peri-urban and rural settings.

There are at this provisional stage two aspects to the study. The first is a Retrospective Review of data from many circumcision sites, reporting on the outcome of the procedures for the period from the start of the programme during early 2010 until the end of October. For this part of the study only 5 day adverse rates have been available. The second aspect is of the study, a Concurrent Review, currently still under way, seeks to measure the adverse events more carefully, including a six week telephone review of the later adverse effects.

It is possible to say provisionally at this stage, even given the limitations of the adverse event follow-up only being limited to 5 days, that the reported adverse event rate of the TCD approach being used in KZN (1.5%), is many orders of magnitude lower than the alarmingly high rate of 37% reported by Legarde et al in their trial and feared by the TAC and Media. It is very similar, and possibly even lower than the adverse event rate achieved in the major RCTs undertaken in Africa (2.7%).

While undoubtedly there have been some adverse events in the KZN MMC programme, as would be anticipated in a mass circumcision of this scale, describing the outcomes as “mutilating” would appear to be excessive and not based on the evidence from the Province. However, given the limitations of the Retrospective analysis, it is hoped that information from the Concurrent cohort where there has been closer independent scrutiny and an intended six week follow up of the results, a more accurate picture of the adverse events rate for KZN MMC programme may be possible.

In summary, at this provisional stage

* Adverse events and comparison with the clinical outcomes in the KZN MMC programme have focussed on the immediate and intermediate term. There has been no attempt to document the late surgical complications of the procedures after one month either using the TCD or FG approaches;
* Given the available records, the severity of the complications of the different procedures, TCD or FG, in terms of additional medical treatment, referral for specialist treatment and the duration of treatment seem comparable;
* The records thus far provide no insight into the educational or cultural activities associated with the MMC to assess the extent to which this might contribute to future gender sensitivity and sexual practices;
* From a formative assessment perspective there do not seem to be grounds to believe that the KZN MMC programme is grossly unsafe. Although there is undoubtedly considerable room for operational improvement, the available retrospective data suggests adverse event rates that are typical of MMC programmes undertaken on a large scale elsewhere in Africa.

# 1. INTRODUCTION

This report is a provisional progress statement on work carried out in fulfilment of the proposal submitted to the Male Medical Circumcision (MMC) Steering Committee on 24 October 2010 in response to the request by the KwaZulu-Natal Department of Health (KZN DoH), the National Department of Health (NDoH) and the World Health Organisation (WHO), to conduct a Retrospective Analysis of Male Medical Circumcision [MMC] Records in Kwa-Zulu Natal [KZN].

Since 2006 there has been robust evidence that male circumcision reduces the risk of HIV in several African settings including South Africa[[1]](#endnote-1). From early 2010, spurred on by this evidence, the MMC programme in KZN, championed by His Majesty, King Goodwill Zwelithini, the National Minister of Health, Dr A. Mostwaledi, the Premier, Dr Z. Mkhize and the MEC for Health in the Province, Dr S. Dhlomo has been growing rapidly to provide safe male circumcisions, as an intervention to reduce the risk of HIV in men and boys.[[2]](#endnote-2)

Evidence-based reporting on the attitudes, impact and community knowledge regarding male circumcision as an HIV-prevention tool suggests that it is among the most effective current preventive interventions, particularly if sound cautionary guidance regarding the importance of this measure not being regarded as a magic bullet is heeded. Although MMC reduces the risk of circumcised men in acquiring HIV, it does not eliminate such risk and it is essential that it is accompanied by sex and gender education which emphasizes the need to continue practicing safe sex including delay in sexual debut, non penetrative sex, use of condoms, sticking to one partner, as well as being considerate and responsible.[[3]](#endnote-3)

Although a range of surgical approaches have been used, including the conventional Forceps Guided [FG] technique, the KZN programme has primarily been using the Tara KLamp™ Circumcision Device [TCD], which has become an intense source of controversy and confusion. Despite that by 17 December 2010, close to 20,000 circumcisions had been undertaken in just under a year from the start of the programme, because of the criticism, there is some uncertainty regarding the future.[[4]](#endnote-4) The KZN Government has indicated repeatedly that the circumcisions are safe. Some civil society organisations and certain media have however, become increasingly strident and vociferous regarding the use of the TCD. In an extraordinarily vitriolic report on their website[[5]](#endnote-5) entitled *Money from mutilation: The Tara KLamp Story,* the Treatment Action Campaign, widely respected for their advocacy for antiretroviral medication, vilifies the programme in uncompromising terms: “*A massive unethical medical intervention is unfolding in Kwazulu-Natal (KZN). It could harm many men. At the root of it is greed and also cowardice….. The Kwazulu-Natal government is using an unsafe circumcision device that will injure thousands of men.”* This message has been picked up by the media including several newspapers. For example in an article “*Money From Mutilation[[6]](#endnote-6)*” which substantially raises the same allegations as the TAC report, The Witness, a respected Pietermaritzburg-based newspaper reported “*the provincial government has also rolled out a dangerous plastic circumcision device called the Tara KLamp. It works by clamping shut on the foreskin so that the blood supply to it is cut off. Over a period of seven to 10 days the foreskin is supposed to die and fall off, along with the clamp, but sometimes the clamp must be surgically removed.”* For the above reason, there is considerable urgency in completing this study.

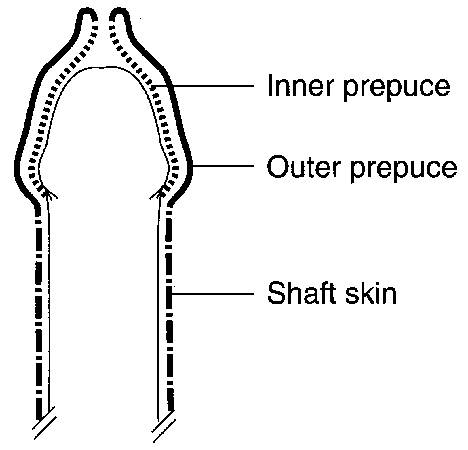
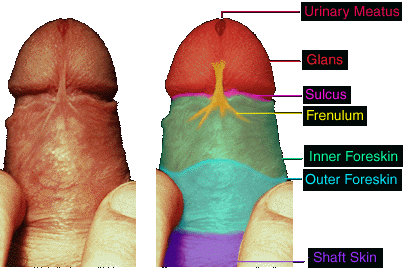
While recognizing potential shortfalls of any large mass campaign, advocates for progressive change based on evidence should not become victims of what they accuse others – a failure to consider the facts and allowing personal preferences and vested interests to intervene. One should not overlook the complexity and cost implications that are associated with mass male circumcision, which explains why, despite the growing body of work on cost-effectiveness of male-circumcision procedures, there is still uncertainty. Operational research is important to help improve safety, refine estimates of programme costs, identify strategies for lowering them, and making further improvements to cost-effectiveness through techniques such as “task-shifting” of surgical procedures from medical officers and professional nurses to newer cadres such as clinical associates, as well as negotiation for affordable supplies.

Given the evidence in favour of the effectiveness of mass male circumcision, it should be extremely encouraging to male circumcision advocates that the senior leaders of the country and KZN Province, in particular, have begun looking beyond traditional cultural and religious practices and now view medical circumcision as a HIV prevention method, thereby providing a powerful additional impetus to efforts to physically reduce the HIV transmission. It should be recognized, with considerable concern, that there are powerful constituencies that argue forcibly against the scientific evidence in favour of circumcision for a variety of reasons and will likely continue to do so regardless of the data on its HIV-and other prevention benefits.[[7]](#endnote-7)[[8]](#endnote-8) This could, if allowed to feature in the current debate, significantly impair the broader adoption of male circumcision as a technique to prevent the spread of HIV, much as the denialist arguments led to resistance to anti-retroviral treatment until late 2003, by which stage 343,000 deaths[[9]](#endnote-9) were estimated to have resulted.

# 2. PERTINENT ASPECTS OF THE LITERATURE

Although male circumcision is generally defined as the removal of the foreskin that covers the head of the flaccid penis, one of the oldest and most common surgical procedures known, this definition is insufficiently precise for a Medical Male Circumcision [MMC] programme aimed at reducing risk of acquiring HIV. Traditionally, circumcision was undertaken as a mark of cultural identity[[10]](#endnote-10), for religious reasons [[11]](#endnote-11),[[12]](#endnote-12) for personal hygiene or to decrease the risk of genital problems or infections [[13]](#endnote-13),[[14]](#endnote-14) where it was relatively unimportant to be specific about which part of the foreskin was removed. For the purpose of this study, however, MMC is defined as the surgical removal of the major part or all of the inner prepuce, also known as peritomy.[[15]](#endnote-15) This is particularly important because the evidence suggests that the Langerhans glands, macrophages and dendritic cells concentrated in the epidermis of the inner prepuce and frenulum are the most likely portal of entry for the HIV virus during sexual intercourse by binding to the receptors found on “antigen presenting cells” in the genital mucosa.[[16]](#endnote-16) Therefore the optimum style of circumcision, in terms of HIV protection, is likely to be one that removes the greatest proportion of inner foreskin. It should be noted that there are several groups opposed to male circumcision on any grounds and regard it is a form of genital mutilation, depriving circumcised males of what they regard as the physiologically important prepuce.

Figure : Penile skin and the prepuce



Sources: Denniston, GC (1996) “Modern" Circumcision: The Escalation of a Ritual, Circumcision**[[17]](#endnote-17)**;

http://www.circlist.com/glossarymale/m-anatdetail/anatpics.html

While it is *medical* circumcision carried out by trained doctors or nurses which forms the subject of this Review, it is important to note that in South Africa, *traditional* male circumcision (TMC) is still widely practiced in Xhosa, Tswana and other communities, where it is part of a rite of passage, marking the transition from boyhood *(ubukhwenkwe)* to manhood *(ubudoda)[[18]](#endnote-18),* sometimes undertaken by those of dubious competence. This is of concern to public health authorities because of the high rate of adverse events and even deaths among those so circumcised. This is of particular importance among Zulu communities in KwaZulu Natal, where male circumcision has not been practiced since it was banned by King Shaka, who believed that the time it took to heal, diverted too many young warriors away from their military duties in his army. Circumcision has therefore hitherto been unusual among Zulu men. Interestingly, as a major shift in the circumcision paradigm in contemporary Zulu society, His Majesty, King Zwelithini has been prepared to end nearly two centuries of tradition in the interest of reducing the risk of young men acquiring HIV, saving lives, and avoiding unnecessary deaths[[19]](#endnote-19). Without in anyway denigrating the value of cultural traditions, in contrast to the TMC approach elsewhere, the KZN strategy has adopted an MMC approach aimed at ensuring the practice of safe medical circumcisions by health personnel qualified to perform the procedure[[20]](#endnote-20) while acknowledging the value of traditional culture.

Since the 1980s, over 30 observational studies have suggested a protective effect of male medical circumcision on HIV acquisition in heterosexual men. In 2002, three randomised controlled trials to assess the efficacy of male circumcision for preventing HIV acquisition in men commenced in Africa. A Cochrane Review [[21]](#endnote-21) published in September 2008 evaluated the results of these trials, ANRS 1265[[22]](#endnote-22), Bailey 2007[[23]](#endnote-23) and Gray 2007[[24]](#endnote-24). The meta-analysis specifically considered the effectiveness and safety of male circumcision for preventing the acquisition of HIV in heterosexual men. There was strong evidence that medical male circumcision reduced the transmission of HIV to heterosexual men by between 38% and 66% over 24 months. Circumcision was performed using commonly used surgical techniques, the forceps-guided technique or sleeve resection under local anaesthesia. Incidence of adverse events was very low, indicating that male circumcision, when conducted under these conditions, was a safe procedure. Inclusion of male circumcision into current HIV prevention measures guidelines was therefore warranted. Further research was needed to assess the feasibility, desirability, and cost-effectiveness of implementing the procedure within local contexts. Meta-analysis of the secondary outcomes measuring sexual behaviour for the Kenyan and Ugandan trials between circumcised and uncircumcised men found no significant differences. For the South African trial, the mean number of sexual contacts at the 12-month visit was 5.9 in the circumcision group versus 5 in the control group, which was a statistically significant difference (p < 0.001). This difference remained statistically significant at the 21-month visit (7.5 versus 6.4; p = 0.0015). No other significant differences were observed.

The incidence of adverse events following the surgical circumcision procedure was low in all three trials. Each trial recorded adverse events including those considered related and not related to circumcision. In ANRS 1265, however, only adverse events for the circumcised group were reported. In ANRS 1265, 60 (3.8%) adverse events were recorded during the first month post surgery for the 1,568 participants who were circumcised; this included the 73 HIV-positive men who also were circumcised and not included in the final analysis. Adverse events were categorised according to event and not severity. No deaths were recorded and the most common adverse events were pain (31.7%), excessive bleeding (15%), swelling or haematoma (16.7%), and problems with appearance (15%). Other events recorded were infection (5%), damage to the penis (6.7%), insufficient skin removed (6.7%), delayed wound healing (3.3%), and other causes not further defined (8.3%). At 21 months post-circumcision, 11 adverse events were noted in the 1,131 men returning for their 21-month visit. These included problems with urinating (3/1131), problems with appearance (4/1131), and mild or moderate erectile dysfunction (4/1131).

In Bailey 2007, 24 adverse events were recorded as possibly, probably, or definitely related to circumcision in 23 (1.7%; 95%CI: 1.2 to 2.6) of 1334 participants. None of these events were classified as serious and included post-operative bleeding (5), infections (5), wound disruptions (4), delayed healing (3), swelling at the incision site (2), convulsion following anaesthetic (1), wound at base of penis (1), pubic abscess (1), folliculitis (1), and erectile dysfunction (1). All events resolved within hours or days except for the erectile dysfunction—the investigators note that erectile dysfunction post-randomisation occurred with an incidence of 1.5% in the circumcised group and at 1.0% in the control group. This was not statistically significant (p = 0.24). A total of 10,154 unrelated adverse events were recorded among 71% of participants. Of those events classified as serious, 17 occurred in 16 men in the intervention group and 15 in 14 men in the control group. Marginally statistically significant differences in abdominal or gastrointestinal conditions were noted in the control group (p = 0.047), and the incidence of balanitis, phimosis, and paraphimosis was statistically significantly higher in the control group (p < 0.0001).

In Gray 2007 there were 178 adverse events in the 2,328 circumcisions that were carried out, with five events classified as severe, including wound infection (1), haematoma requiring re-exploration and ligation of active bleeding vessels (2), wound disruption (1), and post-operative herpetic ulceration not involving the surgical wound (1). An additional 79 moderate events and 94 mild events related to surgery were recorded. All severe and moderate events were managed and resolved. Overall, the number of all adverse events reported was 1,391 in the intervention group and 1,320 in the control group (56% versus

52%; p = 0.083). Of the events in the control group, none were considered to be related to the trial; 87% of events in the circumcision group were considered to be related to the trial.

Table : Summary of the adverse event rates of MMC in three foundational MCC clinical trials

|  |  |  |  |
| --- | --- | --- | --- |
| **Trial name** | **ANRS 1265** | **Bailey 2007** | **Gray 2007** |
| Trial site | Orange Farm, South Africa  (N = 3,274) | Kisumu,  Kenya (N = 2,784). | Rakai, Uganda  (N = 4,996), |
| Duration | 2002 – April 2005 | 2002 to December 2006 | 2002 to December 2006 |
| Surgical technique | Forceps Guided | Forceps Guided | Sleeve Resection |
| Adverse events | 60 | 24 | 178 |
| Total circumcisions | 1,568 | 1334 | 2,328 |
| **Adverse event rate** | **3.8%** | **1.7%** | **7.65%** |
| Maximum follow-up | 21 months | 24 months | 24 months |
| Occurrence | Adverse events in the first month post surgery. At 21 months post-circumcision, A futher 11 adverse events were noted in the 1,131 men returning for their 21-month visit. | Adverse events were recorded as possibly, probably, or definitely related to circumcision | Mild (94), moderate (79) or severe (5) events related to surgery |
| Findings | Pain (31.7%), excessive bleeding (15%), swelling or haematoma (16.7%), and problems with appearance (15%). Other events recorded were infection (5%), damage to the penis (6.7%), insufficient skin removed (6.7%), delayed wound healing (3.3%), and other causes not further defined (8.3%). | None of these events were classified as serious and included post-operative bleeding (5), infections (5), wound disruptions (4), delayed healing (3), swelling at the incision site (2), convulsion following anaesthetic (1), wound at base of penis (1), pubic abscess (1), folliculitis (1), and erectile dysfunction (1). | The five events classified as severe, included wound infection (1), haematoma requiring re-exploration and ligation of active bleeding vessels (2), wound disruption (1), and post-operative herpetic ulceration not involving the surgical wound (1) |

In summary, since the evidence from the three clinical trials confirmed male circumcision as the first new biomedical HIV-prevention strategy in over a decade[[25]](#endnote-25) capable of reducing men’s risk of acquiring HIV infection during vaginal sex by roughly 60%, there has been advocacy for the large scale introduction of the intervention, even though the rates of protection may not be as high outside of the controlled environment of a clinical trial[[26]](#endnote-26). It has been argued that adding an offering of safe, sterile mass male circumcision to the existing HIV prevention programmes could avert many infections and save many lives[[27]](#endnote-27). Adverse events in the first post-operative month, as found in the three RCTs should be no higher than about 5%. These findings have led HIV-prevention advocates to strongly lobby for an adult male circumcision programme with the suggestion that these programs could also provide a new way to reach men and adolescent boys who are frequently under-represented in health clinics and HIV-prevention programs. The South African National AIDS Council and the National Department of Health have further been reported as being in the process of finalizing the country’s policy and guidelines on medical male circumcision, which will be added to the HIV prevention basket[[28]](#endnote-28).

A model for the roll out of an Adult Male Circumcision programme in low-cost African settings has recently been developed by Lessouba et al (2010).[[29]](#endnote-29) This study demonstrated that a quality Adult Male Circumcision (AMC) programme adapted to African low-income settings is feasible and can be implemented quickly and safely according to international guidelines. The approach was suitable for the scale-up of comprehensive AMC services, and could be tailored for other rural and urban communities of high HIV prevalence and could achieve low AMC rates in Eastern and Southern Africa. The approach demonstrated that by using an innovative surgical organization consisting of three task-sharing teams of one medical circumciser and five nurses, up to 150 AMCs per day could be performed under local anaesthesia, with sterilized circumcision disposable kits and electrocautery. As of November 2009, 14,011 men had been circumcised, averaging 740 per month over the twelve months of the study. The rate of adverse events, none of which resulted in permanent damage or death, was 1.8%. Most of the men surveyed (92%) rated the services provided positively. Community support for the project was high and 27.5% of project participants agreed to be tested for HIV. The rate of 1.8% adverse events in this paper is taken as the benchmark for this Review.

The KZN MCC programme strategy[[30]](#endnote-30) estimated the number of males in the Province in early 2010 at 4,321,830, of whom about 54% were in the 15-49 year age group. This implied that the goal for the MCC Programme should be approximately 1.8 million adult males for immediate circumcision as part of a “catch-up” programme and a further 95,000 infants each year thereafter as part of an “ongoing” circumcision programme. The target for neonatal circumcision was set at 47,055 for 2010.

Partners in the KZN MMC programme were initially envisaged as (1) Government: Departments of Health; Social Development; Arts, Culture, Sport and Recreation; Education; Cooperative Government and Traditional Affairs; Defence (2) Donors and NGOs: HSRC, MAtCH, CAPRISA, McCords Hospital, St Mary’s Hospital, Broadreach Healthcare, Kethimpilo and Africa Centre (3) Volunteer doctor groups and initiatives: The Jewish Medical Association, The KZN Managed Care Association; Khanya Africa; Muslim Doctors Group, Ramakrishna Doctors Group and Operation Abraham Initiative (OAC).

Since the success of the medical circumcision procedure, like any other surgical technique, depends on the competence of the practitioner, the KZN MCC programme envisaged a 3 day WHO approved training programme performed by an experienced group of surgeons within facilities. The intention was that doctors who were trained would then be in the position to go back to the training facilities to cascade the training. MAtCH was to fund all the training activities and Operation Abraham was also to assist with the facility-based training and mentorship.

There are two methods currently being used in the mass male medical circumcision programme (MMC) in KwaZulu-Natal, namely the forceps-guided method [FG] and the Tara KLamp™ Circumcision Device [TCD]. The standard FG method is usually done under local anaesthetic [LA] in a hospital or clinic, but has also been done in other aseptic community-based settings where it has been reported that the complication rate is low[[31]](#endnote-31). At the start of the MCC programme in KZN the Province made the decision that it would also use, in addition to the conventional circumcision techniques, The Tara KLamp™ Circumcision Device (TCD). This is a Malaysian invention, developed by Dr. Gurcharan Singh Tara Singh during the 1980s and early 1990s, and was first marketed in 1995. The TCD is highly regarded in SE Asia and is also making inroads into the sub-Saharan African market. In June 2009, Dr. Singh’s work promoting safe circumcision earned him the Malaysian Medical Association’s Outstanding Public and Healthcare Services Award, a rare honour equivalent to a Lifetime Achievement Award.[[32]](#endnote-32) The TCD is a relatively new device and although it is being promoted as safe, as far as we are aware, published evaluation studies unequivocally demonstrating its safety have been conducted among young children only [[33]](#endnote-33).

The principle of operation of the TCD is illustrated by the following diagrams, based upon the manufacturer’s original publicity material dating from the 1990s:

Figure : Circumcision using the TaraKlamp Circumcision Device

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| tarasequence-1 (3065 bytes) | tarasequence-2 (2056 bytes) | tarasequence-3 (1927 bytes) | tarasequence-4 (2886 bytes) | tarasequence-5 (2923 bytes) |

Source: http://www.circlist.com/instrstechs/taraklamp.html

The TCD consists of an inner funnel-shaped tube to protect the glans and an outer ring joined by a ratcheted clamp. The prepuce is drawn between the funnel and outer ring to the correct position. Once the clamp is closed, the fate of the foreskin is sealed. There’s no going back; the powerful crushing action causes necrosis of distal portion of the prepuce. In theory an option exists not to cut with a scalpel, instead leaving the condemned part of the foreskin in place to necrotize - the clamping action having totally cut off the blood supply. However, this approach is not recommended due to the possibility of the considerable quantity of dead tissue harbouring infection during the week or so until the clamp drops off naturally. Normally, a scalpel is used to sever the foreskin immediately after the clamp is applied. The correct position of the cut is 2mm to 3mm clear of the distal face of the clamping ring to avoid the cut end of the prepuce retracting past the tightening ring. When marking out a circumcision using one of these clamps, it is vital to realise that the eventual scar line will form at the position of the proximal face of the clamping ring, not at the position of the scalpel cut. Careful selection of cases is important and surgical techniques need modification with pre-existing anomalies such as hypospadias and phimosis.

The inventor, manufacturers and distributors of the TCD claim the following benefits viz-a-viz conventional circumcision surgery:

* The device is delivered pre-sterilised. The latching mechanism is designed to ensure single use only, thus guarding against cross-infections (hepatitis, HIV);
* A sterile environment is not required. The device can be used in homes, schools, at religious sites and other non-medical places.
* The device totally shields the glans from the scalpel, making the procedure very safe. It protects against accidental amputation and other injuries caused by experienced circumcisers;
* The method is non-invasive; no sutures, ligatures or dressings are required;
* Haemostasis is maintained during surgery. There is no or very limited bleeding during or after the procedure and its does not require either cautery, sutures, ligatures or bandages;
* There is no post-surgical bleeding or oozing. The patient can resume normal activities straight away;
* Results are predictably neat and even across a wide range of style choices;
* Easy to implement because it required minimal training;
* Faster than conventional methods;
* Applicable to all age groups from infants to adults;
* Less restrictive in that it allowed an immediate return to routine, no bathing restrictions
* Cheaper both from a programmatic as well as individual point of view;
* Able to achieve a circumcision showing a uniform and even cut with a good cosmetic result when healed.

Evidence cited by Taramedic, the manufacturers of the TCD include at least two papers published in peer reviewed journals, the first in the *British Journal of Urology International* in June 2001 and the second, a month later in the *Tropical Doctor* during July 2001.

The first paper[[34]](#endnote-34) entailed a prospective comparison of two methods of religious circumcision that were being used by the Islamic community in the Netherlands since 1998, the conventional dissection technique (CDT) and the TCD. Surgery was carried out in outpatient clinics by residents and GPs, supervised by a surgeon. The ethics committee of the University Medical Centre of Utrecht approved the study. Inter alia, the authors considered the duration of the procedure, complications, postoperative pain and degree to which parents were satisfied with the cosmetic result. 275 boys were included in the study with a median age of 3 years (range 2-5 years). 15 parents chose the CDT instead of the TCD. Thirteen boys were lost to follow-up, mostly because they had moved to an unknown address. The median operative duration was 8 minutes longer for the CDT (15 minutes versus 7 minutes p<0.0001). In two TCD procedures it was necessary to convert to the CDT, once because the device disconnected spontaneously during the procedure and once because the clasp slipped directly after cutting the foreskin. There was no bleeding in the TCD group when the clamp was in situ but in two cases bleeding had to be controlled with a suture after the clamp was removed on the fourth day. No clamp was removed earlier than intended and most of the inner tubes fell off on the day when the clamp was disconnected. Postoperative pain was comparable in both groups, but the boys in the TCD group had more disturbed nights and more analgesics. However, they recovered earlier to normal daily activity. There was no difference in complication rate between the TCD and CDT (Bleeding: one vs. two. Infection two vs. three). The cosmetic results were significantly better in the TCD group (P<0.001), where the parents’ satisfaction score for the procedure, including the return for the removal of the clamp was the same in both groups. The author’s conclusion was the TCD is quicker and leads to a better cosmetic result that the CDT, without increasing morbidity.

The second study[[35]](#endnote-35), examined the results of the use of the (TCD) among 64 Muslim boys ranging in age from 7 to 12 years (median age: 10 years) operated on by Medical Assistants supervised by Medical Doctors in a hall in Kuala Lumpur, Malaysia during December 1998. The median operating time was 10 minutes (range: 5-25 minutes). Apart from mild postoperative pain, no major complications occurred, apart from two intra-operative incidents, where there was reversion to the conventional dissection technique, once because there was a roll-up of the inner mucosal layer of the foreskin and once because the device slipped directly after cutting the foreskin. The authors reported that there was mostly good cosmetic results and that 90% of parents would recommend this new clamp to others. They concluded that the TCD was safe although proper patient selection and adequate training is using the device was mandatory.

To our knowledge, there has been one study, a Randomised Controlled Trial in young adult men to evaluate the safety and complications associated with the use of the TCD in MC in South Africa, the study by Legarde E, et al mentioned above[[36]](#endnote-36). This trial compared circumcisions using the TCD versus the FG methods and found adverse events in 37% versus 3%, respectively, thus providing suggestive evidence that caution should be exercised in the use of the TCD.[[37]](#endnote-37) The authors found that the TCD method compared unfavourably with the FG method when used for MMC among young adults and the unacceptably high complication rate resulted in early interruption of the study.[[38]](#endnote-38) The numbers were small (35 in TCD arm and 35 in FG arm) and in terms of their own description in their paper, the GPs performing the circumcisions using the TCD had limited experience with the technique. As a result there has been very high profile adverse publicity about the TCD with groups such as the Treatment Action Campaign (TAC), a non-governmental organization (NGO) objecting to the use of the device because it is considered unsafe for use on either adult or adolescent males[[39]](#endnote-39). A representative of the marketing company of the TCD defended the use of this device stating that complications arose because of the way they were used. (Radio interview of the TCD representative: 17 July 2010). The Department of Health in KZN has also defended the use of the TCD for MMC, arguing that complications are unusual.

In the KZN Programme, the TCD technique described above has undergone an important modification to circumvent many of the potential complications of the previous approach.[[40]](#endnote-40) In this modified technique, care is taken to ensure that the complete inner prepuce is removed. First, the junction between the preputial and shaft skin is identified and marked prior to the placement of the TCD. Then normal skin from the shaft of the penis is retracted back through the ring prior to clamping. This ensures that only the mucosa from the inner prepuce, the region through which it is believe HIV predominantly gains access to the body, is excised. Only 3-5mm of preputial skin in the vicinity of the sulcus of the glans remains. This surgical approach ensures that there is sufficient skin from the shaft of the penis left over to prevent wound dehiscence and allow for ample expansion during erection and sexual activity.

Figure : Modified KZN technique to excise only inner prepucial mucosa during TCD procedure



In the modified KwaZulu-Natal TaraKLamp procedure (as demonstrated above by Dr MA Quazi), the junction between the penile shaft skin and inner prepuce is first identified with forceps (left above). The band of prepuce to be removed is indicated between the two circumferential lines (centre above). After placing the TCD in position (right above), normal shaft skin is retracted back through the plastic outer ring, until only the identified preputial mucosa remains distal to clamping zone. This saves several centimetres of normal penile skin which would otherwise have been excised, thus achieving the goal of complete medical circumcision of the entire inner prepuce. The modified technique appears to reduce possible adverse events compared to the conventional TCD procedure. Antibiotics are not routinely used, unless indicated by the presence of an infection such as balanitis or prosthitis. The dorsal slit procedure followed by application of the TCD is used in all cases of tight preputial rings or phimosis, abnormalities which appear quite commonly. Only petroleum jelly is applied after bathing to ensure that the rim of necrotic tissue remains soft. This greatly reduces discomfort when the device is removed on the fifth day postoperatively. Standard local analgaesia is provided during the procedure and oral medication for the postoperative period consists of a combination of ibuprofen and paracetamol.

Thus it is, that despite progress in mobilizing for a large scale MCC programme in KZN, widely regarded as the epicentre of the HIV pandemic, the current contestation and debate regarding when to circumcise and which methods should be used, is threatening progress. The major current debate is centred on which of the two dominant methods should be used, the TCD[[41]](#endnote-41) or FG.[[42]](#endnote-42) In Africa, the most common surgical techniques for adult male circumcision have been described in the World Health Organisation (WHO) manual using one of the freehand methods such as the FG, dorsal slit or sleeve method.[[43]](#endnote-43) Other established techniques that protect the penis during the excision of the foreskin, such as the Plastibell method, Gomco clamp and Mogen clamp are used in infants and are not suitable for use in adult men or post-pubertal boys[[44]](#endnote-44). The Disposal Clamp and the relatively new device the Shang Ring, [[45]](#endnote-45),[[46]](#endnote-46) may offer alternatives that might be further tested. The basic principle is that these various devices serve to protect the glans of the penis when removing the prepuce. All vary in the time it takes to perform the procedure, as well as the cost.

Because of the adversarial nature of the current debate, this review is focussing on the comparison TCD[[47]](#endnote-47) and published results on FG methods, currently regarded as best practice.

# 3. TERMS OF REFERENCE

The Terms of Reference for this study were to conduct a retrospective analysis of data on MMC performed in KwaZulu-Natal. Data was to be sourced from the health institutions around KZN and circumcision camps in KZN organised for the purposes of conducting MMC.

Detailed information was to be obtained about the completeness of data recording and the safety of male medical circumcision practices as carried out at these sites throughout KZN using record reviews including:

* A review of the MCC sites both public and NGO sectors and in a few instances, the surrounding areas such as clinics or hospital, checking for complications or cases of penile injury;
* In addition, any supportive evidence of complications during, immediately after or in the weeks following the procedure was to be sought.

# 4. PROGRESS WITH THE STUDY

The original schedule for the study was to be over a three month period from 1 November 2010 to 31 January 2011. This schedule has been delayed for several reasons, outside of the control of the investigators. Firstly, the contractual obligations for initiating the study were only completed by WHO in the alter part of November 2010 and secondly the Steering Committee to which the original proposal was submitted was reported to be in a process of reconstitution by the KwaZulu-Natal Department of Health and National Department of Health. Until this is done, it has not been possible to finalise the terms of reference for this study. This has meant that because of the urgency of the study, it has been necessary to proceed with the study on the basis of it being an extension of *Male Circumcision for HIV Prevention,* the PhD thesis of Dr Joseph Mokete Titus the lead investigator for the team. This Protocol outlines a retrospective chart review of patients who have undergone Male Circumcision at predominantly at Northdale Hospital, Edendale Hospital and Imbalenhle Community Health Centre. Dr Titus, in his role as Principal Specialist (Obstetrics and Gynaecology) at the Greys Hospital had prior KZN Provincial and ethical permission to proceed with his study, which forms part of a study pursuant to a PhD degree at the University of KwaZulu Natal. As a result of this limitation, the investigative team has strictly limited its role to working with and observing the work of the MCC outreach team based at Northdale Hospital in Pietermaritzburg and lead by Dr MA Quazi, who is an experienced general surgeon and Principal Specialist. While this has allowed us to accumulate sufficient data from a range of settings to present a meaningful analysis, it has not been possible to proceed exactly as originally envisaged. The Northdale Hospital is regarded as the Provincial Centre of Excellence for the MCC programme and provides a teaching base for doctors and nurses working on the programme. Complications resulting from MMC wherever these occur in the Province are referred to Northdale Hospital. The number of referrals have been very limited, mostly due to post-operative pain, bleeding or the removal of too little prepuce or too much skin. Some of these have entailed re-operating and repeating the circumcision using a sleeve resection or surgical skin plasty. While there is no systematic register of these events, the surgical team do not know of any that have resulted in permanent deformity, other serious morbidity or mortality.

# 5. METHODOLOGY

## 5.1 Purpose of Research

The main goal of the analysis has been to:

* To undertake a record review of patients who have undergone MMC in health institutions and mass circumcision camps in Kwa-Zulu Natal in order to determine the safety of available methods of MMC instituted.

## 5.2 Primary Objectives

The primary objective for the study has been to assess whether there is any significant increase in adverse events in the use of the TCD in the KZN mass circumcision programme as compared to the published standards such as those obtained in randomised control trials or the “Roll-out model” of 1.8% described by Lissouba et. Al (ibid) using the conventional FG technique.

In all the settings that have been selected for the implementation of the KZN MMC Review, the following has guided the collection of data:

Availability of data and quality of the records for review at these sites to

* Assess adverse events documented and compare the clinical outcomes in terms of immediate, medium term and late surgical complications of the procedures, according to the surgical approach TCD or FG;
* compare the severity of the complications of the different procedures, TCD or FG, in terms of additional medical treatment, referral for specialist treatment and the duration of treatment;
* investigate complementary educational or cultural activities associated with the MMC to assess the extent to which this might contribute to future gender sensitivity and sexual practices;
* make a formative assessment of the programme and provide guidance that could help to reduce complications of MMC.

## 5.3 Type of research

Observational study for the period 1 January 2010 to 31 December 2010 divided into two components a retrospective and concurrent analysis.

## 5.4 Research design

The null hypothesis for the study is that there is no significant difference in the adverse events rates between the conventional FG technique and the TCD technique.

The basic research design has comprised a review of available patient records. For practical purposes this has been divided into a:

(1) **Retrospective Cohort** comprising an analysis of male circumcision records from commencement of the MCC Programme in KZN predating the commencement of this study and

(2) **Concurrent Cohort** being an analysis of client records from the time that the study commenced until it end on 31 January 2011.

The Retrospective Cohort component has focussed on analysing data from registers at the sites at which the circumcisions were done prior to the arrival of the team, and forms the basis of this preliminary report.

The final report will also analyse data collected after the investigative team began its work in November. This is regarded as Concurrent Cohort data whose final results will only partially available by the end of January 2011 allowing for a period of six weeks from the end of the circumcision to assess situation 42 days after the procedure.

*Quantitative data handling:*

All members of the research team were trained in the use of study measurement instruments. Quantitative data was captured into MS Excel files is further being analysed and exported to statistical packages.

*Basic characteristics of the MMC participants:*

The review has aimed to capture all useful information present in the records, including age and any other history, with the exception of personal identifiers. Unfortunately data such as marital status, employment, residence has not been consistently collected in the past. There is information regarding informed consent, blood tests (Hb, RPR, HIV), antibiotics, type of procedure (FG or TCD), the staff performing the surgery and the anaesthesia as well as intraoperative complications, postoperative complications, return date, premature return and reason with treatment, client complaints and sometimes comments on other intermediate or late complications. However, the documentation side of the programme, although planned to be comprehensive, is rarely more than cursory.

*Educational and other cultural interventions associated with the medical circumcision:*

The review has with the assistance of the clerical staff, in addition to capturing information regarding the medical aspects of the intervention, attempted, at least for the Concurrent Cohort to gather data on educational and other activities associated with the circumcision such as the content, duration and outcomes of the process, together with other preparation or follow-up programmes

*Outcome Measures:*

The primary outcome measure is a successful circumcision. The adverse event rate comprises a complication arising as

1. *Immediate* adverse events are those related directly to the surgery (or within 24 hours) viz. abnormal pain, bleeding, an anaesthetic-related event, excessive skin removal or damage to the penis.
2. *Intermediate* adverse events (assessed on day five) include abnormal pain, excessive bleeding, removal of too much or too little skin, swelling or haematoma formation, damage to the penis, infection, delayed wound healing/disruption, difficult urination, or problems with the appearance.
3. **Late** adverse events (assessed at six weeks) would include complications such as infection, delayed wound healing/disruption, difficult urination, or problems with the appearance, removal of too much or too little skin, damage to the penis, torsion or bending of penis, erectile dysfunction or psycho-behavioural problems, swelling or haematoma persistence.

It is hoped that for the Concurrent Cohort it will also be possible to comment on adverse events six weeks after the circumcision.

Table :Definitions of immediate adverse events at surgery (or within 24 hours):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Abr** | **Adverse event** | **Mild** | **Moderate** | **Severe** |
| AP | Abnormal pain[[48]](#endnote-48) | Pain scale 3-4  1 Very Mild  2 Discomforting  3 Tolerable | Pain scale 5*-*6  4 Distressing  5 Very Distressing  6 Intense | Pain scale of 7 and above  7 Very Intense  8 Utterly Horrible  9 Excruciating Unbearable  10 Unimaginable Unspeakable |
| EB | Excessive bleeding | More bleeding than usual, but easily controlled | Bleeding that requires pressure dressing to control | Blood transfusion or transfer to another facility required |
| AN | Anaesthetic related event | Palpitations, vaso-vagal reaction or emesis | Reaction to anaesthetic requiring medical treatment  in clinic, but not transfer to another facility | Anaphylaxis or other reaction requiring transfer to  another facility |
| ES | Excessive skin  removed | Adds time or material needs to the procedure, but does not result in any discernible adverse condition | Skin is tight, but additional operative work not  necessary | Requires re-operation or transfer to another facility to  correct the problem |
| DP | Damage to penis | Mild bruising or abrasion, not requiring treatment | Bruising or abrasion of the glans or shaft of the penis  requiring pressure dressing or additional surgery to  control | Damage to the  penis  Part or all of the glans or shaft of the penis severed |

Table :Definitions of intermediate adverse events- 1 day and one month: (Day 5)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Abr** | **Adverse event** | **Mild** | **Moderate** | **Severe** |
| AP | Abnormal pain  1 Very Mild  2 Discomforting  3 Tolerable  4 Distressing  5 Very Distressing  6 Intense  7 Very Intense  8 Utterly Horrible  9 Excruciating Unbearable  10 Unimaginable Unspeakable | Pain scale 3-4  Does not interfere with most activities. Able to adapt to pain psychologically and with medication or devices such as cushions. | Pain scale 5-6  Interferes with many activities. Requires lifestyle changes but patient remains independent. Unable to adapt to pain. | Pain scale of 7 and above  Unable to engage in normal activities. Patient is disabled and unable to function independently. |
| EB | Excessive Bleeding | Dressing soaked through with blood at a routine  follow-up visit | Bleeding that requires a special return to the clinic for medical attention | Bleeding not controlled by dressing, requires re-exploration |
| ES | Excessive skin  removed | Client concerned, but there is no discernable  abnormality | Skin is tight, but additional operative work not  necessary | Requires re-operation or transfer to another facility |
| IS | Insufficient skin  removed | Foreskin partially covers the glans only when  extended | Foreskin still partially covers the glans and re-operation  is required |  |
| SH | Excessive swelling/ haematoma | More swelling than usual, but no significant  discomfort | Swelling involving glans and part of shaft; significant tenderness and discomfort, but surgical  re-exploration not required | Swelling involving glans and most of shaft; surgical re-exploration required |
| DP | Damage to penis | Mild bruising or abrasion, not requiring treatment | Bruising or abrasion of the glans or shaft of the penis requiring pressure dressing or additional surgery to control | Damage to the penis  Part or all of the glans or shaft of the penis severed |
| IN | Infection | Erythema (redness) more than 1 cm beyond incision line | Purulent discharge from wound | Cellulitis with wound necrosis |
| DH | Delayed wound healing | Healing takes longer than usual, but no extra  treatment necessary | 4-6 weeks before healing with sinus or raw wound present. Additional non-operative treatment required | >6 weeks before healing with sinus or raw wound present. Requires re-operation |
| PA | Problem with appearance | Client concerned, but no discernible abnormality | Significant wound disruption or scarring with cosmetic problem but operation not required. | Rotation or other problem requires cosmetic treatment.  Requires re-operation |
| DU | Difficult urination | Transient complaint that resolves without treatment | Severe pain in passing urine. Requires a special return to the clinic, but no additional treatment required | Inability to pass urine. Requires referral to another facility for management |
| WD | Wound disruption or breakdown | Minor separation of wound edges but not requiring any treatment | FG: 3 to 5 continuous stitches missing  TCD: separation of wound edges over more than 1 cm without inflammation | FG: 5 or more continuous stitches missing  TCD: separation of wound edges over more than 2 cm or 1cm with inflammation |

Table :Definitions of late adverse events at one month or more after surgery: (Six weeks)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| IN | Infection | Erythema (redness) more than 1 cm beyond incision line | Purulent discharge from wound | Cellulitis or wound necrosis |
| DH | Delayed wound healing | Healing takes longer than usual, but no extra  treatment necessary | 4-6 weeks before healing with sinus or raw wound present. Additional non-operative treatment required | >6 weeks before healing with sinus or raw wound present. Requires re-operation |
| PA | Problem with appearance | Client concerned, but no discernible abnormality | Significant wound disruption or scarring with cosmetic problem but operation not required. | Rotation or other problem requires cosmetic treatment.  Requires re-operation |
| ES | Excessive skin  removed | Client concerned, but there is no discernable  abnormality | Skin is tight, but additional operative work not  necessary | Requires re-operation or transfer to another facility |
| IS | Insufficient skin  removed | Foreskin partially covers the glans only when  extended | Foreskin still partially covers the glans and re-operation  is required |  |
| TP | Torsion or bending of  Penis | Torsion is observable, but does not cause pain or discomfort | Causes mild pain or discomfort, but additional operative work not necessary | Requires re-operation or transfer to another facility |
| ED | Erectile  dysfunction | Client reports occasional inability to have an  erection | Client reports frequent inability to have an erection | Client reports complete or near complete inability to have an erection |
| PP | Psycho-  behavioural problems | Client reports mild dissatisfaction with the  circumcision, but no significant psychobehavioural  consequences | Client reports significant dissatisfaction with the  circumcision, but no significant psychobehavioural  consequences | Significant depression or other psychological problems attributed by the client to the circumcision |

Table : Pain scale[[49]](#endnote-49)

|  |  |  |
| --- | --- | --- |
|  | **0** | No pain. Feeling perfectly normal. |
| **Minor**  Does not interfere with most activities. Able to adapt to pain psychologically and with medication or devices such as cushions. | **1 Very Mild** | Very light barely noticable pain, like a mosquito bite or a poison ivy itch. Most of the time you never think about the pain. |
| **2 Discomforting** | Minor pain, like lightly pinching the fold of skin between the thumb and first finger with the other hand, using the fingernails. Note that people react differently to this self-test. |
| **3 Tolerable** | Very noticable pain, like an accidental cut, a blow to the nose causing a bloody nose, or a doctor giving you an injection. The pain is not so strong that you cannot get used to it. Eventually, most of the time you don't notice the pain. You have *adapted* to it. |
| **Moderate**  Interferes with many activities. Requires lifestyle changes but patient remains independent. Unable to adapt to pain. | **4 Distressing** | Strong, deep pain, like an average toothache, the initial pain from a bee sting, or minor trauma to part of the body, such as stubbing your toe real hard. So strong you notice the pain all the time and *cannot completely adapt*. This pain level can be simulated by pinching the fold of skin between the thumb and first finger with the other hand, using the fingernails, and squeezing real hard. Note how the similated pain is initially piercing but becomes dull after that. |
| **5 Very Distressing** | Strong, deep, piercing pain, such as a sprained ankle when you stand on it wrong, or mild back pain. Not only do you notice the pain all the time, you are now so preoccupied with managing it that you normal lifestyle is curtailed. Temporary personality disorders are frequent. |
| **6 Intense** | Strong, deep, piercing pain so strong it seems to partially dominate your senses, causing you to think somewhat unclearly. At this point you begin to have trouble holding a job or maintaining normal social relationships. Comparable to a bad non-migriane headache combined with several bee stings, or a bad back pain. |
| **Severe**  Unable to engage in normal activities. Patient is disabled and unable to function independently. | **7 Very  Intense** | Same as 6 except the pain completely dominates your senses, causing you to think unclearly about half the time. At this point you are effectively disabled and frequently cannot live alone. Comparable to an average migraine headache. |
| **8 Utterly  Horrible** | Pain so intense you can no longer think clearly at all, and have often undergone severe personality change if the pain has been present for a long time. Suicide is frequently contemplated and sometimes tried. Comparable to childbirth or a real bad migraine headache. |
| **9 Excruciating  Unbearable** | Pain so intense you cannot tolerate it and demand pain killers or surgery, no matter what the side effects or risk. If this doesn't work, suicide is frequent since there is no more joy in life whatsoever. Comparable to throat cancer. |
| **10 Unimaginable Unspeakable** | Pain so intense you will go unconscious shortly. Most people have never experienced this level of pain. Those who have suffered a severe accident, such as a crushed hand, and lost consciousness as a result of the pain and not blood loss, have experienced level 10. |

## 5.5 Study setting

The study setting has been observing the Provincial MCC Outreach team based at Northdale Hospital and with them visiting community (circumcision camp) based sites for the implementation of MMC (n=10 sites) across KZN province. This has included hospitals, community centres and prisons.

## 5.6 Study population

The population of interest has been all males who have participated in the MMC roll-out in KZN within the selected health facilities and mass circumcision camps.

*Inclusion criteria:*All post-pubertal males who had MMC procedures in health institutions or who participated in mass circumcision campaigns in KZN.

Table 6 : Total targetted number of participants in the study

1. **Central Institutional setting**

|  |  |  |
| --- | --- | --- |
| **Health Institutions** | **No of circumcised boys/men: TCD** | **No of circumcised boys/men: FG** |
| Northdale Hospital, Edendale Hospital and Imbalenhle CHC | 200 | 176 |

1. **Community setting**

|  |  |  |
| --- | --- | --- |
| **Mass Circumcision Campaign sites** | **No of circumcised boys/men: TCD** | **No of circumcised boys/men: FG** |
| 1. **Retrospective Review**   Plessislaer, Ladysmith Ngwelezana , Clairwood, Appelsbosch, Edendale, Vryheid, Nongoma Hospitals and Bruntville CHC | 1,855 | 374 |
| 1. **Concurrent Review**   Appelsbosch, Greytown, Richmond and Benedictine Hospitals plus Sevontein & Medium B Prisons | 700+ | 100+ |

## 5.7 Study sample

Because of the difficulty in obtaining permissions to visit sites throughout the Province at will, this has been limited to the sites visited by the KZN MMC outreach team based at Northdale Hospital. Nevertheless, this is a diverse range of sites, both urban, peri-urban and rural settings. Wherever possible all available data from the sites where it has been available has been collected and used for the analysis so that the planned size of the final sample should be essentially unbiased and ensure *adverse events* confidence interval of less than 5% with a 95% confidence level in comparison to the published rate of 1.8% in the study by Lissouba et al.(ibid). The total study planned size of 1176 will be exceeded should be able to improve the precision of the findings.

1. **Restrospective Cohort.** Each hospital or circumcision camp has routinely collected data in systematic MCC registers since the onset of the MMC campaign noting patient particulars from hospital records including age, counselling and testing, fitness for operation, consent for operation, HIV status, type of circumcision and clinical observations during the operation and at 5 days after the circumcision. All the results from these registers are routinely extracted and submitted to the Provincial Health Information System where they are ultimately entered into the DHIS. A range of indicators have been developed by the Provincial DOH. This information has been submitted to the Provincial MMC team and includes some information on adverse events. The submissions have been signed off by the focal person at each MMC centre, most often the Hospital manager. This Review has used these submissions as the basis of its preliminary analysis using data from 1 January 2010 to 30 October 2010. The limitations are that while the information is generally systematic, there are some gaps in the information available. A further limitation is that patients are seen once at 5-days and if free of complications at that stage are not routinely seen again. The findings cannot therefore preclude the possibility that there have been a few adverse events that occurred after the 5-day follow up visit. For this reason, it has been felt necessary to encourage the Provincial MCC to review a cohort of patients after six weeks to determine if there are any adverse events occurring after the five day visit.
2. **Concurrent Cohort:** A systematic list of all circumcisions performed by the Provincial MMC Team based at Northdale Hospital during the period 1 November 2010 to 31 December 2010, was reviewed and data extracted on the age of the man and circumcision method used. Besides medical circumcisions at Northdale and Edendale Hospitals, outreach camps have been undertaken at Appelsbosch Hospital, Greytown Hospital, Richmond Hospital and two prisons Sevontein and Medium B. The advantage in this Concurrent Cohort is that the investigative team has been able to witness the majority of circumcisions and 5-day postoperative visits to observe the process of data entry into the MCC register. The data collection staff will be telephoning all the patients during January for the six week follow up. Any patients who have any adverse events will be asked to return to their centre for review.
3. If permission is obtained in the first few weeks of January a retrospective sample of the records from other circumcision sites, especially where the FG method was used will be compared with those where the TCD method was used.
4. Records containing incomplete and missing data will be included in the analysis. For pragmatic reasons the study has been be segmented not only into a retrospective and concurrent cohort, but also into an investigation of the records in the central institutional setting (Northdale and Edendale Hospitals), but also into community-based decentralised settings (rural hospitals and circumcision camp) as indicated in Figure 4. At two intensive sites, in addition to the record review at the sites, neighbouring facilities and GP practices will be visited to ascertain adverse events reported in the period 42 days following the circumcision to provide additional information.

**Figure 4: Protocol Algorithm for MCC**

Boys/ Young adults who had MMC at the study sites

Collect Records: 01 Jan 2010-31 January 2011

Enter relevant study data into structured format without identifiers

(Data obtained from GP visits to be included here)

Analysis

Report

# 6. RESULTS

**6.1 Progress with milestones**

**September 2010:**

* Review, refinement of first draft of research proposal: 20 September 2010 - completed
* Submission of first draft of proposal: 22 September 2010 - completed

**October 2010 :**

* Review and refinement and approval of the draft proposal and protocol: 6 Oct 2010 - completed
* Drafting and submission of sub-contracts by 22 October 2010 - completed
* Final approval of protocol by MCC Steering Committee by 22 October 2010 – interim protocol approved; final approval pending
* Finalisation of the contracts by 22 October - completed
* Submit for ethics approval by 29 October 2010 – completed

**November 2010 :**

* Development of the web-based research tools and instruments by 15 Nov, 2010 - completed
* Preliminary visits to interview key programme staff and a few pilot sites to familarise team and collect operational information to form the basis of a situational analysis by 15 Nov, 2010 - completed
* Pilot phase to test tools and incorporate necessary amendments by 15 Nov, 2010 - completed
* Training of fieldworkers for data collection by 15 Nov, 2010 - completed
* Obtaining ethical approval to proceed with the study – provisional ethics approval in terms of approval given to Dr MJ Titus for his PhD; full extension dependent on final approval of MCC Steering Committee and finalisation of sample size

**December 2010 :**

* Conduct assessment within one month of obtaining ethics approval – Retrospective Cohort analysis completed; all data for Concurrent Cohort identified

**January 2011 :**

* Interim progress reports – on schedule
* Data analysis and draft report – on schedule
* Final report writing – will provide a two week period for Steering Committee comments and one week to incorporate these comments into the report
* Dissemination of research findings once the final report has been tabled and accepted by the National Department of Health

## 6.2 General observations

Patient records from health institutions and circumcision camps have been captured and analysed for documented adverse events following MMC with the procedures, TCD and FG. Records have been reviewed for completeness and quality. In general terms great emphasis is placed on sound clinical work, and less on documentation. While MMC registers have been instituted at all centres and the results tallied and forwarded for central analysis, the emphasis has been on recording the numbers of MCC and not adverse events. While adverse events are sometimes noted in the registers, this has not been done consistently. Although the general impression is that the numbers of moderate or severe adverse events is very low and even minor adverse events less than 10%, it is difficult to be sure because of inconsistent or inadequate documentation.

Since most of the men circumcised in camps spend only a few hours passing through counselling and testing and a few hours waiting for circumcision, there are limited opportunities for them to obtain general education and counselling. The investigative team has however witnessed several education sessions. The general approach is only to review the patients again once at 5-days post-operatively unless there is an adverse event at that time. Anecdotally there are very few moderate or severe adverse events, most of which are dealt with promptly after referral.

In order to capture potential later complications following the FG or TCD procedures, discussions have been held with staff at health facilities where circumcisions have been performed asking whether men with complications may have presented for follow-up care in the relevant time period. The clinic or health facility managers where this has been done regularly report that there are now very few complications related to the TCD. There were a few incidents early on in the programme when relatively inexperienced doctors performed circumcisions. Adverse events occurred equally frequently with the FG as the TCD.

Figure : Adverse event following use of FG technique: Persistent bleeding



The presenting symptom in this case was persistent bleeding as the sutures had also not achieved effective haemostasis. In the photo to the above left it will be noted that on the dorsal surface of the penis considerable inner preputial mucosa remains. Even conventional surgical techniques, if not undertaken correctly can produce significant adverse events.

**6.3 Findings in the Retrospective Cohort**

Data was collected related to 14 distinct mass circumcision camps undertaken at ten different facilities. All the results were extracted from MCC registers recording information related to the circumcision itself and the five-day follow up visit. Each of the set of results was formally signed and submitted by the focal person to the Principal Specialist overseeing the MCC programme. In most cases where there were adverse events these were individually itemised or commented on as a group. Particularly from centres which had experience in using the FG technique, there were strong views expressed by the staff that they found the TCD simpler, more effective and resulting in fewer adverse events.

A retrospective analysis was undertaken of the results of 2,229 circumcisions these from ten different MMC sites for a period of approximately three months from 1 July 2010 to 4 October 2010. This related to the quarter immediately before the commencement of the study. The adverse event rate for each of ten sites is shown table 4. The majority of the circumcisions used the TCD approach (83.2%) rather than the conventional FG approach (16.8%). Adverse events noted at follow up about five days after the circumcision were noted.

Table 7: KZN MCC: July to October 2010 – Adverse events at 5 days

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **TARA KLAMP** | | | **FORCEPS GUIDED** | | |
| **KZN MMC** | **SITE** | **n** | **Adverse events** | **AE Rate** | **n** | **Adverse events** | **AE Rate** |
| 01-Jul-10 | Plessislaer |  |  |  | 176 | 35 | 19.89% |
| Jul-Oct | Ladysmith | 90 | 0 | 0.00% | 198 | 20 | 10.10% |
| 17-Jul-10 | Ngwelezana | 81 | 0 | 0.00% |  |  |  |
| 01-Aug-10 | Northdale | 54 | 0 | 0.00% |  |  |  |
| 03-Aug-10 | Northdale | 191 | 0 | 0.00% |  |  |  |
| 04-Aug-10 | Clairwood | 94 | 0 | 0.00% |  |  |  |
| 11-Aug-10 | Appelsbosch | 276 | 0 | 0.00% |  |  |  |
| 12-Aug-10 | Edendale | 53 | 0 | 0.00% |  |  |  |
| 21-Sep-10 | Northdale | 39 | 0 | 0.00% |  |  |  |
| 23-Sep-10 | Vryheid | 154 | 12 | 7.79% |  |  |  |
| 02-Oct-10 | Northdale | 30 | 0 | 0.00% |  |  |  |
| 03-Oct-10 | Northdale | 119 | 6 | 5.04% |  |  |  |
| 04-Oct-10 | Bruntville CHC | 139 | 1 | 0.72% |  |  |  |
| Apr | Nongoma | 535 | 9 | 1.68% |  |  |  |
|  | **TOTAL** | **1855** | **28** | **1.51%** | **374** | **55** | **29.99%** |

χ2=151.2 p<0.0001

The adverse event rate was higher (chi square in the FG group (30%) compared to the TCD group (1.5%). The findings are statistically significant.

Due to the fact that adverse events in KZN are only available for the five day period when the TaraKLamps are removed, a strict comparison with the adverse rates with the four African RCTs previously described are not strictly comparable. It is likely that a more rigorous follow-up at six weeks would find additional adverse events. Nevertheless for the purpose of this review the results are compared in the following table:

Table : Comparison of adverse event rate of TCD in KZN (5 days) vs. FG in RCTs (all)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **KZN TARA KLAMP** | | | **FORCEPS GUIDED RCTs** | | |
| **DATE** | **SITE** | **n** | **Adverse events at 5 days** | **AE Rate** | **n** | **Adverse events**  **(all)** | **AE Rate** |
| 2002 TO 2005 | ANRS 1265 |  |  |  | 1568 | 60 | 3.83% |
| 2002 TO 2006 | Bailey 2007 |  |  |  | 1334 | 24 | 1.80% |
| 2002 TO 2006 | Gray 2007 |  |  |  | 2328 | 178 | 7.65% |
| In 2008 | ANRS 12126 |  |  |  | 14011 | 257 | 1.83% |
| Jul-Oct | Ladysmith | 90 | 0 | 0.00% |  |  |  |
| 17-Jul-10 | Ngwelezana | 81 | 0 | 0.00% |  |  |  |
| 01-Aug-10 | Northdale | 54 | 0 | 0.00% |  |  |  |
| 03-Aug-10 | Northdale | 191 | 0 | 0.00% |  |  |  |
| 04-Aug-10 | Clairwood | 94 | 0 | 0.00% |  |  |  |
| 11-Aug-10 | Appelsbosch | 276 | 0 | 0.00% |  |  |  |
| 12-Aug-10 | Edendale | 53 | 0 | 0.00% |  |  |  |
| 21-Sep-10 | Northdale | 39 | 0 | 0.00% |  |  |  |
| 23-Sep-10 | Vryheid | 154 | 12 | 7.79% |  |  |  |
| 02-Oct-10 | Northdale | 30 | 0 | 0.00% |  |  |  |
| 03-Oct-10 | Northdale | 119 | 6 | 5.04% |  |  |  |
| 04-Oct-10 | Bruntville CHC | 139 | 1 | 0.72% |  |  |  |
| Apr | Nongoma | 535 | 9 | 1.68% |  |  |  |
|  | **TOTAL** | **1855** | **28** | **1.51%** | **19241** | **519** | **2.70%** |

χ2= 64.6 p<0.0001

The adverse event rate was higher (chi square in the RCT - FG group (2.7%) compared to the TCD group (1.5%). The findings are statistically significant. It should be noted that the adverse event rate in the TCD group is very much lower than the 37% TCD adverse incidence rate found in the study by Legarde et al[[50]](#endnote-50) which has caused so much consternation in Civil Society groups.

# DISCUSSION

The primary objective for the study has been to assess whether there is any significant increase in adverse events in the use of the TCD in the KZN mass circumcision programme as compared to the published standards such as those obtained in randomised control trials or the “Roll-out model” of 1.8% described by Lissouba et. Al (ibid) using the conventional FG technique. It is possible to say provisionally at this stage, even given the limitations of the adverse event follow-up only being limited to 5 days, that the reported adverse event rate of the TCD approach being used in KZN (1.5%), is many orders of magnitude lower than the alarmingly high rate of 37% reported by Legarde et al in their trial and feared by the TAC and Media. It is very similar, and possibly even lower than the adverse event rate achieved in the major RCTs undertaken in Africa (2.7%).

While undoubtedly there have been some adverse events in the KZN MMC programme, as would be anticipated in a mass circumcision of this scale, describing the outcomes as “mutilating” would appear to be excessive and not based on the evidence from the Province. However, given the limitations of the Retrospective analysis, it is hoped that information from the Concurrent cohort where there has been closer independent scrutiny and an intended six week follow up of the results, a more accurate picture of the adverse events rate for KZN MMC programme may be possible.

In summary, at this provisional stage

* Adverse events and comparison with the clinical outcomes in the KZN MMC programme have focussed on the immediate and intermediate term. There has been no attempt to document the late surgical complications of the procedures after one month either using the TCD or FG approaches;
* Given the available records, the severity of the complications of the different procedures, TCD or FG, in terms of additional medical treatment, referral for specialist treatment and the duration of treatment seem comparable;
* The records thus far provide no insight into the educational or cultural activities associated with the MMC to assess the extent to which this might contribute to future gender sensitivity and sexual practices;
* From a formative assessment perspective there do not seem to be grounds to believe that the KZN MMC programme is grossly unsafe. Although there is undoubtedly considerable room for operational improvement, the available retrospective data suggests adverse event rates that are typical of MMC programmes undertaken on a large scale in Africa.

# NEXT STEPS

The next and final steps in the study will be:

1. Revise the provisional report in the light of comments received
2. Request a meeting of the MMC Steering Committee and get the formal permissions documented
3. Work with one of the clerical staff of the Northdale Hospital Team, Manqoba Buthelezi to phone all the patients and do a six week follow-up of any adverse events. This will be part of the formal record KZN MMC database, but rom which we will extract the essential information that is currently still missing
4. Subject to receiving the necessary permissions in time, visit the East Boom Clinic and Imbalenhle CHC to collect comparable data on the FG technique
5. Analyse the data
6. Write the final report and invite comments
7. Edit the final report and present it to the MMC Steering Committee

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