FACTORS ASSOCIATED WITH POST OPERATIVE ADVERSE EVENTS FOLLOWING VOLUNTARY MEDICAL MALE CIRCUMCISION AMONG CLIENTS IN MIGORI COUNTY HOSPITAL

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Factors Associated With Postoperative Adverse Events Following Voluntary Medical Male Circumcision among Clients in Migori County Hospital

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DECLARATION

This thesis is my original work and has not been presented for a degree in any University

Signature ……. Date…….

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This thesis has been submitted for examination with our approval as the University Supervisors

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DEDICATION

I dedicate this work to my dear wife who has always been my source of encouragement, my parents for their wonderful support, and all my siblings for being there for me when I needed them.

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ADFU	Adherence to Follow Up
AE	Adverse Events
DNA	Deoxyribonucleic Acid
FACES	Family Aids Care and Education Services
FGD	Focus Group Discussion
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counseling
LTFU	Loss to Follow Up
MOH	Ministry of Health
KEMRI	Kenya Medical Research Institute
MC	Male Circumcision
NASCOP	National Aids Control Programme
PEPFAR	Presidential Emergency Plan For AIDS Relief
PPTC	Prevention of Parent to Child Transmission
RCT	Randomized Controlled Trial
STI	Sexually Transmitted Infection
UNAIDS	United Nations Programme on AIDS
VMMC	Voluntary Medical Male Circumcision

WHO	World Health Organization

ABSTRACT

Male circumcision is one of the oldest surgical procedures in human history. Scientists predicted the medical benefit of this procedure as early as mid-19th century. Results from three clinical trials conducted in Kenya, Uganda and South Africa between 2005 and 2007 confirmed male circumcision reduced the incidence of HIV acquisition by approximately 50-60%. This evidence led the World Health Organization (WHO) to recommend male circumcision as an additional strategy for prevention of HIV acquisition. Consequently, sub- Saharan Africa countries implemented and rapidly scaled up male circumcision from 2008. WHO has reported an increase in infection-related AEs in sub-Saharan Africa. These include cases of postoperative wound infection. In VMMC, occurrence of adverse events like excessive bleeding or serious infection affects safety of men receiving these services, leads to loss in man hours and put a strain of the health care delivery system. There is a need to continuously monitor the incidences and determinants of AEs in the current VMMC activities to improve safety and quality of the service. There also a need to ensure that the quality and effectiveness of care is delivered to the highest standard to improve and foster acceptability of VMMC. This study set out to determine the risk factors of adverse events (mild, moderate and severe) following voluntary medical male circumcision among clients within the Family AIDS Care and Education Services (FACES) program in Migori sub county hospital. This was a quantitative cross sectional study design involving 138 men attending their follow up visits at Migori Sub-County Hospital. The participants were recruited via systematic sampling and interviewed and examined to obtain information on adverse events. The mean age of the participants was 22 years while the mode was 18 years. (Range: 18-48). At least half 70(50.7%) were between 18-20 years. Most participants 97(70.3%) were circumcised using the surgical method while 41(29.7%) opted for the Pre-pex method. The prevalence of mild adverse events following male circumcision were 58% while the prevalence of moderate adverse events was 2.9 %. Results showed infrequent bathing after circumcision (P=0.001) and washing of underpants (P<0.001) significantly increased the chance having moderate adverse event. Most participants (72%) were aware of possible Adverse Events of VMMC Almost all (99%) of the participants were highly satisfied with the circumcision procedure and the post-operative care services they received. The findings imply that VMMC services offered within FACES program are perceived as safe and that VMMC can be delivered safely and effectively in a program setting within those communities where circumcision is not carried out for cultural reasons. More effort should be directed towards ensuring adherence to instructions including good hygiene practices post circumcision.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Male circumcision is one of the oldest surgical procedures dating back to the times of Abraham in the Bible (Genesis 17:10-11). Hutchinson initially documented the health benefits of male circumcision in 1855 by observing circumcised Jewish men. It was established that they were protected from syphilis infection (Robert Darby BA, 2014) . Scientists later predicted the link between the foreskin and Acquired Immunodeficiency Syndrome(AIDS)(Al-Jabri, 2007) . The link between cervical cancer in women to their uncircumcised male partners had earlier been described in 1954 (Castellsague, Bosch, & Munoz, 2003) . Results from three Randomized Clinical Trials (RCT) conducted in Kenya, Uganda and South Africa between 2005 and 2007 confirmed that male circumcision reduced risk of incident HIV infection by approximately 50-60% (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007).

Based on these three RCTs, the WHO and UNAIDS in 2007 determined there was sufficient evidence that male circumcision reduces the risk of acquiring HIV through heterosexual intercourse(WHO/UNAIDS, 2007a) . The two organizations recommended male circumcision as an additional strategy for preventing HIV transmission in countries with high prevalence. This implied that VMMC should always be considered as part of a comprehensive HIV prevention package which includes: HIV testing and counseling; correct and consistent use of female or male condoms; Treatment for sexually transmitted infections; and promotion of safer sexual practices, such as avoidance of penetrative sex(WHO/UNAIDS, 2007b)

The recommendations identified 13 priority VMMC countries with generalized HIV epidemics, high HIV prevalence, and low male circumcision prevalence. The recommendations were broad, addressing issues ranging from the significance of conducting situation analysis across all the identified countries to policy considerations and ethical, cultural, legal, and human rights considerations(Katz & Wright, 2008). The

evidence further led to widespread advocacy for male circumcision as an additional strategy for the prevention of heterosexually acquired HIV infection among men in Sub-Saharan Africa. Most campaigns targeted areas with high HIV prevalence where a high percentage of men were not circumcised. The endorsement of Voluntary Medical Male Circumcision (VMMC) as a preventive measure against HIV led to implementation and the rapid scale-up by most countries in Sub Saharan Africa (Dickson et al., 2011), however the rapid expansion has raised concerns regarding the capacity of the health systems to provide quality and safe VMMC services for a sustained period (Herman-Roloff et al., 2012) . Setting up standard operating procedures (Auvert et al., 2005) and ensuring compliance is critical to the achievement of program goals and preventive outcomes of VMMC (Musau et al., 2011)

The Kenyan government launched the National VMMC program in the former Nyanza region in 2008. By 2014, 66.3% (over 270,000) of men aged 15-64 years in Nyanza region had been circumcised through this program (NASCOP, 2014). Some studies on the safety of VMMC have been conducted since it was included as a strategy to combat HIV. In 2011 Herman-Roloff, Llewellyn, et al. (2011) reported post-operative Adverse Events (AE) incidence rate at 7% with infection as the leading cause of AE in program setting. However, another study in rural Nyanza in Kenya detected severe adverse events at a rate of 1.3% (Ngo & Obhai, 2012) which is comparable to the three RCTs (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007). Although previous studies report low adverse events rates albeit with differing percentages, it is evident that there is a need for more knowledge regarding post–operative complications of male circumcision especially in different settings. No program safety data from FACES VMMC services have yet been published. Assuring high quality of delivered care represents a substantial challenge in the implementation of proven HIV prevention interventions(Kim & Goldstein, 2009)

The Family AIDS Care and Education Services (FACES) program is centered on advancing health through high quality medical and social research, health care services, and training in collaboration with local partners in Kenya and internationally. FACES offers VMMC service at 16 health facilities in Migori, Kisumu and Homabay counties. Over 59,000 males have undergone VMMC surgery since the rollout of the program in

2009 (FACES-KEMRI, 2015). Between October 2013 and September 2014, 7191 clients were circumcised, 48% of whom were 15 years and older (FACES-KEMRI, 2015).

Circumcision procedures and all associated VMMC services are carried out in accordance with the ‘‘Policy on Male Circumcision in Kenya.’’ All providers in the FACES sites are trained on male circumcision techniques, through a training program, based on the WHO/UNAIDS ‘‘Manual for Male Circumcision Under Local Anaesthesia.’’. The manual covers screening, preparation for surgery, surgical procedures, postoperative care, infection control, management of complications, and follow-up care. All providers are trained to competence in male circumcision per Kenya’s policy on VMMC—that is, competency is achieved after following a formal training based on the WHO/UNAIDS manual. The facilities managed by the FACES program adequate have equipment and supplies as well as space where confidential counseling and safe and hygienic procedures can be provided. Per Kenya’s policy on male circumcision, in addition to the circumcision procedure, all study sites provide comprehensive HIV-prevention services, including: Behavior change communication and risk reduction counseling about safer sex practices Provision of male condoms and education about the need to use condoms consistently and correctly HIV testing and counseling and services for sexually transmitted infections (STIs) HIV care and treatment services, as appropriate.

No program safety data from FACES VMMC services have yet been published. Assuring high-quality care is delivered to all the clients in the HIV program is a substantial challenge (Kim & Goldstein, 2009). This study evaluated the occurrence of Adverse Events related to VMMC within FACES sites in Nyanza. Findings may be used to improve the delivery of VMMC services especially in regard to post-operative care to ensure proper and timely healing among men receiving VMMC services. The main objective of this study was to determine the prevalence and factors associated with adverse events following VMMC in Migori County Hospital.

1.2 Statement of the Problem

Over six million adult voluntary medical male circumcisions have been conducted over the past 3 years in 14 sub-Saharan Africa countries for partial prevention of HIV(Sgaier, Reed, Thomas, & Njeuhmeli, 2014). The Kenyan Ministry of Health in collaboration with other partners has promoted and scaled up VMMC as a way of preventing the spread of HIV since 2008. The rapid scale-up resulted in over 270,000 (66.3%) of men in Nyanza region circumcised—aged 15-64 years by 2011, up from 48.2% in 2007 (NASCOP, 2014) and a total of 792,931 circumcisions by 2013(MOH, 2014). As the government and its partners continue to implement VMMC services to reach greater numbers of males, higher frequency, and prevalence of adverse events may be experienced due to a large number of clients seeking VMMC services. The prevalence of complications in clinical settings in Africa are poorly documented but vary between 2% to as high as 17·5% (Bailey et al., 2007). Surgical procedures are naturally risky; and although they are rare, adverse events do occur. Possible complications of male circumcision include excessive bleeding, the formation of hematoma, infection, an unsatisfactory cosmetic effect, lacerations of the penile or scrotal skin, and injury to the glans(WHO/UNAIDS/JPIEGO, 2008). Prolonged bleeding is a common adverse event that has been shown to occur although it can be managed, some cases may be life-threatening(Moses Galukande, Carol Kahendehe, Eria Buuza, & Denis Bbaale Sekavuga, 2015). WHO has reported an increase in infection-related AEs, including severe ones in sub-Saharan Africa(WHO, 2016). These include cases of postoperative wound infection with tetanus after both surgical and device-enabled VMMC. In VMMC, the occurrence of adverse events like excessive bleeding or serious infection affects safety of men receiving these services, leads to loss in man hours and put a strain of the health care delivery system(Gyan et al., 2017). Additionally, research has shown that circumcision-related morbidity is a strong factor that negatively affects the acceptability of voluntary male circumcision among non-circumcising communities in Africa(Lukobo & Bailey, 2007). Apart from achieving the projected numbers, achieving them with minimal adverse events (AEs) is key for VMMC programs in Kenya. Therefore, identifying AEs, documenting, and sharing these data are important in realizing this goal.

1.3 Justification

Nyanza region, has a large representation of Luo community (a non-traditionally circumcising community) with the lowest MC coverage (48%) and the highest prevalence of HIV (14.9%). Kenya and other Sub Saharan African countries have continued to scale up VMMC services to avert possible 2 million new HIV infections and over 300,000 AIDS related deaths in over a span of 10 years (Williams, 2006).

As VMMC implementers aim to maintain the scale-up and rapid in resource-limited health systems, it is critical to periodically assess adverse events (AE) prevalence to inform safe and effective program implementation. Randomized clinical trials of VMMC demonstrated AE rates ranging from 1.5 to 8 % (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007). Findings on AE prevalence in program setting remain scanty and inconsistent. (Frajzyngier, Odingo, Barone, Perchal, & Pavin, 2014; Herman-Roloff et al., 2012; Phili, Abdool-Karim, & Ngesa, 2014). A review of VMMC task-shifting to studies showed AE rates from <1 to 38 % (Ford, Chu, & Mills, 2012), similarly, other Kenyan programs documented AE rates ranging from 1 to 18 % during early implementation (Bailey, Egesah, & Rosenberg, 2008; Ngo & Obhai, 2012; Reed et al., 2015) to 3–7 % post scale-up. No program safety data from FACES VMMC services have yet been published. Assuring high quality of delivered care represents a substantial challenge in the implementation of proven HIV prevention interventions(Kim & Goldstein, 2009). Inability to provide VMMC services safely and with patient-centered focus may curtail further progress in the scale-up of VMMC services. Monitoring to improve service quality is one of seven pillars in the Joint Strategic Action Framework to Accelerate the Scale-up of VMMC for HIV Prevention in Eastern and Southern Africa(WHO, 2011).

To address the concern of safety among clients receiving VMMC. It is hence critical to investigate the prevalence and correlates of the adverse events to inform the programmatic scale-up of MMC (Musau et al., 2011). There is a need to continuously monitor the incidences and determinants of AEs in the current VMMC activities to improve safety and quality of the service. There also a need to ensure that the quality

and effectiveness of care is delivered to the highest standard to improve and foster the acceptability of VMMC.

This study was conducted to document postoperative complications by examining adverse events trends, the demographic characteristics and satisfaction with regards to circumcision services at Migori Sub-District Hospital. The study provides information for both VMMC project managers and the Ministry of Health (MOH), who are entrusted in the long-term management of HIV services in Kenya. Furthermore, the findings related to the safety of VMMC services may be used to improve VMMC services within the FACES VMMC clinics, in addition to possibly inform policymakers within the VMMC National Program under the Ministry of Health

1.4 Research questions

1. What is the Prevalence of postoperative adverse events among men receiving free VMMC service within FACES program in Migori Sub-County Hospital?
2. What are the risk factors associated with post-operative adverse events among men receiving VMMC within FACES program in Migori Sub-County Hospital?
3. What is the clients' level of satisfaction with male circumcision service provided by FACES circumcision program at Migori Sub-County Hospital?

1.5 Study Objectives

1.5.1 General Objective

To determine the prevalence of and risk factors associated with Adverse Events, and satisfaction following Voluntary Medical Male Circumcision among clients within the FACES program in Migori Sub county Hospital.

1.5.2 Specific objectives

1. To determine the Prevalence of postoperative circumcision adverse events in Migori Sub-County Hospital VMMC FACES Program
2. To determine the risk factors associated with postoperative circumcision adverse events within FACES VMMC program at Migori Sub-County Hospital

3. To describe the clients' level of satisfaction on the Voluntary male medical circumcision service within FACES VMMC program at Migori Sub-County Hospital

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Male circumcision is one the oldest surgical procedures in the human history and one of the most commonly performed surgical procedures today (Krill, Palmer, & Palmer, 2011). Male circumcision is classified as: spiritual and non-spiritual circumcision. Spiritual circumcision is carried out to portray a community's religious identity that is mostly linked to a unique significance related to the bible or myths held by that community. Non-religious circumcision, on the other hand is done for perceived medical benefits or for social reasons including community membership. This is exemplified by the traditional African culture and Western (Europe and USA) model(WHO/UNAIDS, 2008). Advances in medicine from the 19th century coupled with widespread migration in the 20th century led to the spread of the practice to previously non circumcising communities for medical and social reasons. Male circumcision is now prevalent across all the continents of the world and continues to be practiced for both medical and cultural reasons.

2.2 Medical aspect of male circumcision

2.2.1 Mechanisms of penile infection

Apart from observational studies demonstrating that uncircumcised men are prone to reproductive tract infections (Weiss, Quigley, & Hayes, 2000), experimental studies have confirmed circumcised men have a lower risk of acquiring HIV than uncircumcised men (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007). The warm, moist environment within the foreskin enables pathogens to multiply especially if proper hygiene is not maintained (Alanis & Lucidi, 2004). The foreskin increases the likelihood of HIV transmission through increased risk of genital ulcer in uncircumcised men that provides point of entry of the HIV virus. Secondly, the foreskin may increase in the risk of HIV infection directly as tissue from the inner surface of the foreskin

mucosa contains accessible HIV-1 target cells (CD4+ T cells, macrophages and Langerhans cells) (McCoombe & Short, 2006). Infectivity of the foreskin inner mucosal surface is greater compared to cervical tissue, which is the primary site of HIV-1 infection in women (Patterson et al., 2002). Furthermore, infectivity of the inner mucosal surface (assessed by quantity of HIV-1 DNA one day after ex vivo infection with explant culture) was greater than that of cervical tissue, which is a known primary site of HIV-1 acquisition in women(Patterson et al., 2002). In an uncircumcised man, the cells in the inner foreskin and frenulum are directly exposed to vaginal secretions during intercourse, and this superficial location of the HIV-1 target cells presumably increases risk of infection.

2.2.2 Methods of adult and adolescent medical circumcision

Adult and adolescent circumcision is mostly carried out using either one of three methods: the forceps-guided method, the sleeve method or pre-pex method (WHO/UNAIDS/JPIEGO, 2008). The procedure is more complex in adults than in neonates or children, requiring local or general anaesthesia. Local anaesthesia is the preferred method because it has less systemic issues and is more economical. The nerve supply of the penis consists of the twin dorsal penile nerves and anaesthesia blocks the dorsal penile nerves and its branches. The forceps-guided method is most common. In this method, the foreskin is pulled and stretched using clamps; forceps are used to hold the extended skin at the position where the cut is to be made. Using a scissors or scalpel and the foreskin is cut off. The method is tidy but sometimes does not result in a smooth line as there is no pre-sealing of cut edges (Al-Ali, 2005)

The pre pex method is relatively new and was pre-qualified by the WHO in 2007 (Odoyo-June et al., 2016). Pre-Pex is a technology developed by Israel based Circ MedTech. The method is intended to help to achieve rapid scale-up of voluntary medical male circumcision (VMMC) in resource-limited settings (Lebina et al., 2015). Pre-Pex is the first known device that facilitates non-surgical adult MC. The device works with no injected anesthesia, no surgery, no sutures and no sterile settings. It comes with two plastic rings and a placement device. One ring is placed inside the foreskin and another ring is placed on top. This cuts down blood supply to the foreskin causing necrosis of

the foreskin. After one week, the necrotic skin is cut off and a non-adhesive dressing applied. The wound will take another 3 weeks to heal completely.

The third method is known as sleeve method produces the best result but requires more expertise than all the other methods but is currently not being carried out within the FACES program. Unlike the forceps-guided method which can be performed without an assistant and is suitable for resource-limited settings, the sleeve method requires more skill than the forceps-guided method. In this method, the inner and outer preputial layers are dorsally divided; the slit is then extended to the corona. This frees the prepuce completely and enables cutting off it directly (Lukong, 2012).

The South African (Auvert et al., 2005) and Kenyan Randomized Clinical Trials (Bailey et al., 2007) employed the forceps-guided method, whilst the Ugandan (R. H. Gray et al., 2007) trial, used the sleeve method. All methods of adult and adolescent circumcision require suturing and dressing. Minor bleeding should stop with a few minutes of pressure with gauze. Once bleeding has ceased, the wound is dressed and the dressing left in place for 24–48 hours. A follow- up visit should occur within seven days of surgery to assess the progress of healing and to look for signs of infection.

2.3 Determinants of male circumcision

2.3.1 Religion

Among the Jews, male circumcision is an ancient practice that has been carried out by Jewish parents for more than 3,000 years. Circumcision is a rite of passage for every boy child. The initiation is carried out in a ceremony called brit millah in the presence of family and even community members. Circumcision is so important among the Jews that it can be performed during Sabbath or other holy days when drawing of blood is not allowed by religion in these days. According to the Torah (Bible)(Genesis 17: 9-14), God commanded Abraham to circumcise himself and all members of his household, his descendants and his slaves as a covenant between him and God. In Jewish law, failure to adhere to the covenant of circumcision attracts the punishment called Karet (being cut off from the rest of the community of God).The Torah (Genesis 16:14) also states that

any uncircumcised male who is not circumcised in the flesh of his foreskin shall be cut off from his people for breaking God's Commandment.

Male circumcision is widely practiced by Muslims. In line with their Abrahamic faith, Muslims practice neonatal circumcision to sanctify their relationship with God. The Quran does not mention circumcision but it is mandatory (wajib) in one of the Islamic schools of law (the Shafi'ite school)(Gray, 2004) . Circumcision is a requirement for a man to lawfully make the hajj (pilgrimage) to Mecca, one of the five pillars of Islamic belief (Rizvi, 1999). The global spread of Islam beginning 7th century AD led to widespread adoption of circumcision by previously non-circumcising communities. For instance in Rakai district in Uganda, 99% of Muslim men are circumcised compared to 4 % of the non-Muslims. Among 38 sub-Saharan African countries, the percentage of Muslims within countries predicted low HIV prevalence (Gray, 2004). The low prevalence of HIV among Muslims in Sub Sahara is due to strict religious sexual constraints and male circumcision.

There is no clearly prescribed age for circumcision in Islam, although the prophet Muhammad recommended it be carried out at an early age and reportedly circumcised his sons on the seventh day after birth (Rizvi, 1999). Many Muslims, therefore, perform the rite on the 8th day, although a Muslim may be circumcised at any age

Circumcision among the Christians varies across different denominations. The Coptic Christians in Egypt and the Ethiopian Orthodox Christians still practice two of the oldest surviving forms of Christianity and retain many of the features of early Christianity, including male circumcision– 97% of Orthodox men in Ethiopia are circumcised (DHS, 2006).

Other forms of Christianity do not advocate circumcision, going by the Gospel preached by St Paul in Galatians 5:6 *"In Christ Jesus neither circumcision nor circumcision count for anything"*. Coming to Africa, there is no clear consensus among Christians in regards to circumcision and Christian believes either (Westercamp & Bailey, 2007). Some Christians churches oppose male circumcision because it is viewed as a pagan ritual (Rain-Taljaard et al., 2003), whereas some other churches including the Nomiya in

Kenya insist on circumcision for membership to be granted (Mattson, Bailey, Muga, Poulussen, & Onyango, 2005)

In Malawi and Zambia, most Christians believe that Christians should practice circumcision since Jesus was circumcised and the Bible teaches the practice (Lukobo & Bailey, 2007; Ngalande, Levy, Kapondo, & Bailey, 2006). In some West African countries, circumcision prevalence is relatively lower among those of traditional religion than among Christians (66% vs. 93% in Burkina Faso, 68% vs. 95% in Ghana) (DHS, 2006).

Although religion and ethnicity can be closely correlated, religion can be a strong determinant within an ethnic group. For example, among the Mole-Dagbani in Ghana 97% of Muslims are circumcised, 78% of Christians, 43% of those with traditional religion and 52% of those with no religion (DHS, 2006). In Cameroon, circumcision is almost universal among all religions except the Animists (79% prevalence), among whom there is one particular ethnic group, the Mboum, who tend not to circumcise (40%), compared with a circumcision prevalence of 89% among Non-Mboum Animists. Despite the evident variation across communities in regards to the time of circumcision, religion is a strong influence of the circumcision ritual.

2.3.2 Ethnicity

Ethnicity is a strong determinant of male circumcision, especially in the Africa traditional context. In Kenya, 84% of all Kenyan men are circumcised but some communities do not practice circumcision , among the Luo and the Turkana communities, for instance, only 17% and 40% of men are circumcised respectively (DHS, 2006). The majority of other ethnic groups in Kenya consider male circumcision as an integral part of a rite of passage to manhood. In these tribes, circumcision is done from the age of 12 years to 20 years to instill bravery and endurance (Doyle, 2005).

Many rituals attach specific meaning to circumcision that justifies its purpose within this context.

For example, certain ethnic groups, including the Dogon and Dowayo of West Africa and the Xhosa of South Africa, view the foreskin as the feminine element of the penis, the removal of which (along with passing certain tests) makes a man out of the child (Wilcken, Keil, & Dick, 2010)

In some other culture, such as the Yao in Malawi, the Lunda and Luvale in Zambia, or the Bagisu in Uganda it is unacceptable to remain uncircumcised, to the extent that forced circumcisions of older boys are not uncommon (Lukobo & Bailey, 2007; Ngalande et al., 2006), Among the Xhosa in South Africa men who have not been circumcised can suffer extreme forms of punishment, including bullying and beatings (Wilcken et al., 2010) . This discrimination may extend to entire ethnic groups, as in the case of the Luo in Kenya, who do not traditionally practice circumcision and report that they are often ridiculed and considered lesser men by other Kenyans because of this (Bailey, Muga, Poulussen, & Abicht, 2002)

2.3.3 Perceived Health and Sexual Benefits

Studies on the acceptability of male circumcision in Sub-Saharan Africa have found that sexual satisfaction and the health benefits are the main determinants (Westercamp & Bailey, 2007). A similar study on barriers and facilitators of VMMC among uncircumcised men Nyanza region Kenya revealed that protection against HIV and other sexually transmitted infections was a major facilitator of acceptability. Men's circumcision preference was associated with the belief that it is more likely for uncircumcised men to get penile cancer, sexually transmitted diseases, and HIV/AIDS, and that circumcised men have more feeling in their penises, enjoy sex more, and confer more pleasure to their partners (Herman-Roloff, Otieno, Agot, Ndinya-Achola, & Bailey, 2011). In Malawi 55% of uncircumcised men believed that women were more satisfied sexually by circumcised men- this was a strong predictor after controlling for education, employment and health benefits of MC. Equally, women believed that sex was more enjoyable with circumcised men despite the fact that most women in the region had never had sex with circumcised men (Ngalande et al., 2006).

Further down in South Africa, a qualitative study was conducted in a high HIV prevalence district in KwaZulu-Natal to identify barriers and facilitators to the uptake of VMMC amongst adolescent boys. Individual cognitive factors facilitating uptake included the belief that VMMC reduced the risk of HIV infection, led to better hygiene and improvement in sexual desirability and performance (George et al., 2014). A quantitative and qualitative study conducted to explore barriers and motivating factors to

VMMC for HIV prevention in Zimbabwe reported HIV/STI prevention (44%), improved hygiene (26%), enhanced sexual performance (6%) as the main motivators (Hatzold et al., 2014). In Tanzania, Focus Group Discussions of 142 purposefully selected participants in 3 districts of Iringa and Njombe regions, facilitators included awareness of the HIV-prevention benefit and perceptions of cleanliness and enhanced attractiveness to women (Plotkin et al., 2013).

2.4 Voluntary Medical Male Circumcision for HIV Prevention.

Upon publication of the Kenya and Uganda RCT results concluding that male circumcision lowers the risk of HIV acquisition, the WHO/ UNAIDS called for a consultative meeting. The meeting agenda was to review scientific evidence, decide on the way forward and develop technical and policy guidance.

2.4.1 International community response to the evidence

A consultative meeting, held in March 2007, led to 11 conclusions containing 43 recommendations for VMMC as an HIV prevention strategy(WHO/UNAIDS, 2007b). WHO and UNAIDS recommended that VMMC should always be considered as part of a comprehensive HIV prevention package which includes: HIV testing and counseling; correct and consistent use of female or male condoms; Treatment for sexually transmitted infections; and promotion of safer sexual practices, such as avoidance of penetrative sex(WHO/UNAIDS, 2007b)

The recommendations identified 13 priority VMMC countries with generalized HIV epidemics, high HIV prevalence, and low male circumcision prevalence. The recommendations were broad, addressing issues ranging from the significance of conducting situation analysis across all the identified countries to policy considerations and ethical, cultural, legal, and human rights considerations(Katz & Wright, 2008). The WHO formulated a simple package of HIV prevention services to be offered with male circumcision. The additional services comprise of HIV testing and counseling (HTC) (voluntary); screening and treatment of sexually transmitted infections; pre-operative and postoperative education and risk-reduction counseling; and, promotion and provision of condoms(WHO, 2007). As implementation started, WHO and UNAIDS

convened another stakeholders meeting to develop guidelines and tools. The meeting resulted in many guidelines that addressed complex cultural, religious, political, and ethical issues not directly linked to male circumcision, such as gender dimensions of programming, task shifting, sensitivity to cultural norms and religious practices, communications strategies, and informed consent(WHO, 2014).

2.4.2 Kenya's Response to WHO Recommendations and the Evidence

WHO/UNAIDS prioritized the former Nyanza province as one of the regions in Sub Saharan Africa for implementation of Male Circumcision. Despite more than 80% of men in Kenya being circumcised (NASCOP, 2009), Male Circumcision coverage varies culturally and geographically. Nyanza region, which is largely Luo, had the lowest MC coverage (40%) as at 2007 and the highest prevalence of HIV (14.9%) in Kenya (NASCOP, 2014).

Given these data and the WHO recommendations, the government of Kenya, through the Ministry of Health, recognized medical Male Circumcision as an additional and important strategy for the prevention of heterosexually acquired HIV infection in men and developed a national strategy that aimed to circumcise 80% of uncircumcised HIV-negative men aged 15–49 years (approximately 860,000 men throughout the country, 426,000 in Nyanza region alone) between 2009 and 2013 (Council, 2009). As at 2014, Progress across eastern and Southern Africa countries varied with Ethiopia (Gambella province), Kenya and the United Republic of Tanzania reaching over 80% coverage. Mozambique and Uganda reached between 50–79% coverage. Six countries increased the annual number of VMMCs performed compared with 2013. (WHO, 2014) .

The Kenyan Ministry of Health and the National AIDS and STI Control Programme (NASCOP) held a consultative meeting with donors, researchers and policymakers. The meetings outlined how Kenya should respond to the results of the trials in Kisumu and Rakai after the studies were stopped because of overwhelming evidence of the efficacy of MC in reducing HIV transmission.

The Ministry of Health constituted a male circumcision taskforce to provide a way forward and draft guidelines for implementation of VMMC in the country. To complement the work of the Kenya National MC task force, a Nyanza region Male Circumcision task force and district coordinating bodies were also established in early

2007. Additionally, an assessment of health facilities in Nyanza region was conducted to determine the region's preparedness to provide VMMC services. The identified gaps were fixed with support from international donors.

As the work on the national policy document proceeded, the Kenyan government engaged the Luo Council of Elders in Nyanza region in the scale-up of medical MC. The main objective was to gain the support of these protectors of Luo culture for medical MC scale-up, to achieve this objective; the government explained the medical benefits of VMMC and emphasized its role in HIV prevention. In addition, the government needed to improve its understanding of the council's potential concerns. Repeated discussions satisfied the Luo Council of Elders that MC for HIV prevention would be voluntary and provided for medical and not cultural reasons.

The day before the official launch of VMMC services in October 2008, three community-based stakeholders' meetings were held with cultural leaders, government ministers local politicians, youth, religious and women's groups, and health professionals. In addition, several members of parliament and cabinet ministers from the Luo community publicly disclosed that they were circumcised, as a show of support for Kenya's VMMC programs for HIV prevention. It is estimated that as at 2013, 927,156 men had been circumcised in Kenya since the VMMC program was implemented, the majority from Nyanza region(WHO, 2014).

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2.5 Acceptability of male circumcision

Male circumcision prevalence varies across the population in most sub- Saharan nations (WHO/UNAIDS, 2008). HIV prevention rather than treatment has been a major area of interest among advocacy groups and experts in the HIV field. The evidence that circumcision partially protects against acquisition of HIV was a step against the virus albeit acceptability challenges(Bailey et al., 2007). Many communities that do not traditionally circumcise did not easily embrace this practice(Westercamp & Bailey, 2007). Many studies had been conducted on acceptability before the 3 RTC that showed a relationship between circumcision and reduced risk of HIV transmission(Lukobo & Bailey, 2007).

In a review by Westercamp and Bailey (2007), eight of the thirteen studies reviewed included quantitative assessments of the acceptability of MC in six countries using interview questionnaires. Four of the eight studies included women respondents. The Willingness of uncircumcised men to become circumcised varied from 29% in Uganda to 87% in Swaziland. Across studies, the median proportion of uncircumcised men willing to become circumcised was 65% (range 29–87%). Sixty-nine percent (range 47–79%) of women favored circumcision for their partners, and 71% (50–90%) of men and 81% (70–90%) of women were willing to circumcise their sons (Westercamp & Bailey, 2007).

2.6 Barriers to acceptability

Three salient barriers are evident from various acceptability studies: Fear of pain, concerns about safety and cost of the procedure. The apprehension about pain is evidenced from studies conducted across sub-Saharan Africa (Hatzold et al., 2014; Lukobo & Bailey, 2007; Mattson, Muga, Poulussen, Onyango, & Bailey, 2004; Ngalande et al., 2006). Participants from non-circumcising ethnic groups feared the practice based on information from neighboring circumcising tribes where the pain is an important part of the procedure. As a rite of passage to becoming a man, the endurance of the pain from circumcision is often an integral aspect of the ceremony. For example, of 108 circumcised participants in South Africa, 42.6% termed the traditional procedure as “very painful”, 34.4% as “mildly painful”, and 18.5% as “not painful” (Lagarde, Dirk, Puren, Reathe, & Bertran, 2003). Pain is subjective and hence the difference in degree felt by the men undergoing the procedure.

2.6.1 Safety concerns

Safety concerns hinder acceptability to VMMC. FGDs conducted among men and women in Malawi revealed that men feared bleeding or contracting infection post the operation, Women expressed concerns about their sons’ safety especially young boys (Ngalande et al., 2006). Fears were reported of excessive bleeding especially where the operation is performed in the traditional settings by traditional circumciser (Bailey et al., 2002). Infection and difficulty in healing were main concerns about traditional circumcision which the participants thought were less common in clinical settings

(Lukobo & Bailey, 2007). On the other hand, some clients confessed that the comfort of having the operation under the trained arms of a surgeon was a motivator to them accepting VMMC. VMMC conducted under trained hands is less likely to cause associated complications such as severe bleeding and post-surgical would infection((Muhamadi, Ibrahim, Wabwire-Mangen, Peterson, & Reynolds, 2013) Women's opposition to traditional circumcision feared the children may die or get injured in the course of the procedure (Rain-Taljaard et al., 2003)

2.6.2 Cost

The cost of undergoing circumcision is a barrier to acceptability especially in resource limited- settings (Lukobo & Bailey, 2007; Ngalande et al., 2006). Many parents and young men would embrace MC if it is affordable or provided in the government hospitals free of charge (Bailey et al., 2002), Moreover, both male and female participants in Zambia believed that, if the MC procedure was free or relatively cheaper, more men would embrace the cut (Lukobo & Bailey, 2007). In another instance, as many as 34% of participants who initially stated that their preference was to remain uncircumcised changed their minds when the proposed cost of the procedure was lowered to only US$3.00(Mattson et al., 2005). Furthermore, the cost of traditional circumcision was considered too high leading to a slow shift to medical circumcision in many areas (Bailey et al., 2008; Lukobo & Bailey, 2007; Ngalande et al., 2006).

The second aspect of cost is transportation; the cost to the circumcision site impedes acceptability. For example, placing circumcision services strategically closer to the communities through carefully planned outreaches makes it affordable. Otherwise, without the outreaches, clients who live far from the facilities are likely to be discouraged by the cost incurred for transport to access the service (Muhamadi et al., 2013).

A slightly different aspect of cost is the effect of circumcision on employment. Men fear losing income during the procedure

> *"Financial concerns included concern about missing work and losing income during the procedure and healing, potentially losing one's job from being*

absent, and how one's family would survive if the father was out of work during the recovery period. This last concern was mentioned only by men. Some men described difficulty in taking even a short break away from work for fear that they would lose their jobs."(Evens et al., 2014)

2.6.3 Other Barriers

Other barriers that vary across different parts in sub-Sahara include culture and religion, post-surgical abstinence period, fear of HIV testing, lack of partner support and female provided circumcision (George et al., 2014; Hatzold et al., 2014; Herman-Roloff, Otieno, et al., 2011). FGD in Nyanza and Kwazulu Natal revealed that men complained of the need to abstain from sex and losing time from work and other social activities (George et al., 2014; Herman-Roloff, Otieno, et al., 2011). Additionally, men in Zimbabwe reported a lack of support from their spouses and fear of HIV testing before circumcision as some of the factors that hinder utilization of VMMC services (Hatzold et al., 2014).A study targeting teenage boys in Kwa- Zulu Natal found that boys were reluctant to be circumcised when involved in sports activities and during exams. Consequently, the timing of VMMC intervention needs to be considered.

Cultural factors affect acceptability but are less reported, (Skolnik, Tsui, Ashengo, Kikaya, & Lukobo-Durrell, 2014).For instance, provider gender is an issue in Lesotho, out of 161 men interviewed for the study, 18% were uncomfortable with being circumcised by female provider due to cultural reasons. Similarly, men from Luo Nyanza were reluctant to undergo circumcision for cultural and religious reasons (Herman-Roloff, Otieno, et al., 2011)

2.7 Facilitators of male circumcision

2.7.1 Hygiene

Hygiene is a major facilitator of male circumcision and a significant benefit of MC.(George et al., 2014; Hatzold et al., 2014; Herman-Roloff, Otieno, et al., 2011). An overwhelming number of participants (men and women) from many studies viewed circumcision as a way of maintaining hygiene and cleanliness (Mattson et al., 2004; Ngalande et al., 2006). Moreover, women's priority was found to be mainly men's

penile hygiene. The impact of circumcision on hygiene is possibly the reason for women embracing circumcision (Bailey et al., 2002; Lukobo & Bailey, 2007; Mattson et al., 2005). In particular, women were worried of men failing to maintain proper hygiene, on the contrary, men attributed poor penile hygiene to lack of water yet women are the primary providers of water (Bailey et al., 2002).

2.7.2 Protection from STIs and HIV

Many studies highlight the preventive effect of circumcision against STI, HIV and penile cancer as a facilitator.(Bailey et al., 2002; Lukobo & Bailey, 2007; Ngalande et al., 2006). The majority of men believe that most agents causing disease thrive in uncircumcised penis beneath the foreskin (Bailey et al., 2002) . Additionally FGD with men in Zambia also revealed that they believed that it was easy to diagnose and treat rashes/ulcerations in the circumcised penis (Lukobo & Bailey, 2007) . Similarly, Rain-Taljaard et al. (2003) reported that the foreskin was considered as an entry point for STI due to its susceptibility to injury during sex. In Nyanza region 79% of uncircumcised men and 81% of participants stated that it was easy for uncircumcised men to contract STI than circumcised men, nonetheless, this belief dropped to 43% and 60%, respectively, concerning the acquisition of AIDS (Bailey et al., 2002). On the contrary, a minority of respondents in Zambia reported that the circumcised penis was “always dry”, “susceptible to cracking”, and that this state provided a portal of entry for bacteria and (Lukobo & Bailey, 2007). Seventy percent of Botswana study participants willing to circumcise their male child listed protection from STIs or HIV among their reasons for doing so (Kebaabetswe et al., 2003).

In Tanzania, STIs were considered more severe and more infective in uncircumcised men with ulcers healing faster in those who are circumcised (Nnko, Washija, Urassa, & Boerma, 2001).Finally, nearly all commercial sex workers believed that there exists a strong association between lack of circumcision and STIs, including HIV (Ngalande et al., 2006). In South Africa (Scott, Weiss, & Viljoen, 2005) found no association between willingness to be circumcised and perceived health benefits.

2.7.3 Enhanced sexual performance

Most studies have analyzed the association of sexual performance, sexual pleasure and circumcision status in both men and women. Fifty percent of circumcised and 30% of uncircumcised participants in South Africa believed that MC enhanced sexual performance, while only 21% and 14%, respectively, believed that MC decreased sexual pleasure (Lagarde et al., 2003). Other studies found that a high proportion of men and a majority of women believed that circumcised men enjoyed sex more than uncircumcised men (Mattson et al., 2005; Rain-Taljaard et al., 2003). Furthermore, a study in South Africa found that men were 8 times more likely to opt for circumcision if it is true that sex is more enjoyable, and 6 times more likely to prefer circumcision if women enjoy sex more with circumcised men (Scott et al., 2005). Nevertheless, other studies did not find a consensus about circumcision status and sexual pleasure on the part of the man or the woman (Bailey et al., 2002; Lukobo & Bailey, 2007; Ngalande et al., 2006). Some view sex as an emotional experience and pleasure and performance were irrelevant to them (Ngalande et al., 2006). Attitudes about circumcision and pleasure vary across different areas (Lukobo & Bailey, 2007).

2.7.4 Peer/Partner Influence

Men need a lot of support from their partners and other available social networks to give VMMC priority (Muhamadi et al., 2013). Peer/partner influence has been shown to give men emotional and psychological support to seek MC in Kenya and other Sub-Saharan settings (Westercamp & Bailey, 2007), (WHO/UNAIDS;2012).

In Uganda, peer educators have been found to be instrumental in mobilizing communities to embrace various HIV prevention activities including VMMC. Similarly, studies in South Africa, Malawi, Zambia, India and, Brazil reported the association between peer/partner influence and social support with improved adherence to treatment and acceptability of preventive interventions (WHO/UNAIDS, 2012). Consequently, it is imperative to consider contextual social settings to maximize the benefits of social support in facilitating acceptability of VMMC (Muhamadi et al., 2013). More importantly, perceived sexual benefits and better sexual satisfaction to women has been found to be a motivator of men seeking MC (Scott et al., 2005)

Other common reasons given for favoring MC were the social, political, and sexual benefits that could accrue when interacting with those in predominantly circumcising groups (Bailey et al., 2002; Lukobo & Bailey, 2007; Ngalande et al., 2006). The Luo for example believed that they were often ridiculed by other Kenyans due to their circumcision status which leads to discrimination (Bailey et al., 2002), while young men from non-circumcising communities attributed importance of circumcision as a requirement to marrying women who come from traditional circumcising communities (Nnko et al., 2001).

2.8 Adverse events in VMMC

Given the scientific evidence of the benefits of male circumcision in reducing HIV incidence rates among men (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007), the WHO recommended the scale-up voluntary medical male circumcision (VMMC) services for adult and adolescent males in Sub Saharan African countries with high prevalence of HIV (Mwandi et al., 2011). It is predicted that VMMC services provided safely with high coverage could prevent up to 3.4 million new HIV infections (Njeuhmeli et al., 2011). However, the rapid expansion of VMMC programs has raised concerns regarding the extent to which health systems can deliver VMMC safely on a large scale (Herman-Roloff, Llewellyn, et al., 2011; Mahler et al., 2011). Consequently, ensuring the safety of VMMC will improve acceptability and help in realizing the potential health impact of averted HIV infections and in reducing health systems costs for HIV-related care(Musau et al., 2011)

Operative complications of male circumcision include excessive bleeding, haematoma formation, sepsis, unsatisfactory cosmetic effect, lacerations of the penile or scrotal skin and injury to the glans. The WHO Manual for Male Circumcision Under Local Anesthesia (WHO/UNAIDS/JPIEGO, 2008) recommends grading of AE as follows:

Mild: Evident AEs that resolve without requiring any medical treatment.

Moderate: Notable symptoms requiring intervention or treatment by a health care provider or medication (parenteral, oral or topical).

Severe: AEs that lead to serious deterioration of patient's health, or result in life threatening illness or injury e.g. events that result in permanent injury of a body structure or function, require in-patient hospitalization or prolongation of existing hospitalization or result in medical or surgical intervention to prevent permanent impairment to body structure or body function. An example is continuous bleeding due to severe penile injury.

Table 1: Adverse events case definition

POST CIRCUMCISION: ADVERSE EVENTS CASE DEFINATION		
	Description	Severity
Pain	N/A	Mild
	Results in disability for 4-7 days	Moderate
	Results in disability for more than 7 days	Severe
Bleeding	Dressing soaked through with blood at a routine follow-up visit	Mild
	Bleeding that requires a special return to the clinic for medical attention	Moderate
	Bleeding that requires surgical re- exploration	Severe
Problems with Appearance	May be some concern by client but appearance within normal range	Mild
	Scarring; cosmetic problem but operation not required	Moderate
	Rotation or other problem; requires cosmetic	Severe

	correction	
	More swelling than usual, but no significant discomfort	Mild
Haematoma / Swelling	Significant tenderness and discomfort, but surgical re-exploration	Moderate
	not required	
Infection / Swelling	Surgical re-exploration required	Severe
	Erythema more than 1 cm beyond incision line	Mild
	Purulent discharge from the wound	Moderate
	Cellulitis or wound necrosis	Severe
Difficulty or pain when urinating	Transient complaint that resolves without treatment	Mild
	Partial obstruction	Moderate
	Cannot urinate	Severe
Wound disruption (without signs of haematoma or	1 to 2 adjacent stitches missing	Mild
	Re-stitching of at least 3 stitches required	Moderate

infection)	Patient incapacitated – bed rest required	Severe

2.9 Factors associated with male circumcision Adverse Events in clinical settings

Many studies have been conducted evaluating the safety of Male Circumcision; however few studies that have evaluated factors associated with AEs since the 2008 implementation of VMMC for HIV prevention.(Frajzyngier et al., 2014; Herman-Roloff et al., 2012; Kigozi et al., 2014; Phili et al., 2014; Reed et al., 2015)

The three initial RCT (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007) conducted in South Africa, Uganda and Kenya reported adverse events rates between 1-3.6 %. As implementation continued other studies on safety were conducted across the Sub Sahara region. In Nyanza region (Reed et al., 2015), evaluating loss to follow up and safety factors reported 6.8% adverse events in the LFTU and 3.3% in the ADFU group. The authors also emphasized the importance of follow-up and actively contact LTFU clients to ensure care is provided throughout the entire post-operative course for all.

Provider Related Factors

Providers experience has an impact on the AE rates. A study on factors associated with the incidence of adverse reported AE rate of 0.1% intra-operatively and 2.1% post-operatively among clinic system participants with 7.5% post-operatively among participants under active surveillance. It was reported that providers who performed more than 100 procedures achieved an adverse event rate of 0.7% and 4.3% in the clinic and active surveillance systems, respectively, and had decreased odds of performing a procedure resulting in an adverse event. With provider experience, the mean duration of the procedure also dropped from 24.0 to 15.5 minutes. Among providers who had performed at least 100 procedures, nurses and clinicians provided equivalent services.

There is however, no difference in rates of moderate and severe AEs across the cadres of staff performing the operation(Frajzyngier et al., 2014).

Facility related factors

There are concerns about safety of VMMC in resource-limited settings (Mattson et al., 2004). The lack of basic medical instrument and supplies were identified as the major limiting factors in Kenya. VMMC can be delivered safely at resource-limited settings. In South Africa, the frequency of moderate AEs was 0.7, 0.3 and 0.6% at 2-, 7- and 21-day visits, respectively. The frequency of severe AEs was 0.4, 0.3 and 0.6% at 2-, 7- and 21-day visits; respectively (Phili et al., 2014). The authors further reported intensive three-visit post-operative review practice may be unfeasible due to high attrition rates over time, particularly amongst older men.

Individual factors

Disease status is an important factor in male circumcision but few studies have been conducted on the association of Conditions like diabetes, bleeding disorders and HIV and prevalence of AEs (Andrea Wilcken 2009) . The trials of elective male circumcision among men in Africa provided essential information on risks of surgery in adults. In the South African RCT, the overall risk of adverse events during surgery or in the first month post-surgery was 3.6% among the 1495 HIV-seronegative men and 8.2% among the 73 HIV-seropositive men (Auvert et al., 2005) while the Kenyan RCT reported slightly lower adverse events among the HIV-seronegative 1.5 % compared to 1.8% among the HIV- seropositive men recruited into the trial ,(Bailey et al., 2007). A study on the difference in wound healing between HIV positive and HIV negative men reported that at week 4, 59.3% of HIV-positive men and 70.4% of age-matched HIV-negative men were healed. At week 6, these percentages rose to 93.4% in HIV-positive men and 92.6% in age-matched HIV-negative men(Rogers, Odoyo-June, Jaoko, & Bailey, 2013). In the advent of mass male circumcision for the partial prevention of HIV, undiagnosed and diagnosed cases of bleeding disorders are likely to be increasingly encountered, A study in Uganda found 3 cases of uncontrolled recurrent bleeding among circumcised teenagers (M. Galukande, C. Kahendehe, E. Buuza, & D. B. Sekavuga, 2015)

The safety of male circumcision depends crucially on the setting, equipment and expertise of the providers (WHO/UNAIDS, 2008), the current body of evidence suggests that circumcision can be provided safely in most settings with trained personnel and adequate infrastructure, however continuous evaluation of safety must be done to ensure safe medical male circumcision, thereby facilitating increased acceptability of circumcision services.

3.0 Satisfaction on among men receiving services

There is overwhelming evidence that male circumcision has no significant detrimental effect or might have beneficial effects on male sexual function and satisfaction for the great majority of men circumcised as adults(Krieger et al., 2008; Nordstrom, Westercamp, Jaoko, Okeyo, & Bailey, 2017). However, information on patient satisfaction on the VMMC procedure and services at health facilities is still scanty. Information on satisfaction is key in improving service delivery at circumcision facilities and also aid in the acceptability of circumcision(Westercamp & Bailey, 2007). In Kenya, two studies have been conducted on satisfaction among patients receiving VMMC. The randomized clinical trial in Kisumu in 2007 found that (99·5%) individuals in the intervention arm were "very satisfied" and six (0·5%) were "somewhat satisfied" with their circumcision; one person was "somewhat dissatisfied", and none were "very dissatisfied"(Bailey et al., 2007)

Mari Stopes Kenya assessed postoperative complications and patient satisfaction associated with mid-level provision of male circumcision in rural western Kenya among children, adolescents, and adult men undergoing male circumcision from. Findings showed that a majority of patients (>99%) were satisfied with the procedure, counseling, and information received (Ngo & Obhai, 2012). Male circumcisions can be delivered safely and successfully by mid-level providers in rural settings with high client satisfaction, thereby increasing access to human immunodeficiency virus prevention services in Kenya(Ngo & Obhai, 2012)

The safety and efficacy of the PrePex device for voluntary medical male circumcision (VMMC) has been demonstrated in studies in Rwanda, Uganda, and Zimbabwe, leading to the conditional prequalification of the device for use in adults(WHO, 2013). A Study done on the safety and efficacy of the device for males in Harare showed that

adolescents were highly satisfied with the results of their circumcision(Tshimanga et al., 2016).An assessment of the frequency, type and severity of adverse events following VMMC among 427 adult men surgically circumcised in southeastern Botswana showed that Patient satisfaction was high: >95% were very or somewhat satisfied with the procedure and subsequent follow-up care(Wirth et al., 2017).

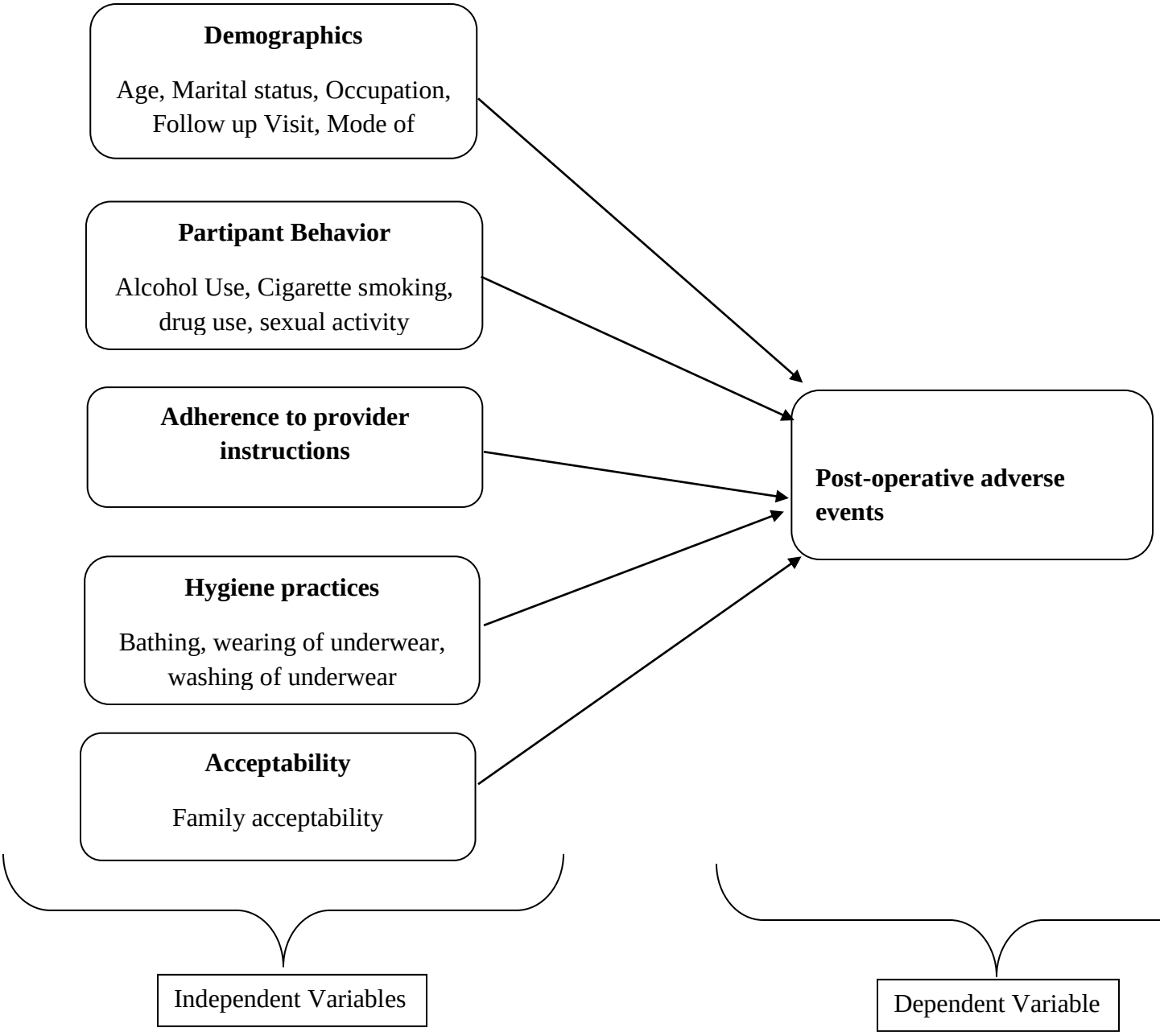
The Spear and Shield study among Zambian men indicated that Men were satisfied overall with the procedure (mean satisfaction score, 8.4 out of 10), and nearly all men (96%) and women (94%) stated they would recommend VMMC to others (Zulu, Jones, Chitalu, Cook, & Weiss, 2015).

3.1 Conceptual Framework: Adverse Events Risk Factors

The conceptual framework used in this study will be based on the Health Action Process Approach (HAPA) as a Theoretical Framework to Understand Behaviour Change(Schwarzer, 2016). To efficiently integrate and adapt HAPA, the conceptual framework illustrated below in Fig 1, will be used to guide the study.

Figure 1: Illustrates the conceptual framework that relates the factors considered to have an influence on adverse events following VMMC. The dependent variable was the adverse events recorded post-circumcision. The independent variables in the study were demographic characteristics of participants their behaviors, adherence to provider instructions on wound care, participant's hygiene practices and acceptability within the family of participants

Fig 1: A conceptual framework illustrating the factors associated with adverse events among made receiving VMMC services in Migori County Hospital



CHAPTER THREE

MATIRIALS AND METHODS

3.1 Study Site

This study was conducted at Migori County Hospital in Migori County located in the Nyanza region. The Nyanza region is one of the regions in sub-Saharan Africa prioritized by WHO and UNAIDS for implementation of Medical MC due to the low circumcision prevalence. The region, which is largely inhabited by the Luo community, has the lowest MC coverage (48%) and the highest prevalence of HIV (14.9%). Most of the VMMC services are currently being implemented by FACES and other PEPFAR funded health organizations. FACES offers free VMMC service at 16 sites within health facilities in Kisumu East, Migori, Suba, Mbita, Suna East, Suna West, Rongo, Uriri and Nyatike Sub-Counties. All of these facilities are under the management of the respective county governments as per the devolved health system in Kenya.

3.3.1 Study Context

The Family AIDS Care and Education Services (FACES) is a family-focused, comprehensive HIV prevention, care, and treatment program funded by PEPFAR working collaboratively with the Kenyan Ministries of Health (MOH) to build sustainable HIV care systems in Nyanza region and in Nairobi.

FACES was launched with one site in Nairobi in 2004 and second site in Kisumu, Nyanza region in 2005, with a focus on HIV care and treatment, as well as HIV testing and counseling services. FACES rapidly expanded in Kisumu and other neighboring districts including the island district of Suba. It also serves the fishing community along Lake Victoria's shores with an HIV prevalence of 27% – the highest in the country. From 2007, FACES support extended to Prevention of Parent-to-Child Transmission (PPCT) and Voluntary Medical Male Circumcision (VMMC) services and expanded geographically to the underserved, rural districts of Migori, Rongo, and Nyatike.

FACES program currently supports 148 health facilities in Kisumu, Migori, and Homabay counties. The Voluntary Medical Male Circumcision (VMMC) services are provided at 16 health facilities. Over 84,444 males have undergone VMMC surgery as at

September 2015. Within the period of July-September 2015, 6005 males had circumcision surgery.

3.2 Study population

The study population was composed of men circumcised and attending follow up visits as required by the MOH guidelines. The men were recruited from Migori County Hospital which is one of the FACES supported sites in Nyanza.

3.2.1 Inclusion and Exclusion criteria

a) Inclusion criteria

- Male aged 18 years and above
- Must have undergone circumcision within the last 45 days in Migori County Hospital
- Those attending post operation circumcision follow up visit (either scheduled or non-scheduled)
- Willing to provide written informed consent to participate in the study.

b) Exclusion criteria

- Men attending follow up visit but not willing to be interviewed for the study

Men over the age of 18 were selected for ethical reasons while the 45 days period is per recommended guidelines for complete healing and resumption of sexual activity among men circumcised.

3.3 Study design

This was a descriptive cross-sectional study utilizing quantitative methods. A total of 138 Men were recruited when attending either scheduled or unscheduled follow up visit in Migori County Hospital. Those who consented to participate were interviewed and examined at the facility during follow up to obtain data on demographic characteristics and the post-operative complications. Adverse events were defined based on the existing WHO/MOH guidelines.

3.4 Sampling

3.4.1 Site Selection

FACES offers free VMMC service in 16 sites within Kisumu East, Migori, Suba, Mbita, Suna East, Suna West, Rongo, Uriri and Nyatike sub counties. Migori Sub-County Hospital was selected based on high client volume as per the last FACES VMMC program report.

3.4.2 Client sampling strategy

Clients were recruited using systematic sampling. The average daily client flow was estimated at 30, therefore every 3rd client that was attended to in the facility was recruited to yield an average of 10 clients interviewed daily for 15 days until the target sample was reached.

3.4.3 Sample size determination.

The sample size was calculated based on Cochrane's 1963 formula for categorical data sample size determination(Cochran, 1963). The 10% prevalence of complications of VMMC used to calculate sample size is based on the findings of a VMMC study conducted in Nyanza that reported adverse events at 10% for clients who turned up for follow up visits (Herman-Roloff et al., 2012)

$$N = \frac{Z^2 \times p\,(1-p)}{\delta^2}$$

$$= \frac{[(1.96)^2 \times [0.10 \times 0.90]}{(0.05)^2}$$

$$= \frac{0.345744}{0.0025}$$

$$= \mathbf{138}$$

- N = The estimated sample size

- P – The estimated prevalence of circumcision complications in the study population
- $Z = Z_{0.025}$ – critical value corresponding to 95% Confidence interval = 1.96
- δ – level of precision = 0.05

3.5 Study Procedures

3.5.1 Enrolment and Examination

Enrollment was done during any follow-up visits occurring after the first day of circumcision to the 45^{th} day after the surgery. After surgery, men were required as stipulated in the MOH guidelines to visit the clinic 7 days after the procedure. During this routine visit, the provider assesses the progress of healing and looks for signs of infection or any other adverse events. The operation site was examined, and additional examinations were done as required by the case history, symptoms or complaints of the client. If the client had a problem that could not be resolved, another visit was scheduled or the client was referred to a higher level of care. However, follow up visits could occur any day after surgery depending on the condition of the patient or at any other visits that may be scheduled by the clinicians within health facilities.

Men who met study criteria were approached during the follow-up visit and requested to participate in the study. Those who agreed were directed to a private room and given information about the study goals, risks and benefits of the study. Those who consented were requested to either sign an informed consent to participate in the study or provide a thumbprint in the presence of a witness before the interview was conducted in the designated private section followed by examination by a clinician in a private room.

3.5.3 Safety and adverse events

Quantitative data on demographics was collected by PI while Adverse Events was collected through examination by clinicians who were on duty examining the clients during the visit. The men were approached as they waited to get attended to by the healthcare providers during follow up visits at the Migori Sub County Hospital.

Those who consented were led to a private room within the Clinic where a structured questionnaire was administered. The interview took at most 20 minutes. The researcher used the questionnaires to obtain information on socio-demographic characteristics and a different examination tool was used by the examining clinician to collect any adverse events post-surgery that may have occurred. Clinical examination was used to obtain information on pain, swelling, haematoma, bleeding, infection, difficulty in urinating, wound disruption/delayed healing, problems with penis appearance, and injury to the glans. Each of these adverse events was graded as mild, moderate or severe as per stipulated WHO manual for male circumcision under local anesthesia(WHO/UNAIDS/JPIEGO, 2008). *(Appendix VII)*

3.6 Data Management

3.6.1 Data storage

Data on patient demographics and self-reported symptoms during post-surgical follow-up was recorded on the questionnaires and the examination tool and subsequently captured on Epi Info 7. Data was also backed-up in an external hard disk and Dropbox. The computer used to store data was password protected. The questionnaires were filed and kept in lockable drawers in the FACES VMMC site office at Migori county Hospital for security and confidentiality. After data collection was completed, the study tools were sealed in a waterproof metal box and transported to Nairobi by the Wells Fargo courier services for analysis. In Nairobi, the tools were stored in lockable cabinets at the RCTP offices at the KEMRI-CMR offices within Kenyatta National Hospital. Only the PI has access to the information. The hard copies will be stored until when the publication of manuscripts and thesis report has been submitted to JKUAT then they will be shredded.

3.6.2 Data Entry and Data Cleaning

Research data entry was conducted manually by the PI using Epi Info 7. Before analysis, data cleaning was done to detect and correct any errors, inaccuracies and omissions.

3.6.3 Data Analysis

STATA 12 was used to perform data analysis. Frequency distributions, measures of central tendency (mean, median, and mode) were used to describe demographic data, the prevalence of adverse events and the clients' level of satisfaction towards VMMC services at Migori Sub County Hospital.

Bivariate analysis was conducted to test for association between the independent variable and the moderate adverse events following circumcision. The bivariate analysis was done using fishers exact test due to the low number expected values. The significance level at or below 0.05. The variables tested included age, level of education, marital status, occupation, and distance from the hospital, mode of transport, bathing frequency, rest after VMMC, circumcision method hygiene practices, drug use and family acceptability of circumcision. The cross-tabulation categories were classified as normal (Mild events and normal healing without adverse events) against the moderate adverse.

3.7 Ethical Considerations

3.7.1 Ethical Approval

Ethical clearance was obtained from KEMRI Scientific and Ethics Review Unit *(Appendix I).* Permission to carry out the study was granted by the FACES Country Director. The management of the County Health facilities supported by FACES was informed of the study details.

3.7.2 Informed Consent

Informed consent was a requirement for participants in this study, therefore all participants were informed of all the study procedures and their right to voluntarily choose to participate and withdraw at the anytime from the study without any penalties. Accordingly, only those who provided consent were enrolled in this study. A copy of the duly signed consent form was provided to the participant for their own records.

3.7.3 Privacy and confidentiality

To protect privacy, the interviews and examination were conducted in a private room to protect participants' privacy during consenting and interview sessions, No identifiable information was collected, additionally, confidentiality was ensured by restricting access to the study documents to only the PI. All the study documents were filed confidentially in the data office at FACES Migori FACES site under lock-and-key, with access to the signed forms was limited to the study investigator. After a data collection was completed, the documents were sealed and transported to RCTP- Kenyatta offices in Nairobi where they were stored under lock- and -key.

3.7.4 Risks and Benefits

This study involved minimal risk to the participants. The participants were only interviewed and routinely examined without performing any further clinical procedures. Privacy and confidentiality was assured and ensured as described in the preceding section. The participants got no direct benefits from the study. The interview took approximately 20 minutes; the participants incurred no cost since they were recruited while attending their post-operative follow-up visits. Information obtained from this study will be disseminated to FACES, in addition to sharing publications from this study at seminars, workshop or conferences.

CHAPTER FOUR

RESULTS

4.1 Demographic Characteristics

Table 4.1 Demographic characteristics of 138 study participants

Parameter	Frequency	%
Sub- County		
Awendo	2	1.5
Kuria East	11	8
Kuria West	9	6.5
Rongo	2	1.5
Suna East	84	60.9
Suna West	30	21.7
Age		
<21 years	70	51
21-30 years	58	42
≥31	10	7
Follow up visit		
48 hours	1	0.7
3rd day	6	4.3
7 Days	129	3.4
Other	2	1.6
Education		
Primary	23	16.7
Secondary	88	63.8
Tertiary	26	18.8
None	1	0.7
Marital status		
Cohabiting(not legally married)	9	6.5
Married	27	19.6
Never Married	100	72.5
Separated	2	1.4
Occupation		
Employed	44	31.9
Farmer	13	9.4
Student	69	50.0

Other	12	8.7
Distance to Hospital		
<5km	30	21.7
5-15 km	51	37.0
>15	57	41.3
Mode of transport		
Car/Bus	2	21.0
Motorbike	81	58.7
Walking	28	20.3

The mean age of the participants was 22 years while the mode was 18 years. (Range: 18-48). At least half 70(50.7%) were between 18-20 years. Most participants 97(70.3%) were circumcised using the surgical method while 41(29.7%) opted for the Pre-pex method. Pre pex utilizes a ring and rubber to block blood supply to the foreskin hence causing necrosis. The Majority of participants 84(60.9%) came from Suna East Sub-county. Almost two-thirds 88(63.8%) had reached secondary level education, 26(18.8%) tertiary level, 23(16.7%) primary level and only 1(0.7%) had no education. The majority (72.5%) were never married, 27(19.6%) were married, 9(6.5%) cohabiting and only 2(1.5%) were separated. Half 69(50%) of these men were students, followed by 44(31.9%) who were employed and only 13(9.4%) were farmers. Majority 57(41.3%) traveled a distance of more than 15km to receive the service and 30(21.7%) traveled less than 5km. Majority 81(58.7%) used motorbikes to the clinic, 29(21%) used either a car or a bus while 28(20.3%) walked to the clinic.

4.2 Adverse Events

4.2.1 Moderate and severe adverse events

Out of the 138 participants, none experienced an adverse event that was severe. A total of 4 out of 138 participants (2.9%) had adverse events which were categorized as moderate. One participant experienced a moderate delay in wound healing, two had moderate infections and one had swelling leading to the early removal of pre-pex device. Out of the 4 moderate adverse events, 3 (75%) were recorded during the 7th day follow up visit. Among those who experienced AEs, 2(50%) of the adverse event cases

occurred among participants who went through circumcision by surgery. All these participants were treated at the VMMC clinic during the follow-up visit.

Table 4.2 Prevalence of mild and moderate Adverse Events among participants

Visit	Frequency	Percent	Adverse Events	
			Moderate	Mild
48 hours	1	0.72%	0	0
3 days	6	4.35%	0	5
7 days	129	93.48%	3	75
Other	2	1.45%	1	1
Total	**138**	**100.00%**	**4**	**81**

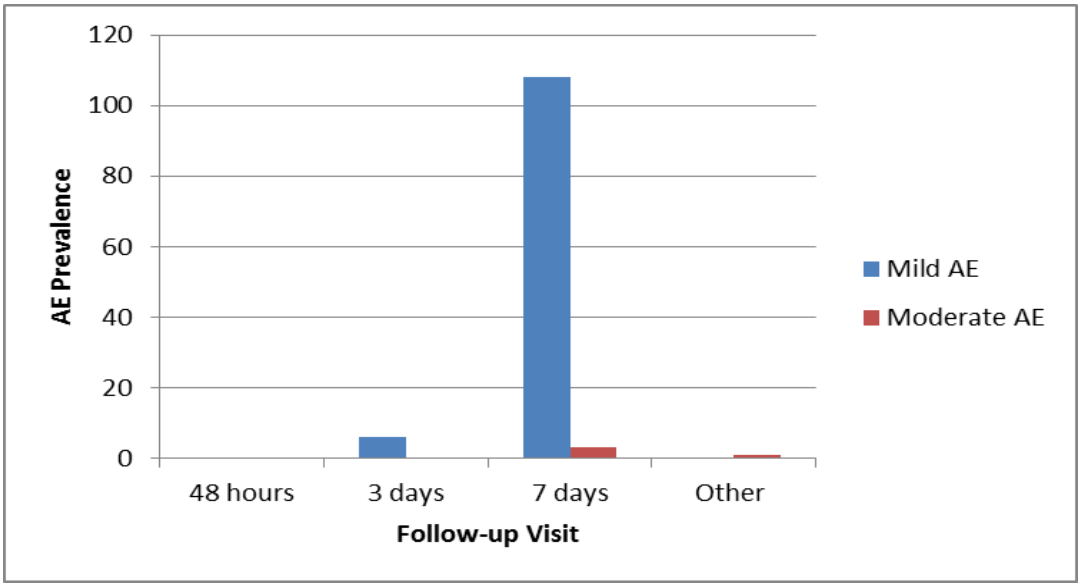


Figure 4.1: Prevalence of adverse events in the different follow-up visit

4.3.2 Mild adverse events

The prevalence of mild adverse events was 58.7%. The prevalence of the mild adverse events on the 7th Day follow up was 92.5%, 6.2% on 3rd day follow up and 1% after 7 days. Within the specific categories of the adverse events, multiple incidences were recorded; pain was most prevalent at 54%, swelling of the penis 28.3%, delayed wound healing at 6.1%. A further 5.3% of the mild cases were due to bleeding, 4.4% due to

excessive skin removed and 1.7 due to difficulty in urinating. These events of mild nature required no intervention from the clinician, the participants were counseled to continue keeping the penis in an elevated position and reassured that the mild events were expected and would resolve with time.

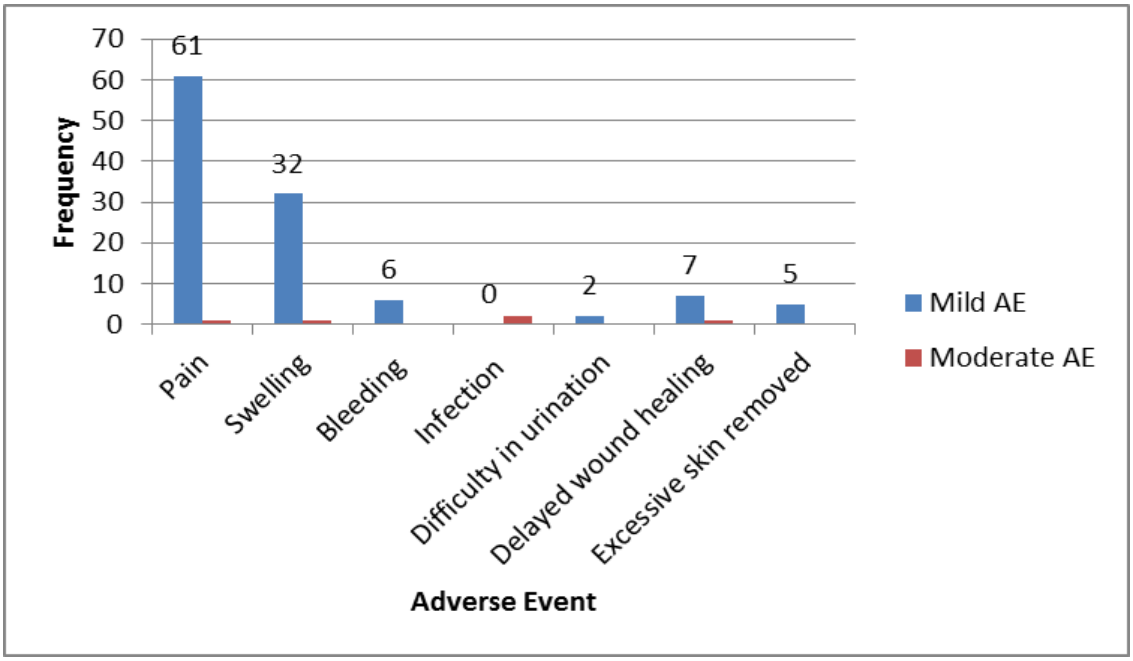


Figure 4.2: Categorized prevalence of Adverse Events

4.4 Participants Post Circumcision Practices

4.4.1 Wound care

A total of 135 (98%) participants reported having adhered to the instructions of wound care delivered during the pre-circumcision counseling at the clinic. Only 3(2%) participants reported a violation of the instructions.

4.4.2 Bathing

Out of 138 participants, 52(43%) took a shower daily after circumcision while 25(18%) showered once in two days. 47(34%) reported bathing at least once in three days whereas 4(3%) bathe after more than 3 days. Only 3(2%) participants never took a bath until the day of follow up.

4.4.3 Rest after circumcision

Majority of participants 56(41%) abstained from work for three days, a further 22(16%) took between 4 to seven days off work after circumcision. A total of 19(14%) participants resumed work after 2 days whereas only 6(4%) of the participants reported having rested for only a day. 35(25%) participants did not take rest after circumcision.

4.4.4 Removal of the wound dressing

Among the 97 participants who were circumcised surgically, 87(89%) participants removed the wound dressing after 3 days while 7(7%) participants removed the dressing after two days. Only 3(3%) participants reported having removed the dressing after the recommended three days.

4.4.5 Wearing of underpants

A total of 122 (89%) participants reported putting on underwear during the period after circumcision while 15(11) participants did not underwear.

4.4.6 Change/Washing of underpants

A total of 55(45%) reported a daily change of their underpants, 44(36%) changed the underpants after two days. 17(14%) reported changing underpants after three days while only 6(5%) did not change or wash their underpants.

Table 4.3 Comparison of Post operation practices by circumcision method.

Measure	Surgical n (%)	Pre- Pex n(%)	Total N=138 n (%)
Adherence to wound care			
No	3(3.1)	0(0)	3(2.17)
Yes	94(96.9)	41(100)	135(97.83)
Bathing			
Daily	29(29.90)	30(73.17))	59(42.75)
At least once in 3days	63((64.95)	8(19.51)	71(51.45)
> 3 days	2(2.06)	2(4.88)	4(2.90
Never bathe	3(3.09)	1(2.44)	4(2.90)
Rest			
No rest	1(1.03)	34(89.93)	35(25.36)
≤ 3 days	79(81.44)	2(4.88)	81(58.70
4-7 days	17(17.53)	5(12.20)	22(15.94)
Removal of wound dressing/Device			
2 days	7(7.22)	0(0)	7(5.07)
3 days	87(89.69)	0(0)	87(63.04)
> 3days	3(3.09)	41(100)	44(31.88)
Wearing of underpants			
No	11(11.34)	5(12.20)	16(11.59)
Yes	86(88.66)	36(87.80)	122(88.41)
Washing of underpants			
Daily	36(40.91)	19(51.35)	55(39.86)
At once in 3days	47(53.41)	15(40.55)	62(44.93
>3 days	0(0)	2(5.41)	2(1.45)
No Change	5(5.68)	1(2.70)	6(4.34)
No underpants	9(69.23)	4(30.77)	13(9.42)

4.5 Participants' Behavior and Adverse Events Awareness

4.5.1 Participant's drug and alcohol use

The Majority 110(80%) of the participants reported being non-users of alcohol, cigarette or any other drugs. A total of 27(19%) were alcohol users while only one participant used both cigarette and alcohol.

4.5.2 Sexual activity

All participants (138) reported having abstained from either sexual intercourse, masturbation or any other sexual activity between the day of circumcision and the day of follow up visit.

4.5.3 Difficulty during sexual intercourse

All the participants (138) had not engaged in any sexual activity from the day of circumcision to the day of the follow-up visit.

4.5.4 Awareness on adverse events

A total of 100(72%) reported being aware of possible adverse events following male circumcision. However, 38(28%) indicated they were not aware of any possible complication of VMMC. Among those who were aware of complications following circumcision; majority 90(65%) mentioned that they were aware of pain, 86(62%) were aware of penile infection. 76(55%) reported awareness on excess bleeding, 70(51%) on wound disruption. Majority 92 (67%) knew about penile swelling, 36(26%) pain during urination and 26(19%) excess penile sensitivity.

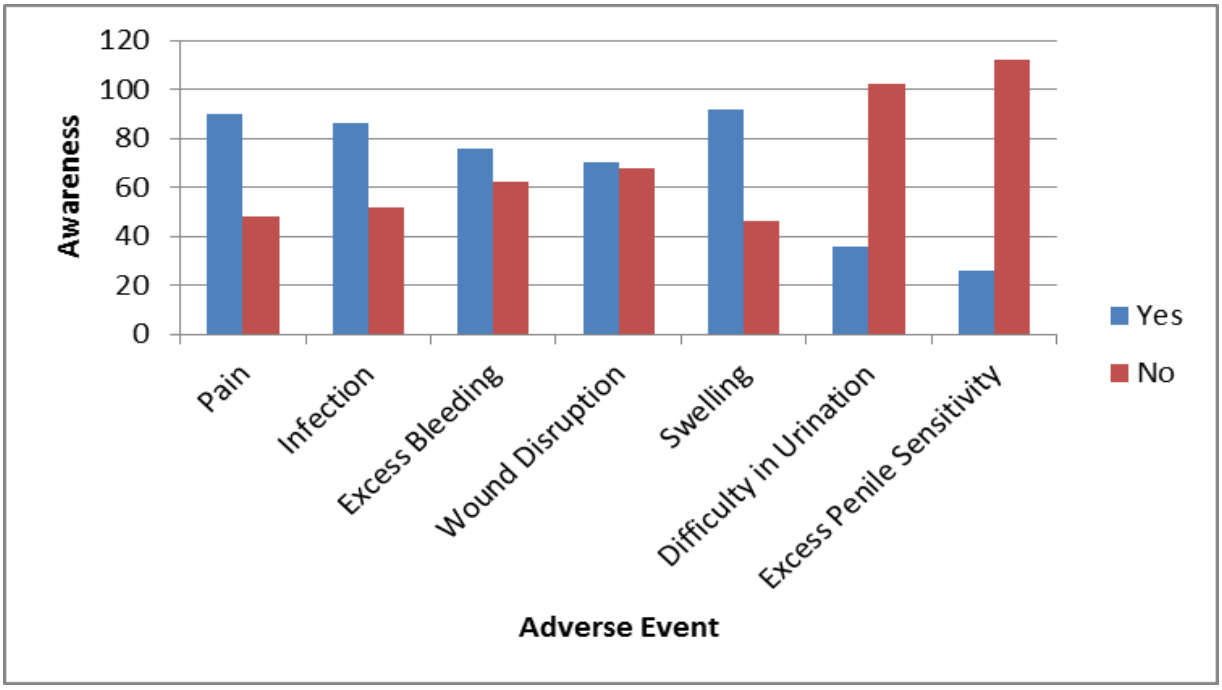


Figure 4.3: Participants'awareness of different adverse events

4.6 Family Acceptability towards VMMC.

A majority, 134(97%) reported that none of their family members opposed from them undergoing circumcision, with only 4(3%) reporting opposition from at least a family member to them going through medical circumcision. Among the 4 participants who reported family opposition, only one reported being affected negatively during the recovery.

4.7 Factors associated with moderate adverse events

Bivariate analysis was conducted to test for association between the independent variable and the moderate adverse events following circumcision. The bivariate analysis was done using fishers exact test with a significance level at or below 0.05. The variables tested included age, level of education, marital status, occupation, and distance from the hospital, mode of transport, bathing frequency, rest after VMMC, circumcision method hygiene practices, drug use and family acceptability of circumcision. The cross-tabulation categories were classified as normal (Mild events and normal healing without adverse events) against the moderate adverse. Results showed infrequent bathing after circumcision (P=0.001) and washing of underpants (P<0.001) significantly increased the chance of having a moderate adverse event. (Table 4.4)

Table 4.4 Demographic factors associated with moderate adverse events

Measure	**Normal n (%)**	**Adverse Events n(%)**	**N=138 (%)**	**P. Value (Fishers exact test)**
Age				
< 21 years	68(97.14)	2(2.86)	70(50.72)	1.000
21-30 years	56(96.55)	2(3.45)	58(42.03)	
≥ 30 years	10(100)	0(0)	10(7.25)	
Level of Education				
Other	1(50)	1(50)	2(1.45)	
None	1(100)	0(0)	1(0.72)	0.110
Primary Level	21(91.30)	2(8.70)	23(16.67)	
Secondary Level	87(98.86)	1(1.14)	88(63.77)	

Tertiary Level	25(96.15)	1(3.85)	26(18.84)	
Marital status				
Cohabiting	9(100)	0(0.00)	9(6.52)	
Married	27(100)	0(0)	27(19.57)	0.123
Never Married	97(97)	3(3)	100(72.46)	
Separated	1(50)	1(50)	2(1.45)	
Occupation				
Employed	43(97.73)	1(2.27)	44(31.88)	
Farmer	13(100)	0(0)	13(9.42)	
Student	68(98.55)	1(1.45)	69(50)	0.108
Other	10(83.33)	2(16.67)	12(8.70)	
Distance to hospital				
5-15 km	49(96.08)	2(3.92)	51(36.96)	
<5km	29(96.67)	1(3.33)	30(21.74)	0.831
>15 km	56(98.25)	1(1.75)	57(41.30)	
Mode of transport				
Car/Bus	27(93.10)	2(6.90)	29(21.01)	
Motorbike	80(98.77)	1(1.23)	81(58.70)	0.191
Walking	27(96.43)	1(3.57)	28(20.29)	

Table 4.5 Behavioral factors associated with moderate adverse events

Adherence to wound care				
No	3(100)	0(0.00)	3(2.17)	1.000
Yes	131(97.04)	4(2.96)	135(97.83)	
Bathing				
Daily	59(100)	0(0)	59(42.75)	
At least once in 3days	70(98.59)	1((1.14)	71(51.45)	0.001
> 3 days	3(75)	1(25)	4(2.90)	
Never	2(50)	2(50)	4(2.90	
Rest after circumcision				
No rest	33(94.29)	2(5.71)	35(25.36)	0.621
≤ 3 days	79(97.53)	2(2.47)	81(58.70)	
4-7 days	22(100)	0(0)	22(15.94)	
Circumcision Method				
Pre pex	39(95.12)	2(4.88)	41(29.71)	0.582
Surgical	95(97.94)	2(2.06)	97(70.29)	
Removal of wound dressing				
2 days	6(85.71)	1(14.29)	7(7.22)	

3 days	86(98.85)	1(1.15)	87(89.69)	0.197
> 3days	3(100)	0(0)	3(3.09)	
Wearing of underpants				
No	15(93.75)	1(6.25)	16(11.59)	0.393
Yes	119(97.54)	3(2.46)	122(88.41)	
Washing of underpants				
Daily	55(100)	0(0)	55(44)	0.001
At once in 3days	61(98.39)	1(1.61)	62(49.60)	
>3 days	2(100)	0(0)	2(1.60)	
No Change	3(50)	3(50)	6(4.80)	
Knowledge on VMMC Adverse Events				
No	35(92.11)	3(7.89)	38(27.54)	0.063
Yes	99(99)	1(1)	100(72.46)	
Drug use				
Alcohol	28(100)	0(0)	28(20.29)	0.582
None	106(96.36)	4(3.64)	110(79.71)	
Family non acceptability				
No	131(97.76)	3(2.74)	134(97.10)	0.112
Yes	3(75.00)	1(25)	4(2.90)	
Effect on non-acceptability				
No	134(97.81)	3(2.19)	137(99.28)	0.029
Yes	0(0)	1(100)	1(0.72)	

Factors associated with mild and moderate adverse events

Cross tabulation analysis was done incorporating both mild and moderate adverse event with a level of significance of $P \geq 0.05$ (Table 4.5). Mild and moderate events were cross tabulated against the normal category (those who had no adverse events. The independent variables tested included age, level of education, marital status, occupation, and distance from hospital, mode of transport, bathing frequency, rest after VMMC, circumcision method hygiene practices, drug use and family acceptability of circumcision. Results showed that infrequent bathing (P=0.00) and wearing of underpants ($P < 0.005$) was associated with adverse events. Clients who never changed their underpants were more likely to experience adverse events (P=0.00). The number of days rested after circumcision was also a predictor for adverse events ($P<0.031$).

Clients who reported family non-acceptability were also likely to present with adverse events (P<0.033)

Table 4.6: Demographic factors associated with mild and moderate adverse events

Measure	Moderate n(%)	Mild n(%)	Normal n (%)	Total N=138 (%)	P. Value (Fishers exact test)
Age					
<21 years	2(2.86)	41(58.57)	27(38.57)	70	0.2
21-30 years	2(3.45)	29(50)	27(46.55)	58	
≥ 30 years	0(0)	9(90)	1(10)	10	
Level of Education					
None	0(0)	0(0)	1(100)	1	0.246
Primary Level	2(8.70)	11(47.83)	10(43.48)	23	
Secondary Level	1(1.14)	54(61.36)	33(98.86)	88	
Tertiary Level	1(3.85)	14(53.85)	11(42.31)	26	
Marital status					
Cohabiting	0(0.00)	6(66.67)	3(33.33)	9	
Married	0(0)	13(48.15)	14(51.85)	27	0.174
Never Married	3(3)	59(59)	38(38)	100	
Separated	1(50)	1(50)	0(0)	2	
Occupation					
Employed	1(2.27)	25(56.82)	18(40.91)	44(31.88)	
Farmer	0(0)	4(30.77)	9(69.23)	13(9.42)	
Student	1(1.45)	44(63.77)	24(34.78)	69(50)	
Other	2(16.67)	6(50)	4(33.33)	12(8.70)	0.065
Distance to Hospital					
5-15 km	2(3.92)	31(60.78)	18(35.29)	51(100)	
<5km	1(3.33)	21(70)	8(26.)	30(100)	0.162
>15 km	1(1.75)	27(47.37)	29(50.88)	57	
Mode of transport to hospital					
Car/Bus	2(6.90)	15(51.72)	12(41.38)	29	
Motorbike	1(1.23)	43(53.09)	37(45.68)	81	0.069
Walking	1(3.57)	21(75.00)	6(21.43)	28	

Table 4.7 Behavioral factors associated with mild and moderate adverse events

Adherence to

wound care					
No	0(0.00)	2(66.67)	1(33.33)	3	1.000
Yes	4(2.96)	77(57.04)	54(40.00)	135	
Bathing					
Daily	0(0)	41(69.49)	18(30.51)	59	
At least once in 3days	1((1.14)	36(50.70)	34(47.89)	71	0.000
> 3 days	1(25)	0(0.00)	3(75)	4	
Never	2(50)	2(0.00)	2(50)	4	
Rest After circumcision					
No rest	2(5.71)	21(60)	12(34.29)	35	0.031
One Day	0(0)	5(83.33)	1(16.67)	6	
2 days	1(5.26)	6(31.58)	12(63.16)	19	
3 days	1(1.79)	29(51.79)	26(46.43)	56	
4-7 days	0(0)	18(81.82)	4(18.18)	22	
Circumcision Method					
Pre pex	2(4.88)	27(65.85)	12(29.27)	41	0.179
Surgical	2(2.06)	52(53.61)	43(44.33)	97	
Removal of wound dressing					
2 days	1(14.29)	3(42.86)	3(42.86)	7	
3 days	1(1.15)	48(55.17)	38(43.68)	87	0.222
> 3days	0(0)	1(33.33)	2(66.67)	3	
Wearing of underpants					
No	1(6.25)	14(87.50)	1(6.25)	16	0.005
Yes	3(2.46)	65(53.28)	54(44.26)	122	
Washing of underpants					

Daily	0(0)	36(65.45)	19(34.55)	55	0.000
At once in 3days	1(1.61)	28(45.16)	33(53.23)	62	
>3 days	0(0)	1(50)	1(50)	2	
No Change	3(50)	1(16.67)	2(33.33)	6	
Awareness on VMMC Adverse Events					
No	3(7.89)	23(60.53)	12(31.58)	38	0.068
Yes	1(1)	56(56)	43(43)	100	
Drug use					
Alcohol	0(0)	15(53.57)	13(46.43)	28	0.607
None	4(3.64)	64(58.18)	42(38.18)	110	
Family non acceptability					
No	3(2.74)	76(56.72)	55 (41.04)	134	0.033
Yes	1(25)	3(75.00)	0(0.00)	4	
Effect on non-acceptability					
No	3(2.19)	79(57.66)	55(40.15)	137(99.28)	0.029
Yes	1(100)		0(0)	1(0.72)	

4.8 Clients' Level of Satisfaction

4.8.1 Satisfaction with the VMMC service

A majority, 122(88%) of the participants reported being very satisfied with the circumcision procedure and the results while 16(12%) were satisfied with the circumcision procedure and the results.

4.8.2 Satisfaction with the post-operative care service

A total of 110(80%) of the participants reported being very satisfied with the post-operative services they received at faces clinic. 28 indicated they were satisfied with the post-operative services.

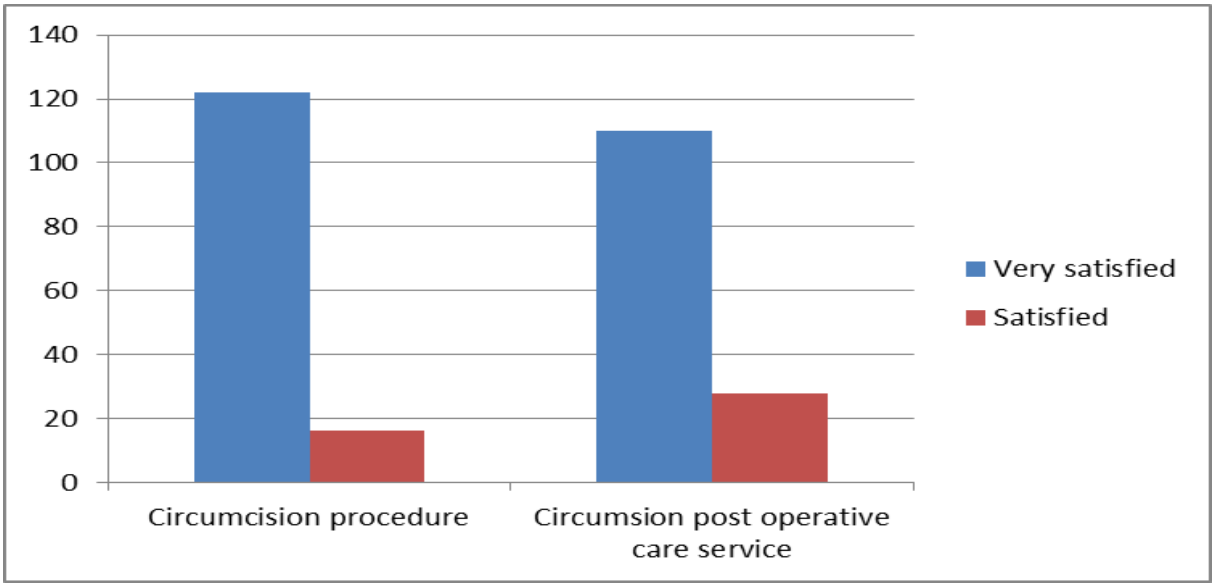


Figure 4.4 Participants level of satisfaction

4.8.3 Recommendation of VMMC to peers

A total of 135 participants indicated that they would recommend medical male circumcision to their uncircumcised peers. Only 3 participants were not sure they would recommend circumcision until when they were completely healed.

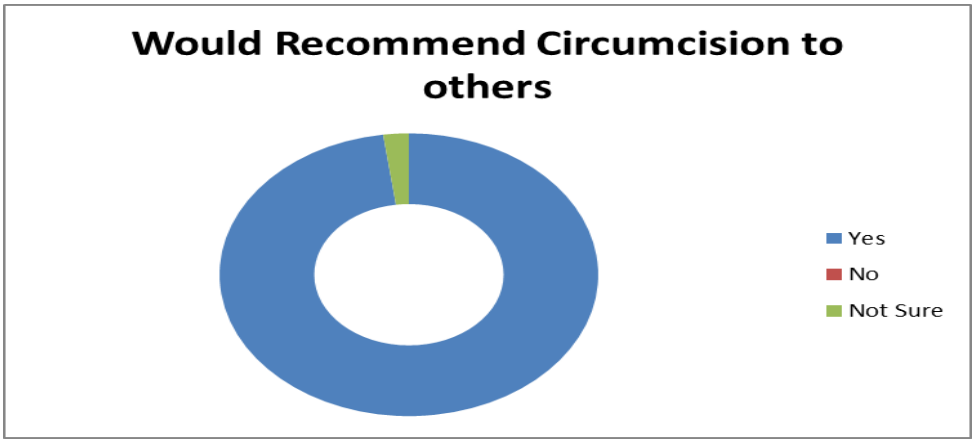


Figure 4.5: Participants recommendation of VMMC to others.

CHAPTER FIVE

DISCUSSION

The main aim of this study was to determine prevalence and factors associated with Adverse Events following Voluntary Medical Male Circumcision among clients within the FACES program at Migori County Hospital. This study showed low rates of adverse events among men receiving free voluntary medical male circumcision at Migori District Hospital. This study found no severe adverse events, 4/138 (2.9%) moderate adverse events and 81/138 (58.6%) mild adverse events among men receiving VMMC in Migori district hospital during the study period. The study showed that moderate adverse events were associated with the frequency of bathing after circumcision and the wearing of underpants. The findings on adverse events prevalence are similar to those of the three Randomized Clinical Trials conducted in South Africa, Kenya and Uganda which registered moderate and severe adverse events from the range of 1.5-3.6%. (Auvert et al., 2005; Bailey et al., 2007; R. H. Gray et al., 2007). Moreover, studies evaluating the safety of VMMC in program and service delivery settings in Sub-Sahara have reported AE rates of between 0.5%- 1.3%. (Herman-Roloff et al., 2012; Ngo & Obhai, 2012; Phili et al., 2014).

This study found out that having a moderate adverse event significantly differed with the frequency of bathing after circumcision and the wearing of underpants. Regular bathing helps remove the excess outermost layer of the skin, consisting of keratinized cells thus limiting the risk of infections. It also maintains skin flexibility, smoothness and barrier integrity which is crucial in protecting against the entry of pathogens and reducing discomfort, and pain(Mrdjenovich & Fleck, 2011) . Wearing of underpants is recommended to VMMC clients to help keep the penis in an elevated position by lifting the dorsal surface against the abdomen(WHO/UNAIDS/JPIEGO, 2008) . This eases pressure and allows free blood flow hence reducing cases of swelling and hematoma on the penis(Rogers et al., 2013). However, the study did not find association between the moderate adverse events and various other factors related participants such as participant

age, occupation, circumcision procedure, participants' behavior; this was mainly because of the low rates of adverse events.

The low prevalence of adverse events within the faces program can be attributed to three major factors: facility-related factors, provider-related factors and client-related factors. Within the facility, the availability of adequate medical supply improves the safety of VVMC (Mattson et al., 2004). The WHO further emphasized the need for adequate medical equipment and supplies for effective and safe delivery of VMMC (WHO/UNAIDS, 2007a). The FACES program has adequate medical equipment to provide VMMC, in addition, through the PEPFAR funding, medical supplies are adequately provided.

Secondly, the relationship between provider's years of experience on the rates of adverse events has been well documented; the rates of Adverse Events (AE) in VMMC decrease with increased years of experience (Herman-Roloff et al., 2012). The FACES VMMC site in Migori had adequate personnel that includes three qualified clinical officers dedicated to VMMC. All the clinical officers who performed VMMC surgeries on the participants had over 5 years' experience of actively performing circumcision surgeries. The program also has adequate VMMC support staff in the VMMC clinic.

Most of the participants (97.8%) reported having adhered to wound care practices. Low AE and faster wound healing are mainly due to the adequate delivery of instructions on wound care and participants adherence to the would care practices(Phili et al., 2014). More than half 71(51.5%) bathed at least once in 3 days, 59(42.8%) daily and 8(5.8%) either bather after 3 days or never bathed at all. Failure to take a birth was associated with an adverse event. There was no difference in adverse rates among those who opted for surgical circumcision. Most participants 34(82.9%) who were circumcised through pre-pex did not rest compared 73 (75.3%) who rested for at least three days among those who had a surgical operation. Pre-pex method is thus suitable for men actively involved in full-time jobs without leave from work for over two weeks. Majority 87(89.9%) removed their wound dressing within 3 days, as instructed and also majority 122(88.4%) wore underwear after circumcision with almost half 62(49.6%) washing them once in 3 days and 55(44%) washed them daily. The adherence to wound care and hygiene

practices may have contributed to low AE rate AE rates reduced the time of wound healing.

Most participants (72%) were aware of possible Adverse Events of VMMC. The awareness of AE is crucial in enabling the adherence to post-operative wound care instructions and greatly improves the outcome of circumcision. Among those who reported awareness on VMMC, the majority were aware of penile swelling (67%), pain (65%), and infection (62%). Participants had least knowledge on excessive penile sensitivity (19%) and Difficulty in urination (26%). The lack of awareness of the latter may be attributed to the fact it is an adverse event that is rarely mentioned even during pre-surgery counseling. It was encouraging for HIV prevention that most participants circumcised were young males, who were still single and most (80%) respondents did not use any drugs, alcohol or cigarettes.

Other alternative factors that might contribute to the low complication rate in this study were the use of the guided forceps technique and pre pex device. A study in Nigeria that evaluated adverse events related to male circumcision showed high complication rates (43%) attributed the high complication rates to their techniques (plastic bell method and traditional method) that were performed by poorly trained performers(Osuigwe, 2004). Compared with these two studies, the guided forceps method used in this study might have been easier to learn and perform by mid-level providers. The PrePex device has been found to safe and effective for nonsurgical adult male circumcision without anesthesia or sterile settings and may be useful in mass circumcision programs(Tshimanga et al., 2016)

It was noted that majority of respondents 131 (97.8%) in this study reported no objection from their family on them getting circumcised. Additionally, almost all 136(98%) of those who were interviewed after circumcision indicated that they would recommend circumcision to other who were not circumcised. This is consistent with the findings of (Frajzyngier et al., 2014) who reported that 99 percent of men would recommend VMMC to a friend. The high acceptability is encouraging and is expected to continue owing to continued efforts to scale up from the ministry and other NGOs in male circumcision consortium.

Men receiving VMMC service in Migori district hospital were satisfied with their circumcision. All the participants reported satisfaction with the procedure while majorities (99%) were also satisfied with the postoperative care and services delivered at the clinic. This finding is consistent with those who reported 99% satisfaction rate also in Marie Stopes international mobile VMMC site in Nyanza region Kenya(Ngo & Obhai, 2012). This indicates the impressive quality of services delivered by FACES sites in Migori. High satisfaction will also help in spurring acceptability as noted by (Westercamp & Bailey, 2007).

The results of this study indicate that the current prevalence of adverse events is low and within acceptable rates. The results show that the majority of those seeking VMMC are youth, who are not sexually active, which is encouraging to the policy makers who have advocated for the implementation of mass circumcision in Nyanza to avert new incidences of HIV. The low adverse event prevalence and high satisfaction is therefore encouraging and will give confidence to continued roll out and scale-up of VMMC in Nyanza province.

There were limitations in this study. This was a cross-sectional study hence it was difficult to make a causal inference. The study considered adverse events and factors only among those who came back for the follow-up visit. This study was not able to determine loss to follow up and also the rates of adverse events among those who were not able to come back for review after one week as required by the providers. The study did not look at psychological factors and their effects on adverse events, this may be an area for future research. The study also was limited to males over the age of 18 years thus we not able to compare rates and correlates of Adverse events among teenagers younger than 18 years who may have undergone circumcision.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

1. This study has determined that the current prevalence of adverse events among men receiving VMMC in Migori County are at 2.9% for the moderate adverse event and 58.6%. The findings are consistent with findings from studies on Adverse Events done among VMMC clients.

2. The study also shows that lack of frequency bathing among those circumcised and not wearing underpants after circumcision was associated with adverse events. This underlines the importance of hygiene post-circumcision.

3. The study further demonstrated high satisfaction among the participants both on the circumcision procedure and the post-operative services provided at the Migori county hospital. These results imply that VMMC can be delivered safely and effectively delivered in those communities that do not circumcise their boys/men traditionally. The findings indicate that the VMMC services in Migori county hospital are delivered efficiency and safely.

6.2 Recommendation.

1. There is a need for continuous active monitoring of adverse events and also an emphasis on participant adherence to post-circumcision instructions on wound care.

2. As the Ministry of Health in collaboration with male circumcision implementation partners in Kenya continue to provide VMMC more emphasis should be placed on proper and adequate counseling on post-operative wound care.

3. VMMC service provision in Migori county should continue since the services can be delivered safely and effectively with high client satisfaction in this setting.

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APPENDICES

Appendix 1: Ethical Clearance

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840 - 00200 NAIROBI - Kenya
Tel: (254) (020) 2722541, 254 (020) 2713349, 0722-205901, 0733-400003 Fax (254) (020) 2720030
Email: director@kemri.org info@kemri.org Website:www.kemri.org

KEMRI/RES/7/3/1 **September 28, 2015**

TO: **MR. TIMOTHY KIPKOSGEI,**
PRINCIPAL INVESTIGATOR

THROUGH: **THE DIRECTOR, CMR,**
NAIROBI

Forwarded on 02/10/2015

Dear Sir,

RE: **KEMRI/SERU/CMR/P00027/3137 (*RESUBMISSION OF INITIAL SUBMISSION*): RATES AND CORRELATES OF POST-OPERATIVE ADVERSE EVENTS FOLLOWING VOLUNTARY MEDICAL MALE CIRCUMCISION AMONG CLIENTS WITHIN FACES PROGRAM IN MIGORI SUB-COUNTY HOSPITAL. (*VERSION 1.8 DATED 16TH SEPTEMBER, 2015*)**

Reference is made to your letter dated 17th September, 2015. KEMRI/Scientific and Ethics Review Unit (SERU) acknowledges receipt of the revised study documents on 22nd September, 2015.

This is to inform you that the Committee notes that the issues raised during the 243rd A meeting of the KEMRI/Scientific and Ethics Review Unit (SERU) held on 8th September, 2015 have been adequately addressed.

Consequently, the study is granted approval for implementation effective this day, **28th September, 2015** for a period of one year. Please note that authorization to conduct this study will automatically expire on **September 27, 2016.** If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **August 17, 2016**.

You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advise SERU when the study is completed or discontinued.

You may embark on the study.

Yours faithfully,

MR. AMBROSE RACHIER,
CHAIRMAN,
KEMRI/ETHICS REVIEW COMMITTEE

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200 NAIROBI - Kenya
Tel: (254) (020) 2722541, 254 (020) 2713349, 0722-205901, 0733-400003 Fax (254) (020) 2720030
Email: director@kemri.org info@kemri.org Website: www.kemri.org

KEMRI/RES/7/3/1 **September 14, 2016**

TO: **TIMOTHY KIPKOSGEI**
PRINCIPAL INVESTIGATOR

THROUGH: **THE DIRECTOR, CMR**
NAIROBI

forwarded 22/9/16

Dear Sir,

RE: **KEMRI/SERU/CMR/P00027/3137(*REQUEST FOR ANNUAL RENEWAL)* RATES AND CORRELATES OF POST-OPERATIVE ADVERSE EVENTS FOLLOWING VOLUNTARY MEDICAL MALE CIRCUMCISION AMONG CLIENTS WITHIN FACES PROGRAM IN MIGORI SUB-COUNTY HOSPITAL**

Thank you for the continuing review report for the period **28 September 2015** to **9 August 2016.**

This is to inform you that during the 255th Committee A meeting of the KEMRI Scientific and Ethics Review Unit (SERU) held on 13 September, 2016, the Committee **conducted the annual review and approved** the above referenced application for another year.

This approval is valid from **28 September, 2016** through to **27 September, 2017**. Please note that authorization to conduct this study will automatically expire on **27 September, 2017**. If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the **SERU** by **17 August, 2017.**

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SERU for review prior to initiation.

Yours faithfully,

FOR:
DR. EVANS AMUKOYE,
ACTING HEAD
KEMRI/SCIENTIFIC AND ETHICS REVIEW UNIT

Appendix II: Approval of Proposal and Supervisors

JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY
DEAN
SIGN:
SCHOOL OF PUBLIC HEALTH

0721131579

OFFICE OF THE GRADUATE
RECEIVED
03 DEC 2015
PROGRAM COORDINATOR
ITROMID

JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY

DIRECTOR, BOARD OF POSTGRADUATE STUDIES

P.O. BOX 62000
NAIROBI – 00200
KENYA
52711/52181-4
Email: director@bps.jkuat.ac.ke
602225

TEL: 254-067-

MOBILE: 0708-

REF: JKU/ 2/11/ TM309-1141/2013

4nd November, 2015

Mr. Kipgosgei Timothy Kiplagat
C/o SPH
JKUAT

Dear Mr. Kipkosgei

RE: APPROVAL OF MSc. RESEARCH PROPOSAL AND SUPERVISORS

Kindly note that your research proposal entitled: **"(Rates and correlates of post operative adverse events following voluntary medical male circumcision among clients within faces program in Migori Sub County Hospital"** has been approved. The following are your approved supervisors:-

1. Prof. Elizabeth Bukusi
2. Dr. Peter Mwaniki

Yours sincerely

PROF. MATHEW KINYANJUI
DIRECTOR, BOARD OF POSTGRADUATE STUDIES

Copy to: Dean, SPH
rl/

Appendix III: Interview Questionnaire

RATES AND CORRELATES OF POST OPERATIVE ADVERSE EVENTS FOLLOWING VOLUNTARY MEDICAL MALE CIRCUMCISION AMONG CLIENTS WITHIN FACES PROGRAM IN MIGORI SUB COUNTY HOSPITAL

Participant's Identification Number _____ Date of interview _____

Age at Last Birthday_____

Facility/ site name_____

Sub- County_____ County_____

PART A

DEMOGRAPHICS

1. **Which one of the following visits are you attending?**
    1. VMMC Surgery
    2. 48hr
    3. 3 day
    4. 7 day
    5. Other, please specify_____

2. **Where did you receive the VMMC Service**
    1. At one of the health facilities supported by FACES
    2. During FACES circumcision outreach campaigns
    3. At one of the FACES VMMC mobile clinics

3. **What is your level of school education?**
    1. None
    2. Primary Level
    3. Secondary level
    4. Tertiary level
    5. Other_____

4. What is your marital status?

1. Never Married
2. Married
3. Separated
4. Widowed
5. Divorced
6. Cohabiting

5. What do you do for a living?

1. Employed
2. Self-employed/ Business
3. Fisherman
4. Farmer
5. Student
6. Other_____

6. Were you diagnosed with any of the following disease before you were circumcised?

1.	Bleeding disorder	YES	NO
2.	Hypertension	YES	NO
3.	Diabetes	YES	NO
4.	Anemia	YES	NO
5.	Any other disease_____		

7. How would you describe the distance traveled to clinic from your home?

1. Less than 5 km,
2. 5 km
3. More than 5 km

8. What mode of transportation do did you use to get to the health facility after you were circumcised?

1. Walking
2. Car or Bus,
3. Motorcycle or Bicycle,
4. Other_____

9. Were you given any medicine to take or apply to the wound after circumcision

1. Yes
2. No

If yes

10. Did you use the medicine as prescribed?

1. Yes
2. No

11. How regularly do you bathe since you were circumcised?

1. Daily
2. Once in two days
3. Once in three days
4. Other _____

12. How many days of rest did you have after circumcision

1. No rest
2. One day
3. Two days

4. Three days
5. Other_____

13. After how many days from the day of surgery did you remove the wound dressing?

1. One day
2. Two days
3. Three days
4. Other_____

14. Have you been wearing any underpants since the time you were circumcised?

1. Yes
2. No

If yes

How regularly have you been changing and washing the pants

1. Daily
2. One in two days
3. Once in three days
4. Other_____

15. Have you engaged in any of the following sexual activity since the day of circumcision?

1. Sexual intercourse
2. Masturbation
3. Other _____

16. Do you know of any possible complications that you may experience after circumcision?

1. Yes
2. No

If yes

Do you know of the following?

1. Excessive pain
2. Infection
3. Bleeding
4. Would disruption
5. Swelling
6. Difficulty in urination
7. Excessive penis sensitivity

17. Do you use any of the following?

1. Alcohol
2. Cigarette
3. Other drugs_____

18. Do you know of anyone within your family or within the neighbourhood who was against your circumcision?

1. Yes
2. No

If yes

If yes, has it affected you negatively during the recovery?

Yes

No

PART B: SATISFACTIONS WITH VMMC

19. How satisfied are you with the complete circumcision procedure and the result?

1. Very satisfied
2. Somewhat satisfied
3. Very dissatisfied
4. Somewhat dissatisfied

20. How satisfied is post-operative care services you received at the Clinic?

1. Very satisfied
2. Somewhat satisfied
3. Very dissatisfied
4. Somewhat dissatisfied

21 Would you recommend male circumcision to others?

1. Yes
2. No
3. Not sure

23. Have you experienced any difficulty during sexual intercourse?

1. Yes
2. No
3. NA(Never had sexual intercourse after circumcision)

If yes Please specify the challenge

1. Penile pain and discomfort
2. Erectile dysfunction

3. Premature ejaculation
4. Excessive penile sensitivity
5. Other_____

PHYSICAL EXAMINATION TOOL

Adverse event	**Description**	**Severity**	√
B. < 1 month after surgery			
Pain	3 or 4 on pain scale	Mild	
	5 or 6 on pain scale	Moderate	
	7 on pain scale	Severe	
Excessive bleeding	Dressing soaked through with blood at a routine follow-up visit	Mild	
	Bleeding that requires a special return to the clinic for medical attention	Moderate	
	Bleeding that requires surgical re-exploration	Severe	
Excessive skin removed	Client concerned, but there is no discernable abnormality	Mild	
	Skin is tight, but additional operative work not necessary	Moderate	
	Requires re-operation or transfer to another facility	Severe	
Insufficient skin removed	Foreskin partially covers the glans only when extended	Mild	
	Foreskin still partially covers the glans and re-operation is required	Moderate	
Swelling or haematoma	More swelling than usual, but no significant discomfort	Mild	
	Significant tenderness and discomfort, but surgical re-exploration not required	Moderate	
	Surgical re-exploration required	Severe	
Damage to the penis	Mild bruising or abrasion, not requiring treatment	Mild	
	Bruising or abrasion of the glans or shaft of the penis requiring pressure dressing or additional surgery	Moderate	
	Part or all of the glans or shaft of the penis severed	Severe	
Infection	Erythema more than 1 cm beyond incision line	Mild	
	Purulent discharge from the wound	Moderate	
	Cellulitis or wound necrosis	Severe	
Delayed wound healing	Healing takes longer than usual, but no extra treatment necessary	Mild	
	Additional non-operative treatment required	Moderate	
	Requires re-operation	Severe	

Appearance	Client concerned, but no discernible abnormality	Mild	
	Significant wound disruption or scarring, but does not require re-operation	Moderate	
	Requires re-operation	Severe	
Problems with urinating	Transient complaint that resolves without treatment	Mild	
	Requires a special return to the clinic, but no additional treatment required	Moderate	
	Requires referral to another facility for management	Severe	

C. ≥ 1 month after surgery			
Infection	Erythema more than 1 cm beyond incision line	Mild	
	Purulent discharge from the wound	Moderate	
	Cellulitis or wound necrosis	Severe	
Delayed wound healing	Healing takes longer than usual, but no extra treatment necessary	Mild	
	Additional non-operative treatment required	Moderate	
	Requires re-operation	Severe	
Appearance	Client concerned, but no discernible abnormality	Mild	
	Significant scarring or other cosmetic problem, but does not require re-operation	Moderate	
	Requires re-operation	Severe	
Excessive skin removed	Client concerned, but there is no discernible abnormality	Mild	
	Skin is tight, but additional operative work not necessary	Moderate	
	Requires re-operation or transfer to another facility	Severe	
Insufficient skin removed	Foreskin partially covers the glans only when extended	Mild	
	Foreskin still partially covers the glans and re-operation is required to correct	Moderate	
Torsion of penis	Torsion is observable, but does not cause pain or discomfort.	Mild	
	Causes mild pain or discomfort, but additional operative work not necessary	Moderate	
	Requires re-operation or transfer to another facility	Severe	
Erectile dysfunction	Client reports occasional inability to have an erection	Mild	
	Client reports frequent inability to have an erection	Moderate	
	Client reports complete or near complete inability to have an erection	Severe	
Psychobehavioural problems	Client reports mild dissatisfaction with the circumcision, but no significant psychobehavioural consequences	Mild	
	Client reports significant dissatisfaction with the circumcision, but no significant psychobehavioural	Moderate	

	consequences		
	Significant depression or other psychological problems attributed by the client to the circumcision	Severe	

Appendix IV- Interview Questionnaire (Luo Version)

OBOKE MAR III: OBOKE MAR PENJO

GIGO MA OTUDORE GI BEDO MAKARE MAR JOGO MAYUDO NYANGE MAG CHUO E MIGAO MAR FAMILY AIDS CARE AND EDUCATION SERVICES (FACES) E ALUORA MAR NYANZA

Namba mar jachiwre_____ Odiochieng' mar penjo

_____

Higa_____

Nying osiptal_____

-Kaonti matin_____ Kaonti_____

DEMOGRAPHICS

1. En mane kuom limbe gi ma ibire kawuono

1. Yeng'o mar tero joma chuo nyange
2. Seche 48
3. Ndalo 3
4. Ndalo 7
5. Mamoko, ndiki_____

2. Ne otim ni nyange kar kanye ?

1. E achiel kuom osiptende ma isiro gi FACES
2. E kinde mar keyo chenro mar nyange e gweng'
3. E achiel kuom klinik mar FACES ma iwuothogo.

3. Rang'iny mari mar somo en mane?

1. Onge

2. Kind klass1 - 8
3. Kind klass 9 - 12
4. Kar tiegruok
5. Mamoko_____

4. Chal ni mar keny en ang'o?

1. Pok ikendo
2. isekendo
3. Uweru/jaherani otho
4. Idak gi jahera to pok ukendoru

5. Chal ni mar tich en ang'o?

1. Ondika t
2. Andikora kenda
3. Jalupo/Japur
4. Aonge tich
5. Japuonjre

6. Bende oseyudi gi tuoche ma oluwo gi?

1. Tuo mar remo chwer mang'eny	Eeh	Ooyo
2. Tuo mar 'Hypertension'	Eeh	Ooyo
3. Tuo mar sukari	Eeh	Ooyo
4. Tuo mar aremo (Anemia)	Eeh	Ooyo

7. Inyalo wacho ang'o kuom bor ma iwuotho nyaka e klinik?

1. Tin ne kilomita 5
2. Kilomita 5
3. Ng'eny ne kilomita 5

8. En yoo mane mar wuoth mane itiyo godo mondo ichopi e klinik?

1. Wuotho gi tielo
2. Mtoka/Nyamburko
3. Apiko kata ndiga
4. Mamoko_____

9. Bende ne omiyi yath moro amora bang' nyange?

1. Eeh
2. Ooyo

Ka eeh,

10. Bende ne ikawo yath kaka ondiki?

1. Eeh
2. Ooyo

11. Nyaka ne teri nyange iluokori mang'eny machal nade?

1. Pile
2. Dichiel kuom ndalo ariyo
3. Dichiel kuom ndalo adek
4. Mamoko_____

12. Ne in gi ndalo adi mag yweyo bang' nyange?

1. Onge yweyo
2. Odiochieng' achiel
3. Ndalo ariyo
4. Ndalo adek
5. Mamoko_____

13. Bang' ndalo adi bang' nyange mane igoloe bandej?

1. Odiochieng' achiel
2. Ndalo ariyo
3. Ndalo adek
4. Mamoko_____

14. Bende isebedo kirwako siruaru maiye nyake ne teri nyange?

1. Eeh
2. Ooyo

Ka eeh

Isebedo kiwilo kendo iluoko siruaru maiye nyadidi?

1. Pile
2. Dichiel kuom ndalo ariyo
3. Dichiel kuom ndalo adek
4. Mamoko_____

15. Bende iseriwore kata timo timbe mag riwruok e ringruok achiel moluwogi nyaka ne teri nyange?

1. Riwruok e ringruok achiel
2. Rwanyruok (masturbation)
3. Mamoko _____

16. Bende ing'eyo moro amora kuom rach manyalo wuok/bet nikech nyange?

1. Eeh

2. Ooyo

Ka eeh

Bende ing'eyo kuom moluwogi?

1. Lit mathoth
2. 'Infection'
3. Chuer mar remo
4. Wuorruok mar adhola
5. Kuot
6. Chandruok e olo pi/layo
7. Yunga bedo ma 'sensitive'

17. bende itiyo gi moro amora kuom magi?

1. Kong'o
2. Ndawa
3. Yedhe mamoko_____

18. Bende ing'eyo ng'at moro amora e odu kata e gweng'u mane ok dwar ni mondo teri nyange?

1. Eeh
2. Ooyo

Ka eeh

Ka eeh, dibed ni osechwanyi e yo marach kichango?

Eeh

Ooyo

KARE MAR B: MOR GI NYANGE

19. Imor maromo nade gi yore mag nyange tee gi duoko ne?

1. Amor ahinya
2. Amor matin
3. Ok amor ahinya
4. Ok amor matin

20. Imor maromo nade gi rit mar bang' nyange mane iyudo e klinik?

1. Amor ahinya
2. Amor matin
3. Ok amor ahinya
4. Ok amor matin

21Bende inyalo puodho nyange ne joma moko?

1. Eeh
2. Ooyo
3. Aonge gi adier

23. Bende isewinjo /bedo gi chanduok moro amora e seche ma iriwori e ingruok achiel??

1. Eeh
2. Ooyo
3. Pok ariwora ringruok achiel nyaka ne tera nyange

Ka eeh, ler ane kuom chanduok

1. Lit mar duong'ni
2. Duong'ni ok tii
3. Golo pi nyodo awiye awiye

4. Excessive penile sensitivity
5. Mamoko_____

Appendix V: Informed Consent Form

TITLE: RATES AND CORRELATES OF POST OPERATIVE ADVERSE EVENTS FOLLOWING VOLUNTARY MEDICAL MALE CIRCUMCISION AMONG CLIENTS WITHIN FACES PROGRAM IN MIGORI SUB COUNTY HOSPITAL

INVESTIGATORS

NAME	INSTITUTION	UNIT
Timothy Kipkosgei	JKUAT-ITROMID	Principal investigator
Prof Elizabeth Bukusi	KEMRI	Supervisor
Dr Peter Mwaniki	JKUAT	Supervisor

PURPOSE

My Name is _____and I am conducting a study to find out the occurrence of problems arising from male circumcision and the causes that contribute to these problems. Male circumcision has been shown to reduce the chance of getting HIV infection, however as you may have been told during counseling, you should still protect yourself as you can still get HIV even if you have been circumcised. Concerns about the safety of Medical Male circumcisions are sometimes discourage men from getting circumcised. This study seeks to investigate safety and the factors that contribute to complications during male circumcision within Family AIDS Care and Education Services Voluntary Medical Male Circumcision program. The study is important for officers in charge of the circumcision services within FACES to help improve the quality standards of safety of the circumcision program. You can ask any questions you have at any time.

Being in the study is voluntary and you can decide to withdraw at any time without any penalties and you still will be entitled access to medical services within the FACES program: This consent form describes the study and the risks involved. Once you

understand the study, and if you agree to take part, you will be asked to sign on this form. You may decide not to answer any question that you feel uncomfortable with.

STUDY PROCEDURES

Upon your agreement to take part in this study, I will ask questions to decide if you are eligible. I will then interview you on many things that are related to your circumcision service that you were offered at the clinic. The questions will also ask about your satisfaction of the services offered. I will write down the information as the interview goes on. If there is any question you will be uncomfortable providing answer you will be free to do so. The interview will take about 20 minutes. After that you will proceed to the examination room where a clinician will perform physical examination of the wound to check the progress of your healing and if there are any problems. The clinician will record the results of the examination which will be used in this study.

WHO WILL TAKE PART IN THIS STUDY?

The study group will include men recently circumcised and are attending their follow up visit as required by the clinician or any other follow up visit after undergoing circumcision within the FACES program. We will interview 138 men.

BENEFITS

The study will not offer any direct benefits to you, nevertheless the information from the study will help the Health workers to improve the quality standards and enhance safety of the services provided for the benefit of future clients accessing the services. This will help improve acceptability of VMMC. The study will also provide information that will inform and guide policies in these appropriate areas by providing evidence on current activities including: prevalence of adverse events and other complications and the factors that contribute to problems in circumcision

RISK

There is no major risk of participating in this research. Some people may be uncomfortable providing details about themselves for fear of loss of privacy. To ensure

privacy, the interview and physical examination will be conducted in a private section, moreover, no identifiable information will be collected, and codes will be used instead. Additional measures have been put in place to safeguard your privacy and confidentiality as described in the next section.

DATA SECURITY AND CONFIDENTIALITY

All the information gathered by the researcher will be used in confidence for the only purpose of this research only. All interviews will be conducted face-to-face in a private room or area to ensure that other people do not hear the information you give. Your full names will not appear in the forms we fill out your responses. Data will be kept in folders, which will be locked in cabinets for storage throughout the study period. Computer documents will have passwords only accessible to the researcher. The strict data management procedures are intended to ensure confidentiality of the study subjects. The data will be stored for a maximum period of 5 years after the time of collection

COSTS TO YOU

There is no cost to you for participating in this study.

NEW FINDINGS

Results will be shared with the FACES clinics, Ministries of Health in the county, before being published in scientific journals and magazines.

PROBLEMS AND QUESTIONS: If you have any questions about this study, you can contact the Principal Researcher, Timothy Kipkosgei at Mobile 072113579, Email, timokips@gmail.com **YOUR RIGHTS AS A STUDY PARTICIPANT**: This research has been reviewed and approved by the Scientific and Ethical Review Unit of the Kenya Medical Research Institute (KEMRI).

If you have any questions about your rights as a research participant you may contact the secretary of the KEMRI Scientific and Ethical review unit (a team of professionals who review the research to protect your rights) at the Secretary, KEMRI Ethics Review

Committee, P.O Box 54840-00200, Nairobi; telephone numbers 020-2722541, 0717719477, 0722205901, 0733400003; Email address seru@kemri.org

Your statement of consent and signature: If you have read the informed consent, or had it read and explained to you, and you understand the information and voluntarily agree to join this study, please carefully read the statements below and think about your choice before signing your name or making your mark below. No matter what you decide, it will not affect the normal care you would receive:

- I have been given the chance to ask any questions I may have and I am content with the answers to all of my questions.
- I know that my records will be kept confidential and that I may leave his study at any time.
- I have been told the name, phone number and address of the person to contact in case of an emergency, and this information has also been given to me in writing.
- I agree to take part in this study as a volunteer, and will be given a copy of this informed consent form to keep.

_____

_____

Participant name Participant signature and date

_____

_____

Name of Researcher Signature and date

Thumb Print

_____

_____

Name of Witness Signature and date

NOTE: You are not giving up any legal rights by signing this informed consent document

Appendix VI: Informed Consent Form (Luo Version)

THORORO:

GIK MA OTUDORE GI NGIMA MAKARE MAR JOGO MAYUDO NYANGE E CHENRO MAR FAMILY AIDS CARE AND EDUCATION SERVICES (FACES) E ALUORA MAR NYANZA(CHECK UPPER CORRECTIONS)

JOTIM NONRO

NYING	**MIGAO**	**TICH**
Timothy Kipkosgei	JKUAT-ITROMID	Jatim nonro maduong'
Prof Elizabeth Bukusi	KEMRI	*Jang'i*
Dr Peter Mwaniki	JKUAT	*Jang'i*

GIMA OMIYO

. Nyinga en_____ kendo atimo ro mondo afweny chandruoge mawuok kaluwore gi nyange mar joma chuo kod gigo mag jotuo Ma otenore kod chandruoge gi (chalre). Nyange mar joma chuo osenyisore ni duoko chien thuolo mar gamo kute mag ayaki, kata kamano, kaka dipo ni osenyise e kinde mag hocho, ber ka imedo ritori nikech, ber ka imedo ritori nikech pod inyalo gamo kute mag ayaki kata ka oseteri nyange. Paruok ewi nyange makare seche moko en rageng' ne yie/rwako nyange. Nonoroni rango matut bedo makare to kod yore makelo chachni e kinde mar nyange ei chenro mar Family Aids Care and Education Services Nonoroni duong' ne apisa ma ochung'ne yore mag nyange ei FACES mondo okony jiwo rang'iny mar bedo makare ne migao mar nyange Inyalo penjo penjo moro amora ma in go saa asaya.

Bedo e nonro en kuom chiwruok kendo inyalo yiero mondo iwuogi saa asaya maonge kum moro amora kendo pod ibiro nyalo yudo thieth e migao mar FACES: Andike mar yie ni lero nonoro kod rachne. Ka isewinjo nonro, kendi ka iyie mondo idonje,

ibirikwayi mondo iket koki e oboke ni. Inyalo yiero mondo kik iduok penjo moro amora ma ok in go thuolo

STUDY PROCEDURES

Bang' yie mari mar donjo e nonro, abiro penji penjo mondo ang'e go ka iwinjori. Bang'e to abiro penji penjo ewi chandruoge kata paro ewi paro ewi yore makare maluwore gi nyange mane otimni e klinik. Penjo kendo kendo biro penjo ewi romo mari gi thieth ma iyudo. Abiro ndiko piny duoko magi kaka penjo dhi nyime. Ka nitiere penjo ma ok ibi bedo thuolo chiwo duoko, in thuolo mar timo mano. Penjo biro kawo dakika madirom 20. Bang' mano ibiro teri e ot ming'iyoe ji mondo laktar ong'i adhola mondo onegodo kaka ichango ka dibedi ni nitie chandruok moro amora. Laktar biro ndiko weche moyudo ma ibiro tiyogodo e nonro.

NG'AWA MA BIRO CHIWORE E NONRONI?

Kanyakla mar jochiwre e nonro biro riwo joma chuo ma nyiche eka oter nyange kendo koro dhiye limbe mar thieth ma bang' nyange ei migao mar FACES. . Wabiro penjo joma chuo 384 penjo.

BER Nonoro ok bi chiwo ni ber ma achiel ka achiel, kata ka mano duoko ma oa e nonro biro kono jochiew thieth mar medo jiwo rang'iny kendo medo keto makare yore mag thieth ma ichiwo ne jogo ma didwar yorego e kinde ma biro. Ma biro konyo jiwo rwako nyange ;mar joma chuo. Nonro kendo biro chiwo weche mabiro medo ng'eyo kod rieyo chike e yore makare gi endi ka ochiwo duoko ma adieri ewi weche ma sani gi koriwo: ng'eny mar hinyruok kod chandruoge mamoko to kod gik makelo chandruoge e nyangi.

RACH

Onge rach maduong' kuom donjo e nonro ni. Jomoko ok nyal bedo thuolo mar chiwo weche matut ma otenore kodgi nikech giluoro wito maling'ling' margi. Mondo rit maling'ling', penjo gi ng'iyo dendi ibiro tim kama opondo, kendo, weche manyalo

yangi ok bi kaw, ibiro tii kod namba kar nying. Mamoko maoseketi mondo omed riti kod maling'ling' magi nitie kaka oler e kidieny maluwe ni.

ARITE MAR DUOKO KOD MALING'LING'

Duoko duto tee ma ochok kod jotim nonro ibiro tii godo apanda mana e yor nonro kende. Penjo duto tee ibiro tim wang' gi wang' e ot mopondo kata kamoro mondo mi jok mamoko kik winji duoko ma ichiwo. Nyinge ni tee ok bi ndiki e oboke wa ikete duoko ni. Duoko ibiro kan e kar keno, ma ibiro lor e sanduge e kinde duto mar nonro. Oboke mag duoko mag kompyuta biro bedo gi namba ma siri ma iyawgi go ma biro bedo gi jatim nonro. Arita makende ma ong'aw gi en mar kano maling'ling' mar jochiwre e nonro. Duoko gi ibiro kan kuom kinde mang'eny madirom higni 5 bang' kao gi.

CHUDO MAKORI

Onge chudo ma kori kuom chiwori mondo ibed e nonroni

NWENG'O MANYIEN

Duoko ibiro riw gi klinik mar FACES, migao mar ngima mar kaonti, kapok ogoye e oboke mag sayans kod oboke mamoko.

CHANDRUOGE KOD PENJO: Ka in gi penjo moro amora ewi nonro, inuyalo tudori kodi jatim nonro maduong', Timothy Kipkosgei e namba mar simo 072113579, nying mar mbuyi, timokips@gmail.com. **RATIRO MAGIKAKA JACHIWRE E NONRO:** Nonro ni osenon kendo opuodhi kod jonon kendo jopuodh nonro mar kar timo nonro mar thieth mar Kenya (KEMRI).

Ka in gi penjo moro amora kuom ratichi kaka jachiwre e nonro, inyalo tudori gi jagoro mar jonon kendo jopuoth nonro mar thieth mar Kenya (kanyakla mar joma ni gi lony ma nono kendo puodho nonro mondo orit ratichi) e ka jagoro, KEMRI Ethics Review Committee, P.O.Box 54840-00200, Nairobi; nambe simo 020-2722541, 0717719477, 0722205901, 0733400003; nying mar mbuyi seru@kemri.org.

Weche magi mag yie kod seyi: ka isesomo oboke mar yie ni, kata osesomni kendo oler ni go, kendo iwinjo kod iyie kuom chiwruok mondo idonji e nonro, ikwayi mondo isom maber weche ma oluwo piny kanyo go kendo ipar kuom yiero mari kapok iketo nyingi kata keto thuon lweti piny kanyo. Kuom yiero ni moro amora, ok bi chacho yore gi mag thieth ma inyalo yudo:

- Osemiya thuolo mar penjo penjo ma ne anyalo bedo go kendo awinjo ka aromo kod duoko duto mag penjo ga.
- Ang'eyo ni duoko ka ibiro kan maling'ling'kendo ni anyalo weyo nonro ni saa asaya.
- Osenyisa nying, namba simo, namba posta mar ng'ama anyalo tudorago ka nitiere dwaro mapiyo, kendo wechegi osemiya e andike.
- Ayie mondo adonji e nonro ni kaka jachiwre, kendo ibiro miya achiel kuom oboke mar yie ni mondo abedgo/akan.

_____

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Nying jachiwre seyi mar jachiwre kod tarik

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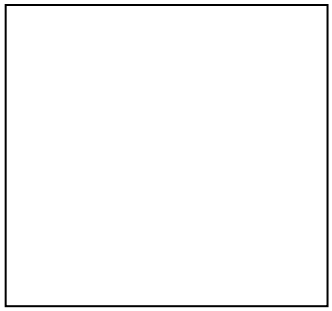
Nying jatim nonro Seyi kod tarik



Thuon lwedo

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Nying janeno Seyi kod tarik

Ng’e: Ok chiw ratiro ni moro amora kuom keto seyi e oboke mar yie ni.

_____

_____

Jina la mshiriki Sahihi ya mshiriki

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Jina la Mchunguzi Sahihi na Tarehe

Alama ya kidole

KUMBUKA- Haki zako za kisheria zingalipo hata baada ya kutia sahihi kwenye fomu hii.

Appendix VII: Voluntary Medical Male Circumcision Adverse Events Descriptions Form

Ministry of Health

Note: Refer to this form when completing AE information on the clients form

DURING CIRCUMCISION			
Adverse event	**Code**	**Description**	**Severity**
Pain	P1	N/A	Mild
		N/A	Moderate
		Pain that requires additional intervention	Severe
Bleeding	B1	Bleeding that is easily controlled	Mild
		Bleeding that requires pressure dressing to control	Moderate
		Blood that requires transfusion or transfer to another facility	Severe
Anaesthetic-related event	A1	N/A	Mild
		Palpitations, vaso-vagal reaction or emesis	Moderate
		Anaphylactic shock or other reaction requiring transfer to another facility	Severe
Excessive skin removed	E1	Adds time or material needs to the procedure, but does not result in any discernible adverse condition	Mild
		Skin is tight, but additional operative work not necessary	Moderate
		Requires re-operation or transfer to another facility to correct the problem	Severe
Damage to the penis	D1	Mild bruising or abrasion, not requiring treatment	Mild
		Bruising or abrasion of the glans or shaft of the penis requiring pressure dressing or additional surgery to control bleeding	Moderate
		Part or all of the glans or shaft of the penis severed	Severe
POST CIRCUMCISION:			
	Code	Description	Severity
Pain	P2	N/A	Mild
		Results in disability for 4-7 days	Moderate
		Results in disability for more than 7 days	Severe
Bleeding	B2	Dressing soaked through with blood at a routine follow-up visit	Mild

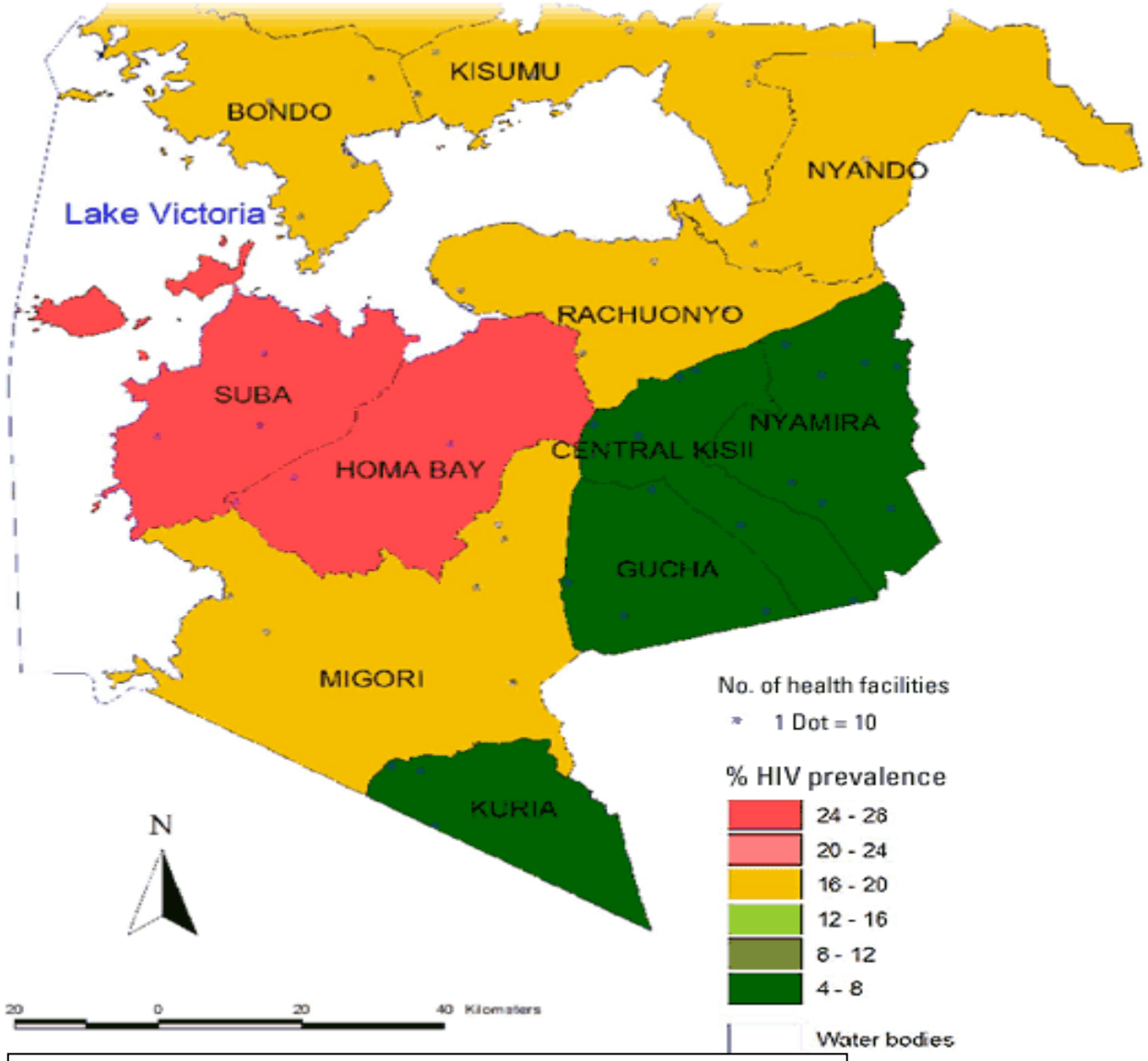
		Bleeding that requires a special return to the clinic for medical attention	Moderate
		Bleeding that requires surgical re- exploration	Severe
Problems with appearance	PA2	May be some concern by client but appearance within normal range	Mild
		Scarring; cosmetic problem but operation not required	Moderate
		Rotation or other problem; requires cosmetic correction	Severe
Haematoma / Swelling	HS2	More swelling than usual, but no significant discomfort	Mild
		Significant tenderness and discomfort, but surgical re-exploration not required	Moderate
Infection / Swelling	IS2	Surgical re-exploration required	Severe
		Erythema more than 1 cm beyond incision line	Mild
		Purulent discharge from the wound	Moderate
		Cellulitis or wound necrosis	Severe
Difficulty or pain when urinating	DU2	Transient complaint that resolves without treatment	Mild
		Partial obstruction	Moderate
		Cannot urinate	Severe
Wound disruption (without signs of haematoma or infection)	WD2	1 to 2 adjacent stitches missing	Mild
		Re-stitching of at least 3 stitches required	Moderate
		Patient incapacitated – bed rest required	Severe

Appendix VIII: Table showing annual numbers of male circumcisions in Eastern and Southern African Countries, 2008-2013 and progress towards goals.

Country	2008	2009	2010	2011	2012	2013	Total	Progress towards target of 80% coverage
Botswana	0	5,424	5,773	14,661	38,005	46,793	110,656	32.10%
Ethiopia, Gambella Province	0	769	2,689	7,542	11,961	16,393	39,354	98.40%
Kenya	11,663	80,719	139,905	159,196	151,517	190,580	733,580	85.3%*
Lesotho	0	0	0	0	10,835	37,655	48,490	12.90%
Malawi	589	1,234	1,296	11,881	21,250	40,835	77,085	3.70%
Mozambique	0	100	7,633	29,592	135,000	146,046	318,371	30.10%
Namibia	0	224	1,763	6,123	4,863	1,182	14,155	4.30%
Rwanda	0	0	1,694	25,000	138,711	116,029	281,434	16.10%
South Africa	5,190	9,168	131,117	296,726	422,009	514,991	1,379,201	31.80%
Swaziland	1,110	4,336	18,869	13,791	9,977	10,105	58,188	31.70%
Tanzania	0	1,033	18,026	120,261	183,480	329,729	652,529	47.50%
Uganda	0	0	21,072	77,756	368,490	801,678	1,268,996	29.90%
Zambia	2,758	17,180	61,911	85,151	173,992	294,466	635,458	32.60%
Zimbabwe	0	2,801	11,176	36,603	40,755	112,084	203,419	10.60%
Total	21,310	122,988	422,924	884,283	1,710,845	2,658,566	5,820,916	27.90%
* Kenya's target is 94% coverage								

(Source: Global AIDS Response Reporting, WHO/UNAIDS/UNICEF 2013)

Appendix IX: Map of study area



Source: *FACES website* http://www.faces-kenya.org/about/about-faces/