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ABSTRACT

Background: The World Health Organization (WHO) recommended Voluntary Medical Male Circumcision (VMMC) as an HIV prevention option for men based on evidence showing a reduction in HIV acquisition of 50% to 60%. Based in this evidence, the rapid expansion of VMMC in sub Saharan Africa has raised concerns on the capacity of VMMC programs to provide sustainable high quality and safe VMMC services.

Objective: To determine the rates and correlates of adverse events following VMMC among clients attending Migori County Hospital.

Design: Descriptive cross sectional study

Setting: Migori County Referral Hospital, Kenya.

Subjects: Between November and December 2015, 138 men receiving VMMC services at Migori County hospital were interviewed during their follow up visits within 7 days following the procedure. We systematically sampled every third participant attending their follow up visit. Face to face interviews were conducted to obtain data on demographics and levels of satisfaction, and physical examination to determine any adverse events after circumcision. Fishers exact was used to test for correlates of adverse events among participants.

Results: The mean age of participants was 22 years, Standard Deviation (SD) ± 5 . About two-thirds (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 100(72.5%) reported being aware of possible adverse events following male circumcision and almost all 135 (97.8%) participants reported having adhered to wound care instructions. The rate of mild and moderate adverse events was 58.7% and 2.9%, respectively. There was no severe adverse event reported. Bathing and not changing underpants was associated with adverse events. The Majority 137 (99.3%) of participants were highly

satisfied with the circumcision procedure and the post-operative care services they received.

Conclusion: These results imply that VMMC in this setting can be delivered safely and effectively with high client satisfaction.

INTRODUCTION

The three randomized controlled clinical Trials conducted in South Africa, Kenya and Uganda between 2005 and 2007 showed that male circumcision reduces the risk of HIV acquisition among men by 60% (1-3). Voluntary Medical Male Circumcision (VMMC) has since then gained significant acceptance from global HIV policy makers, donors and nations due to its cost effectiveness and anticipated long term benefits of hiv prevention(4). Over 5.82 million males in East and Southern Africa have been circumcised since 2008 (5), with Kenya accounting for 12% (733,580) of these numbers. However, the mass roll out circumcision programs in sub Saharan Africa has raised concerns on the capacity of the health systems to provide sustainable, high quality and safe VMMC services for a sustained period (6).

There is a need for active monitoring of adverse events to ensure VMMC programs are safe and also to encourage demand for VMMC among the uncircumcised. Existing findings on adverse events of VMMC in Kenya are based on VMMC studies conducted in research settings. Studies conducted between 2008 and 2011 reported adverse events rates ranging from 1.3% and 7%. (7, 8). Program settings and research settings differ in clients, provider experience and the medical supplies needed for circumcision.

Few studies have focused on circumcision adverse events in a programmatic setting. This study sought to determine the

prevalence and risk factors for adverse events and satisfaction towards VMMC among men receiving VMMC services within the Family AIDS Care and Education Services (FACES) program.

METHODS

Study design and population: This was a descriptive cross sectional study involving men aged 18 years and older attending post-operative follow up visit after receiving free VMMC at Migori County Hospital from 23rd November 2015 to 11th December 2015. The post-operative visits took place on either the 2nd, 3rd or 7th day after surgery. Migori county hospital a Level 4 hospital in Migori County, one of 4 counties in Nyanza province with high HIV prevalence and low circumcision rates. Migori County Hospital is a level 4 hospital and the biggest in Migori County. Migori county hospital is one of the sites where the FACES program supports HIV care and VMMC. Migori county hospital was selected because of its high client volume within the FACES circumcision program.

Subject selection: Males aged 18 years and above who had undergone VMMC within the last 7 days and attending either scheduled or unscheduled follow up visit were eligible for inclusion. Only those who consented to participate were interviewed and examined at the facility

Human Subjects: Informed consent was a requirement for participation in this study; 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. Ethical approval to conduct the study was obtained from KEMRI Scientific and Ethics Review Unit.

Study procedures: Data on demographics and satisfaction with VMMC services was collected through structured interviews while adverse events were collected by clinicians through physical examination using a structured tool on adverse events. The interview took at most 20 minutes. Questionnaires were used to obtain information on socio-demographic characteristics and a different examination tool was used by the examining clinical 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 penile 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(9).

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. Fisher's exact test was used to test for association between various client related factors and adverse events. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 138 men were interviewed and most of them 84(60.9%) came from Suna East Sub-county. The mean age of participants was 22 years (SD \pm 5) and 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. Most participants 129(93.48%) reported back on the 7th day, 6(4.35%) on the 3rd day and only 1(0.72%) after 48hours. Others 2(1.45%) reported after 7 days.

Table 1
Demographics

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
\geq 31	10	7
Follow up visit		
48 hours	1	0.7
3 rd 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

Adherence to wound care and hygiene practices: Almost all participants 135(97.8%) adhered to wound care instructions after circumcision with 59(42.8%) taking a bath daily, 71(51.5%) bathing at least once in three days and 8(5.8%) either bathed after 3 days or never bathed at all. The majority (58.7%) rested for less than 4 days after circumcision, 22(15.9%) rested 4-7 days while 35(25.4%) never rested. Among the 70.3% circumcised through surgery, the majority 87(89.9%) removed their wound dressing on day 3 as required, 7(7.2%) removed their wound dressing after 2 days and 3(3.1%) after 3 days. Most participants 122(88.4%). Among those who wore under pants after circumcision, 49.6% washed them once in 3 days, 55(44%) daily, 2(1.6%) after 3 days and 4.8% never changed their under pants.

Participants' Behavior and Adverse Events Awareness: Eighty percent of participants

reported being non users of alcohol, cigarettes or any other drugs. Nineteen percent were alcohol users while only one participant used both cigarettes and alcohol. 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 the follow up visit.

Awareness on adverse events: Almost three-quarters 100(72%) reported being aware of possible adverse events following male circumcision. However, 38 (27.5%) indicated they were not aware of any possible complication of VMMC. Among those who were aware of complications following circumcision; almost two-thirds (90%) mentioned that they were aware of pain and 86(86%) were aware of penile infection. 76% (n=76) reported awareness on excessive bleeding and 70(70%) on wound disruption.

A majority 92 (92%) knew about penile swelling, 36(36%) pain during urination and 26(26%) excessive penile sensitivity.

Family Acceptability towards VMMC: Almost all, 134(97%) reported that none of their family was opposed to them undergoing circumcision, with only 4(3%) reporting opposition from at least a family member. Among the 4 participants who reported family opposition, only one reported being affected negatively during the recovery.

Adverse events prevalence

Mild adverse events: The rates of mild adverse events at 48 hour, 3rd day and 7th day visits was 58.7% (n=81). Within the mild adverse events category, 92.5% of the adverse events occurred on 7th day, 6.2% on 3rd day follow up and 1% after 7 days. Within the specific categories of the adverse events, 113 incidences among the 81 participants were

recorded; pain was most prevalent at 61 (54%), swelling of the penis 32 (28%), delayed wound healing 7 (6%), 6 (5%) due to bleeding, 5(4 %) excessive skin removed and 2(2%) difficulty in urinating.

Moderate 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 moderate delay in wound healing, two had moderate infections and one had swelling leading to 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.

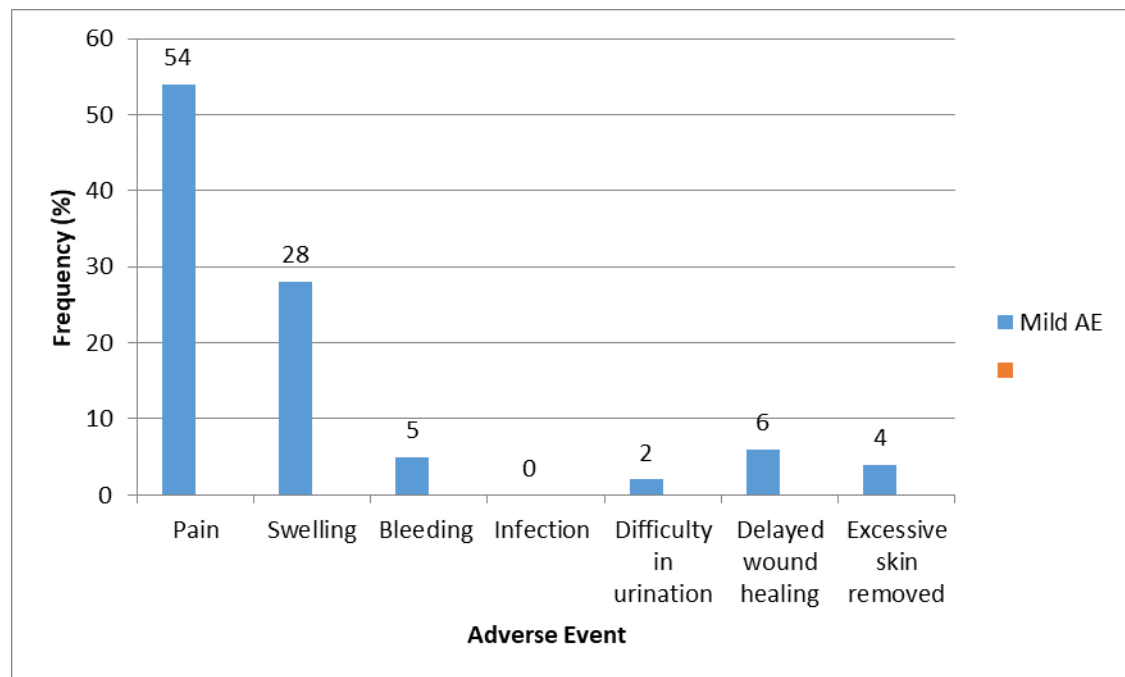


Figure 1: Categorized prevalence of Adverse Events

Factors associated with moderate adverse events: In bivariate analysis the infrequent washing of underpants ($p < 0.001$) significantly increased the chance having moderate bathing after circumcision ($p = 0.001$) and adverse event. (Table 2)

Table 2
Factors Associated with 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)	
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)	

Clients' Level of Satisfaction

Satisfaction with the VMMC service: All 138(100%) participants reported being satisfied with the circumcision procedure and the results with majority 122(88%) being very satisfied.

Satisfaction with the post-operative care service: All 138(100%) participants reported being satisfied with the post-operative services they received at faces clinic with more than three quarter 128(92%) reporting to be very satisfied.

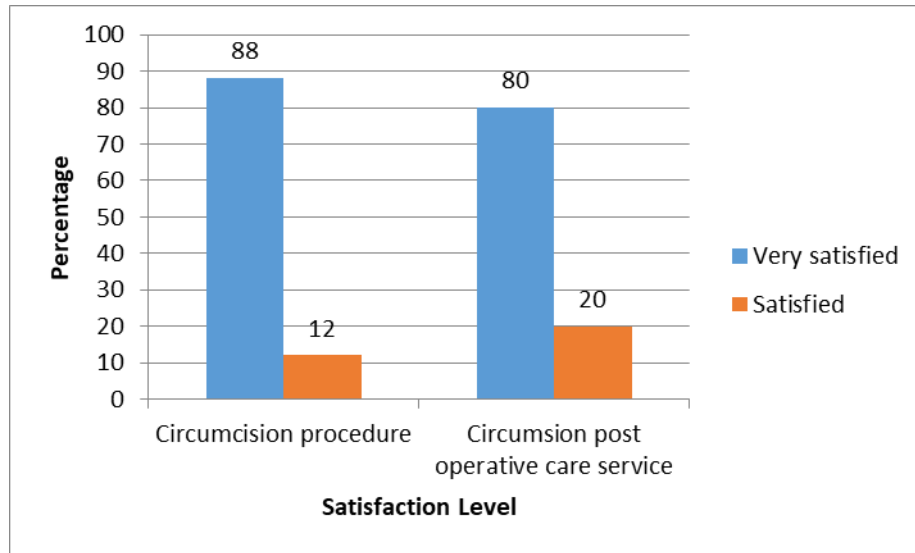


Figure 2: Participants level of satisfaction

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.

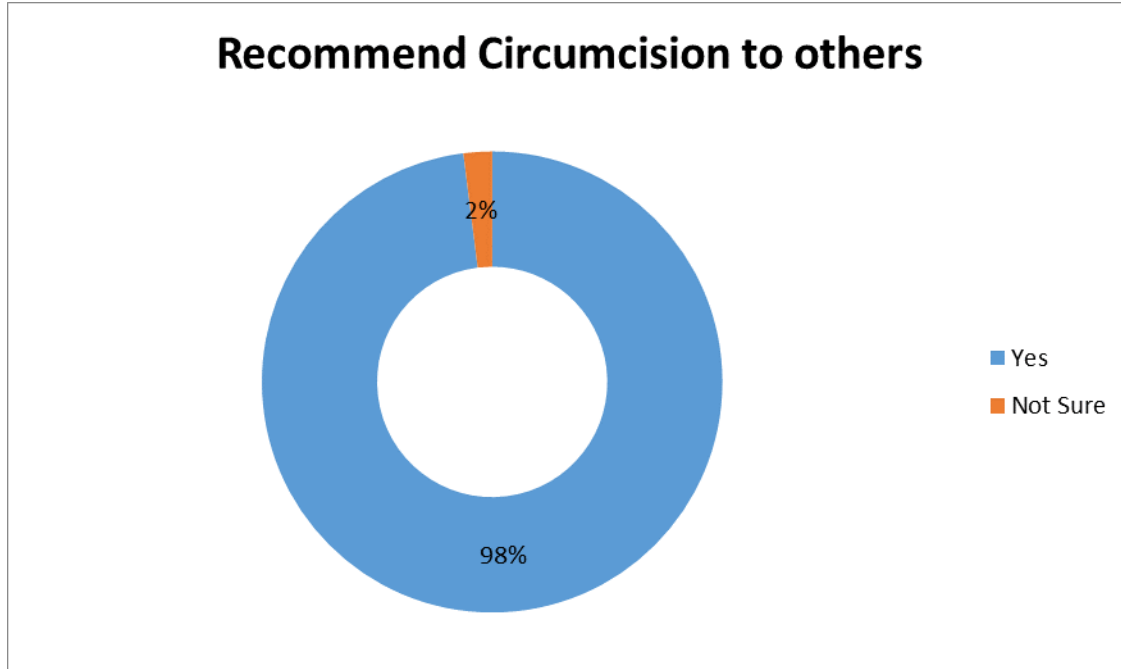


Figure 3: Participants recommendation of VMMC to others

DISCUSSION

The main aim of this study was to determine rates and correlates of adverse events following VMMC among clients within the FACES program at Migori county Hospital. This study shows low rates of adverse events among men receiving free VMMC at Migori District Hospital. This study found no severe adverse events and 4/138 (2.9%) moderate adverse events. All these participants were treated at the VMMC clinic during the follow up visit. A total of 81/138 (58.6%) incidences of mild adverse events were registered among men receiving VMMC in Migori district hospital during the study period. 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.

The findings on moderate adverse events 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%. (1-3). Moreover, studies evaluating the safety of VMMC in program and service delivery settings in Sub-Saharan have reported AE rates of between 0.5%-1.3%. (7, 8, 10).

Findings indicate that having a moderate adverse event significantly differed with the frequency of bathing after circumcision $p=$ (0.001) and the wearing of underpants $p<0.001$. Regular bathing helps remove excess stratum corneum thus limiting the risk of infections. It also maintains skin flexibility, smoothness and barrier integrity which is crucial in protecting against entry of pathogens and reducing discomfort, and

pain(11). 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(9). This eases pressure and allows free blood flow hence reducing cases of swelling and hematoma on the penis(12). However, the study failed to 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 rates of adverse events in Migori county hospital can be attributed to three major factors: facility related factors, provider related factors and client related factors. Within the facility, adequate medical supply improves the safety of VMMC (13). The WHO further emphasized the need for adequate medical equipment and supplies for effective and safe delivery of VMMC (14). 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 the impact of provider 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 (7). The FACES VMMC site in Migori has adequate personnel that include 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 participants (97.8%) reported having adhered to wound care practices. Low AE and

faster would healing are mainly due to adequate delivery of instructions on wound care and participants adherence to the wound care practices(10). More than half 71(51.5%) bathed at least once in 3 days, 59(42.8%) daily and 8(5.8%) either bathed after 3 days or never bathed at all. Participants who never bathed and changed pants regularly were more likely to report moderate adverse events. There was no difference in adverse rates among those who opted for surgical circumcision 97(70.3%) and 41(29.7%) were done for pre-pex 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 surgical operation. Pre-pex method is thus suitable for men actively involved in full time jobs without leave or break from work for over two weeks. This study found out that majority 87(89.9%) removed their wound dressing within 3days, as instructed and also majority 122(88.4%) wore under pants 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 time of wound healing.

Most participants (72%) were aware of possible Adverse Events of VMMC. The awareness on 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, 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 on the latter may be attributed to the fact it is an adverse event that are 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.

It was noted that majority of respondents 131 (97.8%) in this study reported no objection from family on them getting circumcised. Additionally almost all (98.55%) 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 (15) 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 post-operative care and services delivered at the clinic. This finding is consistent with those of who reported 99% satisfaction rate also in Marie Stopes international mobile VMMC site in Nyanza region Kenya(8). This indicates impressive quality of services delivered by FACES sites in Migori. High satisfaction with also help in spurring acceptability as noted by (16)

The results of this study indicate that the current rates 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 implementation of mass circumcision in Nyanza to avert new incidences of HIV. The low adverse event rates and high satisfaction levels 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. Only those who came back for the follow up visit were considered in investigating for adverse events and factors. The 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 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.

CONCLUSION

In conclusion, this study has determined that the current rates of adverse events among men receiving VMMC in Migori county is low and consistent with findings from studies on Adverse Events done among VMMC clients, it has also demonstrated high acceptability and satisfaction among the participants which is encouraging for the scale up of VMMC to reach the National targets. These results imply that VMMC can be delivered safely and effectively delivered in program setting. However, there is need for continuous active monitoring of adverse events by organizing house to house visit to track those who may not come back for reviews after circumcision due to the inadequacies of passive monitoring. As the Ministry of Health in collaboration with male circumcision partners in Kenya continue to scale up VMMC, they should also emphasize the importance of proper counseling on post-operative wound care and adherence to follow -up visits putting into consideration the socio-economic differences of clients seeking free medical

circumcision in the rural and urban areas of Nyanza region.

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