Factors associated with the safety of voluntary medical male circumcision in Nyanza province, Kenya

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Objective To determine factors associated with the incidence of adverse events associated with voluntary medical male circumcision (VMMC) for the prevention of HIV infection in Nyanza province, Kenya.

Methods Males aged 12 years or older who underwent VMMC between November 2008 and March 2010 in 16 clinics in three districts were followed through passive surveillance to monitor the incidence of adverse events during and after surgery. A subset of clinic participants was randomly selected for active surveillance post-operatively and was monitored for adverse events through a home-based, in-depth interview and a genital exam 28 to 45 days after surgery. Performance indicators were assessed for 167 VMMC providers.

Findings The adverse event rate was 0.1% intra-operatively and 2.1% post-operatively among clinic system participants ($n = 3705$), and 7.5% post-operatively among participants under active surveillance ($n = 1449$). Agreement between systems was moderate (κ: 0.20; 95% confidence interval, CI: 0.09–0.32). 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.

Conclusion To reduce the adverse event rate, one must ensure that providers achieve a desired level of experience before they perform unsupervised procedures. Adverse events observed by the provider as well as those perceived by the client should both be monitored.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

Medical male circumcision is the surgical removal of the foreskin of the penis by a trained health professional. The results of three randomized controlled trials (RCTs) have demonstrated that medical male circumcision reduces the incidence of infection with Type 1 human immunodeficiency virus (HIV-1) in heterosexual men by at least one half.[1–3] As a result, the World Health Organization and the Joint United Nations Programme on HIV/AIDS recommend voluntary medical male circumcision (VMMC) as one component of a comprehensive preventive strategy in regions with low male circumcision rates and a high prevalence of HIV-1 infection and where heterosexual sex is the main mode of transmission.[4]

Despite the endorsement of VMMC for the prevention of HIV infection, safety became a concern once mass programmes were implemented in resource-limited settings. In developed countries, adverse events following neonatal circumcision are well documented and their incidence is very low, from 0.2 to 0.6%.[5] Before the RCTs, outcomes in Africa for male circumcision among adults were poorly documented. In a review,[6] adverse event rates following African male circumcisions ranged from 0 to 24%. The RCTs, which provided services in a clinical trial setting, reported the following adverse event rates: 3.8% in Orange Farm, South Africa; 1.5% in Kisumu, Kenya; and 3.6% in Rakai, Uganda.[1,7,8] Most recently, at the former Orange Farm RCT site, 1.8% of medical male circumcisions offered in one high-volume facility resulted in an adverse event.[9]

Historically, intra- and post-operative adverse events have been detected through passive or active surveillance systems. Passive systems rely on providers to report adverse events on a standardized form. Although passive systems have advantages, such as their low cost, they also have limitations in terms of timeliness, completeness and positive predictive value.[10–12] Active surveillance involves outreach by a provider to identify and report health events. Many believe that active surveillance produces better data than passive systems[11] and is most feasible on a small scale where resources are scarce.[13] Currently, the surveillance of surgical procedures is conducted in developed countries and is primarily passive and restricted to in-patient monitoring of surgical site infections.[14–16] However, the number of surgical procedures being provided on an out-patient basis in resource-limited settings, such as medical male circumcision, is increasing. This creates the need for new approaches to post-discharge surveillance.[17]

To our knowledge, no research has been published to date on clinical outcomes from a large-scale, multi-site VMMC programme in a resource-limited setting. In this study, passive and active surveillance methods were used to monitor factors, including provider characteristics, potentially associated with the incidence of adverse events occurring during and after VMMC procedures provided as part of the national programme for the prevention of HIV infection.

Methods

Study context

The Government of Kenya launched the national VMMC programme in Nyanza province in November 2008 and plans to have circumcised 860 000 males by 2013.[18] Nyanza province is the geographic home of the Luo ethnic group. Luo

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men do not traditionally practice male circumcision and have a relatively high prevalence of HIV infection; 21.5% of Luo men are circumcised and 17.1% are HIV-positive, compared with 85.9% and 4.6% of Kenyan males, respectively.[19]

Study design and participants

The study design and recruitment procedures were detailed in a previous paper.[20] In summary, VMMC clients 12 years of age or older in 16 study facilities in Nyanza province, Kenya, were followed between November 2008 and March 2010 to detect any adverse events occurring during the procedure or within the following 45 days.

The study had two surveillance components:

- A passive, clinic-based surveillance system that collected and managed routine intra-operative and post-operative clinical data on participants who sought VMMC services at 16 health facilities in Kisumu East, Kisumu West and Nyando districts in Nyanza province ($n = 4010$).
- An active surveillance system in which a random subsample of clinic system participants was monitored by research staff 28 to 45 days after circumcision through a home-based, in-depth interview and a genital exam. A target sample size of 1449 was achieved to detect at least a 2.0% difference in the frequency of adverse events between the two systems with an overall type-I error rate of $\alpha = 0.05$ and 80% power.

Circumcision services provision

All circumcisions were performed at no cost by a trained clinician or nurse who completed a two- to three-week training programme. Clinicians included medical officers and clinical officers with five and three years of medical training, respectively. Training in VMMC involved assisting during at least10 procedures and performing at least 20 procedures under supervision. All clients were encouraged to undergo voluntary HIV testing and counselling, which were available on site. Clients were screened for several comorbidities (urethral discharge, genital ulcers, genital warts, general pallor, chronic wound and arterial hypertension), and those who presented with an acute sexually-transmitted infection (STI) were treated and asked to return once they completed treatment. Clients were circumcised using the forceps-guided method; local anaesthesia was infiltrated at the base of the penis using dorsal nerve and ring block techniques. The incision site was closed with absorbable sutures using a combination of mattress and simple stitching.[21] At discharge, clients were given written instructions detailing wound care and the 42-day sexual abstinence period. Clients were scheduled to return to the facility for one follow-up visit seven days after the procedure.

Ethical considerations

The study was approved by the institutional review board of the University of Illinois in Chicago, United States of America (protocol: 2007–0913) and by the Kenyatta National Hospital Ethics and Research Committee in Nairobi, Kenya (protocol: P338/11/2007).

Data collection and statistical analysis

We monitored several adverse events including pain, swelling, hematoma, bleeding, infection, difficulty urinating, wound disruption, local disfigurement, injury to the glans and "others". Moderate adverse events were defined as those that prevented a participant from performing normal activities and required treatment, and severe adverse events as those that were incapacitating and required bed rest or hospitalization. Since pain is often associated with other identifiable adverse events, we report on pain separately (as in the RCTs). The primary outcome was the incidence of a moderate or severe adverse event other than pain that resulted in treatment at a health facility. The duration of the procedure was defined as the time that transpired between the first incision and placement of the last suture.

Data were analysed with SAS version 9.1 (SAS Institute Inc., Cary, USA). Differences in independent proportions were assessed by means of Pearson's χ^2. The magnitude of the associations was assessed through logistic regression and characterized by means of odds ratios (ORs), 95% confidence intervals (CIs) and P-values. Unadjusted models explore bivariate associations between a risk factor and the primary outcome. An adjusted model that included age and all marginally significant factors ($P < 0.10$) from the unadjusted analysis was developed using manual forward selection. All factors included in the adjusted model were assessed for confounding, effect modification and multi-colinearity. Surveillance system results were compared using per cent agreement, the kappa statistic (κ) and McNemar's X^2 for dependent proportions.

Results

Study population

Of the 4288 VMMC clients who were invited to participate in the study, 4010 (93.5%) enrolled as study participants. Participants' median age was 20.0 years (range: 12–78; inter-quartile range, IQR: 18–24). The majority (95.7%) of participants were Luo ($n = 3837$); 39.4% completed secondary school ($n = 1580$); 29.9% were married ($n = 1198$) and 66.7% were students/unemployed ($n = 2673$).

Passive surveillance system

Among the 4010 enrolled participants, 3705 underwent circumcision. Participants who were not circumcised either changed their minds or had comorbidity on physical examination that prevented them from getting circumcised. More than one fourth of all participants (27.5%; $n = 1018$) presented with at least one comorbidity, the most common one (26.3%; $n = 975$) being arterial hypertension, defined as an arterial blood pressure > 120/80 mmHg. All of these participants were circumcised. A few participants presented with an acute STI (0.9%; $n = 33$) and their circumcision was deferred until they completed treatment.

Of the participants who were circumcised, 1335 (36.1%) were tested for HIV on site: 3.4% ($n = 45$) tested positive; 96.1% ($n = 1283$) tested negative, and ($n = 7$) 0.5% underwent testing but declined to have their test results recorded. Participants who were not tested or who declined having their results recorded were classified as having "unknown HIV status"; participants who reported being HIV-positive ($n = 74$) and/or who tested positive for HIV on site ($n = 45$) were classified as HIV-positive.

Staff from the Nyanza Reproductive Health Society, a Kenyan implementing organization, provided most procedures and resembled their Government of Kenya staff counterparts in every respect except that their only duty was to provide VMMC services (Table 1).

Table 1. **Characteristics of men circumcised and of procedures performed in the clinic surveillance system, Nyanza province, Kenya, 2008–2010**

Characteristic	Clinic system[a] (n = 3 705)
Age (years)	
< 18	241 (6.5)
18–24	2551 (68.9)
25–34	684 (18.4)
≥ 35	229 (6.2)
HIV status	
HIV-positive[b]	119 (3.2)
HIV-negative[c]	1283 (34.6)
Unknown[d]	2303 (62.2)
STI at screening	
Yes	33 (0.9)
No	3672 (99.1)
Comorbidity at screening[e]	
Yes	1018 (27.5)
No	2687 (72.5)
Duration of procedure (min)[f]	
< 14 (25% IQR)	685 (18.5)
14–23 (IQR)	2138 (57.7)
> 23 (> 75% IQR)	882 (23.8)
MMC during high-volume month	
Yes	2296 (62.0)
No	1409 (38.0)
MMC provider	
Clinician (CO or MO)	2480 (66.9)
Nurse	1225 (33.1)
Employer of MMC provider	
Government of Kenya	425 (11.5)
Nyanza Reproductive Health Society	3280 (88.5)
Dose of local anaesthesia	
≤ 10 ml	1768 (47.7)
> 10 ml	1937 (52.3)
Returned for follow-up	
Yes	1672 (45.1)
No	2033 (54.9)
Days to normal activities, mean (SD)	2.4 (± 2.0)
Adverse events	
Intra-operative	3 (0.1)
Post-surgical[g]	78 (2.1)

CO, clinical officer; HIV, human immunodeficiency virus; IQR, interquartile range; MMC, medical male circumcision; MO, medical officer; SD, standard deviation; STI, sexually-transmitted infection.

[a] Unless otherwise indicated, all values in this column are absolute numbers followed by percentages in parentheses.
[b] Completed on-site test or self-report.
[c] Completed on-site test.
[d] Declined on-site test or declined to have result recorded.
[e] Comorbidities included urethral discharge, genital ulcers, genital warts, general pallor, chronic wounds, and arterial hypertension.
[f] Mean duration: 17 minutes (IQR: 14–23).
[g] Outcome variable in logistic regression modelling.

Active surveillance system

Of the participants who were randomly selected for the active surveillance system (n = 1449), 92.8% were 18 years of age or older (n = 1344), 39.1% had completed secondary school (n = 567), 31.3% were married (n = 454) and 66.3% were students/unemployed (n = 961). More than one fourth (28.6%; n = 415) reported engaging in sexual activity before the end of the 42-day abstinence period. In this system, 7.5% of participants reported having received treatment at a health facility for a moderate or severe adverse event (n = 108). Nearly half of the participants returned for at least one follow-up visit (46.7%; n = 677). The reported adverse event rate was 10.0% (n = 677) among the participants who returned for follow-up and 5.2% (n = 772) among those who did not return.

Evaluation of adverse event ascertainment

The clinic surveillance system detected 119 incident adverse events among the 1672 participants who returned for a follow-up visit (25 clients were classified as having more than one adverse event). Infection was the most common (2.2%; n = 37), followed by wound disruption (1.7%; n = 28) and bleeding (1.4%; n = 23). The clinic surveillance system recorded three severe adverse events: one infection, one case of wound disruption and one case of swelling. The clinic system recorded 11 incidents of pain (0.7%), one of them severe. Participants in the active surveillance system reported 437 adverse events. The most common were swelling (4.3%; n = 62); infection (3.3%; n = 48); bleeding (2.3%; n = 33) and "other" (2.3%; n = 33), which included intense itching, unabsorbed sutures and scarring around the suture line (these adverse events were directly observed by the research team). In the active surveillance system, 20 severe adverse events were reported. They included 5 cases of swelling, 4 hematomas, 5 cases of bleeding, 2 infections, 2 cases of difficulty urinating and 2 cases of wound disruption. The active surveillance system recorded 143 incidents of pain (9.9%), 30 of which were reported as severe.

Agreement between the clinic-based and the active surveillance systems was assessed on the basis of the 677 participants who completed both a follow-up clinic visit and an active surveillance interview. Twenty-eight adverse events were detected by the clinic system (27 moderate and one severe) and 68 were detected by the active system (57 moderate and 11 severe). Overall, the two systems agreed 89.4% of the time over whether the client did (n = 12) or did not have (n = 593) an

Table 2. **Agreement in adverse event detection between clinic surveillance system and active surveillance system, Nyanza province, Kenya, 2008–2010**

Clinic system	Active system		Total
	Adverse event reported	Adverse event not reported	
Adverse event reported	12	16	28
Adverse event not reported	56	593	649
Total	68	609	677[a]

[a] Per cent agreement between systems = 89.4 (605 ÷ 677 = 0.8936); κ statistic = 0.20 (95% confidence interval: 0.09–0.32); McNemar's X^2 for dependent proportions = 21.13; $P < 0.001$.

adverse event. Of participants who were classified as having an adverse event by the clinic surveillance system, 43% (12/28) were similarly classified by the active surveillance system. Of participants who were classified as having an adverse event by the active surveillance system, 18% (12/68) were similarly classified by the clinic surveillance system (Table 2). Overall agreement between systems was moderate ($\kappa = 0.20$; 95% CI: 0.09–0.32), yet adverse event detection differed significantly (McNemar's $X^2 = 21.13$; $P < 0.001$).

Risk factors for adverse events

A total of 167 providers performed between 1 and 302 male circumcisions each in this study population. The mean duration of the procedure and the incidence of adverse events decreased significantly with increased provider experience (Table 3).

In the adjusted model for the clinic surveillance system, performance of the procedure by a clinician (adjusted OR, aOR: 0.60; 95% CI: 0.37–0.98) and by someone who had performed more than 100 male circumcisions (aOR: 0.37; 95% CI: 0.17–0.81) were significantly protective against developing an adverse event. In the adjusted model for the active surveillance system, a high dose of anaesthesia was a risk factor (aOR: 2.1; 95% CI: 1.4–3.4); performance of the procedure during a high-volume month that coincided with official or school holidays (aOR: 0.62; 95% CI: 0.41–0.93) or by a provider who had performed more than 100 medical male circumcisions (aOR: 0.61; 95% CI: 0.34–1.1) were protective factors (Table 4).

Discussion

This study assessed the incidence of adverse events and the factors associated with the risk of such events following medical male circumcisions in 16 health facilities in Nyanza province, Kenya. RCTs have shown that more experienced providers perform faster and safer circumcisions,[8,22] and our results confirm these findings. In our study, the providers who had performed only 20 male circumcisions under supervision took an average of 21.0 minutes to perform their first 20 procedures; however, providers who had performed more than 100 circumcisions and those who had performed over 200 procedures took an average of 17.6 and 15.5 minutes, respectively. Auvert estimated that trained providers could perform 10 medical male circumcisions per day;[23] however, our results suggest that an experienced provider may be able to perform up to 20 procedures daily (assuming ample client flow). Additionally, the most experienced clinicians recorded an adverse event rate of 0.7% and 4.3% in the clinic and active surveillance systems, respectively. Such rates are equivalent to the low rates observed in the RCTs. Furthermore, providers who had performed at least 100 male circumcisions were 63.0% and 39.0% less likely to perform a procedure resulting in an adverse event than less experienced providers in the clinic and active surveillance systems, respectively. This study lends support to recommendations that providers must perform a minimum of 20 male circumcision procedures to qualify as a VMMC provider, and ideally over 100 procedures to reach and maintain a desired level of clinical expertise.[8,22]

In Kenya, legislation was passed in 2009 to allow nurses to provide VMMC services as part of the national VMMC programme. While adjusting for provider experience reduced the magnitude of the protective effect conferred by having a clinician rather than a nurse perform the circumcision, in the clinic system a procedure performed by a clinician was still 40.0% less likely to result in an adverse event than one performed by a nurse. These results were not corroborated in the active surveillance system. Of interest, participants whose circumcision was performed by a clinician were also 25.0% less likely to report for a follow-up visit than those whose procedure has been performed by a nurse (95% CI: 0.65–0.86). When we limited the analysis to participants whose provider had performed at least 100 male circumcisions, the association between provider type (clinician or nurse) and the odds of developing an adverse event was no longer significant (OR: 0.41; 95% CI: 0.08–2.1). Thus, nurses and clinicians with sufficient experience can provide equivalent services.

In the adjusted active surveillance system model, receiving a high dose of anaesthesia was a risk factor for devel-

Table 3. **Provider experience, duration of male circumcision procedure and adverse event rates, Nyanza province, Kenya, 2008–2010**

No. of MMCs performed	Mean duration, min (SD)	Clinic system			Active system		
		No.	%	OR (95% CI)	No.	%	OR (95% CI)
≤ 20 MMCs (ref)	24.0 (9.6)	1069	3.4	–	390	11.3	–
21–100 MMCs	18.3 (6.4)	1385	2.7	0.71 (0.43–1.16)	469	6.8	0.58 (0.36–0.93)
101–200 MMCs	17.6 (6.1)	813	1.1	0.24 (0.11–0.54)	404	5.9	0.50 (0.30–0.83)
201–302 MMCs	15.5 (5.5)	438	0.7	0.31 (0.09–1.01)	186	4.3	0.35 (0.16–0.77)

CI, confidence interval; MMC, medical male circumcision; OR, odds ratio; SD, standard deviation.

Table 4. **Factors associated with an adverse event following medical male circumcision, by surveillance system, Nyanza province, Kenya, 2008–2010**

Factor	Clinic system ($n = 1\,672$)			Active system ($n = 1\,449$)		
	No. (%)	OR (95% CI)	aOR (95% CI)	No. (%)	OR (95% CI)	aOR (95% CI)
Age (years)						
< 18	76 (4.6)	Ref	1.1 (0.36–3.2)	105 (7.3)	Ref	0.88 (0.36–2.1)
18–24	1133 (67.8)	0.9 (0.3–2.5)	Ref	976 (67.4)	1.4 (0.6–3.4)	Ref
25–34	345 (20.6)	1.0 (0.3–3.2)		289 (19.9)	1.2 (0.5–3.1)	
≥ 35	118 (7.0)	0.5 (0.1–2.2)		79 (5.4)	0.9 (0.2–3.2)	
HIV status						
Positive	49 (2.9)	1.3 (0.41–4.4)	–	42 (2.9)	0.61 (0.15–2.6)	–
Negative and unknown	1623 (97.1)	Ref	–	1407 (97.1)	Ref	–
Comorbidity at screening						
Yes	504 (30.1)	1.2 (0.7–1.9)	–	398 (27.5)	1.1 (0.7–1.7)	–
No	1168 (69.9)	Ref	–	1051 (72.5)	Ref	–
MMC during high-volume month						
Yes	962 (57.5)	1.2 (0.7–1.9)	1.1 (0.67–1.8)	791 (54.6)	0.7 (0.5–1.1)	0.62 (0.41–0.93)
No	710 (42.5)	Ref	Ref	658 (45.4)	Ref	Ref
Duration of procedure						
Less than 25% IQR (< 14 minute)	224 (13.4)	0.3 (0.1–0.9)	0.50 (0.17–1.4)	290 (20.0)	0.7 (0.4–1.2)	0.96 (0.53–1.7)
IQR (14–23 minute)	976 (58.4)	Ref	Ref	811 (56.0)	Ref	Ref
More than 75% IQR (> 23 minute)	472 (28.2)	1.8 (1.1–2.9)	1.3 (0.75–2.1)	348 (24.0)	1.4 (0.9–2.1)	0.83 (0.51–1.4)
Dose of local anaesthesia						
≥ 10 ml	1083 (64.8)	1.0 (0.6–1.7)	0.86 (0.51–1.4)	721 (49.8)	2.0 (1.4–3.1)	2.1 (1.4–3.4)
≤ 10 ml	589 (35.2)	Ref	Ref	728 (50.2)	Ref	Ref
Cadre of MMC provider						
Clinician (CO or MO)	1178 (70.5)	0.4 (0.3–0.7)	0.60 (0.37–0.98)	1010 (69.7)	0.7 (0.5–1.0)	0.75 (0.48–1.2)
Nurse	494 (29.5)	Ref	Ref	439 (30.3)	Ref	Ref
Employer of MMC provider						
Government of Kenya	198 (11.8)	2.0 (1.1–3.5)	1.1 (0.54–2.2)	138 (9.5)	2.2 (1.3–3.7)	1.5 (0.81–2.9)
Nyanza Reproductive Health Society	1474 (88.2)	Ref	Ref	1311 (90.5)	Ref	Ref
Premature sexual activity (< 42 days after procedure)						
Yes	–	–	–	415 (28.6)	1.0 (0.7–1.5)	–
No	–	–	–	1034 (71.4)	Ref	–

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Factor	Clinic system ($n = 1\,672$)			Active system ($n = 1\,449$)		
	No. (%)	OR (95% CI)	aOR (95% CI)	No. (%)	OR (95% CI)	aOR (95% CI)
Provider experience (No. of MMCs performed)						
Level 1: 0–20 (Ref)	497 (29.7)	Ref	Ref	390 (26.9)	Ref	Ref
Level 2: 21–100	649 (38.8)	0.71 (0.43–1.16)	0.89 (0.50–1.6)	469 (32.4)	0.58 (0.36–0.93)	0.64 (0.37–1.1)
Levels 3 & 4: 101–302	526 (31.5)	0.26 (0.13–0.52)	0.37 (0.17–0.81)	590 (40.7)	0.45 (0.28–0.73)	0.61 (0.34–1.1)

aOR, adjusted odds ratio; CI, confidence interval; CO, clinical officer; IQR, interquartile range; HIV, human immunodeficiency virus; MMC, medical male circumcision; MO, medical officer; OR, odds ratio; Ref, reference.

oping an adverse event. Inexperienced providers tend to administer a higher dose of anaesthesia because they take longer to complete the procedure. Furthermore, more time may be required and more anaesthesia may be given if a complication arises during the procedure. In the adjusted active surveillance model, undergoing circumcision during a high-volume month was protective against developing an adverse event. This finding, which was surprising, may have resulted from the presence of an increased number of circumcision providers in the field and related improvements in access to care and in internal quality control of services. In our study population, 26.3% of participants were classified as having high arterial blood pressure. Medical male circumcision can generate temporary physical or emotional stress and raise blood pressure, but hypertension was not associated with the incidence of adverse events in either the clinic or the active surveillance system.

Historically, post-discharge surveillance has consisted mainly of direct observation by a trained professional and participant self-report.[15] In our study we used both methods, each of which has inherent strengths and weaknesses. For example, the low rate of follow-up visit attendance (45.1%) impacted the validity of the results from the clinic system, and although interviewing active surveillance system participants 28 to 45 days after circumcision allowed us to assess non-adverse-event indicators of interest (e.g. the resumption of sexual activity), the time was not ideal for assessing adverse event history.

Although the overall per cent agreement between the clinic and the active surveillance systems was high with respect to the detection of adverse events, the two systems succeeded in detecting events of different types. For example, the majority of the 56 clients who were classified as having an adverse event only by the active surveillance system reported having some disfigurement ($n = 19$) or an adverse event belonging to the "other" category ($n = 17$). Since such adverse events went nearly undetected by the clinic surveillance system, we conclude that they may not be detectable at the one-week follow-up visit. This highlights the importance of providing mechanisms for continued provider–client interaction after the one recommended follow-up visit. Most of the 16 participants classified as having an adverse event only by the clinic surveillance system had either an infection ($n = 6$) or local swelling ($n = 5$), both of which are easily detectable during the week following male circumcision.

VMMC has been implemented on a large scale. Thus, it is important to monitor those adverse events identified by the provider as well as those perceived by the client, since satisfied clients are the most effective mobilizers for the national VMMC programme. A VMMC programme that plans to rely solely on passive surveillance for monitoring must promote attendance at follow-up visits, even though clients who experience an adverse event are more likely to attend a follow-up visit than those who experience no adverse event, according to our findings. The adverse events most often identified by both surveillance systems were bleeding (a mean of 6.7 days after circumcision) and infection (a mean of 9.0 days after circumcision), which lends support to a recommended follow-up appointment one week after surgery.

Our study has limitations. Fewer than half of the participants returned for follow-up, and since adverse events were rare, some cell sizes were small (less than 20 participants). Since our research staff members were stationed at study facilities, clinic system surveillance data may be more complete than they would have been without this level of staffing. Most circumcisions were performed by Nyanza Reproductive Health Society members, who provide VMMC services on a full-time basis. Thus, these findings may not be generalizable to programmes staffed mostly by providers not fully dedicated to VMMC services.

In summary, ensuring that providers have ample experience before performing unsupervised circumcisions is the most important factor in reducing incident adverse events and in decreasing the duration of the procedure during widespread provision of VMMC services. With proper training and experience, nurses can perform male circumcisions as safely as physicians. As VMMC programmes continue to be launched, developing a robust and comprehensive adverse event surveillance system is crucially necessary to identify factors that could improve the safety of procedures. ■

Competing interests: None declared.

ملخص

العوامل المرتبطة بسلامة ختان الذكور الطبي التطوعي في مقاطعة نيانزا، بكينيا

الغرض تحديد العوامل المرتبطة بوقوع الأحداث الضائرة المرتبطة بختان الذكور الطبي التطوعي (VMMC) بغية الوقاية من الإصابة بعدوى فيروس العوز المناعي البشري في مقاطعة نيانزا، بكينيا.

الطريقة تمت متابعة الذكور الذين يبلغون من العمر 12 سنة فما أكثر الذين خضعوا لختان الذكور الطبي التطوعي في الفترة من تشرين الثاني/ نوفمبر 2008 إلى آذار/ مـارس 2010 في 16 عيادة في ثلاث مقاطعات من خلال الترصد السلبي لرصد وقوع الأحداث الضائرة أثناء الجراحة وبعدها. وتم انتقاء فئة فرعية من المشاركين في منظومة العيادات بطريقة عشوائية للترصد النشط بعد العملية وتم رصدها من أجل الأحداث الضائرة من خلال مقابلة منزلية متعمقة وفحص تناسلي بعد الجراحة بفترة تتراوح من 28 يوماً إلى 45 يوماً. وتم تقييم مؤشرات الأداء الخاصة بمقدمي خدمة ختان الذكور الطبي التطوعي البالغ عددهم 167 موفراً.

النتائج بلغ معدل الأحداث الضائرة 0.1 ٪ أثناء العملية و2.1 ٪ بعد العملية بين المشاركين في منظومة العيادات (n = 3705) و7.5 ٪ بعد العملية بين المشاركين الخاضعين للترصد النشط (n = 1449). وكان الاتفاق بين النظم معتدلاً (κ: 0.20؛ فاصل الثقة: 0.09–0.32). وحقق مقدمو هذه الخدمة الذين أجروا ما يزيد عن 100 عملية معدل أحداث ضائرة بلغ 0.7 ٪ و4.3 ٪ في نظم العيادات والترصد النشط، على التوالي وخفّضوا احتمال إجراء العملية التي قد يتسبب عنها حدث ضائر. كما انخفض متوسط فترة العملية من 24.0 إلى 15.5 دقيقة بفضل خبرة مقدمي هذه الخدمة. ومن بين مقدمي هذه الخدمة الذين أجروا 100 عملية على الأقل، قدمت الممرضات والخبراء السريريون خدمات مكافئة.

الاستنتاج لخفض معدل الأحداث الضائرة، يتعين التأكد من تحقيق مقدمي هذه الخدمة لمستوى مرغوب من الخبرة قبل إجراء العمليات غير الخاضعة للمراقبة. وينبغي رصد كل من الأحداث الضائرة التي تتم ملاحظتها من جانب مقدم الخدمة وتلك المعنية من جانب العميل.

摘要

肯尼亚尼安萨省自愿性医疗男性包皮环切术安全性相关的因素

目的 确定肯尼亚尼安萨省预防艾滋病毒感染的自愿性医疗男性包皮环切术（VMMC）的相关不良反应发生率的相关因素。

方法 通过被动监测跟踪三个地区16个诊所中在2008年11月至2010年3月期间接受VMMC的年龄在12岁及以上的男性以监控术中和术后的不良反应发生率。随机抽取就诊者的子集，进行术后的主动监测，并通过以家庭为基础、深入访谈和术后28至45天的生殖器检查，以监控不良反应。对167例VMMC提供者进行性能指标估计。

结果 诊所系统就诊者中不良反应发生率术中为0.1%，术后为2.1%（n =3705），主动监测的就诊者中术后不良反应率为7.5%（N =1449）。系统之间的一致性中等（κ：0.20，置信区间，CI：0.09-0.32）。执行100例以上手术的提供者在诊所和主动监测系统中的不良反应发生率分别为0.7%和4.3%，且导致不良反应的手术执行几率下降。随着提供者经验增加，手术的平均时长也从24.0分钟下降到15.5分钟。在执行至少100例手术的提供者中，护士和诊所医生提供同等的服务。

结论 要减少不良反应发生率，必须确保提供者的经验达到理想水平，然后才能执行无人指导的手术。对于提供者观察到的不良反应以及由患者感知的不良反应都应该得到监控。

Résumé

Facteurs associés à l'innocuité de la circoncision masculine médicale volontaire dans la province de Nyanza, Kenya

Objectif Déterminer les facteurs associés à l'incidence des effets indésirables liés à la circoncision masculine médicalisée volontaire (CMMV) dans le cadre de la prévention de l'infection par le VIH dans la province de Nyanza, Kenya.

Méthodes Une surveillance passive des sujets masculins de 12 ans et plus ayant subi une CMMV entre novembre 2008 et mars 2010 dans 16 cliniques de trois districts a été réalisée afin de détecter l'incidence d'effets indésirables pendant et après l'acte chirurgical. Un sous-groupe de participants a été sélectionné de manière aléatoire pour une surveillance postopératoire active et était contrôlé quant aux effets indésirables par le biais d'un entretien approfondi à domicile et d'un examen génital 28 à 45 jours après l'opération. Il a été procédé à une évaluation des indicateurs de performance de 167 prestataires de CMMV.

Résultats Le taux d'événements indésirables était de 0,1% pendant l'opération et de 2,1% après l'opération chez les participants du système clinique ($n = 3705$), et de 7,5% après l'opération chez les participants sous surveillance active ($n = 1449$). La concordance entre les systèmes était modérée (κ: 0.20; intervalle de confiance, IC: 0,09–0,32). Les prestataires ayant effectué plus de 100 procédures ont obtenu des taux d'événements indésirables de respectivement 0,7% et 4,3% pour le système clinique et les systèmes de surveillance active, et ont diminué la probabilité de réalisation d'une procédure susceptible de générer des effets indésirables. En outre, la durée moyenne de l'acte a été réduite de 24,0 à 15,5 minutes par l'expérience du prestataire. Parmi les prestataires ayant réalisé au moins 100 actes, le personnel infirmier et les médecins ont fourni des services équivalents.

Conclusion Afin de réduire le taux d'effets indésirables, il convient de s'assurer que les prestataires acquièrent un niveau souhaité d'expérience avant de réaliser des procédures non supervisées. Les événements indésirables observés par le prestataire, ainsi que ceux perçus par le patient, devraient tous deux faire l'objet d'une surveillance.

Резюме

Факторы, влияющие на добровольную медицинскую циркумцизию у мужчин в провинции Ньянза, Кения

Цель Определить, какие факторы влияют на распространение неблагоприятных явлений, связанных с добровольной медицинской циркумцизией у мужчин (ДМЦМ), проводимой в целях профилактики распространения ВИЧ в провинции Ньянза, Кения.

Методы Мальчики и мужчины в возрасте от 12 лет, которые подверглись операции ДМЦМ в период от ноября 2008 года до марта 2010 года в 16 клиниках трех районов, находились под пассивным наблюдением с целью отследить распространение неблагоприятных явлений во время и после проведения операции. Определенная группа из пациентов клиники случайным образом выбиралась для активного наблюдения в период после операции, с целью отследить распространение неблагоприятных явлений путем проведения расширенных опросов на дому и обследования гениталий в период от 28 до 45 дней после проведения операции. Показатели результативности оценивались 167 специалистами, проводящими ДМЦМ.

Результаты Степень распространения неблагоприятных явлений составила 0,1% во время проведения операций и 2,1% в послеоперационный период среди пациентов, систематически наблюдаемых в клинике ($n = 3705$), и 7,5% в послеоперационный период среди пациентов, находящихся под активным наблюдением ($n = 1449$). Соответствие между результатами, полученными с помощью этих систем было умеренным (κ: 0,20; доверительный интервал, ДИ: 0,09–0,32). Специалисты, которые произвели более 100 процедур, достигли степени распространения неблагоприятных явлений 0,7% и 4,3% для клинической и активной систем наблюдений соответственно, и снизили вероятность проведения процедур, в результате которых возникают неблагоприятные явления. С ростом опыта специалиста средняя продолжительность процедуры также снизилась с 24,0 до 15,5 минут. Среди специалистов, которые провели как минимум 100 процедур, представлены также медсестры и врачи-консультанты, принимавшие участие в аналогичных операциях.

Вывод Чтобы уменьшить количество неблагоприятных явлений, необходимо убедиться, что специалисты достигли достаточного уровня мастерства и могут проводить процедуры без стороннего руководства. Необходимо осуществлять наблюдения за неблагоприятными явлениями, замеченными как проводящими операции специалистами, так и выявленными самими клиентами.

Resumen

Factores asociados con la seguridad de la circuncisión médica masculina voluntaria en la provincia de Nyanza, Kenya

Objetivo Determinar los factores asociados con la incidencia de acontecimientos adversos asociados con la circuncisión médica masculina voluntaria (CMMV) para la prevención de la infección por el VIH en la provincia de Nyanza, Kenya.

Métodos Se realizó un seguimiento, a través de una vigilancia pasiva, de varones de 12 años en adelante que se sometieron a una CMMV entre noviembre de 2008 y marzo de 2010, en 16 clínicas de tres distritos, con el objetivo de controlar la incidencia de acontecimientos adversos durante y después de la intervención. Se seleccionó aleatoriamente un subconjunto de participantes clínicos para realizar una vigilancia activa después de la intervención, y este subconjunto se sometió a un control de los acontecimientos adversos mediante una entrevista en profundidad y un examen genial, ambos realizados en el domicilio del participante, entre 28 y 45 días después de la intervención. Se evaluaron los indicadores de rendimiento de 167 proveedores de CMMV.

Resultados La tasa de acontecimientos adversos fue del 0,1% durante la intervención y del 2,1% después de la intervención entre los participantes del sistema clínico ($n = 3705$), y del 7,5% después de la intervención entre los participantes sometidos a vigilancia activa ($n = 1449$). La concordancia entre los sistemas fue moderada (κ: 0,20, intervalo de confianza, IC: 0,09-0,32). Los proveedores que realizaron más de 100 intervenciones lograron una tasa de acontecimientos adversos del 0,7% y del 4,3% en los sistemas clínico y de vigilancia activa, respectivamente, y presentaron menos probabilidades de practicar una intervención que desembocase en un acontecimiento adverso. Con la experiencia profesional, la duración media de la intervención también se redujo desde 24,0 hasta 15,5 minutos. Los proveedores que habían realizado al menos 100 intervenciones, el personal de enfermería y los médicos brindaron unos servicios equivalentes.

Conclusión Con el fin de reducir la tasa de acontecimientos adversos, se ha de garantizar que los proveedores alcancen un nivel deseado de experiencia antes de realizar intervenciones sin supervisión. Se debe realizar un seguimiento de los acontecimientos adversos observados por el proveedor, así como de aquellos percibidos por el cliente.

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