

Assessing Two Strategies for Expanding Coverage of Adult Male Circumcision in Nyanza Province, Kenya:

1. TASK SHIFTING TO NONPHYSICIAN CLINICIANS
2. OUTREACH SERVICES

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This publication was prepared under a subagreement funded by FHI under Grant No. 47394, funded by the Bill & Melinda Gates Foundation. The content of this publication does not necessarily reflect the views, analysis, or policies of FHI or the Bill & Melinda Gates Foundation, nor does any mention of trade names, commercial products, or organizations imply endorsement by FHI or the Bill & Melinda Gates Foundation.

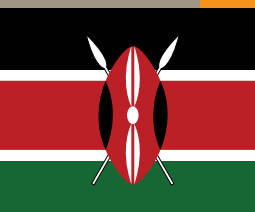
Suggested citation: Pavin, M., Odingo, G., Jeon, C., et al. 2011. *Assessing two strategies for expanding coverage of adult male circumcision in Nyanza Province, Kenya: 1) Task shifting to nonphysician clinicians, and 2) Outreach services*. New York: EngenderHealth.

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MCC
MALE CIRCUMCISION
CONSORTIUM

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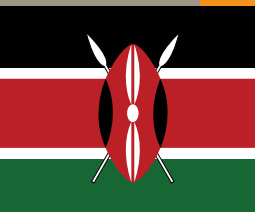
ACKNOWLEDGMENTS

EngenderHealth would like to thank the following people for their contribution to this report:

EngenderHealth would like to thank the following people for their contributions to this report: Melinda Pavin, George Odingo, Christie Jeon, Veronica Frajznygier, and Paul Perchal, for conducting the analyses and writing the final report; Mark Barone, Rosemary Were, Evans Yanga, Feddis Mumba, Fredrick Ndede, for helping conduct the research; the Male Circumcision Consortium, the AIDS, Population, and Health Integrated Assistance (APHIA) II Nyanza Project, the Kenya Ministry of Public Health and Sanitation, the Kenya Ministry of Medical Services, and the Nyanza Provincial Health Management and District Health Management teams, for their ongoing collaboration and support; Sharone Beatty, Mark Barone, Jared Moguche, Jackson Kioko, Nicholas Muraguri, Peter Cheratich, Paul Feldblum, Mario Chen, and Barbara Janowitz, for reviewing earlier drafts of this report; Michael Klitsch, for editing the manuscript and managing the publication process; and Lerner Design Group, for designing and formatting the report.

The authors also thank all of the health care providers and research assistants who helped make this study possible. They also acknowledge the technical assistance provided by the APHIA II Nyanza Project at the study sites, with the generous support of the American people through the U.S. Agency for International Development (USAID).

FHI, EngenderHealth, and the University of Illinois at Chicago, working with the Nyanza Reproductive Health Society, are partners in the Male Circumcision Consortium, which is funded by a grant to FHI from the Bill & Melinda Gates Foundation.



ACRONYMS & ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
APHIA	AIDS, Population, and Health Integrated Assistance
DASCO	district AIDS/STI coordinator
DCO	district clinical officer
DHBCC	district home-based care coordinator
DHS	Demographic and Health Survey
DMOH	district medical officer of health
DPHN	district public health nurse
DRHC	district reproductive health coordinator
GOK	Government of Kenya
HCT	HIV counseling and testing
HIV	human immunodeficiency virus
HQ/HV	high-quality, high-volume [approach]
KEPH	Kenya Essential Package for Health
KNBS	Kenya National Bureau of Statistics
MC	male circumcision
MCC	Male Circumcision Consortium
MOH	Ministry of Health
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
NASCO	National AIDS and STD Control Program
PHMT	provincial health management team
QA	quality assurance
SBCC	social and behavior change communications
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
VMMC	voluntary medical male circumcision
WHO	World Health Organization

EXECUTIVE SUMMARY

The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommend voluntary medical male circumcision (VMMC) for adult men as one important component of a comprehensive HIV prevention package (WHO 2007; WHO/UNAIDS Technical Consultation 2007).

WHO's HIV/AIDS Programme estimates that over the next 10 years, as many as 2 million new HIV infections in Sub-Saharan Africa can be averted with careful, intentional scale-up of safe, high-quality male circumcision (MC) services (WHO 2007).

In Kenya, HIV prevalence is more than four times higher among uncircumcised men aged 15–49 (13%) than among comparable circumcised men (3%) (KNBS and ICF Macro 2010). Nationwide, 6.3% of adult men aged 15–49 are infected with HIV. In Nyanza Province, prevalence rates vary widely by ethnic community, ranging from 20.2% among the Luo to 4.7% among the Kisii. Furthermore, only 22% of Luo men in Nyanza are circumcised, compared with more than 90% in other provinces and among other ethnic groups in Kenya (KNBS and ICF Macro 2010).

The Kenya National Strategy for Voluntary Medical Male Circumcision (Kenya MOPHS 2009) set as a target for 2009–2014 in Nyanza Province that 525,000 eligible men aged 15–49 would need to be circumcised. To rapidly scale up MC provision to achieve the desired impact and ensure sustainability of the service, the Government of Kenya plans to adopt a high-quality, high-volume approach based on the most efficient models of MC service delivery. VMMC services are being delivered through a combination of fixed and outreach/mobile MC services in the short term (3–5 years) (Kenya MOPHS 2009).

To help support the scale-up of adult MC for HIV prevention in Kenya, two prospective studies were conducted to

assess two different modes of MC service delivery in the public sector. Both studies examined clinical outcomes of and client satisfaction with two modes of delivering comprehensive MC services:

1. **The nonphysician clinician (NPC) study** assessed MC services provided through task shifting by trained nurses and clinical officers, who worked and delivered MC services in their adequately equipped base (static site) health care facilities. Participating men in this study were aged 13–54.
2. **The outreach study** assessed MC services provided in adequately equipped outreach health care facilities, with MCs performed by trained itinerant clinical officers. Men in this study were aged 18–54.

Results for both studies were analyzed separately, except for analyses of behaviors prior to and following circumcision.

In the NPC study, 3.8% of the men presented with an adverse event (AE) at seven days post-MC. These AEs included excessive swelling, infection, and delayed wound healing. Correlates of an AE included taking a car or bus to or from the service site (as opposed to walking to/from it) and being older (aged 26–35). Men who had their circumcision performed by a nurse had a higher rate of AEs; however, the occurrence of AEs among nurse providers was well within the published acceptable range of 1.5–8.2% (Auvert, Taljaard et al. 2005; Bailey, Moses et al. 2007; Gray, Kigozi et al. 2007; Krieger, Bailey et al.

2007; Kigozi, Gray et al. 2008). Waiting two days before resuming normal work activities was associated with fewer AEs, as was being married or living with a partner.

The outreach study found that 3.6% of the men presented with an AE at seven days following their circumcision. AEs included excessive swelling, infection, and delayed wound healing. Clients who had their MC performed by older providers and those who resumed only some leisure activities were less likely to have experienced an AE. In contrast to the NPC study findings, those who did not resume work soon were more likely to experience an AE than were those who resumed normal work within two days of circumcision.

Almost all men in both studies were satisfied with their circumcision and would recommend MC to a friend or relative.

We were also interested in sexual risk behaviors post-MC. Our findings show that men who were married or living with a partner were less likely to have used a condom during their last sexual experience post-MC than were those who were single. Furthermore, men who were older, who had at least some secondary education, and who had multiple partners were more likely to report speaking to their partners about preventing HIV.

Based on the findings of these two studies, we conclude that both task shifting to NPCs and mobilizing itinerant outreach providers are safe and effective approaches to providing adult MC in Kenya. Given the Government of Kenya's national MC targets, both of these approaches can be employed to improve access and coverage for MC services.

Recommendations based on the findings include:

1. Expedite efforts to ensure timely involvement of clinical officers and nurses in performing MC at their base static sites.
2. Expedite efforts to ensure timely involvement of clinical officers in MC outreach services.
3. Consider using MC-trained nurses, as well as clinical officers, as outreach MC providers to expand the number of providers and locations where MC services are provided.
4. Increase demand for MC services offered through both task shifting outreach approaches.
5. Stress within MC counseling and community social and behavior change communication efforts issues related to the ongoing need for preventive sexual practices, even following the MC.

BACKGROUND

Male circumcision (MC) is one of the oldest and most common surgical procedures worldwide and is undertaken for religious, cultural, social, and medical reasons (NASCOP and Kenya MOH 2008).

Based on three clinical trials and other accumulated evidence demonstrating that MC reduces the risk of HIV acquisition among men, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommend safe, voluntary MC for adult men as one important component of a comprehensive strategy to prevent HIV infection (WHO 2007; WHO/UNAIDS Technical Consultation 2007). The public health impact of MC on HIV transmission is difficult to quantify outside of a clinical trial. However, WHO's HIV/AIDS Programme estimates that as many as 2 million new infections in Sub-Saharan Africa can be averted in the next 10 years with careful, intentional scale-up of safe, high-quality MC services (WHO 2007).

In Kenya, there is a strong relationship between HIV prevalence and circumcision status, with HIV prevalence more than four times higher among men aged 15–49 who are uncircumcised (13%) than among those who are circumcised (3%) (KNBS and ICF Macro 2010). Nationwide, 6.3% of adult men aged 15–49 are infected with HIV. In Nyanza Province, HIV prevalence rates vary widely by ethnic community, ranging from 20.2% among the Luo to 4.7% among the Kisii. Only 22% of Luo men in Nyanza Province are circumcised, compared with more than 90% of men in other provinces and among other ethnic groups in Kenya (KNBS and ICF Macro 2010). MC could offer tremendous benefits in HIV prevention efforts in Nyanza and other provinces, including Nairobi, Rift Valley, and Western, where there are large numbers of uncircumcised men.

Experts agree that MC should be considered as part of a comprehensive HIV prevention package (WHO/UNAIDS Technical Consultation 2007) that also includes promoting

delay in the onset of sexual relations, abstinence from penetrative sex, and reduction in the number of sexual partners; providing and promoting correct and consistent use of male and female condoms; providing HIV counseling and testing (HCT) services; and providing services for the treatment of sexually transmitted infections (STIs). MC should be performed by well-trained practitioners in hygienic settings with free and informed consent, confidentiality, and risk reduction counseling. National health systems need to provide high-quality MC services, including ensuring adequate infrastructure, training, equipment, and supplies.

To endorse the introduction of MC services for HIV prevention, the Kenya Ministry of Health (MOH) developed a *National Guidance on Voluntary Male Circumcision* (NASCOP and Kenya MOH 2008). The document provides a framework for ensuring the provision of safe, accessible, and sustainable MC services in Kenya. In 2009, the Kenya MOH released the *Kenya National Strategy for Voluntary Medical Male Circumcision* (Kenya MOPHS 2009). This document outlines the strategic directions for voluntary medical male circumcision (VMMC) for men ages 15–49 and the national plan of operations for the fiscal years 2009–2010 through 2011–2012.

The MOH's key strategy for overall health service delivery is the decentralization of services to the districts, with implementation of the Kenya Essential Package for Health (KEPH) (Kenya MOH 2006). Service delivery is provided at the following six levels:

- ◆ Level I — Community level
- ◆ Level II — Dispensaries
- ◆ Level III — Health centers, maternity homes, nursing homes

- ◆ Level IV — Primary hospitals
- ◆ Level V — Secondary hospitals
- ◆ Level VI — Tertiary hospitals

In Nyanza Province, the Government of Kenya (GOK) has set a target to circumcise 525,000 eligible men ages 15–49 between 2009 and 2014 (Kenya MOPHS 2009). To meet this need for rapid scale-up of MC services, the GOK, like many countries, plans to adopt a high-quality, high-volume approach, based on the most efficient models of MC service delivery. This includes a combination of fixed, outreach, and mobile MC services, utilizing both public and private health care services (Kenya MOPHS 2009). To address this undertaking, to improve quality, and to increase the volume of MCs, a variety of strategies are being employed or are under consideration, including task shifting, task sharing, hiring contract staff, optimizing the surgical space (e.g., design/layout, client flow, client scheduling), using mobile outreach services, and practicing alternative surgical techniques (i.e., MC devices, electrocautery). These strategies, alone or in combination, require further evaluation to assist the GOK and others, as they move forward in rolling out and scaling up MC services to meet their vast needs.

New health services, such as MC, will stretch the capacity of the current health system. Adequate health infrastructure, equipment, and supplies and sufficient numbers of trained health workers are critical logistical aspects of MC programming. A recent study on human resources needed for MC rollout in Nyanza Province (EngenderHealth 2011) suggests that current human resource challenges could potentially be the single greatest constraint on the scale-up of MC services, particularly in the short term. The study revealed a preexisting shortfall of 358 health workers in the four districts that were assessed. The analysis indicates that 64 trained dedicated MC health workers or 320 trained nondedicated health workers per year will be required to

achieve the MC target for these four districts. As of October 2009, there was still a severe shortage of both trained dedicated and trained nondedicated health workers in three out of the four districts assessed, despite an investment of considerable resources by MC implementing partners.

Significant investments are required to prepare health systems in Nyanza to deliver MC services at a scale and speed to meet estimated targets and ensure equitable coverage. A major challenge is to find safe, effective, and quality approaches for ensuring available resources to achieve desired health outcomes. Extending coverage and access to MC cannot be achieved simply by replicating existing modes for service delivery. Two innovative strategies involve deploying mobile outreach units to deliver MC and task shifting MC to well-trained nonphysician clinicians (NPCs), such as nurses or clinical officers.¹

With regard to the former strategy, a health center or dispensary in a rural setting receives supplemental inputs (e.g., trained MC surgeons/surgical assistants, equipment, surgical instruments, supplies, transport) from a district or subdistrict hospital and then provides MCs that meet standard MC surgery requirements during prescheduled MC days. The receiving facility contributes minimal or no inputs (e.g., local technical support, supplies), other than providing a space for surgeries.

Task shifting for MC, on the other hand, is defined by WHO as a process of delegation, whereby all MC surgical tasks are moved, where appropriate, to less-specialized cadres of health workers, including nurses and clinical officers (WHO, 2010). By reorganizing the workforce in this way, task shifting presents a potentially viable solution for improving health care coverage by making more efficient use of the human resources already available and by quickly increasing capacity while training and retention programs are expanded.

¹ Clinical officers are medical practitioners who provide health care services, including advanced advisory, diagnostic, curative, and preventive medical services, either independently or with limited supervision from a physician.

BACKGROUND

Decisions regarding which service delivery modes and strategies to use must consider effectiveness and safety. MC is a relatively simple, quick, and safe procedure when performed in a clinical setting under aseptic conditions by a trained practitioner with proper instrumentation. There are now reliable data on adverse event rates for MC in clinical settings (Auvert, Taljaard et al. 2005; Bailey, Moses et al. 2007; Gray, Kigozi et al. 2007; Krieger, Bailey et al. 2007; Kigozi, Gray et al. 2008). However, such conditions do not always prevail in a real-world setting, even when services have adequate infrastructure, equipment, and supplies. This is due to a variety of factors related to both the provider (e.g., provider ratios, provider cadre, years performing MC) and the client (e.g., distance to the service, HIV status, resumption of normal work and leisure activities, HIV knowledge and prevention practices). No research to date has been published on evaluating the effectiveness and safety of either task shifting or outreach services for MC. Generating evidence on the risks and benefits of these two service delivery strategies and predictors of adverse events consequent to MC will help decision makers prioritize how MC inputs and services are organized and managed, to ensure access, quality, safety, and continuity of care across different locations and over time.

Additionally, as MC provides only partial protection against HIV infection, there are concerns that risk compensation could offset these potential benefits. Risk compensation (or behavioral disinhibition) refers to the concept that once a man feels protected by MC, he may engage in risky behaviors associated with HIV transmission, such as having multiple partners and having unprotected sex. For instance, Auvert and colleagues (Auvert, Taljaard et al. 2005) found that men who had a circumcision were significantly more likely to have multiple partners than those who had not been circumcised. Gray and colleagues (Gray, Kigozi et al. 2007) developed simulation models to assess the impact of MC on the incidence of HIV, including the effects of risk compensation. Through this process, they found that behavioral disinhibition could offset any gains in reducing HIV incidence through MC service provision.

Against this background, EngenderHealth undertook two prospective studies to evaluate the safety and effectiveness of two modes of MC service delivery in Nyanza Province, Kenya: 1) task shifting to NPCs (nurses and clinical officers) working as nondedicated MC providers at their base static sites of employment; and 2) mobilization of clinical officers to provide MC services at outreach MC service sites. Safety and effectiveness were measured in terms of men's experience of adverse events (AEs) and men's satisfaction with their circumcision. Furthermore, due to the potential that risk compensation has to reverse any gains from MC, we also collected data on men's HIV knowledge and prevention practices. We elected to report on both studies in this one report, due to the similarities in methods and outcomes of these studies.



STUDY OBJECTIVES & METHODOLOGY

Goals and Objectives

To help support scale-up of adult MC for HIV prevention in Kenya, two prospective studies were conducted to assess two different modes of MC service delivery in the public sector. Both studies examined clinical outcomes and client satisfaction with comprehensive MC services. The first, called the **NPC study**, assessed MC services provided through task shifting by trained nurses and clinical officers, who worked and delivered MC services in adequately equipped health care facilities that served as the providers' base (static) site of employment. The second, called the **outreach study**, assessed MC services provided in adequately equipped outreach health care facilities, with MCs performed by trained itinerant clinical officers. The primary goal of both studies was to assess whether MC services can be safely and effectively offered through these two modes of service delivery, and whether the services would be acceptable to clients. Thus, specific objectives were as follows:

- I. To determine the proportion of men experiencing AEs at surgery and at seven and 60 days postcircumcision
- II. To evaluate risk factors associated with AEs post-MC surgery
- III. To assess client satisfaction with MC at 60 days post-MC surgery

Given the breadth of data collected on sexual behaviors, we conducted secondary analyses to evaluate the following subobjectives:

1. To determine what influences men to seek VMMC
2. To evaluate men's HIV knowledge and prevention practices pre- and post-MC

Given the limited data available on risk compensation outside of a clinical setting, the latter information can be used to inform community mobilization and social and behavior change communication (SBCC) campaigns, as well as provide insights into the effect of MC on sexual behavior change in the context of routine service provision.

The results of both studies are presented together, given their similar goals and objectives; however, we do not compare results across studies.

Methods

Study Sites and MC Service Provision

The health care facilities where the NPC and outreach studies were conducted are located in Homa Bay, Rongo, Rachuonyo, and Nyando districts in Nyanza Province. Based on GOK recommendations (GOK, 2009), all facilities met the minimum requirements for provision of MC (Figure 1) prior to initiating the studies. In conjunction with the AIDS, Population, and Health Integrated Assistance (APHIA) II Nyanza Project (an EngenderHealth-managed project in Nyanza Province funded by the U.S. Agency for International Development [USAID] and the President's Emergency Plan for AIDS Relief [PEPFAR]), some sites were renovated and equipped as needed to bring their standards up to permit them to offer MC services. The MC services evaluated within both studies were within the public sector, and all providers were employed at government health facilities within Nyanza Province. As such, these studies and all VMMC services associated with these studies were done in accordance with the intent of the Policy on Male Circumcision in Kenya (Kenya Ministry of Health 2007). Per this policy, in addition to the MC procedure, all health care facility study sites provided the following comprehensive components of MC services, either on-site or through referrals:

- ◆ SBCC, including ongoing risk reduction counseling about safer sex practices
- ◆ Male condoms, along with promotion of their consistent and correct use
- ◆ HIV counseling and testing (HCT)
- ◆ Sexually transmitted infection (STI) counseling and services
- ◆ HIV care and treatment services

FIGURE 1: MINIMUM REQUIREMENTS FOR SAFE AND HYGIENIC CONDITIONS FOR PROVIDING MC

<p>Location for performing MC (one of the following):</p>	<ul style="list-style-type: none"> ○ Surgical theater or clean, ventilated room with adequate light ○ Room surfaces and operating table able to be easily and effectively cleaned and disinfected ○ Sufficient workspace in room for table and for surgical supplies and equipment
<p>Handwashing facilities</p>	<ul style="list-style-type: none"> ○ Soap ○ Sink or wash basin w/clean water
<p>Personal protective equipment</p>	<ul style="list-style-type: none"> ○ Gloves ○ Gowns or aprons
<p>Safe disposal of infectious and hazardous waste</p>	<ul style="list-style-type: none"> ○ Sharps container ○ Designated location for proper hazardous waste disposal
<p>Instrument cleaning and high-level disinfection or sterilization (one of the following)</p>	<ul style="list-style-type: none"> ○ Autoclave ○ Pressure cooker ○ Other sterilizing equipment ○ Boiler
<p>Surgical equipment and supplies</p>	<ul style="list-style-type: none"> ○ Forceps ○ Clamps ○ Scissors ○ Scalpels ○ Surgical mask ○ Sutures ○ Antiseptic ○ Local anesthesia

STUDY OBJECTIVES & METHODOLOGY

The NPC study was conducted at 11 health care facilities Homa Bay, Rongo, Rachuonyo, and Nyando districts in Nyanza Province. These facilities had nurses and clinical officers who successfully completed training on MC, adequate equipment and supplies required to perform MC, and space where confidential counseling and safe and hygienic MC could be provided. These facilities are referred to as static or fixed sites. A total of 26 trained MC providers (15 nurses and 11 clinical officers) working at the eligible static study sites performed VMMC on study participants.

The outreach study was conducted at 11 health centers in Homa Bay, Rongo, and Rachuonyo districts in Nyanza Province. As in the NPC study, these health centers had adequate equipment and supplies required to perform MC and space where confidential counseling and safe and hygienic MC could be provided. However, all of these health centers lacked sufficient numbers of trained providers to meet the demand for MCs; therefore, under the study, in collaboration with the Ministry of Health, trained MC providers were mobilized from other health facilities to provide MCs at these health centers. A total of 11 trained clinical officers delivered MC services at the eligible outreach study sites and performed VMMC on study participants. Providers traveled from their primary

facilities of employment to deliver MC services at outreach sites where there were shortages of trained MC providers.

Tables 1, 2, and 3 report the number or percentage of providers and procedures by cadre, and by study, and the average number of years of professional background of MC providers, by study. Thirty-one providers performed MCs in the NPC and outreach studies: Twenty worked only at NPC sites, five worked only at outreach sites, and six (all clinical officers) did MCs at both NPC and outreach sites.

In the NPC study, 26 providers performed 2,244 MC procedures (Table 2). More than half (15) of these providers were nurses. The nurses performed 64% of the MCs, while clinical officers did 36%. More than 80% of the NPC providers were men; 73% were Luo. The providers averaged 37 years of age and 12 years of work experience (Table 2).

In the outreach study, providers were 11 clinical officers (per study protocols), and all were men. Seven (64%) of these providers were Luo, and they averaged 33 years of age, with an average of nine years of professional experience (Table 3).

TABLE 1. NUMBER AND PERCENTAGE OF PROVIDERS AND PROCEDURES, BY CADRE AND BY STUDY

	NPC		Outreach	
	n	%	n	%
Number of providers				
Clinical officer	11	42.3	11	100.0
Nurse	15	57.7	--	--
Total	26	100.0	11	100.0
Number of providers				
Clinical officer	818	36.5	900	100.0
Nurse	1,426	63.5	--	--
Total	2,244	100.0	900	100.0

TABLE 2. BACKGROUND CHARACTERISTICS OF MC PROVIDERS, BY STUDY

	NPC			Outreach
	Clinical officer (n=11)	Nurse (n=15)	All providers (n=26)	Clinical officer (n=11)
Sex				
Male	11	10	21	11
Female	0	5	5	0
Ethnic group				
Luo	8	11	19	7
Other (Kalenjin, Kisii, Kuria, Luhya, Kamba)	3	4	7	4
Age				
Average age (in years)	34.6	39.3	37.3	32.9

TABLE 3. AVERAGE NUMBER OF YEARS OF PROFESSIONAL BACKGROUND OF MC PROVIDERS, BY STUDY

	NPC			Outreach
	Clinical officer (n=11)	Nurse (n=15)	All providers (n=26)	Clinical officer (n=11)
Years working in profession	10.1	13.7	12.2	8.6
Years of experience performing minor surgeries (officially or unofficially)	9.9	10.1	10.0	8.7
Years of experience performing major surgeries (officially or unofficially)	2.3	4.9	3.8	1.2
Years of experience doing MCs (officially or unofficially)	5.3	4.3	4.7	4.5

Study Procedures

All study procedures were carried out by trained providers and research assistants. All MC surgical providers in both the NPC and outreach studies received training on MC standard procedures and guidelines, based on the Kenya MC training curriculum (Kenya MOPHS 2008), which was adapted from the WHO MC training manual (WHO, UNAIDS et al. 2006; WHO, UNAIDS et al. 2009), per Kenya's VMMC guidelines (Kenya Ministry of Health 2007) and strategy (Kenya Ministry of Health 2007; Kenya MOPHS 2009) and based on the WHO/UNAIDS *Manual*

for MC Under Local Anaesthesia (WHO, UNAIDS et al. 2006; WHO, UNAIDS et al. 2009). These procedures cover screening, preparation for surgery, surgical procedures, postoperative care, infection control, management of complications, and follow-up care. The providers then attended an MC study orientation workshop that covered the study procedures and practices, including all issues related to the protection of human subjects, and described the studies, and then they signed a study participation agreement form. Trained research assistants coordinated data collection at all NPC and outreach study sites.

STUDY OBJECTIVES & METHODOLOGY

FIGURE 2: INCLUSION/EXCLUSION CRITERIA

INCLUSION CRITERIA	<ul style="list-style-type: none">○ Freely consents to participate in the study and signs an informed consent form○ <u>Outreach</u>: Is 18–54 years old○ NPC: Is 13–54 years old○ Is in good general health○ Is able to understand the study procedures and requirements○ Agrees to return to the health care facility for follow-up seven days and 60 days after MC
EXCLUSION CRITERIA*	<p>Absolute contraindications to clinic-based MC include:</p> <ul style="list-style-type: none">○ Anatomical deformity of the penis. Men whose urethral meatus is on the underside of the penis (hypospadias) or on the upper side of the penis (epispadias) must not be circumcised, because the foreskin may be needed in a repair operation.○ Chronic paraphimosis, where the foreskin is permanently retracted and the skin is thickened and swollen due to the longstanding nature of the condition.○ Genital ulcer disease is referred for investigation and treatment prior to MC.○ Urethral discharge is referred for investigation and treatment prior to MC.○ Penile cancer—the client should be referred to a specialist.○ Chronic disorders of the penis and foreskin such as filariasis—the client should be referred to a specialist.○ Bleeding disorders such as hemophilia—The client is referred to a higher level. <p>Relative contraindications to clinic-based MC depend on the experience of the surgeon and include:</p> <ul style="list-style-type: none">○ A tight foreskin as a result of scar tissue (<i>phimosis</i>) may make it impossible to retract the foreskin. If there is a history of penile discharge or repeated infections (<i>balanitis</i>), the client should be referred to a specialist. Thick adhesions between the glans and foreskin may also require referral to a specialist.○ Scar tissue at the frenulum—Sometimes, young men suffer from repeated tearing of the frenulum. This can result in thick scar tissue in the frenulum area and may make circumcision and healing more difficult. Depending on the experience of the team, such men should be referred to a specialist.○ Penile warts—Whether to proceed with clinic circumcision depends on the extent of any penile warts. It is usually possible to proceed if there are one or two small warts on the foreskin, as these will be removed with the foreskin. However, if there are extensive warts, then circumcision is best undertaken in a specialist hospital where diathermy is available, since penile warts can cause a lot of bleeding.○ Balanitis xerotica obliterans—A plaque of scar tissue can extend onto the surface of the glans and involve the urethral meatus and the foreskin. In mild cases, circumcision can proceed as normal. If the process involves the urethral meatus, the client should be referred to a specialist, where, in addition to removal of the foreskin, his meatus may be widened.○ Other abnormalities of the genitalia, such as hydrocele causing scrotal swelling—The man should be referred to a specialist centre for assessment. <p>*Source: WHO, UNAIDS, & JHPIEGO, 2006, Chapter 4.3–4.4.</p>

Data were collected by both MC providers and research assistants between December 2009 and December 2010. Clinical data were noted by the MC providers, while all other data were collected from the study participants by the research assistants. For each study, data were collected on the providers' and clients' backgrounds, details of the preoperative clinical examination, the MC procedures used, and any surgical complications or AEs observed at any point following the surgery. Surgical outcomes were evaluated immediately after the circumcision, as well as seven days and 60 days following the procedure. In addition, client satisfaction and behaviors were evaluated at seven days and 60 days following the procedure. Reasons for seeking MC were assessed at admission to the study and again at seven days following the procedure.

Prior to MC surgery, all of the men received MC counseling, during which potential risks of MC were discussed. Potential MC risks were reviewed again during the preoperative period. Prior to discharge, men were given instructions on what to do if they have any questions or concerns or if they experience any complications. This information included where to go for acute and emergency care and a phone number to call with questions and concerns. Informed consent was obtained from all subjects in their local language prior to their participation in either study. Men who declined to participate were given full medical care, per standard VMMC practice, at the health care facility they were attending. Participants were given a modest travel allowance prior to each follow-up visit, to encourage their retention in the study.

Study Participants

Men were considered eligible for inclusion in the MC NPC and outreach studies if they were in good general health, were able to return to the health care facility for follow-up seven days and 60 days following their MC procedure, and had no "absolute" or "relative" contraindications to MC (WHO, UNAIDS et al. 2006; WHO, UNAIDS et al. 2009). Eligibility criteria are shown in [Figure 2](#). Men who did not

fit the eligibility criteria were referred to a specialist for MC consideration.

For the NPC study, we recruited 2,244 study participants from among men coming to the study sites for circumcision. The sample size was calculated using an expected complication rate of 5%, 80% power, and a confidence level of 95%. Men aged 13–54 who came to an NPC static study site for their VMMC and who met the study eligibility criteria were asked to participate. Adult men aged 18–54 provided written consent to participate in the study, while minors younger than 18 were given consent to participate by a parent or legal guardian and were also asked to sign an assent form. The distribution of procedures by district is shown in [Table 4 \(page 18\)](#). Almost all participants (98%) returned for their post-MC exam seven days following their MC procedure, and 82% returned again at 60 days following their MC for an exam and interview ([Table 5, page 18](#)).

As part of the outreach study, we recruited 900 study participants from among men coming to the study sites for MC. The sample size was calculated using an expected AE rate of 2%, 80% power, and a confidence level of 95%. Men aged 18–54 who came to an outreach study site for their VMMC and who met the study eligibility criteria were asked to participate; all participating men provided written consent to participate in the study. The distribution of procedures by district is shown in [Table 4](#). At seven days following their MC procedure, 94% of the men returned for their exam and interview. Sixty days after their MC, 78% of the outreach study participants returned for their follow-up exam and interview ([Table 5](#)).

Measures

Primary Objectives: Risk Factors Associated with Adverse Events and Client Satisfaction with MC Services

We defined AEs based on complications outlined in the WHO MC Manual (WHO, UNAIDS et al. 2006) and

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TABLE 4. NUMBER OF MEN CIRCUMCISED, BY DISTRICT AND STUDY (NPC AND OUTREACH)

	NPC (aged 13–54)	Outreach (aged 18–54)
Homa Bay	822	538
Rongo	585	83
Rachuonyo	746	279
Nyando	91	--
Total	2,244	900

TABLE 5. CLIENT RETENTION AT SCHEDULED FOLLOW-UP, BY DISTRICT AND STUDY

		NPC		Outreach	
		n	% retention	n	% retention
Homa Bay	MC procedure	822	100.0	538	100.0
	7 days post-MC	811	98.7	515	95.7
	60 days post-MC	713	86.7	417	77.5
Nyando	MC procedure	91	100.0	--	--
	7 days post-MC	90	98.9	--	--
	60 days post-MC	82	90.1	--	--
Rachuonyo	MC procedure	746	100.0	279	100
	7 days post-MC	712	95.4	262	93.9
	60 days post-MC	570	76.4	231	82.8
Rongo	MC procedure	585	100.0	83	100.0
	7 days post-MC	578	98.8	73	88.0
	60 days post-MC	480	82.	57	68.7
All Districts	MC procedure	2,244	100.0	900	100.0
	7 days post-MC	2,191	97.6	850	94.4
	60 days post-MC	1,845	82.2	705	78.3

on AEs listed in the GOK's VMMC forms (Government of Kenya, Ministry of Public Health and Sanitation et al.). Additionally, a literature review was conducted to determine AEs associated with MC as defined by other researchers. To refine the list, each AE was graded on level of severity (mild, moderate, or severe). EngenderHealth

convened a panel of research, HIV, and clinical experts to determine AEs and levels of severity at the time of surgery and at seven days and 60 days post-MC. This was done to avoid inclusion of outcomes that are considered within normal limits and not adverse. For example, it was thought to be within the expected range that a man may experience

FIGURE 3: ADVERSE EVENTS ASSOCIATED WITH MC

Surgical Complication	Postdischarge AE
<ul style="list-style-type: none"> <input type="radio"/> Bleeding <input type="radio"/> Excessive skin removed <input type="radio"/> Cosmetic problem <input type="radio"/> Excessive swelling <input type="radio"/> Injury/abrasion of glans penis <input type="radio"/> Anesthesia-related event <ul style="list-style-type: none"> • Problem with anesthetic (e.g., initial dose not effective, additional needed) • Palpitations • Vaso-vagal reaction • Emesis • Anaphylaxis • Convulsions <input type="radio"/> Required transfer to other facility <input type="radio"/> Pain <input type="radio"/> Damage to penis <input type="radio"/> Unspecified/other 	<ul style="list-style-type: none"> <input type="radio"/> Pain <input type="radio"/> Excessive swelling <input type="radio"/> Hematoma <input type="radio"/> Infection <input type="radio"/> Problems voiding <input type="radio"/> Delayed wound healing <input type="radio"/> Problems with appearance <input type="radio"/> Injury to penis <input type="radio"/> Bleeding <input type="radio"/> Torsion of penis <input type="radio"/> Excessive skin removed <input type="radio"/> Insufficient skin removed <input type="radio"/> Unspecified/other

mild pain at seven days post-MC (see Table 9 for severity exceptions at seven days post-MC). By 60 days post-MC, all AE elements were considered an AE, despite the level of severity. Figure 3 summarizes the definitions of AEs used in these studies.

We examined both provider- and client-related factors as possible risk factors associated with AEs. Provider factors included provider's age, sex, years of experience in profession, experience performing minor and major surgeries, and experience performing MC. Additionally, within the NPC analyses, as this study had both nurses and clinical officers performing the MCs, we also examined the cadre of provider who performed the MC. Client factors included client's age, sex, educational level, employment status, marital status, distance traveled to the site of circumcision, mode of transportation, and self-reported HIV status. At seven days and 60 days post-MC, we also

assessed men's satisfaction with their MC and when they resumed routine activities. We asked men how satisfied they were with their MC, how satisfied their partner was with the MC, if they would recommend MC to a friend or relative, and if they were comfortable being circumcised by a female provider.

Secondary Objectives: Demand for MC Services and HIV Knowledge and Prevention Practices Pre-MC and Post-MC

We examined factors influencing demand for MC services, including reasons men decided to seek MC, sources of information about MC (e.g., radio, poster, newspaper, etc.), and reasons for accessing services at a specific facility (e.g., close to home, cost, trust health provider).

HIV prevention practices examined included condom use at last sexual encounter prior to the MC and 60 days

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following the MC and an assessment of the likelihood of men's speaking to their partners about preventing HIV within one month both before the MC was conducted and after the 60-day post-MC assessment. The potential predictors of sexual risk behaviors included client's age, educational level, employment status, marital status, number of partners, and self-reported HIV status.

NPC and outreach studies. We compared the percentage of men reporting condom use and willingness to speak to their partner about HIV, at baseline and at 60 days post-MC. Following univariate analyses, we used multivariate logistic regression to assess the independent predictors of condom use and of speaking to sexual partners about preventing HIV.

Statistical Analysis

Primary Objectives: Risk Factors Associated with Adverse Events and Client Satisfaction with MC Services

We analyzed AE data from the NPC and outreach studies separately. For each study, we calculated the proportion of men who experienced an AE associated with the MC prior to discharge on the day of the MC, at seven days post-MC, and at 60 days post-MC. The risk factors were individually examined in univariate analyses, and a multivariate model was constructed based on risk factors that were associated with AEs at a significance of $p < .20$ in the univariate analyses. We performed regression analyses for AEs at seven days post-MC. We did not repeat these analyses for AEs at 60 days post-MC, as too few AEs were reported 60 days after the circumcision (10 for the NPC setting and seven for the outreach setting). We ran logistic regression models separately for the NPC and outreach settings and measured associations using odds ratios (ORs) and corresponding 95% confidence intervals.

Secondary Objectives: Demand for MC Services and HIV Knowledge and Prevention Practices Pre-MC and Post-MC

To assess demand for MC, we conducted descriptive analyses to explore why men sought MC and their source of information on MC. In addition, we conducted descriptive analyses on factors related to sexual behavior following circumcision; as the levels of these self-reported behaviors were similar regardless of mode of service delivery (NPC at static sites and outreach), these data were pooled across the



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MC Client Background

NPC

Almost all NPC study participants were Luo (98%) and Christian (97%). Per the NPC protocol, men were aged 13–54 years old, with an average age of 23 years. The majority of these men (72%) were single (not married, divorced, widowed, or not living with a partner). Most men had at least some primary education, with more than 70% having at least some secondary education. More than 80% of the NPC MC clients were either students or employed. In general, these men lived relatively close to their NPC MC health care facility, having traveled on average about 5.5 km. Six percent reported that they were HIV-positive, and 2.5% reported they had a sexual partner (wife, primary partner, or any other partner) who was HIV-positive (Table 6).

Outreach

Participants in the outreach study were on average 23 year old (age range, 18–54). Most men were Luo (98%) and Christian (96%). Seventy-four percent were single (not married, divorced, widowed, or not living with a partner). Almost all of these men had at least some primary education (98%), with 63% having at least some secondary education. Most of the men were either students (42%) or were employed (33%). On average, these men traveled 5.1 km to an outreach MC service site. Among men who had their MC at an outreach site, 8% reported they were HIV-positive, and 4% reported that they had a sexual partner (wife, primary partner, or any other partner) who was HIV-positive (Table 6).

Objective I: Determine the proportion of men experiencing adverse event at surgery and at seven and 60 days postcircumcision

We collected data on complications and other AEs at the time of the MC and at the seven- and 60-day follow-up visits.

NPC

At the NPC sites, no one experienced surgical complications or immediate postoperative AEs. At seven days after their MC, 3.8% of the NPC participants had experienced an AE (Table 7). Among those who had an AE, most (84%) had only one. Ten men had two AEs, and three men had three, which was the maximum number of AEs reported. By 60 days post-MC, very few men (0.5%) were experiencing an AE (Table 7), and none of these were severe. The most common AEs were infections and excess swelling (Table 9).

At seven days postcircumcision, 2.2% of the men who had their circumcision performed by a clinical officer experienced an AE, while 4.7% of the men who had a nurse perform their MC had an AE (Table 8). This difference disappeared by the 60-day postcircumcision exam.

Among the men who returned for the seven-day follow-up visit, most had experienced an erection postcircumcision (99%). Among those who had an erection within the first seven days following the MC, 6% said the erection led to bleeding, and 6% said their erection led to their wound opening. By 60 days after their MC, eight men reported they had an erection with bleeding, and only one man reported that his erection led to his wound opening. Among those who reported an erection with bleeding at their seven-day follow-up interview, 6.5% were found to have an AE; among those who reported the wound opening with their erection, 12% had an observed AE. Erections leading to wound opening, in particular, were marginally associated with an AE (erection with bleeding: OR=1.9, 95% CI 0.9, 4.0; erection with wound opening: OR=4.1, 95% CI 2.3, 7.4); however, we did not analyze erection as a risk factor or enter it into the multivariate analysis, as they are likely the same incident as the AE itself. Erection leading to bleeding or wound opening was rare at 60 days after circumcision (0.5%), and only one man who had an erection with bleeding had an adverse event at 60 days post-MC (Tables 10 and 11).

TABLE 6: MC CLIENT SOCIODEMOGRAPHIC CHARACTERISTICS, BY STUDY

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
Age (in years)				
13–17	517	23.0		
18–25	1,137	50.7	711	79.0
26–35	440	19.6	138	15.3
36–54	150	6.7	51	5.7
Average age	22.7	--	22.6	--
Ethnic group				
Luo	2,191	97.6	884	98.2
Religion				
Christian	2,151	95.9	852	94.7
Muslim	18	0.8	13	1.4
Other/no religion	38	1.7	22	2.4
Missing data	37	1.6	13	1.4
Marital status				
Single	1,618	72.1	666	74.0
Never-married	1,596	71.1	658	73.1
Divorced/separated	16	0.7	4	0.4
Widowed	6	0.3	4	0.4
Married/living with partner	606	27.0	229	25.4
Not married, living with partner	34	1.5	6	0.7
Married, not living with partner	83	3.7	6	0.7
Married, living with partner	489	21.8	217	24.1
Missing data	20	0.9	5	0.6
Education				
Some primary education or higher	2,197	97.9	878	97.6
Some secondary education or higher	1,588	70.8	563	62.6
Employment				
Unemployed	401	17.8	220	24.4
Student	950	42.4	377	41.9
Employed	883	39.3	301	33.4
Missing data	10	0.4	2	0.2
Distance to clinic				
Average km traveled to MC facility	5.5	--	5.2	--
HIV status				
Is HIV-positive	131	5.8	69	7.7
Partner (primary or other) is HIV-positive	57	2.5	37	4.1

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TABLE 7. NUMBER (AND PERCENTAGE) OF CLIENTS WHO EXPERIENCED AES, AND NUMBER (AND PERCENTAGE) OF AES AT 7 DAYS AND 60 DAYS POST-MC, BY STUDY

	NPC		Outreach	
	7 days post-MC (n=2,191)	60 days post-MC (n=1,845)	7 day post-MC (n=850)	60 days post-MC (n=705)
AE (any)	83 (3.8%)	10 (0.5%)	31 (3.6%)	7 (1.0%)
Among men with an AE				
1 AE	70 (84%)	9 (90%)	18 (58%)	6 (86%)
2 AEs	10 (12%)	1 (10%)	4 (13%)	1 (14%)
3 AEs	3 (4%)		7 (23%)	
>4 AEs			2 (6%)	

TABLE 8. NUMBER (AND PERCENTAGE) OF NPC CLIENTS WHO EXPERIENCED AN AE AT 7 DAYS AND 60 DAYS POST-MC, BY TYPE OF PROVIDER WHO PERFORMED MC

NPC	7 days post-MC		60 days post-MC	
	Clinical officer (n=807)	Nurse (n=1,384)	Clinical officer (n=694)	Nurse (n=1,151)
AE (any)	18 (2.2%)	65 (4.7%)	4 (0.6%)	6 (0.5%)

Outreach

No man who received an MC at an outreach site experienced any surgical complications or immediate postoperative AEs. At seven days after their MC procedure, 3.6% of the men experienced an AE; among these, 58% had one AE, 13% two, and 23% three (Table 7). The most common AEs were infection, excessive swelling, and delayed wound healing (Table 9). At 60 days after the MC, only 1% had an AE (Table 7), and none of these were severe (Table 9).

At their seven-day follow-up visit, most outreach study participants reported they had experienced an erection postcircumcision (99%). Among those men who had an erection, 7% experienced erection leading to bleeding; the incidence of AEs among these men was 10%. Of men who had an erection, 6% had an erection leading to wound opening, and among these men, 12% experienced an AE. As in the NPC study, erection leading to bleeding or wound opening was associated with AE (erection with

bleeding: OR=3.4, 95% CI 1.3, 8.7; erection with wound opening: OR=4.1, 95% CI 1.6, 10.4); however, we did not analyze this as an independent risk factor for AE, as the erection outcomes may be the same incident as the AE. Erection leading to bleeding or wound opening was rare at 60 days after circumcision (1%), and none of these men experienced an AE (Tables 10 and 11).

Objective II: Evaluate risk factors associated with adverse events post MC surgery

NPC

In univariate analyses, experience of an AE seven days after circumcision in the NPC study was associated with the circumcision being performed by a nurse, age greater than or equal to 18 years, and travel by cars/buses after the circumcision. There was an inverse association between experience of an AE and resumption of normal work

TABLE 9. TYPE AND SEVERITY OF AES AT 7 DAYS AND 60 DAYS POST-MC, BY STUDY

AE	Severity	NPC		Outreach	
		Day 7 (n=2,195)	Day 60 (n=1,846)	Day 7 (n=853)	Day 60 (n=706)
Pain	Mild		6		1
	Moderate		1		
	Severe	2		2	
Excess swelling	Mild		1		
	Moderate	23		10	
	Severe				
Hematoma	Mild	2		2	
	Moderate	3		5	
	Severe				
Infection	Mild	39	1	12	
	Moderate	4		3	
	Severe			1	
Problems voiding	Mild	2		1	
	Moderate			1	
	Severe				
Delayed wound healing	Mild				
	Moderate	3		8	
	Severe			1	
Problems with appearance	Mild				3
	Moderate	7	1	3	2
	Severe			1	
Injury to penis	Mild	2		2	
	Moderate		1	2	
	Severe				
Bleeding	Mild	8		1	
	Moderate	1		3	
	Severe				
Torsion of penis	Mild	1			1
	Moderate			1	
	Severe				
Excessive skin removed	Mild				
	Moderate			1	
	Severe				
Insufficient skin removed	Mild				1
	Moderate	1		3	
	Severe				
Other	Mild	1*			
	Moderate				
	Severe				

■ Represents severity levels that were not included in EngenderHealth's definition of an AE at 7 days post-MC.
 *Slight ulcer at frenulum.

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TABLE 10. ERECTION OUTCOMES AT SEVEN- AND 60-DAY FOLLOW-UP VISITS, BY STUDY

	NPC				Outreach			
	7 days post-MC (n=2,191)		60 days post-MC (n=1,845)		7 days post-MC (n=850)		60 days post-MC (n=705)	
	n	%	n	%	n	%	N	%
Had an erection	2,172	99.1	1,820	99.0	839	98.7	698	99.0
Percentage among those who experienced an erection								
Erection led to bleeding	123	5.7	8	0.4	59	7.0	6	0.9
Erection led to opening of wound	125	5.8	1	0.1	51	6.1	1	0.1

TABLE 11. AMONG MEN WHO EXPERIENCED BLEEDING OR WOUND OPENING ASSOCIATED WITH AN ERECTION, PROPORTION WHO EXPERIENCED AN AE AT SEVEN DAYS POST-MC, BY STUDY

	NPC				Outreach			
	Erection led to bleeding (n=123)		Erection led to opening of wound (n=125)		Erection led to bleeding (n=59)		Erection led to opening of wound (n=51)	
	N	%	n	%	n	%	n	%
AE 7 days post-MC	8	6.5	15	12.0	6	10.2	6	11.8

activities after two days and resumption of only some leisure activities within two days after the circumcision (Table 12).

In multivariate logistic regression analysis, men whose MC was performed by a nurse (OR=2.5; 95% CI: 1.3, 4.8) and those who took a car/bus (OR=1.9; 95% CI: 1.1, 3.4) were more likely to experience AEs than were those whose MC was performed by a clinical officer, after adjusting for the factors listed in Table 12. Men aged 26–35 years were also at greater risk for an AE. On the other hand, those who reported resuming normal work activities after two days (OR=0.3; 95% CI: 0.1, 0.6) and those who reported resuming only some leisure activities (OR=0.1; 95% CI: 0.1, 0.4) were less likely to experience AEs than were those who resumed normal work/leisure activities within two days. Furthermore, being married or living with a partner was marginally protective against having an AE (OR=0.5; 95% CI: 0.2, 1.0) (Table 12).

Outreach

In the outreach study, univariate analysis showed that AEs seven days after circumcision were inversely associated with having had a circumcision performed by a provider older than 32 years, a provider 10 or more years of experience in the profession, and a provider with 10 or more years of experience in minor surgeries. Those who resumed normal leisure activities after two days since circumcision and those who resumed only some leisure activities were less likely to experience adverse reactions than were those who resumed normal work/leisure activities within two days (Table 13).

In multivariate analysis, clients whose MC was performed by an older provider (OR=0.3; 95% CI: 0.1, 0.9) and who resumed only some leisure activities (OR=0.2; 95% CI: 0.04, 0.6) were less likely to experience AEs, after adjustment for employment status, mode of transportation, and time to resumption of normal work activities. In contrast, those

TABLE 12. MULTIVARIATE ASSOCIATIONS BETWEEN PROVIDER/CLIENT-RELATED FACTORS AND AES SEVEN DAYS AFTER CIRCUMCISION IN THE NPC SETTING

	Variable	Category	No. of AEs/n	Crude OR	95% CI	Multi-variate OR*	95% CI
Provider	Sex	Male	63/1,833	Ref		Ref	
		Female	20/358	1.6	1.0, 2.79	1.1	0.6, 2.0
	Cadre	Clinical officer	18/807	Ref		Ref	
		Nurse	65/1,384	2.2	1.3, 3.7	2.5†	1.3, 4.8
	Years in the Profession	<10 years	39/1,201	Ref		Ref	
>10 years		44/990	1.4	0.9, 2.2	1.0	0.6, 1.7	
Client	Age	13–17	9/505	Ref		Ref	
		18–25	47/1,102	2.5	1.2, 5.1	1.8	0.8, 3.9
		26–35	20/434	2.7	1.2, 5.9	2.8†	1.0, 7.7
		36–54	7/150	2.7	1.0, 7.4	2.9	0.8, 10.7
	Secondary education	No	24/641	Ref		N/A	N/A
		Yes	59/1,550	1.0	0.6, 1.7	N/A	N/A
	Employment status	Employed	33/739	Ref		Ref	
		Student	26/919	0.6	0.4, 1.1	0.7	0.3, 1.3
		Unemployed/unknown	24/533	1.0	0.6, 1.7	1.1	0.6, 1.9
	Marital status	Single/widowed/divorced	60/1,571	Ref		Ref	
		Married/living with partner	21/599	0.9	0.6, 1.5	0.5	0.2, 1.0
		Unknown/missing	2/21	2.7	0.6, 11.7	3.0	0.6, 14.8
	Distance traveled	<5 km	43/1,143	Ref		N/A	N/A
		>5 km	23/491	1.3	0.8, 2.1	N/A	N/A
		No response/missing	17/557	0.8	0.5, 1.4	N/A	N/A
	Mode of transportation	Walking	35/1,211	Ref		Ref	
		Car/bus	22/379	2.1	1.2, 3.7	1.9†	1.1, 3.4
		Motorcycle/bicycle	20/454	1.5	0.9, 2.7	1.3	0.7, 2.3
		Other/missing	2.41	2.4	1.0, 5.9	2.4	0.9, 6.0
	HIV status	Negative	63/1,777	Ref		Ref	
		Positive	8/130	1.8	0.8, 3.8	1.6	0.7, 3.7
		Don't know/no response	12/276	1.2	0.6, 2.2	1.1	0.6, 2.1
	Resumed normal work activities	Yes, back to normal within 2 days post-MC	32/694	Ref		Ref	
		Yes, back to normal after 2 days post-MC	7/602	0.2	0.1, 0.6	0.3†	0.1, 0.6
		Some work	31/642	1.1	0.6, 1.7	2.4†	1.3, 4.4
		No	13/248	1.1	0.6, 2.2	1.4	0.6, 2.9
		Missing	0/5	<0.01	N/A	<0.01	N/A
Resumed normal leisure activities	Yes, back to normal within 2 days post-MC	22/495	Ref		Ref		
	Yes, back to normal after 2 days post-MC	15/543	0.6	0.3, 1.2	1.0	0.5, 2.2	
	Some leisure	8/615	0.3	0.1, 0.6	0.1†	0.1, 0.4	
	No	38/526	1.7	1.0, 2.9	1.3	0.7, 2.5	
	Missing	0/4	N/A	N/A	N/A	N/A	

* Multivariate analysis only includes variables associated with AE in crude analysis at $p < 0.20$. † Significant at $p < .05$ within the multivariate analysis.

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TABLE 13. MULTIVARIATE ASSOCIATIONS BETWEEN PROVIDER-/CLIENT-RELATED FACTORS AND AES 7 DAYS AFTER CIRCUMCISION IN THE OUTREACH SETTING

	Variable	Category	No. of AEs/n	Crude OR	95% CI	Multivariate OR*	95% CI
Provider	Age	<32	25/447	Ref		Ref	
		>32	6/403	0.3	0.1, 0.6	0.3†	0.1, 0.9
	Years in the profession	<10 years	25/447	Ref			
		>10 years	6/403	0.3	0.1, 0.6	Collinear**	
Client	Age	18-25	24/679	Ref			
		26-35	7/125	1.6	0.7, 3.8	N/A	N/A
		36-54	0/46	<0.01		N/A	N/A
	Secondary education	No	9/321	Ref			
		Yes	22/529	1.5	0.7, 3.3	N/A	N/A
	Employment status	Employed	11/226	Ref			
		Student	13/356	0.7	0.3, 1.7	0.7	0.3, 1.8
		Unemployed/unknown	7/268	0.5	0.2, 1.4	0.6	0.2, 1.8
	Marital status	Single/widowed/divorced	23/634	Ref			
		Married/living with partner	8/210	1.1	0.5, 2.4	N/A	N/A
		Unknown/missing	0/6	<0.01		N/A	N/A
	Distance traveled	<5 km	17/469	Ref			
		>5 km	3/158	0.5	0.2, 1.8	N/A	N/A
		No response/missing	11/223	1.4	0.6, 3.0	N/A	N/A
	Mode of transportation	Walking	15/511	Ref			
		Car/bus	4/69	2.0	0.7, 6.3	1.4	0.4, 4.6
		Motorcycle/bicycle	6/188	1.1	0.4, 2.8	1.0	0.4, 2.6
		Other/missing	6/76	2.8	1.1, 7.6	2.5	0.9, 7.2
	HIV status	Negative	2/66	Ref			
		Positive	24/702	0.9	0.2, 3.8	N/A	N/A
		Don't know/no response	5/82	1.8	0.7, 5.0	N/A	N/A
	Resumed normal work—7 days	Yes, back to normal within 2 days post-MC	4/135	Ref			
		Yes, back to normal after 2 days post-MC	4/195	0.7	0.2, 2.8	1.2	0.3, 5.5
		Some work	13/385	1.1	0.4, 3.6	2.5	0.7, 9.0
		No	10/130	2.7	0.8, 8.9	3.9†	1.0, 15.1
		Missing	0/5	N/A	N/A	N/A	N/A
	Resumed normal leisure—7 days	Yes, back to normal within 2 days post-MC	7/87	Ref			
		Yes, back to normal after 2 days post-MC	2/140	0.2	0.03, 0.8	0.3	0.05, 1.8
		Some leisure	5/303	0.2	0.1, 0.6	0.2†	0.04, 0.6
		No	17/319	0.6	0.3, 1.6	0.3	0.1, 1.2
Missing		0/1	N/A	N/A	N/A	N/A	

* Multivariate analysis only includes variables associated with AE in crude analysis at $p < 0.20$.

** The analysis yielded an unstable estimate due to collinearity with provider age. † Significant at $p < .05$ within the multivariate analysis.

TABLE 14. LEVEL OF SATISFACTION WITH MC AND COMFORT LEVEL WITH FEMALE MC PROVIDER, BY STUDY

	NPC (n=1,845)		Outreach (n=705)	
	n	%	n	%
Satisfied with MC	1,825	98.9	700	99.3
<i>Very satisfied</i>	1,807	97.9	688	97.6
<i>Somewhat satisfied</i>	18	1.0	12	1.7
Partner satisfied with MC	1,200	65.0	493	69.9
<i>Very satisfied</i>	1,113	60.3	476	67.5
<i>Somewhat satisfied</i>	87	4.7	17	2.4
Would recommend friend or relative to get MC	1,830	99.2	690	97.9
Comfortable being circumcised by female provider	1,685	91.3	657	91.8

who did not resume work were more likely to experience AEs compared with those who resumed normal work within two day of circumcision (OR=3.9, 95% CI: 1.0, 15.1). The variable for providers with 10 or more years of experience in the profession was collinear with provider's age and thus was dropped from the multivariate model (Table 13).

Objective III: Assess patient satisfaction with MC at 60 days post-MC surgery

We asked men about how satisfied they were with their circumcision at 60 days following MC surgery.

NPC

At the 60-day postcircumcision interview, almost all (99%) of the NPC participants said they were satisfied with their circumcision (98% were "very satisfied"), and the majority (65%) felt their partner was also satisfied with the circumcision. Nearly all NPC clients (99%) said they would recommend MC to a friend or relative. We were also interested to know if men would be comfortable having a woman as their MC surgeon, and found that 91% said they would be (Table 14).

Outreach

At the 60-day follow-up interview, 99% of the outreach participants said they were satisfied with their MC, and almost all were "very satisfied." The majority of these men thought their partners were satisfied also (70%), and 98% said they would recommend circumcision to a male friend or family member. Ninety-two percent of the men in the outreach study said they would be comfortable having a female provider perform their circumcision (Table 14).

Secondary Objective 1: Assess factors influencing men to seek MC services

We asked men to describe factors influencing their decision to seek MC, sources of information about MC, and reasons for accessing services at a specific facility.

NPC

Eighty-three percent of the participants in the NPC study stated that protection from HIV was their primary or secondary reason for seeking an MC, but only 52% cited this as their primary reason to get circumcised. As with the providers, the second most commonly given reason

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TABLE 15. REASONS MC CLIENTS STATED FOR SEEKING MC SERVICES, BY STUDY

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
Primary reason men seek MC				
HIV protection	1,171	52.2	594	66.0
Improved hygiene	654	29.1	139	15.4
STI protection	274	12.2	121	13.4
Improved sexual experience	18	0.8	10	1.1
Friends' strong recommendation of circumcision	24	1.1	2	0.2
Request of sex partner	13	0.6	11	1.2
Recommendation by health worker	15	0.7	4	0.4
Acceptance by other ethnic groups	11	0.5	3	0.3
Acceptance by women from other ethnic groups	4	0.2	0	-
Parents' recommendation of circumcision	6	0.3	1	0.1
Other	54	2.4	15	1.7
Other reasons men seek MC				
HIV protection	689	30.7	186	20.7
Improved hygiene	1,025	45.7	550	61.1
STI protection	1,392	62.0	609	67.7
Improved sexual experience	223	9.9	124	13.8
Friends' strong recommendation of circumcision	156	7.0	88	9.8
Request of sex partner	118	5.3	95	10.6
Acceptance by other ethnic groups	68	3.0	29	3.2
Acceptance by women from other ethnic groups	32	1.4	16	1.8
Parents' recommendation of circumcision	51	2.3	56	6.2
Health worker's recommendation	51	2.3	63	7.0
Other	93	4.1	33	3.7

for an MC was improved hygiene, with 29% of the NPC participants stating hygiene as primary reason and 46% stating it as a secondary reason for seeking MC services, resulting in 75% listing it as a primary or other reason for their MC. STI prevention was another important reason (primary or other) that many men (74%) gave for why

they wanted to be circumcised. Far less frequently, men also thought that getting circumcised would improve their sexual experience or said that friends and their partners recommended it, and that they thought it was more acceptable to people they knew from other ethnic groups. Some also said that an MC was recommended

by their parents and/or health care worker (Table 15).

Radio (63%) was the most common mass media source of information on MC for the NPC study participants. Men also got information from their health workers (46%) and from friends and family (56%) (Table 16). They came to that specific health facility for their MC because it was close to home (69%) and because the MC procedure was free (47%) (Table 17). Other, less commonly mentioned reasons included that the site is where they receive other health services, that they trusted the health care provider, that they knew someone else who received their MC at the same facility, and that a health worker recommended it.

Outreach

Overall, 87% of men in the outreach study gave protection from HIV their reason (primary or other) for seeking MC services; 66% cited HIV protection as their primary reason. Prevention of STIs was the next most commonly stated reason for an MC, with 13% giving this as their primary reason and 81% overall citing it as a reason. Fifteen percent of the outreach MC clients said that improved hygiene was their primary reason for wanting to be circumcised, with 76% citing hygiene as either a primary or secondary reason. Less frequently, MC outreach clients stated that getting circumcised would improve their sexual experience, that friends and their partners recommended it, and that they thought it was more acceptable to people they knew from other ethnic groups. Some also said that health care worker recommended MC, and although there were no minors enrolled in this study, some also stated that MC was recommended by their parents (Table 15).

Men in the outreach study said they got information about MC over the radio (58%), while even more men said the source of information about MC came more from personal contacts, such as health care workers (64%) and friends and family (53%) (Table 16). Seventy-six percent reported coming to the outreach MC health facility because it was close to home, and 57% because the MC services were free (Table 17). Other, less frequently cited reasons included

that a friend or family member was circumcised at the same site, that they use other health services at the same health facility, and that they trusted the health provider who worked at this facility.

Secondary Objective 2: Evaluate men's HIV knowledge and prevention practices pre- and post-MC

NPC

At baseline, most NPC study participants knew that AIDS is not a curable disease (92%) and that having an STI puts you at risk for another STI, including HIV; yet, when they were asked for what other reasons would they use a condom, only 62% stated STI prevention (Table 18). Seventy-five percent of the men enrolled in the NPC study had been sexually active during the year just before they came in to get their MC (Table 19). Among these sexually active men, 14% reported having multiple partners and 48% had spoken to his partner about preventing HIV in the past month. Only 57% had reported condom use at last sexual encounter, and this figure did not differ by the number of partners (Table 20).

Outreach

Similar to men in the NPC study, most men in the outreach study knew that AIDS is not a curable disease (93%) and that having an STI puts you at risk for another STI, including HIV. On the other hand, a greater percentage of men in the outreach study (80%) gave STI prevention and transmission as reasons for condom usage (Table 18). Seventy-nine percent of the men enrolled in the outreach study had been sexually active during the year just before they received their MC (Table 19). Among these sexually active men, 17% reported having multiple partners, and 48% had spoken to sexual partners about preventing HIV within the past month. Only 55% had reported condom use at last sexual encounter, and this figure did not differ by the number of partners (Table 20).

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TABLE 16. SOURCE OF INFORMATION ABOUT MC, BY STUDY

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
Radio	1,413	63.0	526	58.4
Poster	395	17.6	152	16.9
Television	234	10.4	74	8.2
Newspaper	197	8.8	58	6.4
Brochure	72	3.2	23	2.6
Health professional	1,023	45.6	578	64.2
Friend or relative	1,245	55.5	479	53.2
At school or college	36	1.6	26	2.9
Public address or adverts	26	1.2	3	0.3
Religious leaders or teachings	19	0.8	8	0.9
Government employee or politician	8	0.4	3	0.3
Other miscellaneous sources of information	56	2.5	22	2.4

TABLE 17. REASONS MEN ACCESSED MC SERVICES AT SPECIFIC NPC AND OUTREACH STUDY SITES

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
Close to home	1,558	69.4	684	76.0
Cost (free)	1,047	46.7	516	57.3
Receive other health services here	317	14.1	172	19.1
Trust health care providers	390	17.4	114	12.7
Friend/relative got circumcision here	278	12.4	180	20.0
Heard MC was done in this facility	44	2.0	18	2.0
Health worker recommended this facility	19	0.8	10	1.1
No one knows me here	23	1.0	13	1.4
Friend/relative recommended this facility	6	0.3	4	0.4
Teacher/Instructor/Professor recommended this facility	3	0.1	6	0.7
Convenient location	9	0.4	2	0.2
MC procedure is safe	2	0.1	1	0.1
Mobilized to this facility	8	0.4	0	0.0
Other miscellaneous reasons	24	1.1	6	0.7

TABLE 18. HIV KNOWLEDGE AND PREVENTION PRACTICES AMONG ALL MC CLIENTS, BY STUDY

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
Knowledge				
AIDS is not a curable disease.	2,068	92.2	834	92.7
Having an STI increases the risk of acquiring another STI, including HIV.	2,124	94.7	870	96.7
Practices				
Reasons that client will likely use a condom:				
Prevent HIV transmission	1,555	69.3	602	66.9
Prevent STI transmission or acquisition	1,389	61.9	721	80.1
Prevent pregnancy	1,282	57.1	578	64.2

TABLE 19. HIV KNOWLEDGE AND PREVENTION PRACTICES AMONG MC CLIENTS WHO HAD SEX DURING YEAR PRIOR TO MC, BY STUDY

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
Sexually active during year prior to MC	1,674	74.6	709	78.8
Practices (among those sexually active)				
Number of partners in past year:				
One partner	1,388	85.9	572	80.7
Multiple partners	227	14.1	117	16.5
Last time MC client spoke with his partner about prevention of HIV:				
Within past month	797	47.6	343	48.4
Within past 2–12 months	543	32.5	185	26.1
More than a year ago	55	3.3	14	2.0
Never	211	12.6	135	19.0
MC client used a condom during most recent sexual encounter.	961	57.4	386	54.5
Ever used condom during sexual encounter in year prior to MC.	1,251	74.7	519	73.2

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TABLE 20. CONDOM USE, BY NUMBER OF SEXUAL PARTNERS, AMONG MC CLIENTS WHO HAD SEX DURING YEAR PRIOR TO MC, BY STUDY

	NPC (N=2,244)		Outreach (N=900)	
	n	%	n	%
NPC	n=1,388		n=227	
MC client used a condom during most recent sexual encounter.	807	58.1	129	56.8
Ever used condom during sexual encounter in year prior to MC.	1,027	74.0	185	81.5
Outreach	n=572		n=117	
MC client used a condom during most recent sexual encounter.	314	54.9	64	54.7
Ever used condom during sexual encounter in year prior to MC.	415	72.6	94	80.3

TABLE 21. SEXUAL RISK BEHAVIORS AT 60 DAYS POSTCIRCUMCISION COMPARED WITH BASELINE (AMONG THOSE WHO RETURNED FOR 60-DAY FOLLOW-UP VISIT)

60-day follow-up variables	Response	n	%	Baseline variables	Response	n	%
Sexual encounter since circumcision	Yes	1,201	47.1%	Sexual encounter in 12 months prior to circumcision	Yes	1,961	76.9%
	No	1,326	52.0%		No	487	19.1%
	No answer/missing	23	0.9%		No answer/missing	102	4.0%
Condom use at last sexual encounter	Yes	1,060	88.3%	Condom use at last sexual encounter**	Yes	1,094	55.8%
	No	128	10.7%		No	855	43.6%
	Don't remember/no response	13	1.1%		Don't remember/No response	11	0.6%
Future Risk							
Future likelihood of speaking to partner about preventing HIV*	Within 1 month	1,226	60.3%	Future likelihood of speaking to partner about preventing HIV**	Within 1 month	1,253	63.9%
	>1 month from now	590	29.0%		>1 month from now	476	24.3%
	Never/don't know/no response	217	10.7%		Never/don't know/no response	232	11.8%

[^] Percentage among those sexually active postcircumcision. * Percentage among sexually active pre- and postcircumcision.
^{**} Percentage among sexually active with 12 months precircumcision.

Comparison of baseline and postcircumcision risk behaviors and factors associated with risky sexual practices postcircumcision

Postcircumcision risk behavior data were combined for the NPC and outreach studies, as self-reported condom use among the sexually active men at 60 days post-MC was high and similar in both cohorts (90% for NPC, 87% for outreach). A much higher percentage of men (88%) reported using a condom at the last post-MC sexual encounter than the 55% condom usage at last sexual encounter reported at baseline (Table 21). However, the percentage

of clients who said they would speak to their partners about preventing HIV within one month changed little from baseline (64%) to postcircumcision (60%) (Table 21).

When we examined factors associated with not using a condom at last sexual encounter after circumcision, we found that those who were married or living with a partner were less likely to use a condom than were those who were single (OR=2.3; 95% CI: 1.3, 4.1); conversely, HIV-infected individuals were more likely to use a condom than were those reported being HIV-negative (OR=0.3; 95% CI: 0.1, 0.6) (Table 22).

TABLE 22. FACTORS ASSOCIATED WITH NOT USING A CONDOM AT LAST SEXUAL ENCOUNTER POSTCIRCUMCISION

Variable	Category	No condom use/N	Crude OR	95% CI	Multi-variate* OR	95% CI
Age	13–17	3/50	ref		ref	
	18–25	37/640	0.96	0.29, 3.24	1.09	0.31, 3.89
	26–35	62/361	3.25	0.98, 10.8	2.68	0.70, 10.2
	36–54	26/150	3.29	0.95, 11.4	2.85	0.70, 11.52
Secondary education	No	50/332	ref		ref	
	Yes	78/819	0.70	0.48, 1.02	0.77	0.52, 1.16
Employment status	Employed	81/574	ref		ref	
	Student	17/292	0.38	0.22, 0.65	1.18	0.58, 2.42
	Unemployed/unknown	30/335	0.60	0.39, 0.93	0.78	0.48, 1.25
Marital status	Single/widowed/divorced	32/626	ref		ref	
	Married/living with partner	93/567	3.64	2.39, 5.54	2.29	1.29, 4.08
	Unknown/missing	3/8	11.10	2.55, 48.7	10.30	2.18, 49.1
Number of partners	Single	96/893	ref			
	Multiple	20/209	0.88	0.53, 1.46	na	
	No response	12/99	1.15	0.60, 2.17	na	
HIV status	Negative	103/964	ref		ref	
	Positive	7/117	0.53	0.24, 1.17	0.27	0.12, 0.62
	Don't know/no response	18/120	1.48	0.86, 2.53	1.17	0.66, 2.07

na=not applicable; ref=reference group.

* Multivariate model includes variables associated with not using condom in last sexual encounter in univariate analysis at $p < .20$.

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When we examined factors associated with not planning to speak to one's partner about preventing HIV within one month, we found that individuals older than 18 were significantly more likely to plan to speak with their partners about preventing HIV. Similarly, those with at least some secondary education (OR=0.7; 95% CI: 0.6, 0.9) and

those with multiple partners (OR=0.4; 95% CI: 0.3, 0.6) were more likely to plan to speak to their partners about preventing HIV within one month, compared with those with less than a secondary education and those with only one partner (Table 23).

TABLE 23. FACTORS ASSOCIATED WITH NOT PLANNING TO SPEAK TO PARTNER ABOUT PREVENTING HIV WITHIN ONE MONTH AT LAST SEXUAL ENCOUNTER POSTCIRCUMCISION

Variable	Category	Not speaking to partner within 1 month about HIV/N	Crude OR	95% CI	Multi-variate* OR	95% CI
Age	13–17	115/183	ref		ref	
	18–25	526/1,209	0.46	0.33, 0.63	0.46	0.33, 0.65
	26–35	119/465	0.20	0.14, 0.29	0.28	0.18, 0.44
	36–54	47/176	0.22	0.14, 0.34	0.36	0.21, 0.62
Secondary education	No	258/605	ref		ref	
	Yes	549/1,428	0.84	0.69, 1.02	0.70	0.57, 0.86
Employment status	Employed	256/765	ref		ref	
	Student	340/707	1.84	1.49, 2.27	0.91	0.69, 1.19
	Unemployed/unknown	211/561	1.20	0.96, 1.51	0.87	0.68, 1.12
Marital status	Single/widowed/divorced	614/1,322	ref		ref	
	Married/living with partner	183/692	0.42	0.34, 0.51	0.51	0.39, 0.68
	Unknown/missing	9/19	1.28	0.52, 3.17	1.23	0.48, 3.14
Number of partners	Single	683/1,616	ref		ref	
	Multiple	72/290	0.45	0.34, 0.60	0.44	0.33, 0.58
	No response	52/127	0.95	0.66, 1.37	0.78	0.53, 1.14
HIV status	Negative	673/1,665	ref			
	Positive	55/150	0.85	0.60, 1.21	na	
	Don't know/no response	79/218	0.84	0.63, 1.12	na	

na=not applicable; ref=reference group

* Multivariate model includes variables associated with not speaking to partner within 1 month about HIV in univariate analysis at $p < .20$.

DISCUSSION

Scaling up MC requires delivering effective, safe, quality services without wasting resources. While no universal service delivery modes exist, there are some well-established requirements based on how inputs and services are organized and managed, to ensure access, quality, safety, and continuity of care across health conditions, across different locations, and over time.

The intent of both the NPC and outreach MC studies was to evaluate the safety and effectiveness of two modes of MC service delivery: task shifting to NPCs at static sites, and use of itinerant outreach MC providers, who travel to health care facilities that have limited capacity to provide MC services. This section discusses the key findings and programmatic implications of the research concerning safety and effectiveness for the two modes. This includes the extent to which MC clients experience an AE and ultimately how satisfied they were with their circumcision. Additionally, this section will also discuss findings related to demand generation for MC and sexual behaviors related to risk compensation among men post-MC.

Objective I: Determine the proportion of men experiencing an AE at surgery and at seven and 60 days postcircumcision

There were no immediate adverse outcomes associated with MC surgical and postoperative procedures. Seven-day AE rates in both the NPC and outreach studies (3.8% and 3.6%, respectively) fell within the range (1.5–8.2%) that has been reported in published studies on MC (Auvert, Taljaard et al. 2005; Bailey, Moses et al. 2007; Gray, Kigozi et al. 2007) Krieger et al., 2007; Kigozi et al., 2008). However, our definition may be broader than those used in other studies, as it was based on complications outlined by WHO (WHO, UNAIDS et al. 2006) and AEs associated with VMMC as defined by the GOK, which included pain as an adverse event. While much of the published literature

on this topic fails to provide details on the definition of AEs, some definitions do not include pain associated with MC as an AE.

Objective II: Evaluate risk factors associated with adverse events post MC surgery

No surgical complications were identified in either the NPC or outreach studies; however, men's behaviors and practices post-MC also need to be considered as risk factors for AEs. Therefore, it was important to examine not only clinical factors, but also post-MC behavioral factors associated with AEs.

NPC

Our multivariate analysis found that men who had MCs performed by nurses were more likely to experience AEs than those whose MCs were performed by clinical officers. This effect was independent of provider's sex or experience in the profession. However, given the small number of providers in the study, this finding must be interpreted with caution. Furthermore, even with this increased risk, only 4.7% of men who had their MC performed by a nurse had an adverse event at seven days post-MC, well within the published range. In the NPC study, those who took cars/buses to return home after circumcision were more likely to experience AEs at seven days following their MC than were those who walked home. Reasons for this finding are unclear. While it is possible that travel in a car or bus leads to greater irritation than does walking, this result may

be attributed to unmeasured confounding factors. Being married or living with a partner was marginally protective against AEs; it is possible that partners play a supportive role in recovery, or that men in stable relationships are less likely to engage in behavior that may result in AEs.

Resumption of work or leisure activities was also associated with AEs, though the results are difficult to interpret. People who resumed normal work activity more than two days after circumcision were less likely to experience AEs, suggesting that resting a couple of days after the circumcision may provide needed time for some initial wound healing and reduce the likelihood of an AE. However, those who did not resume work by seven days post-MC or only resumed a limited work schedule did not have the same decreased risk: Not resuming work was associated an AE at Day 7. Similarly, people who resumed only some leisure activities by Day 7 after circumcision were less likely to experience AEs, again suggesting that sufficient post-MC rest provides the time needed for initial wound healing. Reverse causality cannot be excluded as an explanation for these findings: it is possible that AEs prevented men from resuming work or leisure activities.

Outreach

Our findings indicate that among the itinerant outreach providers, those who were older had lower AE rates. This is likely a proxy for work experience. Outreach providers tended to be slightly younger than the clinical officers providing MC services at the base static site. As above, given the small number of providers in the study, these results must be interpreted with caution.

Men in the outreach study who did not resume work after circumcision were more likely to experience AEs, and men who resumed some leisure activities after circumcision were less likely to experience AEs, compared with those who resumed activities within two days of circumcision. As above, reverse causality cannot be excluded as an explanation for these findings: It is possible that AEs prevented men from resuming work or leisure activities.

Objective III: Assess patient satisfaction with MC at 60 days post-MC surgery

Men in both the NPC and outreach studies were very satisfied with their circumcision and would recommend MC to a friend or family member. Given this very high rate of satisfaction, men circumcised in either service delivery mode could be enlisted to help create demand for MC, by providing them support, tools, and information to promote MC to others.

Secondary Objective 1: Explore factors influencing men to seek MC services

Participants in both studies reported hearing about MC on the radio and through friends, relatives, and health professionals. MC providers and clients in both studies said the primary reason to be circumcised was to protect against HIV infection. Improved hygiene and STI prevention were also reasons given for MC. The main reasons for why MC clients had selected the health facility for their circumcision were because it was close to home and there was no charge for the MC. Thus, proximity of services to men's residence is an important factor that the GOK should consider when planning MC services.

To reach more men eligible for MC through either mode of service delivery, the GOK should continue to target men with messages over the radio and through personal contacts, such as friends, family, health workers, and teachers. These radio programs and public service announcements should continue to include messages on the benefits of MC as a way to protect men from the transmission of HIV and other evidence-based supportive messages. Additionally, programs should reach out to the support networks of uncircumcised men, as it is these personal contacts that also influence men to get circumcised.

DISCUSSION

Secondary Objective 2: Evaluate men's HIV knowledge and prevention practices pre- and post-MC

At baseline (prior to their MC), men who enrolled in both the NPC and outreach studies appeared to be informed about HIV and HIV prevention, yet only about half of the men in both studies used a condom with their last sexual partner. We found that condom use at the last sexual encounter among clients circumcised at either NPC or outreach sites rose sharply, from 55% at baseline to 88% postcircumcision. While we did not examine the sustainability of condom use, this single data point suggests that MC may not necessary lead to decreases in condom use. Men who were HIV-positive were more likely to report condom use, which is an indication that HIV-positive men in this community are aware of safe-sex practices for preventing HIV transmission to their partners.

Unlike condom use, there was no change in the clients' intention to speak to their partners about preventing HIV. Given that there are multiple reasons for bringing up the subject of HIV with a partner, especially in relation to a MC, this lack of change is disappointing and may have broader consequences, as our assumption is that the adoption of safer sex practices requires open dialogue with partners. As with most studies, these are self-reported accounts of sexual practices, and the accuracy of these self-reports cannot be confirmed. Older clients, those with at least secondary education, those who were either married or living with a partner, and those with multiple partners were more willing to communicate with their partners about preventing HIV at 60 days post-MC. Thus, counseling and education about communicating HIV prevention should also target younger, less-educated men, who may not necessarily be in a steady relationship.

Study Limitations

Both the NPC and outreach studies are applied prospective research studies, and as such, outcomes were examined

within the real-world setting of health clinics in Nyanza Province. As is often the case in nonrandomized facility-based studies, men were enrolled as they sought MC services. Thus, findings from this study cannot be generalized beyond men seeking MC in similar service delivery settings with similar cadres of providers.

Some multivariate analyses presented in this report may have had limited power. For instance, given the low rate of AEs, especially at 60 days post-MC, some analyses lacked sufficient power to draw conclusions about risk factors associated with post-MC AEs. Similarly, the analysis of risk factors associated with AEs at seven days within the outreach study was limited, given the lower number of occurrences of AEs. Finally, the subsample of men who were HIV-positive in these studies was small, limiting our ability to evaluate HIV status as a predictor of AEs and risk behavior outcomes.

Data collected at the facility level are hierarchically clustered data, whereby individuals are nested within providers and facilities; thus, patient outcomes may be correlated within facilities or surgeons. We did not account for the nonindependence of observations within higher-order units. Thus, the confidence intervals associated with effect estimates in the univariate and multivariate analyses may be artificially narrow. Similarly, given the small number of providers in each study, the role of provider effects on individual outcomes must be interpreted with caution.



CONCLUSIONS

We conclude that both task shifting to NPCs and mobilizing itinerant outreach providers are safe and effective approaches to provide adult MC services in Kenya. Given the number of individuals targeted for MC by the GOK, these approaches seem to be practical ways to increase access and coverage of MC services.

Task shifting has the potential to make better use of available human resources in the short term and to ease bottlenecks in service delivery. Adding to the skill sets of existing cadres, particularly nurses, can be accomplished far more quickly than waiting years for new doctors, clinical officers, and nurses to complete their professional training. The key benefit of mobilizing itinerant MC outreach providers is that this would facilitate access to services in rural and remote areas for men who might not otherwise use MC services due to travel distances. The services need to be close to where these men reside, and information needs to be disseminated widely on the safety and efficacy of these services. Delivering MC services closer to where men live can help ensure that a greater number of men are circumcised in the short term. Another potential benefit is capacity building at lower level health facilities, by assisting current providers and community-based health services to strengthen local infrastructure and human resources.

As Kenya's government moves forward with its ambitious plans to provide adult MC services, the health sector needs to respond with short- and long-term solutions to support MC services that are organized and managed, to ensure access, quality, safety, and continuity of care across health services, across different locations, and over time. While the modes of MC service delivery will vary across provinces, depending on the context (HIV prevalence rates, traditional MC practices, existing levels of uptake of MC services, and existing HIV services, such as HCT), the GOK and donors should continue to support task shifting and outreach as safe and effective short-term strategies for increasing coverage of MC services.

Additional investments in either mode of MC service delivery should not be seen as substitute for ongoing health financing to strengthen other key components of health service delivery, including infrastructure, logistics, integrated health packages, quality and safety, and management. These are also essential for MC services. Given the current shortage of health workers at many health facilities in Kenya, either mode should also complement other long-term strategies to increase the overall workforce.

When these two study protocols were developed, nurses were not permitted to perform MC in Kenya. The GOK anticipated MC scale-up within existing health facilities with their existing staffing. But policies in Kenya have changed; for example, the GOK now permits trained nurses to perform MC (GOK 2009). As such, our findings may find a receptive audience among GOK health authorities. These results also yield insights into improving these services in Kenya and offer lessons to inform MC policies and programs in other countries in Africa where MC scale-up is being considered or is underway.

Our recommendations include:

1. Expedite efforts to ensure timely involvement of clinical officers and nurses in performing MC, including:
 - ◆ Revising scopes of practice to carry out the procedure
 - ◆ Providing adequate training and follow-up, to ensure MC competence
 - ◆ Revising national preservice training curricula for clinical officers and nurses to include more in-depth content on MC, including practical experience

2. Consider the use of trained MC nurses, as well as clinical officers, as outreach MC providers, to expand the number of provider and locations where MC services are provided.

3. Increase demand for MC services offered through both task shifting and outreach approaches, including:

- ◆ Utilizing radio and public service announcements to reach uncircumcised men and youth
- ◆ Recruiting satisfied MC clients as “champions” and community educators, to mobilize uncircumcised peers for MC
- ◆ Utilizing health providers and teachers as community educators and mobilizers for MC

4. Stress within MC counseling and community SBCC efforts issues related to risk compensation and the need for preventive sexual practices, including:

- ◆ Using condoms at every sexual encounter
- ◆ Staying faithful to one partner and understanding the risks of having multiple partners

- ◆ Talking with your partner about HIV and sexual behavior

- ◆ Targeting younger, less educated men, who may not necessarily be in a steady relationship, with relevant interventions to improve their interpersonal communication with their partners

These findings also point to the need to conduct additional research on key questions pertaining to task shifting and MC outreach, including:

1. What are the cost efficiencies of task shifting and MC outreach, based on defined targets and savings?
2. What are appropriate SBCC interventions for improving interpersonal communication among younger, less educated uncircumcised men?
3. What demand generation approaches are appropriate for targeting less educated, older, marginalized, or unemployed uncircumcised men?
4. Once men are discharged after their MC procedure, what occurs that puts them at risk for an AE? ■



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