A Study to Assess the Implementation of Male Circumcision as an HIV Prevention Strategy in Kenya

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THESIS

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This thesis is dedicated to my husband, Kurt Herman-Roloff, and my parents, Charles and Rosanne Herman.

Kurt, thank you believing in me. Thank you for making sacrifices over the past 6.5 years so that I could achieve this goal. You are an incredible husband, and I feel blessed to be married to you.

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LIST OF ABBREVIATIONS

AE	Adverse Event
AIDS	Acquired Immune Deficiency Syndrome
AOR	Adjusted Odds Ratio
CI	Confidence Interval
CDC	The Centers for Disease Control and Prevention
CO	Clinical Officer
DHMT	District Health Management Team
DMO	District Medical Officer
FGDs	Focus Group Discussions
FHI	Family Health International
GoK	Government of Kenya
GPS	Global Positioning System
HIV	Human Immunodeficiency Virus
IQR	Inter-Quartile Range
IRB	Institutional Review Board
KDHS	Kenya Demographic and Health Survey
MC	Male Circumcision
MCC	Male Circumcision Consortium
MO	Medical Officer
NRHS	Nyanza Reproductive Health Society
OR	Odds Ratio
PDA	Personal Digital Assistant
PVP	Predictive Value Positive

LIST OF ABBREVIATIONS (continued)

RCT	Randomized Control Trial
RR	Relative Risk
STIs	Sexually Transmitted Infections
UIC	University of Illinois at Chicago
UNAIDS	Joint United Nations Programme on HIV/AIDS
UOR	Unadjusted Odds Ratio
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

SUMMARY

Research has demonstrated that male circumcision (MC) reduces the incidence of HIV acquisition in heterosexual men by at least half. In 2008, Kenya launched the national Voluntary Medical Male Circumcision (VMMC) program for HIV prevention, and plans to circumcise 860,000 males by 2013. Despite the protective effect of MC, there are concerns about the acceptability and safety of the procedure.

This study was implemented in Nyanza Province, Kenya, and used a mixed method approach to assess components of the VMMC program. The quantitative component of this study used both passive (N = 3,705) and active (N = 1,449) surveillance methods to monitor study participants. The qualitative component of this study included 12 focus group discussions among uncircumcised men.

The primary barriers to VMMC uptake included time away from work; culture and religion; possible adverse events (AEs); and the post-surgical abstinence period. The primary facilitators to VMMC uptake included hygiene; social pressure; protection against HIV and other sexually transmitted infections; and improved sexual performance and satisfaction.

Among the participants who underwent circumcision, the post-MC AE rate was 2.1% in the passive system and 7.5% in the active system. Experienced VMMC providers, who had performed more than 100 procedures, were less likely to provide an MC that resulted in an AE compared to inexperienced providers. Approximately one-third of participants reported engaging in sexual activity during the recommended 42-day abstinence period. In a multivariable analysis, being married was the strongest predictor of engaging in early sexual activity.

To increase VMMC uptake it is important to dispel misconceptions and increase the relevance of MC among men who are already practicing an HIV-prevention method. As

large-scale MC programs continue to be implemented throughout Africa, robust surveillance is crucial to identify factors that may improve the safety and efficacy of the program. The most important factor to reduce the AE rate is to ensure that providers achieve clinical expertise before they perform unsupervised procedures. Strategies to reduce engaging in early sexual activity should be implemented such as including female partners in counseling, mass education campaigns, and targeted programs for VMMC clients.

I. BACKGROUND

A. Human Immunodeficiency Virus

Currently, an estimated 33.3 million people (range: 31.4–35.3 million) are living with the Human Immunodeficiency Virus (HIV) worldwide, including 22.5 million people in sub-Saharan Africa (UNAIDS, 2010). The global HIV epidemic has stabilized, with the annual number of new infections steadily declining since the late 1990s (UNAIDS, 2010). In Kenya, for example, adjusted antenatal clinic sentinel surveillance data indicated that HIV prevalence declined in adults from 10% in the late 1990s to 7% in 2003. Currently, the HIV prevalence in Kenya is 6.3% (Kenya National Bureau of Statistics and ICF Macro, 2010). Despite this encouraging trend, there are geographic pockets within the country with elevated HIV prevalence rates. Nyanza Province, in western Kenya, illustrates this phenomenon. There, a 2004 survey of five antenatal surveillance sites demonstrated HIV prevalence rates ranging from 3% to 30% (Republic of Kenya Ministry of Health, 2005). Additionally, in 2008–09, the Demographic and Health Survey reported that among members of the Luo ethnic group (the predominant ethnic group in Nyanza Province), 22.8% of women and 17.1% of men tested positive for HIV (Kenya National Bureau of Statistics and ICF Macro, 2010).

B. Male Circumcision and HIV Prevention

Several interventions have been implemented to mitigate the spread of HIV. Despite the suggested association between male circumcision (MC) and reduced acquisition of sexually transmitted infections (STIs), the first paper exploring the association between MC and HIV acquisition was not published until 1986 (Fink). More than a decade ago, interest in studying the association between MC and HIV prevalence increased when large discrepancies in HIV prevalence rates were recognized throughout sub-Saharan Africa (Buvé,

2000). Scientists hypothesized that these differences could not be attributed to behavioral and/or STI patterns alone, so researchers used ecologic methods to explore several factors that may explain these discrepancies, one of which was MC. The results from an ecologic study were striking—in African countries where less than 20% of men were circumcised, HIV prevalence rates ranged from 3.1% to 33.4% (all but one country had a rate greater than 14%); meanwhile, in countries where the vast majority of men were circumcised, HIV prevalence rates ranged from 1.5% to 7.9% (Table I is based on a table originally presented in Halperin and Bailey, 1999; however, it incorporates updated data from 2006 UNAIDS country estimates).

TABLE I

ECOLOGIC ANALYSIS OF MALE CIRCUMCISION AND HIV PREVALENCE[a]

Countries with < 20% of men circumcised		**Countries with > 80% of men circumcised**	
Country	**HIV Prevalence**	**Country**	**HIV Prevalence**
Zimbabwe	20.1 [13.3–27.6]%	Kenya	6.1 [5.2–7]%
Botswana	24.1 [23–32]%	Congo	3.2 [1.8–4.9]%
Namibia	19.6 [8.6–31.7]%	Cameroon	5.4 [4.9–5.9]%
Zambia	17 [15.9–18.1]%	Nigeria	3.9 [2.3–5.6]%
Swaziland	33.4 [21.2–45.3]%	Gabon	7.9 [5.1–11.5]%
Malawi	14.1 [6.9–21.4]%	Ghana	2.3 [1.9–2.6]%
Mozambique	16.1 [12.5–20]%	Sierra Leone	1.6 [0.9–2.4]%
Rwanda	3.1 [2.9–3.2]%	Guinea	1.5 [1.2–1.8]%
		Benin	1.8 [1.2–2.5]%

[a] Country estimates from UNAIDS country profiles; table format based on Halperin and Bailey, 1999

In order to explore this relationship using more rigorous epidemiological study designs, the effect of MC on HIV acquisition was studied using observational methods. Based on a 2001 review of 49 studies by Bailey et al., 28 studies reported a significant protective effect of MC against HIV infection, and five reported a trend toward a protective effect. Seventeen of these studies adjusted for possible confounding factors, and the pooled adjusted odds of HIV acquisition among circumcised men ranged from .19 to .69. The results

of this review are consistent with a previous review; Weiss et al. (2000) reviewed 27 studies, all from sub-Saharan Africa, and found that 21 reported a reduced risk of HIV infection among circumcised men (crude RR [relative risk] = .52; 95% CI [confidence interval]: .40–.68). Fifteen of the 27 studies adjusted for potential confounders (adjusted RR = .42; 95% CI: .34–.54) and reported a larger protective effect for high-risk men (adjusted RR = .29; 95% CI: .20–.41) (Weiss et al., 2000). In a 2003 *Cochrane* review article that included 37 observational studies, Siegfried et al. also concluded that male circumcision was associated with a reduced risk of HIV acquisition. All of these review articles stated that despite the increasing evidence provided by observational studies, a causal relationship between MC and HIV infection could only be established by a randomized control trial (RCT).

In order to address this gap in the literature, three RCTs were completed in Africa to assess the efficacy of the MC-HIV association. The RCTs took place in Orange Farm, South Africa; Kisumu, Kenya; and Rakai District, Uganda. All three trials were stopped during interim analysis because the protective effect afforded by MC against HIV acquisition was highly significant at a level that met the predetermined stopping rules. The Orange Farm trial reported 20 HIV infections in the intervention group and 49 infections in the control group (crude RR = .40; 95% CI: .24–.68, $p < .001$). This RR corresponds to a protective efficacy of 60% (Auvert et al., 2005). Bailey et al. (2007) reported similar results in the Kisumu group; among circumcised men the risk of HIV acquisition was RR = .47 (.28–.78) compared to uncircumcised men—this corresponds to a protective efficacy of 53%. After adjusting for non-adherence to treatment and men who were retrospectively found to be positive at baseline, the protective effect of MC was 60%. Among the Rakai participants, Gray et al. (2007) reported a protective effect of 51% ($p = .003$). HIV incidence was lower among circumcised men than uncircumcised men in all sociodemographic and behavioral subgroups.

All three RCTs reported remarkably consistent results suggesting a similar efficacy in divergent populations (Bailey et al., 2007; Gray et al., 2007).

In summary, more than 40 observational studies and three RCTs have established that MC reduces the risk of HIV-1 acquisition in heterosexual men by approximately 60% (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007; Weiss et al., 2008). Given the volume of evidence, in 2007 the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended that MC, provided by trained professionals, be implemented as one component of a comprehensive HIV-prevention strategy in regions with low MC rates, high HIV prevalence, and where heterosexual sex is the mode of transmission (WHO, 2007).

C. **Biological Plausibility of Male Circumcision for HIV Prevention**

Studies have suggested several ways in which MC may mediate HIV acquisition in males. A recent review article categorized how the foreskin might affect HIV transmission in four categories: surface area, microbiologic environment, HIV-1-susceptible cells, and tissue structure (Dinh et al., 2011). In a study conducted in Uganda, the mean foreskin surface area was significantly higher among men who acquired HIV (43.3 cm) compared with men who remained uninfected (36.8 cm) ($p = .01$). Compared with men with foreskin surface areas in the lowest quartile, the adjusted incidence rate ratio of HIV acquisition was 2.37 (95% CI: 1.05–5.31) in men with the largest quartile of foreskin surface area (Kigozi et al., 2009b). In South Africa, a study was conducted among clients at an STI clinic, where it was reported that the prevalence of HIV was greater in those with penile wetness (126 out of 190, 66.3%) compared to those with no penile wetness (90 out of 196, 45.9%). After adjusting for predictors of HIV, confounders, and herpes simplex virus type-2 antibodies, penile wetness was associated with increased odds of HIV infection (AOR[adjusted odds ratio] = 2.38; 95%

CI: 1.42–3.97, $p < .001$) (O'Farrell et al., 2006). The male foreskin contains high densities of HIV target cells, including Langerhans' cells, subepithelial dendritic cells, macrophages, and CD4+ T cells (McCoombe and Short, 2006; Patterson et al., 2002). Langerhans' cells are the most superficial cells in the inner foreskin and frenulum, and therefore likely the most susceptible to HIV uptake. (McCoombe and Short, 2006; Patterson et al., 2002). In addition to this, researchers noted that keratinized skin presents a barrier to HIV, and there is a measurable difference in the degree of keratinization between inner and outer foreskin. The inner foreskin has a mean thickness of 1.8 units, and the outer foreskin has a mean thickness of 3.3 units, suggesting that the outer foreskin will only be involved in primary infection if the keratin layer is compromised by lesions or other abrasions (McCoombe and Short, 2006). However, a review of subsequent studies reported that there may be no significant difference between inner and outer foreskin keratinization (Dinh et al., 2011). Possible explanations for this included that the outer superficial layer is easily sloughed, so an intact layer is unlikely to play a key role in protection against HIV infection. Another argument is that keratinization of the oral mucosa is relatively nonexistent, yet oral transmission of HIV remains the most inefficient route of transmission (Dinh et al., 2011).

D. **Adverse Events and Wound Healing**

Despite the evidence supporting the protective role of MC in preventing HIV acquisition, the international health community has several concerns about a large-scale implementation of MC in Africa, including (among others) the feasibility and safety of MC, particularly in a resource-limited setting, and the acceptability and uptake of MC among people who do not traditionally practice MC (Bailey et al., 2007; Gray et al., 007).

In developed countries, adverse event (AE) rates following neonatal MC are well documented and range from .2% to .6%; for this population, bleeding and infection are the

most common AEs (Kaplan, 1983). Before the RCTs, however, outcomes in Africa for medical (not traditional) MC among adults were poorly documented. In a 2007 review conducted by Muula et al., AE rates among adolescents and adults in Anglophone Africa ranged from 0% to 24%. The RCTs, which provided services in a highly controlled clinical setting, reported the following AE rates: 3.8% in Orange Farm, South Africa; 1.5% in Kisumu, Kenya; and 3.6% in Rakai, Uganda. The most common AEs included pain, swelling, bleeding, problems with appearance, infection, and wound disruption (Auvert et al., 2005; Kigozi et al., 2008a; Krieger et al., 2007). Bailey et al. (2007) hypothesized that the differences in AE rates among the RCTs may be due to surgical technique and the associated healing time. In Uganda, the AE rate was 3.1% and 3.5% in HIV-positive and HIV-negative men respectively; this difference was not statistically significant. Infections were the most common AE, resulting in 2.6% among HIV-positive participants and 3% in HIV-negative participants (Kigozi et al., 2008a). Additionally, participants who had a genital ulcerative disease at enrollment, even though treated prior to surgery, were 1.68 times more likely to develop a moderate or severe AE than participants who did not have genital ulcerative disease (Kigozi et al., 2008a). Most recently, at the Orange Farm RCT site, the Bophelo Pele Project investigated the safety of providing MC services in one large facility outside a trial context and reported an AE rate of 1.8% (Lissouba et al., 2010).

Although the RCTs demonstrated acceptable AE rates, public health professionals were concerned about the incidence of AEs for MCs provided in a resource-limited setting. Bailey and Egesah (2006) conducted two studies among the Babukusu tribe in western Kenya to estimate the outcomes of both clinical and traditional MC procedures performed in the region. In a small in-depth study, 24 MCs were observed—12 clinical and 12 traditional. Of the 24 MC procedures, only one in 12 clinical and two in 12 traditional circumcisions did not result in an AE. Among clinical MC procedures, broken sutures, infection requiring

antibiotics, and the removal of an inappropriate amount of skin were the most common AEs. No men in this small study, regardless of who circumcised them (clinical or traditional practitioner), were healed by day 30. In a second and larger study, including more than 1,000 participants, men circumcised by traditional practitioners were 2.53 times more likely to experience an AE than men circumcised by clinical practitioners. In total, traditional MCs resulted in the most AEs (34.3%), followed by MCs performed at private facilities (22.5%), then public facilities (11.1%), and finally the Anglican Church of Kenya's MC mobile clinic (4.9%) (Bailey et al., 2008).

In the RCTs, time to complete wound healing was measured. In the Kisumu RCT, 1.3% of men were not completely healed at the day-30 visit; wound healing was defined as "no scab, open wound, swelling, or redness." In the Rakai RCT, 13.9% were not healed by day 30, and wound healing was defined as "healthy scar formation; no scab or open wound" (Mehta et al., 2009). In Kisumu, nearly all participants were healed by day 30 (Bailey et al., 2007). In Rakai, at six weeks post-surgery, 92.7% of HIV-positive participants and 95.8% of HIV-negative participants were healed ($p = .007$), suggesting more rapid healing in HIV-negative men (Kigozi et al., 2008a).

The safety of MC provision depends in part on the preparedness of both the practitioner and the health facility. A study was conducted in 1999 among clinical practitioners in Nyanza Province to ascertain knowledge about and frequency of MC procedures. Thirty of the 42 providers (71%) had not performed an MC in the six months prior to the survey. The same number reported receiving training on an MC procedure—of these, 10 had only attended a lecture. Seven (23%) professionals reported performing an MC procedure with no prior training (Mattson et al., 2004). The lack of clinical experience was confirmed by Bailey and Egesah (2006), who reported that traditional practitioners perform more MCs than clinical practitioners (nine out of 21 traditional practitioners had performed

more than 100 MCs in the last two years, while only five out of 20 clinical practitioners had performed as many). Facility preparedness is also essential for performing MCs safely. In their 2006 assessment of the readiness of facilities to perform MCs, Bailey and Egesah reported that only 50% of public facilities and 21% of private facilities had an autoclave, and around half of facilities had the appropriate gauge suture (3/0) for MC. More recently, in Kenya, a facility-needs assessment was conducted to assess seven minimum criteria for MC service provision and reported that no facility was fully prepared to offer MC services (Herman-Roloff et al., 2011).

The RCTs have demonstrated that more experienced providers provide MC services faster and with fewer AEs than less experienced providers. In Kisumu, AE rates per clinician averaged 3.8% for procedures 1–100, and decreased to 2.1% for procedures 101–200, and finally to less than 1% among providers who performed more than 200 procedures ($p < .001$) (Krieger et al., 2007). In Rakai, the mean time required to complete surgery was approximately 40 minutes for the first 100 procedures and decreased to 25 minutes for the subsequent 100 circumcisions. The rate of moderate and severe AEs was 8.8% for the first 19 unsupervised procedures and 4% for procedures 20–99 (13 out of 328), and 2% among providers who had performed the most MCs (900–999) (p-value test for trend < .003). These findings suggest that the completion of at least 20 circumcisions, and ideally more than 100, is required before physicians achieved optimum efficiency and safety for MC service provision (Kiggundu et al., 2009).

E. **Acceptability of Male Circumcision**

Prior to completion of the three RCTs, several studies investigated factors that might facilitate or inhibit uptake of MC. Westercamp and Bailey (2007) reviewed 13 MC acceptability studies from nine countries and concluded that the studies were consistent in

identifying certain factors that facilitated MC uptake, including beliefs that MC: leads to improved hygiene, protects from STIs and HIV, improves sexual pleasure and performance, and provides greater acceptability by other ethnic groups. The barriers to uptake most commonly identified were pain, cultural and/or religious beliefs, cost, possible AEs, and the potential for risk compensation—i.e., an increase in risky sexual behavior following MC (Westercamp and Bailey, 2007). Most acceptability studies have reported an ideal age for MC, often stating that circumcision at 7 to 13 years of age is most preferable because a boy at this age can make the decision for himself, understand the significance of the event, take care of the wound himself, and is unlikely to have initiated sexual activity (Bailey et al., 2002; Ngalande et al., 2006). Across all studies, the median percentage of uncircumcised men willing to be circumcised was 65% (range: 29%–87%) (Westercamp and Bailey, 2007).

A few acceptability studies have been conducted in Nyanza Province, Kenya, and collectively have reported that the primary reasons that men may accept MC in this region included protection from HIV and STIs, improved hygiene, decreased risk of penile cancer, and improved sexual satisfaction for men and their sex partners; alternatively, the primary reasons that men chose not to be circumcised were pain during and after the procedure, long healing period, AEs, cultural or religious opposition, and time away from work (Bailey et al., 2002; Mattson et al., 2005). Focus group discussions (FGDs) in Nyanza Province revealed that cultural tradition was the most prominent barrier to acceptance of MC among the Luo people because the lack of MC is one primary feature differentiating the Luo ethnic group from other groups in Kenya; however, the majority of men in another study in Nyanza Province reported that they would be willing to be circumcised if the pain was minimal (OR [odds ratio] = 26; 95% CI: 7–100) (Bailey et al., 2002). Cost was also identified as a barrier to getting circumcised or to having a son circumcised. In Mattson et al. (2005), 34% of men who reported that they "preferred" not to be circumcised said that they would get the

operation if the cost was less than $3.00. In a 2010 study by Riess et al., after the launch of a large-scale MC program in Nyanza Province, recently circumcised men reported that they were able to perform more rounds of sex, use condoms more easily, and to sustain fewer cuts on their penis during sex after being circumcised.

Some health experts are concerned that MC may reduce sexual function and satisfaction for men and/or their female partners, and thereby impact acceptability of the procedure (de Bruyn et al., 2010; Krieger et al., 2008). Several mechanisms for diminished sexual function and satisfaction have been suggested, including keritanization of the glans penis resulting in lower sensitivity and decreased erectile function (Fink, 2002; Kim and Pang, 2006; Sorrells et al., 2007). Historically, the association between MC and sexual satisfaction remained unclear in the literature, but there is evidence that MC may increase, or at least maintain, the level of sexual satisfaction among clients and their female partners. A review of acceptability studies indicated that many men and women believed that MC increases sexual satisfaction for men and their female partners (Westercamp and Bailey, 2007). In a qualitative study conducted in Nyanza Province, Kenya, Mattson et al. (2005) reported that participants believed that circumcised men have more feeling in their penis, enjoy sex more, and confer more pleasure to their partners. Additionally, some studies have reported that recently circumcised men report that they are able to perform more rounds of sex, to use condoms more easily, and to sustain fewer cuts on their penis during sex than was the case before they were circumcised (Kigozi et al., 2008b; Riess et al., 2010). The Rakai RCT group reported there was no significant change in sexual satisfaction among circumcised men (n = 4,456); that is, they said their sexual satisfaction was neither increased nor diminished when they were circumcised (Kigozi et al., 2008b). The same group also assessed sexual satisfaction among 455 women who had sexual intercourse with RCT participants before and after they were circumcised. The authors reported that 2.9% of

women reported less sexual satisfaction after their partner's circumcision; 57.3% reported no change in satisfaction; and 39.8% reported an improvement in sexual satisfaction following their partner's circumcision (Kigozi et al., 2009a). In Kisumu, 27 out of 30 RCT participants reported that their female partners were "very satisfied" and the remaining three were "somewhat satisfied" with the outcome of their circumcision at 30 days post-MC; at 90 days after circumcision, participants reported that 97% of female partners were satisfied (Krieger et al., 2007). Also in Kisumu, 64% (n = 451 out of 706) of circumcised men reported their penis was "much more sensitive" after they were circumcised; 54.5% (n = 385 out of 706) said they reached an orgasm "much more" easily; and no one reported that MC had caused sexual dysfunction (Krieger et al., 2008).

F. **Onset of Sexual Activity Following Male Circumcision**

Current guidelines recommend that recently circumcised men abstain from sexual activity for at least 42 days, or six weeks, to promote and ensure complete healing (WHO, 2007). If recently circumcised men engage in sexual activity before the surgical site is healed, experts are concerned that MC may actually increase the transmission and acquisition of HIV rather than reduce it (de Bruyn et al., 2010; Weiss et al., 2009). The RCTs each promoted an abstinence period among participants, but of slightly different durations. The Orange Farm RCT advised participants to abstain from sexual activity for six weeks; the Rakai RCT advised participants to abstain until the wound was confirmed as healed based on visual examination by a clinician; and the Kisumu RCT advised participants to abstain for at least 30 days following MC (Mehta et al., 2009). All of the RCTs reported that some participants engaged in early sexual activity. In a combined analysis, in which early sexual activity was defined as engaging in sexual activity less than 42 days after circumcision, 22.5% of Orange Farm, 5.4% of Rakai, and 3.9% of Kisumu participants reported engaging in early sex (Mehta

et al., 2009). In Rakai, the early resumption of sexual activity was significantly associated with increased risk of any AE among HIV-negative men (AOR = 1.56; 95% CI: 1.05–2.34), but it was not associated with an increase in moderate or severe AEs (AOR = .83; 95% CI: .42–1.63) (Kigozi et al., 2008a). In an RCT pooled analysis, participants who reported engaging in early sexual activity did not have higher HIV infection rates at three or six months after circumcision (Mehta et al., 2009). Recently, a large-scale MC program was implemented in the former Orange Farm RCT site, and 12.5% of participants reported engaging in early sexual activity (less than 42 days) following MC (Lissouba et al., 2010). This is nearly half the percentage of participants who reported engaging in early sexual activity during the Orange Farm RCT (Auvert et al., 2005).

G. **Post-Discharge Surveillance**

The Centers for Disease Control and Prevention (CDC, 2001) define public health surveillance as the "ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action," including data collection to "guide the planning, implementation, and evaluation of programs to prevent and control disease, injury, or adverse exposures." Surveillance systems are often classified as *passive* or *active* depending on the way that they collect data. Most health surveillance systems are passive, meaning that a medical, laboratory, or other health professional reports health events on a standardized form. While passive systems have benefits, such as being low cost, they also have known limitations such as incomplete data, lack of timeliness, and underreporting of events (Brachman, 1977; Wood and Adams, 2006; Vogt et al., 1983). Given these limitations, passive systems are often evaluated using active surveillance that involves outreach by a health official to stimulate the identification and reporting of a health event. As a result of actively finding cases, many experts believe that

active surveillance systems produce data that are more accurate than passive systems (Declich and Carter, 1994; Vogt et al., 1983), but due to the time and money expended, some question the cost-effectiveness of active surveillance (Declich and Carter, 1994). Given the resource intensiveness of active surveillance, it is considered most feasible when implemented in a few facilities to examine a focused issue (MacDonald et al., 1997).

To date, most post-discharge surveillance following surgical procedures has been passive and often limited to monitoring surgical site infections in in-patient settings in developed countries (Bruce et al., 2001; Böröcz et al., 2006; German, 2000; Manniën et al., 2006). Based on the review by Bruce et al., 82 studies have conducted post-discharge surveillance. Nearly half of the papers did not summarize their method(s) of case ascertainment (46%); however, among those that did, the most common methods of ascertainment included direct observation by a clinical staff member (35%); postal questionnaires mailed to patients and/or health professionals (5%); and telephone interviews with patients and/or health professionals (5%). Many of the active methods summarized by Bruce et al. rely on self-assessment by the patient post-discharge, but some have questioned the reliability of this method (Manniën et al., 2006). For example, one study of post-discharge surveillance of infections revealed that a patient's self-diagnosis versus a nurse's diagnosis was poorly correlated ($r = .37$). Of more interest, the nurse's diagnosis compared to that of a surgeon ($r = .39$) or an infectious disease physician ($r = .38$) was more poorly correlated than the agreement between the patient and the surgeon and physician combined ($r = .51$) (Whitby et al., 2002). Conversely, Mitchell et al. (1999) compared rates of patient-reported and clinician-reported infections following a surgery, and in doing so, they observed a fairly high agreement ($r = .73$).

The evaluation of a surveillance system usually follows (in whole or part) the "Updated Guidelines for Evaluating Public Health Surveillance Systems" (CDC, 2001). This

framework centers on using the following nine criteria to evaluate a surveillance system, including: simplicity of both the structure of the surveillance system and the ease of operation; flexibility of the surveillance system to adapt to changing information and needs; data quality as measured by the completeness and validity of the data; acceptability of the surveillance system by people and organizations who use the system; sensitivity, or the proportion of cases that truly have a disease or health condition that are detected by the surveillance system; predictive value positive (PVP), or the proportion of detected cases that actually have the health-related event under surveillance; representative to describe the occurrence of the health-related event over time and its distribution in the population by place and person; timeliness of the surveillance system in collecting and managing the data; and stability, referring to the reliability (collection and management of data without failure) and availability (operational when needed) of the surveillance system.

Most evaluations of surveillance systems focus on addressing some, or all, of these criteria. German (2000) reviewed 47 papers that focused on calculating the sensitivity and PVP of a surveillance system. Of interest, none of the papers evaluated a surveillance system for surgical outcomes; instead, they focused primarily on HIV incidence, cancer, cardiac events, injuries, and other syndromes. In his review, German summarized examples of "gold-standard" surveillance methods that had been used to calculate sensitivity and PVP, and included medical charts, registries, secondary reporting systems, telephone interviews, physical exams, and enhanced (or active) surveillance. Despite identifying several options for gold-standard surveillance, he observed that sensitivity and PVP calculations are complicated in the absence of an appropriate gold-standard surveillance system (2000). He noted that it is often assumed that active surveillance is a gold-standard surveillance approach and is implemented when it is expected that more health events are occurring than what is being reported by the passive system. Therefore, it is no surprise that active surveillance systems

usually detect higher rates of events than passive systems (Hsu, 2000; Vogt et al., 1983). Some have speculated that this is due mostly to the incompleteness of passive reporting (Hsu, 2000).

H. Study Context

1. National Voluntary Medical Male Circumcision program

The Nyanza Reproductive Health Society (NRHS), as a member of the Male Circumcision Consortium (MCC), and in collaboration with the University of Illinois at Chicago (UIC), is supporting the Government of Kenya (GoK) to implement and scale-up the national Voluntary Medical Male Circumcision (VMMC) program for HIV prevention. The GoK launched the national VMMC program in November 2008, in Nyanza Province, and plans to circumcise 860,000 males by 2013 (National AIDS and STI Control Programme, 2008).

The national VMMC program provides medical MC services throughout the Luo districts in Nyanza Province at no direct cost to clients. All procedures are performed by a trained medical officer (MO), clinical officer (CO), or nurse who has completed two to three weeks of training, including assisting on at least 10 MC procedures and performing at least 20 procedures under supervision. The VMMC clients are circumcised according to the Kenya national clinical guidelines (National AIDS and STI Control Programme, 2008). All clients are encouraged to undergo voluntary HIV testing and counseling, which is available on site. The provision of VMMC services in Kenya also includes risk-reduction counseling, condom education and distribution, information about the risks and benefits of MC, directions about wound care, and information about the importance of sexual abstinence for at least 42 days after circumcision (National AIDS and STI Control Programme, 2008). Clients are screened to assess their eligibility for surgery through a detailed physical examination based on a

predefined checklist (e.g., assessing pallor, blood pressure, history of bleeding disorder). Clients who present with an acute STI are treated and advised to return for MC once the treatment is complete; those who have a penile congenital malformation or a bleeding disorder are referred to a specialized facility. Male clients who are HIV positive are discouraged from proceeding with the surgery and counseled that MC is unlikely to be of significant health benefit to them; if they persist, however, and they show no clinical signs of AIDS, they are not denied the service. For the procedure, all instruments and supplies are obtained locally. Clients are circumcised using the forceps-guided method; local anesthesia is infiltrated at the base of the penis through the dorsal nerve and ring block techniques (Ministry of Public Health and Sanitation, 2008). The incision site is closed using absorbable sutures through a combination of mattress and simple stitching. At the conclusion of the procedure, clients are counseled and given written instructions that cover bandage removal, penile elevation, general wound care, and the importance of post-surgical sexual abstinence for a minimum of 42 days. Clients are scheduled to return to the facility for one follow-up visit seven days after the procedure; they are also encouraged to return, or to call a 24-hour emergency hotline, if at any time they have a question or concern.

2. Study area

This study was carried out in three districts of Nyanza Province, Kenya: Kisumu East, Kisumu West, and Nyando. Kisumu district, which was recently divided into Kisumu East and Kisumu West districts, is primarily comprised of the Municipality of Kisumu, the third largest city in Kenya, with a population of approximately 576,256 residents (according to projections based on the 1999 census). There is a large urban population with a population density of 583 persons per sq km. The average household income is 600 Ksh per month ($1US = 80 Ksh), and the poverty level is 53% (National Coordination Agency for

Population and Development, 2005). Kisumu West consists of rural and peri-urban areas. Nyando district is 30 kilometers east of Kisumu, an area of 1,168 sq km (Central Bureau Statistics, 2004) that is predominantly rural. The current projected population is about 400,000 people, most of whom make a living by growing sugar and rice or by fishing; however, the district is one of the poorest in Kenya with more than 85% of its households falling into the poorest socioeconomic quintile for Kenya (Central Bureau Statistics, 2004).

The District Medical Officer (DMO) and the District Health Management Team (DHMT) in the three study districts identified 16 health facilities in which we implemented study activities. In order for a health facility to participate in the study, it had to have a water source, adequate space, and staff who completed the VMMC training provided by NRHS. Training, consumables, and medical equipment were provided to facilities by NRHS.

3. Study population

The Luo ethnic group, a Niolotic-speaking people with some traditions and customs different from the surrounding, primarily Bantu-speaking ethnic groups, is the predominant group in the three study districts. Luo men do not traditionally practice MC, and they have a high prevalence of HIV compared to the rest of the country. According to the 2008 Kenya Demographic and Health Survey, 21.5% of Luo men are circumcised and 17.1% are HIV-positive compared to 85.9% and 4.6% among the Kenyan male general population (Kenya National Bureau of Statistics and ICF Macro, 2010).

I. Study Rationale

While the results of studies demonstrating the efficacy of MC in reducing HIV acquisition among heterosexual men in sub-Saharan Africa were encouraging, several questions were unanswered about the operational implementation of a large-scale MC

program. More than 13 published studies indicated that MC was likely to be an acceptable HIV-prevention strategy (Westercamp and Bailey, 2007); before this study there were limited opportunities to document revealed, non-hypothetical preferences about MC among uncircumcised men. Now that MC services are widely available at no cost in Kenya, it is important to learn from recently circumcised men why they chose to become circumcised. Additionally, it is important to learn from uncircumcised men about the factors that influence MC uptake.

Trial participants were circumcised in a highly controlled, clinical setting, with the RCTs monitoring the safety of the MC procedure. Given that large-scale MC programs will be implemented throughout sub-Saharan Africa in a variety of contexts—most settings will be less equipped than an RCT center—it is important to document the outcomes of MC procedures performed as part of a large-scale program that is not a trial site. In this study, VMMC services were provided in both fixed and mobile sites. Fixed sites are large, better-equipped facilities where several staff are available to provide MC services. Mobile sites are small facilities (often health centers) that are usually less-resourced and staffed by one or two providers.

All RCTs reported that some participants engaged in sexual activity before completing the recommended abstinence period. Since men who are not fully healed are likely to be at higher risk of transmitting or acquiring HIV, it is important to understand how many men—who were circumcised as part of a large-scale program, with minimal repeated contact with clients—engage in early sexual activity following MC. Additionally, it is important to explore factors that are associated with engaging in early sexual activity.

To date, most surveillance of surgical outcomes has been passive and largely restricted to in-patient, surgical-site infections in developed countries (Böröcz et al., 2006; Bruce et al., 2001; German, 2000); however, with an increasing number of surgical

procedures being provided on an out-patient basis, post-discharge surveillance, conducted in a variety of settings, may be important for monitoring and improving the quality and safety of services (Vilar-Compte et al., 2007). Given that MC for HIV prevention is a new program in Kenya, and because of the discrepancies found in AE rates in other studies, robust surveillance approaches are essential to evaluate the quality of services being provided by the VMMC program.

J. **Study Aims**

The first aim of the study is to develop and implement a multi-site monitoring and evaluation system to monitor the implementation of VMMC services in Kisumu East, Kisumu West, and Nyando districts in Nyanza Province, Kenya. The system will be comprised of the two components. One component is the clinic system which will collect and manage routine, clinical data on all males who seek circumcision at a study facility. This system is passive in the sense that data are only collected from MC clients who come to a study facility and are evaluated and/or treated by a member of the clinical staff. The second component is an active system which will monitor a random sub-sample of participants in the clinical system. In this context, an active system means that research assistants will actively locate and interview participants in order to collect additional data about their experience post-MC.

The second aim of the study is to evaluate the clinic monitoring and evaluation system, specifically focusing on the sensitivity of the clinic system and the active system in detecting adverse events. The third aim is to describe the incidence and characteristics of AEs, and determine the primary factors that contribute to the development AEs. The fourth aim is to identify factors that either facilitate or serve as barriers to the uptake of MC. The final aim is to assess the time to the onset of sexual activity after the MC procedure.

The following activities were also conducted as part of this study, but analyses of these activities are not included in this dissertation: FGDs with VMMC service providers to assess components of program implementation, an assessment of the satisfaction with the procedure, including appearance, experience at the study facility, and sexual pleasure; and an assessment of the relationship of AE incidence and geographic location.

K. Study Design

This was a prospective study in which we followed all VMMC clients who were circumcised in one of 16 study facilities from their screening through their follow-up care.

1. Clinic system

The clinic system was developed and implemented to collect and store routine clinical data. All MC clients were entered into this system, regardless of their decision to participate in the study. This allowed us to compare demographic characteristics among males who chose to enroll in the study with characteristics of males who did not enroll. Those VMMC clients who chose to enroll in the study were monitored from screening through their follow-up visits using a series of four paper forms that were entered into a Microsoft Access database, with validation rules in place, by research assistants stationed at each study facility (Table II; see also Appendix B).

TABLE II

DATA COLLECTION INSTRUMENTS

Data Collection Forms	**Data Elements**	**Comments**
Form 1: Demographic Data	Name, locator information, age, education level, occupation, religion, and marital status	All MC clients will complete this form, and it will be reviewed by a staff member to ensure completeness and legibility. If the participant is illiterate, staff will complete the form using an interview format.
Form 2: Clinical Consultation	Primary reasons for and concerns about MC, clinical contraindications, HIV/STI status, BMI, consent	Form 2 will be completed by the clinical staff member examining the participant.
Form 3: Surgical Procedure	Length of procedure, VMMC method, surgical adverse events, medical supplies used, names of surgeon and attending staff, notes	Form 3 will be completed by the VMMC service provider completing the procedure (or designee) and will serve as a medical record of the surgical procedure.
Form 4: Follow-up Appointments:	Reason for visit, AEs (moderate/severe and probably/definitely related)	Form 4 will be completed by the VMMC provider who visually inspects the penis of the participant during any follow-up visit (scheduled or unscheduled). At the time of the procedure, a follow-up appointment will be scheduled seven days post-surgery; the appointment will be written on the post-surgical instruction handout.
Form 5: Active Monitoring System	Residential location, hygiene assessment, AE history, examination, satisfaction	Using PDAs for data collection, a research assistant will visit a random sample of clients at home (30–40 days post-surgery) to assess residential location (via a checklist and GPS) as well as history of AEs, healing, and satisfaction with the procedure.

2. Active system

In order to assess the potential limitations of passive clinic reporting, we actively followed a random sub-sample of participants in the clinic system who were circumcised. Active-system participants were visited and interviewed at their homes 30–40 days post-surgery. They were visited by one male research assistant who conducted an oral interview to confirm demographic information and to ask questions about the procedure, personal care/hygiene, satisfaction (i.e., satisfaction with appearance, sex, and clinical care), onset of sexual activity, and the healing process, including if the patient self-treated an AE or sought treatment for an AE at any health facility. At the conclusion of the interview, the research assistant examined the participant's penis to assess the healing progress. Finally, a global positioning system (GPS)-enabled personal digital assistant (PDA) recorded the geographic location of the participant's residence (Table II; see also Appendix C).

L. Sampling Overview

1. Clinic and active systems

Since VMMC services provided in Kenya are voluntary, males self-elect to be circumcised. All males who sought VMMC services were invited to participate in the study. Those who agreed to participate were asked to provide written consent to participate in both the clinic and active monitoring systems. Only participants who were actually circumcised were eligible to participate in the active system. Although all VMMC clients were invited to participate in the study, a client's willingness to participate in the research did not affect his eligibility to be circumcised. Each week, circumcised participants were randomly selected for the active study based on a unique participant identification number. The selected sample was proportional in size to the number of MCs provided in that week, resulting in more participants being selected during a busy week than a less busy week. If research staff were

unable to locate and/or interview a participant after three attempts, he was replaced with the next participant of similar age listed on the same health facility's weekly circumcision register (divided into the following categories based on age: 18–24, 25–30, 31–35, 36–40, and over 40 years of age).

2. Focus group discussions

We conducted 12 FGDs with uncircumcised males between November and December 2009, exactly one year after the launch of the VMMC program, to assess their perceived barriers and facilitators to the uptake of VMMC services. The FGDs were moderated by one experienced male facilitator; a research assistant took notes. The FGD guide consisted of 12 open-ended questions with probes about MC uptake and acceptability (Appendix A). The questions were originally drafted in English, then translated into Kiswahili and Dholuo, and finally verified by the research team. Participants were recruited using a purposive sampling method at markets, shopping centers, and workplaces. Because the aim was to explore the complete range of community opinions about MC among males most at risk for HIV acquisition, participants were recruited from both urban and rural areas and from a variety of employment cadres common to the study area. To be eligible, potential participants had to be 18 to 40 years of age, uncircumcised (based on self-report), have no plans to become circumcised, and reside in one of the three study districts.

M. Conclusion

In summary, this study was designed to build upon the findings of the RCT and contribute to the scientific literature by examining the acceptability, safety, and outcomes of the MCs offered by a large-scale program. The results from this study are presented in the following chapters, and, in partnership with the GoK, will be used to inform and improve

Kenya's VMMC surveillance system, counseling and health education campaign, and clinical training curriculum.

II. ACCEPTABILITY OF MEDICAL MALE CIRCUMCISION AMONG UNCIRCUMCISED MEN IN KENYA[1]

A. **Background**

The surgical removal of the foreskin of the penis, MC is practiced around the world for medical, religious, and cultural reasons. More than 40 observational studies and three RCTs have established that MC reduces the risk of HIV-1 acquisition in heterosexual men by approximately 60% (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007; Weiss et al., 2008). In 2007, WHO and UNAIDS recommended that MC, provided by trained professionals, be implemented as one component of a comprehensive HIV-prevention strategy in regions with low MC rates, high HIV prevalence, and where heterosexual sex is the mode of transmission (WHO, 2007).

Nyanza Province is the geographic home to the Luo ethnic group, a Niolotic-speaking people with some traditions and customs that differ from the surrounding primarily Bantu-speaking ethnic groups. The Luo people comprise the fourth largest ethnic group in Kenya with a population of approximately four million people (Kenya National Bureau of Statistics, 2009).

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[1]The contents of this chapter have been previously published, and are included here with the permission of *PLoS ONE*. (Herman-Roloff, A., Otieno, N., Agot, K., Ndinya-Achola, J., and Bailey, R. C. 2011. "Acceptability of Medical Male Circumcision Among Uncircumcised Men in Kenya One Year After the Launch of the National Male Circumcision Program." *PLoS ONE* 6 (5): e19814. doi:10.1371/journal.pone.0019814.)

A recent population survey reported that 21.5% of Luo men are circumcised and 17.1% are HIV-positive (Kenya National Bureau of Statistics and ICF Macro, 2010). The GoK launched the national VMMC program in November 2008 and plans to circumcise 860,000 males by 2013 (Republic of Kenya, Ministry of Public Health and Sanitation, 2009). Currently, the VMMC program provides high-quality medical MC services throughout Luo districts in Nyanza Province at no cost to clients.

Prior to completion of the three RCTs, several studies investigated factors that might facilitate or inhibit uptake of MC. Westercamp and Bailey (2007) reviewed 13 MC acceptability studies and concluded that the studies were consistent in identifying certain factors that facilitated MC uptake, including the beliefs that MC leads to improved hygiene, protection from STIs and HIV, improved sexual pleasure and performance, and greater acceptability by other ethnic groups. The barriers to uptake most commonly identified were pain, culture and religion, cost, possible AEs, and the potential for risk compensation (i.e., an increase in risky sexual behavior following MC).

Studies conducted in Nyanza Province reported that the primary reasons men chose circumcision were enhanced protection from HIV and STIs, improved hygiene, decreased risk of penile cancer, and improved sexual satisfaction for men and their sex partners; while the primary reasons that men chose not to be circumcised were pain during/after the procedure, long healing period, AEs, culture or religion, and time away from work (Bailey et al., 2002; Herman-Roloff et al., 2010; Mattson et al., 2005; Westercamp et al., 2010). Riess et al. (2010) reported that recently circumcised men said they were able to perform more rounds of sex, were able to use condoms more easily, and sustained fewer cuts on their penis during sex.

Westercamp and Bailey (2007) concluded, "…additional acceptability studies that pose hypothetical questions to participants are unnecessary" because of the consistency of the

results of MC acceptability studies across several regions. This study, conducted among uncircumcised men in Nyanza Province, Kenya, assessed the non-hypothetical barriers and facilitators of MC uptake after it was proven to be effective by the RCTs, was endorsed by WHO and UNAIDS, was widely available at no cost, and was actively promoted by the GoK and implementing partners.

B. Methods

1. Ethics statement

All research staff completed the online Collaborative Institutional Training Initiative training course on human subject protection. Written consent was obtained from all study participants. The study was approved by the Institutional Review Board (IRB) at UIC (protocol: 2007-0913), and the Kenyatta National Hospital Ethics and Research Committee, in Nairobi, Kenya (protocol: P338/11/2007).

2. Study design

We conducted 12 FGDs in three out of the eight Luo districts within Nyanza Province. These three districts were chosen because they had an active VMMC program, were contiguous, and represented typical urban (Kisumu East) and rural (Nyando and Kisumu West) populations in Nyanza Province. The FGDs were conducted between November and December 2009, exactly one year after the launch of the VMMC program. The FGDs were moderated by one experienced male facilitator; a research assistant took notes. The FGD guide consisted of 12 open-ended questions with probes about MC uptake and acceptability (Appendix A) that were originally drafted in English, then translated into Kiswahili and Dholuo, and then verified by the research team. Established moderation

techniques were employed to ensure active participation by all participants (Krueger and Casey, 2000).

Participants were recruited using a purposive sampling method at markets, shopping centers, and work places (Miles and Huberman, 1994); 121 men participated in the study. Because the aim was to explore the complete range of community opinions about MC among males most at risk for HIV acquisition, participants were recruited from urban and rural areas and from a variety of employment cadres common to the study area, including bicycle transporters (n = 32), students (n = 18), informal sector (n = 18), farmers (n = 12), shop/kiosk owners (n = 11), and other cadres, including teachers, fishermen, drivers, and religious leaders. To be eligible, potential participants had to be 18–40 years of age, be uncircumcised (based on self-report), have no plans to become circumcised, and reside in one of the three study districts where VMMC services were being widely provided.

Interested males were asked to participate in an informed consent process in the language of their choice (English, Dholuo, or Kiswahili), and if they chose subsequently to enroll, they provided signed consent. All enrolled males participated in the discussion, and no one terminated his participation prematurely. Each FGD lasted 60–90 minutes and involved 8–12 uncircumcised men. Six FGDs were conducted among young men (18–27 years of age), and six FGDs were conducted among older men (28–40 years of age). For their time, participants were offered a snack, soda, and compensation of 200 Kenya Shillings ($2.50 USD), less than the average daily wage in Kenya.

C. **Data Collection and Management**

Audio recordings were transcribed in the original language of the FGD, translated into English (if necessary), and then the translation was verified by a second staff member who compared it to the original transcript. The translated transcripts were reviewed, themes were

identified, and a codebook was developed collaboratively by three members of the research team. All of the transcripts were imported into ATLAS.ti (version 6) and were coded independently by two research staff members; any discrepancies were discussed and a consensus was reached.

D. Results

1. Facilitators of male circumcision uptake

Three questions were asked to begin the discussion about factors that might act as facilitators to the uptake of MC services including: "What are some things people do to protect themselves, or their sexual partner, against getting HIV?"; "When you hear people talk about male circumcision in the community, what are some of the things they say?"; and "A Luo man, named Onyango, is considering getting circumcised. What are some of the reasons that he might decide to get circumcised?" (Onyango, a common name for a Luo man, was used throughout the FGD dialogue.)

The primary facilitators of MC uptake that were expressed in every discussion included the beliefs that MC improves hygiene, is influenced by social pressure, improves HIV and STI protection, and improves sexual performance and satisfaction, in order of salience.

a. Hygiene

Improved hygiene was the most common facilitator of MC. Participants described the improvement in hygiene resulting from MC in several ways, including: "good smelling," "easy to wipe clean," "no smell after sex or bathing," and "HIV and other germs don't have a place to hide."

b. **Social pressure**

Social pressure was a very common facilitator of MC uptake, especially among young men. Participants discussed, without prompting, several scenarios or social mechanisms that might affect Onyango's MC decision-making process including: a recently circumcised man shares his experience with Onyango and encourages him to become circumcised; Onyango is the only one among his male friends or family who is not circumcised, and he is being teased about being uncircumcised, especially while bathing; Onyango's female sex partner says that she will leave Onyango or withhold sex until he is circumcised; and Female sex partners and/or men from other ethnic groups might call Onyango "kehe," or other derogatory names, to mean that he is a child and not a man since he is not circumcised. Many participants remarked that if a man chose to be circumcised, he might be able to mix more freely with women and men from non-Luo ethnic groups in political, professional, and personal settings.

c. **Prevention of HIV and sexually transmitted infections**

When participants were asked to discuss all HIV-prevention methods, the ABC approach (Abstain, Be faithful, use Condoms) was the most common response, although other prevention strategies, such as HIV testing, were mentioned. One-third (two out of six) of FGDs with young participants and five out of six FGDs with older participants identified MC as an HIV-prevention strategy without prompting. Additionally, when asked why Onyango might decide to get circumcised, HIV prevention was one of the reasons mentioned, although not the most common. A range of protective-effect estimates was mentioned by the participants (range: 30%–100%). Most participants reported that they had heard that MC "reduces the chance of getting HIV"; however, they were confused or

uncertain about two issues: how MC protects against HIV acquisition, and whether the MC-HIV connection is a myth or truly protective.

Although young men were less likely to identify MC as an HIV-prevention strategy without prompting, they had more knowledge than older men about the MC-HIV association and the mechanisms by which MC is protective against HIV. Some mechanisms discussed by young participants included MC "hardens the tip," germs cannot live on a circumcised penis, and the foreskin has many HIV target cells.

Among older men, many comments about the MC-HIV association began with "Some say…," indicating that they might have some skepticism or inadequate information about this association. For example, one participant said, "Some say that after circumcision you cannot acquire HIV easily." The moderator asked, "Why?" The participant replied, "I don't know the reason but I hear them say so."

Participants also reported that MC reduced the incidence of STIs, specifically gonorrhea, syphilis, boils, and cervical cancer. The magnitude of the protective effect afforded by MC against HIV and STIs was often discussed as equivalent.

d. **Sexual performance and satisfaction**

Improved sexual performance and satisfaction, defined as male sexual satisfaction, female sexual satisfaction, and male sexual performance, were common facilitators to MC uptake, especially among young men. There was general consensus across all groups that MC improves sexual performance and satisfaction for men, and sexual satisfaction for female partners. Some reported that MC acts as a "natural condom" and for this reason circumcised men can enjoy sex "skin-on-skin" without needing a latex condom. Additionally, participants reported that MC reduces cuts and bruising on the foreskin during sexual intercourse (this was discussed more by older men). Finally, participants believed that

MC improves male sexual satisfaction by several other mechanisms, especially by reducing the worry of acquiring HIV or an STI during sex; making condom use easier; and by making the penis more "rough," which increases friction during sex. Many participants reported additional sexual benefits for men after MC: men can have sex several times in the same night; the time to ejaculation is increased; penetration is easier; and circumcised men have more "energy" for sex. The positive effect of MC on female sexual satisfaction was mentioned during all discussions. Most participants believed that women find circumcised men more sexually satisfying than uncircumcised men. Also, some participants believed that MC might encourage faithfulness if the female partners of circumcised men are more sexually satisfied. Finally, easier penetration, increased time to ejaculation, and increased friction were believed to affect female sexual satisfaction positively. One participant said, "What women will tell him is that in the past, other tribes have been saying that this [MC] can help with this job, it penetrates well, and it's sweeter than the one that has not been cut."

e. **Other facilitators**

Other motives for MC uptake included the following beliefs: that adolescence is the ideal time for MC (11–18 years of age); that MC clients would receive material incentives ranging from soda to a substantial monetary compensation; that the Christian religion approves of MC because Jesus was circumcised; that MC is offered in a medical setting; and that parents, elders, and celebrities support MC.

Participants agreed that MC is preferable for males before they reach 18 years of age; no participant discussed a man over 30 years of age being circumcised. One participant said, "I've heard the old men say that circumcision should start at the age of 10 up to 18. Because beyond that, the muscles become mature."

Nearly all participants believed that MC services should be performed in a medical setting by a trained provider. Participants discussed several reasons for this opinion, but the two most common were these: (1) if MC is "medicalized," it may minimize resistance among the Luo people because they will not see it as a counter-cultural practice being thrust on them, and (2) if MC is medicalized, AEs would be handled more propitiously by trained medical staff .

In September 2008, before the launch of the national VMMC program in Kenya, Prime Minister Raila Odinga, a Luo political and cultural leader, encouraged Luo men to go for MC for HIV prevention. This endorsement especially impacted younger men. One participant said, "As youths we go for circumcision because we are his disciples. So we will say, 'If Raila did it, why not us?' So we follow our leader."

2. Barriers to male circumcision uptake

We asked participants, "What are some of the reasons that Onyango might decide not to get circumcised?" All groups responded that the primary barriers to MC uptake included (in order of salience): too much time away from work; cultural and religious values; the possibility of AEs; the post-surgical abstinence period; a desire to maintain the status quo; and increased promiscuity.

a. Time away from work

Participants reported that too much time away from work, especially if the man is the sole provider for the family, is the most significant barrier to seeking the service. This barrier was especially noted among older men and men working in the informal sector, including bicycle transporters, security guards, fishermen, and others. Participants

believed that men might be away from work for a minimum of one week up to a maximum of 12 weeks after circumcision.

b. **Cultural and religious values**

Traditionally, the Luo removed the lower six teeth as a rite of passage into adulthood (while the neighboring Bantu groups practiced MC as a rite of passage). Recently, the practice of removing teeth has nearly ceased, and no practice has taken its place (Bailey et al., 2002). In this cultural context, the community has considered the role of MC as a medical practice versus a cultural rite.

Young participants viewed MC as a medical intervention that exists outside of culture, but older men often talked about MC as a cultural practice that is meant for other ethnic groups. Although young men discussed the health benefits afforded by MC, many still believed that getting the approval of elder males in their family was essential if one wished to be circumcised, and the consequences resulting from an unapproved circumcision could include being estranged from family, being forced to move off family land, and even dying. One participant said, "In our community they [the elders] say that circumcision is not good. They even say that that is the reason why the young people are dying because they are going against the rules of our ancestors."

Several participants, especially those who were young, reported that they believed that it would be a sin to get circumcised since circumcision would change God's creation. Older men talked about religion in the sense that if a man is "saved," then he will not be promiscuous, and as a consequence, he will have no need for MC to protect him against HIV.

c. **Adverse events**

The possible incidence of AEs was a common barrier to uptake. The most common AEs discussed included pain and bleeding during and after MC and delayed healing. Other AEs mentioned included negative effects on male reproduction resulting from the anesthetic injection, problems with appearance, torsion, infection, reduction in penile size, and surgical "accidents" that would mar appearance or impair function. Some participants noted that clients who have a bad experience will share their experience in the community. One man said, "So they [recently circumcised men] say there is a lot of bleeding. Another thing is some misconceptions like this local injection can cause you to be infertile in future and another thing is that an accident can occur."

d. **Abstinence period**

Almost all participants knew that an abstinence period of some duration was recommended after MC, and they discussed this as a barrier for both men and their female sex partners. Participants believed that men, especially young men, would be concerned that their female sex partners might seek other lovers while they are recovering. Older men reported that sleeping in the same bed with a wife would make it difficult to observe the abstinence period. Various durations of the abstinence period were discussed (range: 1–8 weeks); some participants who knew the recommended duration of the abstinence period reported that six weeks was too long to abstain from sexual intercourse.

e. **Status quo**

Some participants believed that men did not need or desire MC. Several reasons were given to explain why MC is not "necessary": the protection against HIV and STIs is not 100%; and if a man is already HIV-positive, has good hygiene, or is already

practicing other HIV-prevention methods, such as the ABC method and HIV counseling and testing, he will not benefit from the procedure.

Participants offered other reasons, too, that men might not have the desire to go for MC: they and their sex partner(s) are already sexually satisfied; they do not wish to change the appearance or sensation of the penis; they are too old; and/or they do not want to introduce doubt in their relationship by going for MC. One participant said, "When I told my wife that I wanted to go for circumcision, she told me that I am not faithful to her and so I want to go for circumcision so that I don't get infected. Secondly she told me that she liked that thing the way it was and she didn't want me to change it."

f. **Promiscuity**

The fear that MC will make a man promiscuous was mentioned frequently. On the individual level, participants said that if a man wants to get circumcised, his female sex partner(s), neighbors, and/or friends might think that he is promiscuous. As a community, it is believed that MC might create a generation of men, especially young men, who think that they can have sex without any risk. Some participants feared that if MC led to more promiscuity, it might produce more HIV transmission in the community, not less.

g. **Other barriers**

Other barriers to MC uptake included: a long distance to the health facility; a decrease in male and female sexual satisfaction; and peer influence against MC. A long distance to the facility was also mentioned as a barrier to MC uptake, especially after MC, when a client may be too weak or in pain to travel far, or when a client is considering whether or not to attend a follow-up visit. Discussed mechanisms for decreased male and/or female sexual satisfaction included less natural lubrication on a circumcised penis and

decreased male penile sensitivity. One participant said, "Even . . . circumcised persons have problems when having sex. In fact, when one is erect there are some fluids that lubricate him and after circumcision that place dries up and you'll be harming the girl because it's like you are stepping on her with a sole."

Finally, other barriers to MC uptake included opposition from girlfriends, reports from MC clients who say they have had a bad experience, and resistance from community leaders who oppose MC.

3. **Female service providers**

Many organizations and governments providing MC services have wondered how MC clients would respond to female service providers. To explore this issue, we asked participants, "If Onyango goes to a health facility for male circumcision and finds the following, how might he react - female staff providing counseling and education on circumcision? Female staff performing the circumcision? Female staff attending to clients during follow-up visits?"

Most groups started this conversation thread by talking about interactions with female providers in nonprofessional terms, usually with sexual overtones. For example, one participant said, "Onyango might be happy if he finds that it is a woman who performs the circumcision because he will be sure that the other girls will know that he has been circumcised and he can play sex perfectly."

The most common barrier discussed about a female service provider was that she might make an MC client feel "shy." Some participants believed that Onyango might have an erection when a female provider touches or inspects his penis, thereby creating an awkward situation for both the provider and the client. However, by the end of the discussion, most participants concluded that as long as the provider was a trained professional and the client

did not know her, MC services being provided by females would not be a problem. A few participants believed that a female provider might perform services better than a male provider because women are more "understanding" and "gentle" when providing services compared to men.

4. **Community response**

To explore how men expect their community to react to recently circumcised men, we asked participants, "In the end, Onyango decided to get circumcised. What would his neighbors say about Onyango if they found out he was circumcised?"

The range of expected community responses was wide, and participants attributed the variance to differences in age, education, and level of MC knowledge in the community. Older and/or less educated community members were expected to shun Onyango for abandoning his cultural traditions, while young and/or more educated community members were expected to congratulate Onyango and to be curious about the procedure and his experience. One man said, "It will depend with the kind of the neighbors that Onyango has. If they have the knowledge about circumcision they will encourage him. But if they are not informed, they will laugh at him and even isolate him because he has gone against their customs."

5. **Demand creation**

We asked participants, "The Government of Kenya now recommends male circumcision for HIV prevention. What would be some of the ways to sensitize men, like Onyango, about the benefits and risks of male circumcision?"

Several sensitization approaches were discussed by participants. The following methods were proposed: radio broadcasts (in the local language so that people of all ages can

understand them); women's groups who can then mobilize their husbands, sex partners, and male children; church leaders who can then mobilize the members of their congregation and the community; peer educators (using them to promote MC would create job opportunities for recently circumcised youth), sports rallies, and school curricula/programs.

E. **Discussion**

While more than 13 published studies indicated that MC was likely to be an acceptable HIV-prevention strategy (Westercamp and Bailey, 2007), few studies have been published about revealed, non-hypothetical preferences among uncircumcised men. Now that MC services are widely available at no cost, it is important to learn from uncircumcised men about the factors that influence MC uptake.

To a large extent, our results are consistent with findings from studies conducted prior to the scale-up of MC (Bailey et al., 2002; Mattson et al., 2005; Westercamp and Bailey, 2007); however, some differences are notable. Previous studies explored the impact of cost on MC uptake, but MC services are being provided at no cost in Kenya. Additionally, one study in Malawi reported that free services were viewed as poor quality (Ngalande et al., 2006), but no participant in our study mentioned this; conversely, some believed that males might be more likely to adopt MC because the service is free. While previous acceptability studies explored the impact of time away from work as part of the total cost of the procedure, in this study, time away from work was the most important barrier to MC acceptability, especially among men working in the informal sector (e.g., bicycle transporters) and older men.

Both WHO and UNAIDS recommend a six-week abstinence period following MC (WHO, 2007). Participants in this study were aware that there is a recommended period of abstinence following MC; however, there was confusion about the duration of the period for

abstinence, time away from work, and complete healing. National communication campaigns and couple's counseling should clarify these periods to ensure realistic expectations for MC clients and their sex partners, and to promote wound healing among recently circumcised men.

As noted in previous studies (Westercamp and Bailey, 2007), there was consensus that MC services should be offered in a medical setting, not in traditional settings, because a medical setting is believed to be more safe, and AEs can be handled by medical professionals. In this study, participants believed that medical male circumcision also clarifies the purpose of the national VMMC program—that is, VMMC is not trying to change or dilute any ethnic group's culture; instead, it is promoting MC for medical and health purposes. This might be an important distinction to be made in other regions where MC is being promoted.

When asked about HIV-prevention methods, participants were most familiar with the ABC approach and frequently did not situate MC within their existing HIV-prevention framework—this was especially true among young men. This trend was observed in Uganda, where older men were significantly more aware of MC for HIV prevention than youths, and where overall, only 38.2% of respondents mentioned MC as an HIV-prevention strategy in an open-ended question (Wilcken et al., 2010). In our study, seven out of 12 groups reported MC as an HIV-prevention strategy without prompting. While older men were more aware of MC for HIV prevention, they were less likely to believe that MC was necessary, especially if a man practiced other HIV-prevention methods. This disparity between knowledge and beliefs is important, and should be explored in program implementation and future research.

Several studies are on-going to assess the potential for risk compensation, or the increase in sexually risky behaviors, post-MC. Among the participants in this study, there was a wide range in estimates of the protective effect afforded by MC against HIV

acquisition (range: 30%–100%). Similar to results reported in 2010 by Riess et al. and Wilcken et al., most participants did not know the exact magnitude of the protective effect, but they knew that MC was not fully protective and that other HIV-prevention methods would continue to be necessary. However, some participants believed that men might be motivated to seek MC services because they want to have sex without a condom and/or increase their number of sexual partners. Based on these beliefs, risk compensation remains a possibility, especially when services are provided with less counseling and less recurrent contact with MC clients than during the RCTs. It remains important for a national communication strategy to continue enforcing the general knowledge that MC is only partially protective against HIV acquisition and to clarify the magnitude of the protective effect.

The possibility of discrimination was discussed by participants in this study; specifically, it was believed that some members of the community might shun recently circumcised men, especially when community members are older and/or less educated; this finding is consistent with findings from previous studies (Westercamp and Bailey, 2007). While some participants in this study believed that men might seek MC services because Jesus was circumcised, others, especially young men, reported that it was a sin for men to change the way they were created. Westercamp and Bailey also observed this ambiguity and lack of consensus and recommended that it would be "prudent to consult and collaborate with religious leaders" before promoting MC in a country. This remains an important recommendation in scaling up MC services throughout Africa.

Circumcision for adult men (18 years of age and older) was a barrier to MC adoption expressed by many in this study, and this is consistent with the findings of previous studies. Studies have reported that circumcision at 7 to 13 years of age is most preferable because a boy at this level of maturity can make the decision for himself, understand the significance of

the event, take care of the wound himself, and is unlikely to have initiated sexual activity (Bailey et al., 2002; Ngalande et al., 2006). In this sample, participants believed that adolescent boys and teenagers (11–18 years of age) were best suited to go for MC. While several governments are targeting sexually active males during the initial phase of implementing a large-scale MC program (Republic of Kenya, Ministry of Public Health and Sanitation, 2009; WHO, 2007), community opinions about the ideal age for MC should not be ignored.

The results of this study might be useful for the development or improvement of an MC communication campaign both within and outside of Kenya. A national or regional communication campaign is well positioned to dispel misconceptions like the recommended duration of time away from work (usually a few days, but less than one week) versus the recommended abstinence period (six weeks). Additionally, many participants stated that men are concerned about developing severe AEs post-MC. Preliminary results from a study in Kenya found that 2.7% of clients experienced a moderate or severe AE, and all AEs resolved with treatment (Herman-Roloff et al., 2010); low AE rates were also reported by a large-scale MC program in South Africa (Lissouba et al., 2010). The message that medical MC very rarely results in severe, untreatable AEs should be disseminated widely. Finally, participants were hesitant to believe that MC really protects against HIV acquisition because they did not know the mechanisms that explained this protection, and these mechanisms can be communicated through campaign messages.

The findings reported above should be considered along with the following study limitations. The results from this study might not be generalizable to other programs and countries since they were restricted to Nyanza Province. Additionally, while purposive sampling was employed in an attempt to recruit a representative sample of uncircumcised men (self-report) 18–40 years of age, it is possible that this study might not describe the full

range of beliefs related to MC in Nyanza Province; however, saturation was achieved, and no new themes emerged during the final FGDs conducted within each age category. Also, all participants were uncircumcised with no plans to get circumcised, so their opinions about MC might be more negative than the general population. Finally, the data collected during this study were self-reported opinions about community perceptions of MC; therefore, it is possible that the participants themselves did not hold these opinions and might have withheld or exaggerated information.

The results of this study are very consistent with the results of previous studies, but they add a nuanced understanding of revealed—not hypothetical—acceptability of MC services. These results may be used to implement or improve several program activities to positively impact MC uptake, including: revising communication messages to dispel misconceptions; increasing the involvement of religious leaders, women's groups, and peer mobilizers in MC sensitization; and situating MC within the existing HIV-prevention framework (e.g., ABC, HIV testing, home-based counseling and testing, couples testing and counseling, and STI diagnosis and treatment) to improve the relevance of this intervention for men already practicing some HIV-prevention methods.

III. PASSIVE AND ACTIVE SURVEILLANCE OF SAFETY DURING THE SCALE-UP OF MEDICAL MALE CIRCUMCISION

A. **Background**

Throughout the course of public health history, practitioners have relied on monitoring and surveillance systems to evaluate the performance of public health programs and interventions (Declich and Carter, 1994). In its 2001 updated guidelines for evaluating public health surveillance systems, the CDC defines surveillance as the "ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action"; collected data might be used to "guide the planning, implementation, and evaluations of programs to prevent and control disease, injury, or adverse exposures." The *Dictionary of Epidemiology* defines monitoring as "the ongoing measurement of performance of a health service or a health professional" (Last, 1988). Both of these terms—monitoring and surveillance—capture the importance of using ongoing data collection to evaluate program performance. Throughout this paper we will use the term surveillance to represent this concept. Surveillance systems are often classified as passive or active, depending on the way they collect data. Most health surveillance systems are passive, meaning that a medical, laboratory, or other health professional reports health events on a standardized form. While passive systems have benefits—for example, they are relatively inexpensive—they also have known limitations such as incomplete data and underreporting of events (Brachman, 1977; Vogt et al., 1983; Wood and Adams, 2006). Active surveillance involves outreach by a health official to identify and report a health event. Many health experts believe that active surveillance systems produce data of higher quality than passive systems (Vogt et al., 1983); however, due to resource demands, active data collection is considered most feasible when implemented in a few facilities to examine a focused issue (MacDonald et al., 1997). Currently, most surgical procedure surveillance is passive and

largely restricted to in-patient, surgical-site infections in developed countries (Böröcz et al., 2006; Bruce et al., 2001; German, 2000). Recently, an increasing number of surgical procedures are being provided on an out-patient basis, and in-patient surveillance may not be adequate; therefore, post-discharge surveillance, conducted in a variety of settings, is important for monitoring and improving the quality and safety of services (Vilar-Compte et al., 2007). This recommendation is especially relevant for governments and partner organizations implementing MC for HIV prevention in sub-Saharan Africa.

Practiced worldwide for medical, cultural, and religious reasons, MC is the surgical removal of the foreskin of the penis. The results of three RCTs conclusively demonstrated that MC reduces the incidence of HIV-1 in heterosexual men by at least one half (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). As a result, MC has been recommended by WHO and UNAIDS as an effective component of a comprehensive HIV-prevention strategy in regions with low MC rates, high HIV-1 prevalence, and where heterosexual sex is the mode of transmission (WHO, 2007).

While health experts have recommended large-scale MC programs for HIV prevention, they also have concerns regarding AEs and client safety during the implementation of these programs in resource-limited settings. In developed countries, passive surveillance of AEs following neonatal MC are well documented and range between .2% and .6%; bleeding and infection are the most common (Kaplan, 1983). Before the RCTs, outcomes in Africa for medical (not traditional) MC among adults were poorly documented. In a recent systematic review of MC outcomes conducted by Muula et al. (2007), AE rates performed in Anglophone Africa ranged from 0% to 24%; most complications were minor, but still cause for concern. The RCTs, which provided services in a gold-standard, clinical setting, reported the following AE rates: 3.8% in Orange Farm, South Africa; 1.5% in Kisumu, Kenya; and 3.6% in Rakai, Uganda. The most common AEs included pain, swelling,

bleeding, problems with appearance, infection, and wound disruption (Auvert et al., 2005; Kigozi et al., 2008; Krieger et al., 2007). In Uganda, the AE rate was 3.1% and 3.5% in HIV-positive and HIV-negative men respectively; this difference was not statistically significant (Kigozi et al., 2008). Most recently, at the former Orange Farm RCT site, the Bophelo Pele Project investigated the feasibility of providing MC services to the community in one high-volume facility and reported an AE rate of 1.8% (Lissouba et al., 2010).

To date, no research has been published on the clinical outcomes of a large-scale, multi-site MC program in a resource-limited setting. The NRHS, as part of the MCC, is supporting the GoK to scale-up medical MC services in Nyanza Province by providing clinical training, and conducting monitoring and evaluation and operations research activities. This study used passive and active surveillance to assess the safety of MC procedures provided as part of the national program by assessing AE incidence and factors (including provider experience) associated with the development of an AE.

B. Methods

1. Study context

The GoK launched the national VMMC program in November 2008 and plans to circumcise 860,000 males by 2013 (National AIDS and STI Control Programme, 2008). The VMMC program was implemented in Nyanza Province, which is the geographic home of the Luo ethnic group, a Niolotic-speaking people with some traditions and customs different from the surrounding ethnic groups, most of whom are Bantu-speaking. Luo men do not traditionally practice MC, and they have a high prevalence of HIV compared to the rest of the country; 21.5% of Luo men are circumcised and 17.1% are HIV-positive compared to 85.9% and 4.6% of Kenyan males respectively (Kenya National Bureau of Statistics and ICF Macro, 2010).

2. **Voluntary Medical Male Circumcision service provision**

The national VMMC program provides high-quality medical MC services throughout the predominantly Luo-populated districts in Nyanza Province. All procedures are offered at no direct cost to clients and are performed by a trained clinician (MO or CO) or nurse who has completed a 2–3-week competency-based training program, including assisting on at least 10 MC procedures and performing a minimum of 20 supervised procedures. (In Kenya, COs are health care professionals who provide medical services after completing three years of post-secondary education. MOs complete a minimum of five years of post-secondary education, and supervise clinical practice in large facilities.) All clients are encouraged to undergo voluntary HIV testing and counseling, which is available on site, but testing is not compulsory, and clients can choose not to have their status recorded on the VMMC form even if they chose to be tested. Clients are screened to assess their eligibility for surgery through a detailed medical examination based on a pre-defined checklist (e.g., assessing pallor, blood pressure, and history of bleeding disorders). Clients who present with an acute STI are treated; if they are deemed to have recovered based on a second medical exam during a subsequent visit, they are offered VMMC services. Clients with penile congenital malformations or known bleeding disorders are referred for specialized care. Men who are HIV-positive are discouraged from proceeding with the surgery, but if they insist, and they show no cause for clinical exclusion, they are not denied the service. For the procedure, all instruments and supplies are obtained locally. Clients are circumcised using the forceps-guided method; local anesthesia is infiltrated at the base of the penis through the dorsal nerve and ring block techniques (Ministry of Public Health and Sanitation, 2008). The incision site is closed using absorbable sutures through a combination of mattress and simple stitching. At the conclusion of the procedure, clients are given written instructions on how to

care for the surgical wound. These instructions cover bandage removal, penile elevation, general wound care, and post-surgical sexual abstinence for a minimum of 42 days. Clients are scheduled to return to the facility for one follow-up visit within seven days after the procedure; however, if they have a question or concern, they are encouraged to return at any time or to call a 24-hour emergency hotline.

3. **Study design and participants**

This prospective study followed MC clients from before the procedure through the completion of their follow-up care. Study participants included males 12 years of age or older who voluntarily sought VMMC services between November 2008 and March 2010 at selected study facilities. Interested participants provided written informed consent/assent in the language of their choice (English, Dholuo, or Kiswahili); signed parental/guardian permission was obtained for participants less than 18 years of age. Participants were informed of their right to refuse to answer any question or to terminate their enrollment at any time; however, no participant terminated his participation prematurely. Basic demographic information was obtained from participants who declined to participate in the study.

The study had two surveillance components including, first, a passive, clinic system collected and managed routine clinical data (procedure and follow-up) on participants who voluntarily sought VMMC services at one of 16 health facilities in Kisumu East, Kisumu West, and Nyando districts in Nyanza Province. While clients were scheduled to return to the facility for one follow-up visit seven days after the procedure, a follow-up form was completed each time they sought care post-MC. Since the passive system relied on routine data, participants in the passive system were not compensated for their involvement in the study.

The second surveillance component, an active system, monitored a random sub-sample of circumcised participants in the clinic system through a home-based, in-depth interview conducted by a research assistant 30–40 days post-MC. Research staff attempted to establish contact with each selected participant before the 30–40 day window, making a maximum of three attempts. As a result, some participants were interviewed outside the recommended window (both early and late), resulting in interviews being completed 28–45 days post-MC. For the active system, a target sample size of 1,449 was set to detect a 2% difference in the AE rates between the two systems with an overall type-I error rate of $\alpha = .05$ and 80% power. A total of 39.1% of circumcised participants in the clinic system were interviewed in the active system ($n_{active} = 1{,}449$). Each week, circumcised participants were randomly selected based on a unique participant identification number. The selected sample was proportional in size to the number of MCs provided in that week, resulting in more participants being selected during a busy week than a less busy week. If a participant was not able to be located and/or interviewed by a research assistant, he was replaced with the next participant of similar age listed on the same health facility's weekly circumcision register (in the categories of 18–24, 25–30, 31–35, 36–40, and over 40 years of age). Data collected by the active system focused on the participant's circumcision experience, AE history, and sexual behavior following MC. The data collected were a mixture of self-report (e.g., demographic information, care-seeking behavior, satisfaction, AE history, and sexual activity) and genital examination to assess healing status as well as specific AEs (e.g., problems with appearance). The categories of AEs monitored by the active system and the clinic system were the same. Participants were compensated 200 Kenya Shillings ($2.50 USD) for their time, less than the average daily wage in Kenya, for completing the interview for the active system.

4. Ethical considerations

All research staff completed the online Collaborative Institutional Training Initiative training course on human subject protection. The study was approved by the IRB at UIC (protocol: 2007-0913), and the Kenyatta National Hospital Ethics and Research Committee, in Nairobi, Kenya (protocol: P338/11/2007).

5. Data collection and statistical analysis

Data for the clinic system were collected using four paper questionnaires (Appendix B). Data for the active system were collected using Dell Axim PDAs, programmed using Visual CE (Appendix C).

In total, we monitored 10 types of MC-related AEs, including pain, swelling, hematoma, bleeding, infection, difficulty urinating, wound disruption, problems with appearance, injury to the glans, and "other" AEs (since this was a new program, we wanted to assess any incident event of interest). AEs were classified as moderate or severe. Moderate AEs were those that prevented a participant from performing normal activities and required treatment; severe AEs were defined as those that were incapacitating and required treatment, bed-rest, or hospitalization. Due to the subjectivity associated with measuring pain, and given that pain is often indicative of another identifiable AE, we reported pain separately (as did the RCT reports), and did not include it in summary measures of AE rates. Therefore, the primary outcome was the development of a moderate or severe AE, excluding pain, resulting in treatment at a health facility. The duration of the procedure was defined as the period between the first cut to the last suture.

Data were analyzed using SAS version 9.1 (SAS Institute Inc., Cary, North Carolina). Differences between participants who enrolled in the study and those who did not were assessed using Pearson's chi-square for independence. The magnitude of the associations

between independent variables and the outcome (i.e., the development of a moderate or severe AE resulting in treatment at a health facility) were assessed using univariate logistic regression analysis and characterized with ORs, 95% CIs, and p-values. A multi-variable logistic regression model, including age and all marginally significant variables from the univariate analysis (at $p < .10$), was developed using automated forward selection to estimate AORs, CIs, and p-values; variables significant at $p < .10$ were retained. (Model selection was confirmed using automated backward and score methods.) The following factors were included in the adjusted model and were assessed for confounding, effect modification, and multi-colinearity: age, month of procedure, duration of procedure, dose of anesthesia, cadre of MC provider (i.e., category of provider including nurse, CO, and MO), employer of MC provider, and provider experience. Finally, we assessed the agreement of the clinic system and the active system in identifying AEs that occurred post-MC.

C. **Results**

1. **Study population**

Among the 4,288 MC participants who were invited to participate in the study, 4,010 participants enrolled and 278 declined to participate (93.5% enrollment rate). The median age was 20 years (inter-quartile range [IQR]: 18–24) and ranged from 12 to 78 years. The vast majority of participants were from the Luo ethnic group (95.7%, n = 3,837); 39.4% completed secondary school (n = 1,580); 29.9% were married (n = 1,198); and 66.7% were students/unemployed (n = 2,673). Participants who enrolled in the study were more likely to be younger ($p = .001$), Luo ($p = .03$), less educated ($p = .001$), and less stably employed ($p = .001$) than those who declined enrollment.

2. **Clinic system**

Among the 4,010 enrolled participants, 3,705 underwent circumcision. The most common reasons that participants were not circumcised included changing their mind or having a comorbidity that excluded/deferred them from getting circumcised on that day. More than a quarter of all participants (27.5%, n = 1,018) presented with at least one of the following comorbidities: urethral discharge, genital ulcers, genital warts, pallor, chronic wounds, and high blood pressure. High blood pressure, defined as systolic of more than 140 mmHg or diastolic more than 90 mmHg, was the most common comorbidity (26.3%, n = 975); all participants with high blood pressure underwent circumcision. Less than one percent of participants presented with an acute STI (.9%, n = 33), and these participants were deferred for MC until they completed the STI treatment.

Among participants who underwent circumcision, 1,338 participants (36.1%) were tested for HIV on-site: 3.4% tested HIV-positive (n = 45); 96.1% tested HIV-negative (n = 1,283); and .5% declined to have their test result recorded on the form (n = 7). For the remainder of this analysis, participants who did not test, or declined to report the result of their test, were classified as having an "unknown status" and participants who self-reported that they were HIV-positive (n = 82) and/or tested positive for HIV on-site (n = 51) were classified as being HIV-positive.

The median time for the MC procedure was 17 minutes (IQR: 14–23 minutes). Most procedures were performed by a CO (66.8%, n = 2,475), 33.1% were performed by a nurse (n = 1,225); and the remainder by an MO (.1%, n = 5). Staff from NRHS are similar in background and training to their GoK staff counterparts, but they are "MC-dedicated," meaning that their only duty is to perform MC services; NRHS staff provided 88.5% of the procedures (n = 3,280); the rest were provided by GoK staff (11.5%, n = 425). Nearly all participants (98%, n = 3,631) were given 2% lidocaine without epinephrine for local

anesthesia in the following doses: 47.7% (n = 1,768) received 10 ccs or less and 52.3% (n = 1,937) received 11 ccs or more. Although MC procedures were performed throughout the year, participant flow was not consistent and peaked during high-volume months that coincided with official and school holidays (March–April, July–August, and November–December) (62%, n = 2,296). Less than half of the participants (45.1%, n = 1,672) returned to the facility for a follow-up visit. The participants who completed a follow-up visit returned a mean of 8.1 days post-MC and reported returning to normal activities a mean of 2.4 days after the procedure. The intra-surgical AE rate was .1%—three participants had an AE occur during the MC procedure, including one reaction to the anesthetic, one undiagnosed bleeding disorder, and one hematoma. Post-procedure, 78 participants were classified as having a moderate (n = 75) or severe (n = 3) complication resulting in an AE rate of 2.1% (Table III). Limiting the sample to only those participants who returned for at least one follow-up visit (45.1%, n = 1,672) the post-MC AE rate for the clinic system was 4.7%.

TABLE III

CHARACTERISTICS AND POST-CIRCUMCISION RESULTS AMONG CIRCUMCISED MEN ENROLLED IN THE CLINIC SYSTEM

	Clinic System (N = 3,705) n (%)
Age	
< 18 years	241 (6.5)
18–24 years	2,551 (68.9)
25–34 years	684 (18.4)
≥ 35 years	229 (6.2)
HIV status	
HIV-positive (completed onsite test or self-report)	103 (2.8)
HIV-negative (completed onsite test)	1,283 (34.6)
Unknown (declined onsite test)	2,319 (62.6)
Diagnosed with STI at screening	
Yes	33 (.9)
No	3,672 (99.1)
Diagnosed with comorbidity at screening[a]	
Yes	1,018 (27.5)
No	2,687 (72.5)
Duration of procedure (median, IQR)	17 minutes [14–23]
Less than 25% IQR (< 14 min)	685 (18.5)
IQR (14–23 min)	2,138 (57.7)
More than 75% IQR (> 23 min)	882 (23.8)
MC performed during high-volume month	
Yes	2,296 (62)
No	1,409 (38)
Cadre of MC provider	
Clinician (CO or MO)	2,480 (66.9)
Nurse	1,225 (33.1)

TABLE III (continued)

CHARACTERISTICS AND POST-CIRCUMCISION RESULTS AMONG CIRCUMCISED MEN ENROLLED IN THE CLINIC SYSTEM

	Clinic System (N = 3,705) n (%)
Employer of MC provider	
GoK	425 (11.5)
Nyanza Reproductive Health Society	3,280 (88.5)
Dose of local anesthesia	
≤ 10 cc	1,768 (47.7)
≥ 11 cc	1,937 (52.3)
Returned for ≥ 1 follow-up visit	
Yes	1,672 (45.1)
No	2,033 (54.9)
Mean days to return to "normal activities" [SD]	2.4 days [2]
Client AE rate	
Intra-surgical	3 (.1)
Post-surgical [b]	78 (2.1)

[a] Comorbidities include urethral discharge, genital ulcers, genital warts, pallor, chronic wounds, and high blood pressure

[b] Outcome variable in logistic regression modeling

3. **Active system**

Among the participants randomly selected to be interviewed for the active system (N = 1,449), 92.8% were adults (18 years of age or older) (n = 1,344), 39.1% had completed secondary school (n = 567), 31.3% were married (n = 454), and 66.3% were students/unemployed (n = 961). More than one-quarter (28.6%, n = 415) reported engaging in sexual activity before completing the recommended six-week post-surgical abstinence period. In this system, 11.7% of participants reported having a moderate or severe AE (n = 170), and 7.5% of participants reported receiving treatment at a health facility for a moderate or severe AE (n = 108). Nearly half of the participants returned for at least one follow-up visit (46.7%, n = 677). Among active system participants who returned for a follow-up visit, the AE rate was 10% (n = 677), and among active participants who did not return for a follow-up visit, the AE rate was 5.2% (n = 772).

4. **Evaluation of adverse event ascertainment**

The clinic system detected 119 incident AEs among 1,672 participants who returned for a follow-up visit (incident AEs allow a participant to be classified as having more than one AE—25 clients were classified as having more than one AE); infection was the most common AE (2.2%, n = 37), followed by wound disruption (1.7%, n = 28) and bleeding (1.4%, n = 23). The clinic system reported three severe AEs: one each of infection, delayed wound healing, and swelling. The clinic system recorded 11 incidents of pain (.7%); one event was classified as severe. Participants in the active system reported 437 incident AEs. The most common complaints reported in the active system were swelling (4.3%, n = 62); infection (3.3%, n = 48); bleeding (2.3%, n = 33); and other (2.3%, n = 33), which included intense itching, unabsorbed sutures, and scarring around suture line (several “other” AEs were directly observed by the research assistant who conducted the genital exam). In the

active system, 20 severe AEs were reported including: 5 swelling, 4 hematoma, 5 bleeding, 2 infection, 2 difficulty urinating, and 2 delayed wound healing. The active system recorded 143 incidents of pain (9.9%); 30 were severe.

In order to assess the agreement of the clinic system compared to the active system, we considered the 677 participants who completed both a follow-up visit in the clinic system and completed an interview for the active system. In this sub-sample, 28 AEs were detected by the clinic system (27 moderate and one severe AE) and 68 AEs were detected by the active system (57 moderate and 11 severe AEs). The ability of the clinic system to detect participants classified as having an AE by the active system resulted in an agreement proportion of .18 (12 out of 68); the active system detected 56 AEs that were not detected by the clinic system. The proportion of participants classified as having an AE by the clinic system who were also classified as having AE in the active system was .43 (12 out of 28); the clinic system detected 16 AEs that the active system did not detect (Table IV).

Table IV

AGREEMENT OF CLINIC SYSTEM AND ACTIVE SYSTEM FOR ADVERSE EVENT DETECTION

	Active System		
Clinic System	**AE Reported**	**AE Not Reported**	**Total**
AE Reported	12	16	28
AE Not Reported	56	593	649
Total	68	609	677

5. **Factors associated with the incidence of adverse events**

A total of 167 MC providers performed the circumcisions for participants in this study. After completing the VMMC training, providers performed between 1 and 302 MCs each in this study population. The mean duration of the procedure significantly decreased with experience from 24 minutes among the least experienced providers (performed 0–20 MCs) to 15.5 minutes among the most experienced providers (performed more than 200 MCs) ($p < .001$) (Table V). Additionally, the AE rate decreased significantly within each system with increased provider experience. In a univariate analysis of the clinic system, those who had provided more than 100 procedures were at lesser odds of performing an MC that resulted in an AE than those who had provided 20 MCs or less. In a univariate analysis of the active system, all providers had decreased odds of performing an MC that resulted in an AE than those who had performed 200 or less (Table V).

Table V

EFFECT OF EXPERIENCE ON TIME TAKEN FOR THE PROCEDURE AND ADVERSE EVENT RATES

Num. of MCs Performed	**Mean (SD) Duration (minutes)***	**Clinic System**			**Active System**		
		n	**AE rate**	**OR**	**n**	**AE rate**	**OR**
Level 1: ≤ 20 MCs (ref)	24 (9.6)	1,069	3.4%	--	390	11.3%	--
Level 2: 21–100 MCs	18.3 (6.4)	1,385	2.7%	.71	469	6.8%	.58*
Level 3: 101–200 MCs	17.6 (6.1)	813	1.1%	.24*	404	5.9%	.50*
Level 4: 201–302 MCs	15.5 (5.5)	438	.7%	.31*	186	4.3%	.35*

* Significant trend at $p \leq .05$

In the univariate analyses, none of the following factors were associated with increased odds of developing an AE: age of participant, being diagnosed with any comorbidity, being HIV-positive, or having sex before completing the recommended six-week abstinence period (sexual initiation data are only available for the active system) (Table VI).

Table VI

UNADJUSTED ODDS RATIOS: FACTORS ASSOCIATED WITH THE REPORT OF AN ADVERSE EVENT FOLLOWING MEDICAL MALE CIRCUMCISION

	Clinic System (N = 1,672)		**Active System (N = 1,449)**	
Factor	**n (%)**	**UOR[a] (95% CI)**	**n (%)**	**UOR[a] (95% CI)**
Age				
< 18 years	76 (4.6)	*ref*	105 (7.3)	*ref*
18–24 years	1,133 (67.8)	.9 (.3–2.5)	976 (67.4)	1.4 (.6–3.4)
25–34 years	345 (20.6)	1.0 (.3–3.2)	289 (19.9)	1.2 (.5–3.1)
≥ 35 years	118 (7)	.5 (.1–2.2)	79 (5.4)	.9 (.2–3.2)
HIV status				
HIV-positive	49 (2.9)	1.3 (.41–4.4)	42 (2.9)	.61 (.15–2.6)
HIV-negative and unknown	1,623 (97.1)	*ref*	1,407 (97.1)	*ref*
Diagnosed with a comorbidity at screening				
Yes	504 (30.1)	1.2 (.7–1.9)	398 (27.5)	1.1 (.7–1.7)
No	1,168 (69.9)	*ref*	1,051 (72.5)	*ref*
MC performed during high volume month				
Yes	962 (57.5)	1.2 (.7–1.9)	791 (54.6)	.7 (.5–1.1)*
No	710 (42.5)	*ref*	658 (45.4)	*ref*

Table VI (continued)

UNADJUSTED ODDS RATIOS: FACTORS ASSOCIATED WITH THE REPORT OF AN ADVERSE EVENT FOLLOWING MEDICAL MALE CIRCUMCISION

	Clinic System (N = 1,672)		**Active System (N = 1,449)**	
Factor	**n (%)**	**UOR[a] (95% CI)**	**n (%)**	**UOR[a] (95% CI)**
Duration of procedure				
Less than 25% IQR (< 14 min)	224 (13.4)	.3 (.1–.9)**	290 (20)	.7 (.4–1.2)
IQR (14–23 min)	976 (58.4)	*ref*	811 (56)	*ref*
More than 75% IQR (> 23 min)	472 (28.2)	1.8 (1.1–2.9)**	348 (24)	1.4 (.9–2.1)
Dose of local anesthesia				
≥ 11 cc	1,083 (64.8)	1 (.6–1.7)	721 (49.8)	2 (1.4–3.1)**
≤ 10 cc	589 (35.2)	*ref*	728 (50.2)	*ref*
Cadre of MC provider				
Clinician (CO or MO)	1,178 (70.5)	.4 (.3–.7)**	1,010 (69.7)	.7 (.5–1)*
Nurse	494 (29.5)	*ref*	439 (30.3)	*ref*
Employer of MC provider				
Government of Kenya	198 (11.8)	2 (1.1–3.5)**	138 (9.5)	2.2 (1.3–3.7)**
Nyanza Reproductive Health Society	1,474 (88.2)	*ref*	1,311 (90.5)	*ref*

Table VI (continued)

UNADJUSTED ODDS RATIOS: FACTORS ASSOCIATED WITH THE REPORT OF AN ADVERSE EVENT FOLLOWING MEDICAL MALE CIRCUMCISION

	Clinic System (N = 1,672)		**Active System (N = 1,449)**	
Factor	**n (%)**	**UOR[a] (95% CI)**	**n (%)**	**UOR[a] (95% CI)**
Engaged in early sexual activity (< 42 days)				
Yes	--	--	415 (28.6)	1 (.7–1.5)
No	--	--	1,034 (71.4)	*ref*

[a] Unadjusted odds ratio

[*] Significant at $.05 \leq p \leq .10$.

[**] Significant at $p \leq .05$.

In the clinic system, the risk factors significantly associated with the development of a moderate or severe AE resulting in treatment included having a procedure long in duration (more than 23 minutes) and having the procedure performed by a GoK, rather than an NRHS, employee. Protective factors included having a procedure short in duration (less than 14 minutes), having the procedure performed by a clinician (CO or MO) rather than a nurse, and having a provider with more experience (Table V and Table VI). In the active system, the risk factors significantly associated with the development of a moderate or severe AE resulting in treatment included receiving a relatively large dose of local anesthesia during the course of the procedure (11 ccs or more), and having the procedure performed by a GoK staff member instead of an NRHS staff member. Protective factors included having the procedure performed during a high-volume month (marginally significant), having the procedure performed by a clinician rather than a nurse, and having a provider with more experience (Table V and Table VI).

In the clinic system, after adjusting for other covariates included in the model, the following were significant protective factors against the development of a moderate or severe AE resulting in treatment: having a clinician perform the procedure (AOR = .60; 95% CI: .37–.98) and having a provider who has performed more than 100 MCs (AOR = .37; 95% CI: .17–.81). In the active system, the risk factor associated with the development of an AE, after adjusting for other covariates in the model, was receiving a high dose of anesthesia (AOR = 2.1; 95% CI: 1.4–3.4). On the other hand, having the procedure performed during a high-volume month (AOR = .62; 95% CI: .41–.93) and having an experienced provider (AOR = .61; 95% CI: .34–1.1) were protective factors (Table VII).

Table VII

ADJUSTED ODDS RATIOS: FACTORS ASSOCIATED WITH THE REPORT OF AN ADVERSE EVENT FOLLOWING MEDICAL MALE CIRCUMCISION

	Clinic System	**Active System**
Factor	**AOR (95% CI)**	**AOR (95% CI)**
Minor (< 18 years vs. ≥ 18 years)	1.1 (.36–3.2)	.88 (.36–2.1)
MC performed during high-volume month (Yes vs. No)	1.1 (.67–1.8)	.62 (.41–.93)**
Duration of procedure (Ref: procedures 14–23 minutes)		
Less than 25% IQR (< 14 min)	.50 (.17–1.4)	.96 (.53–1.7)
More than 75% IQR (> 23 min)	1.3 (.75–2.1)	.83 (.51–1.4)
Dose of local anesthesia (≥ 11 cc vs. ≤ 10 cc)	.86 (.51–1.4)	2.1 (1.4–3.4)**
Cadre of MC provider (CO/MO vs. nurse)	.60 (.37–.98)**	.75 (.48–1.2)
Employer of MC provider (GoK staff vs. NRHS staff)	1.1 (.54–2.2)	1.5 (.81–2.9)
Provider Experience (Number of MCs performed)		
Level 1: 0–20 MCs (ref)	*ref*	*ref*
Level 2: 21–100 MCs	.89 (.50–1.6)	.64 (.37–1.1)
Level 3 & 4: 101–302 MCs	.37 (.17–.81)**	.61 (.34–1.1)*

* Significant at .05 ≤ p ≤ .10.

** Significant at p ≤ .05.

D. **Discussion**

This study evaluated the incidence of moderate or severe AEs following medical MC provided in 16 health facilities in Nyanza Province, Kenya. While most surgical surveillance studies have examined the incidence of infection for in-patient surgical procedures (Manniën et al., 2006), this study is one of the first to evaluate surveillance methods for multiple AEs resulting from an out-patient surgery performed in a resource-limited setting.

RCTs demonstrated that more experienced providers perform MC services faster and with fewer AEs (Kiggundu et al., 2009; Krieger et al., 2007). In this study, providers' first 20 procedures (having previously performed at least 20 under supervision) took a mean of 24 minutes to perform, while those who had performed more than 200 MCs completed the procedure in 15.5 minutes. These results have implications for program planning and efficiency. Auvert (2008) estimated that trained MC providers could perform 10 MCs per day; however, our results suggest that an experienced provider may have time to perform up to 20 MCs per day (assuming ample client flow) without compromising the safety of the procedure. Additionally, the most experienced clinicians recorded an AE rate of .7% in the clinic system and 4.3% in the active system—rates equivalent to the low AE rates observed in the RCT sites. This study confirms recommendations from previous studies suggesting that providers should perform at least 20 circumcisions, and ideally more than 100, to reach a desired level of clinical expertise (Kiggundu et al., 2009, Krieger et al., 2007).

In Kenya, legislation was passed in June 2009 to allow nurses to provide MC services. While adjusting for provider experience reduced the protective effect of a clinician providing the procedure compared to a nurse, in the adjusted clinic system analysis, an MC provided by a clinician was still 40% less likely to result in an AE than one provided by a nurse ($p < .05$). While these findings might be cause for concern, we observed that participants may be more comfortable interacting with nurses. Participants who had their MC performed by a clinician

were 25% less likely to report for a follow-up visit than those who had their MC performed by a nurse (UOR = .75; 95% CI: .65–.86, $p < .001$); thus participants circumcised by nurses had increased opportunity to be diagnosed with an AE. Given these caveats, it would be premature to conclude that MCs performed by nurses are more likely to result in an AE than those performed by clinicians, especially given that the active system did not confirm these findings. Additionally, when we limited the analysis to participants whose surgery was performed by a provider who had performed at least 100 MCs, the association between provider cadre and the odds of developing an AE was no longer significant (UOR = .41; 95% CI: .08–2.1). Thus, with sufficient experience, nurses and clinicians provide equivalent services. These results suggest that during the early stages of implementing a large-scale MC program, surveillance is essential for ensuring that all providers (especially new providers—nurses in this case) are delivering equivalent services in the operating theater and during pre- and post-surgical counseling.

The only factor associated with the development of an AE identified by both the clinic and active systems was provider experience. After adjusting for covariates, providers who had performed at least 100 MCs were 63% and 39% less likely to perform an MC that resulted in an AE than less experienced providers in the clinic system and active system respectively. Adjusting for provider experience also impacted the observed difference in risk level by employer (GoK versus NRHS). In the univariate analysis, having an MC performed by a GoK staff member was a significant risk factor in both systems, but after adjusting for experience, this effect was no longer significant. These results accentuate the importance of ensuring that all providers have ample experience before being certified to provide MC services and that they sustain a minimum level of service provision in order to maintain their skills. This recommendation may apply especially to GoK providers. In the study area, more

than 300 GoK staff were trained to provide MC services, but only 11.5% of participants were circumcised by a GoK provider.

In addition to provider experience, this study identified several factors associated with the development of an AE following MC. In the adjusted active system model, receiving a high dose of anesthesia was a risk factor for developing an AE. We have observed that a higher dose of anesthesia may be administered by inexperienced providers because they take longer to complete the procedure. Additionally, if a challenge arises during the procedure, additional time may be required and more anesthesia may be given.

In the adjusted active model, having the procedure performed during a high-volume month was protective against developing an AE. This finding was surprising, and while the present study was not designed to assess this factor, we hypothesize that this positive finding may result from a higher-than-usual number of MC providers in the field resulting in improved access and internal quality control of services. Unlike observations from Uganda (Kigozi et al., 2008), having a comorbidity, including an STI or HIV, was not related to the development of an AE. Additionally, engaging in sexual activity before completing the recommended six-week abstinence period was not associated with the report of an AE.

The most common methods for post-discharge surveillance include direct observation of the wound by a trained professional (often passive) and participant self-report (active) (Bruce et al., 2001); this study utilized both methods. The passive and active surveillance approaches have inherent strengths and weaknesses. For example, the low rate of participants reporting for a follow-up visit (45.1%) impacted the validity of the results from the clinic system. Further, participants who did not return for a follow-up visit were statistically more likely to be young (less than 18 years of age) and less stably employed (results not shown) than participants who did return for a follow-up visit. Additionally, an assessment of the clinic system's data is further complicated by the 24-hour hotline. While forms exist to track

the content of these calls, they are not routinely completed, and therefore not well captured by the clinic system.

While many consider active surveillance to be a gold standard, it cannot be considered as such in this case. Research has reported that it is difficult to consistently compare AEs characterized by a participant, a nurse, a clinician, and a research assistant. One study of post-discharge surveillance of infections revealed that a patient's self-diagnosis versus a nurse's diagnosis were poorly correlated (r = .37), as were the nurse's diagnosis compared to a surgeon (r = .39) or an infectious disease physician (r = .38) (Whitby et al., 2002). Conversely, Mitchell et al. (1999) compared rates of patient-reported and clinician-reported infections following a surgery, and observed a fairly high agreement (kappa = .73).

In this study, we considered the 677 clients who completed both a follow-up visit (clinic system) and an interview for the active system. The clinic system detected 18% of AEs identified by the active system. Since this analysis was performed among clients who had completed both a clinic and an active visit, low rates of follow-up in the clinic system do not explain the low level of agreement. Fifty-six clients were classified as having an AE only by the active system, the majority of whom reported either having a problem with appearance (n = 19) or other AE (n = 17). Despite both of these AEs appearing on the clinic system form, problems with appearance and other AEs went nearly undetected by the passive system. This may indicate that these two conditions are not easily ascertainable just one week after the procedure, and highlight the importance of providing mechanisms for continued interaction after the recommended follow-up period (e.g., the emergency call line).

Among participants identified by the clinic system as having an AE, 43% were also identified as having an AE by the active system. Among the 57% (16 out of 28) participants classified as having an AE only by the clinic system, the majority had either infection (n = 6) or swelling (n = 5). Since swelling usually occurs in the first few days following MC, it is

possible that this AE was most susceptible to recall bias in the active system since the interview often occurred about one month later. Among the six participants classified as having an infection, four only had their incision washed with iodine. This may indicate that if a provider suspected that infection could develop, but was not yet fully present, they cleaned the wound and recorded this case as a moderate AE, when in fact, healing may have been normal. These results that compare the AEs identified by each system indicate that a participant's perception of what constitutes an AE is quite different from his provider's assessment. While we cannot know the true rate of AEs, programmatically it remains important to continue to monitor provider-identified AEs to ensure that VMMC services are being provided safely. Additionally, it remains important to be attentive to AEs perceived by VMMC clients since clients are usually the most effective mobilizers for the program.

These findings confirm the known limitations of passive systems, but also highlight limitations of active surveillance approaches, primarily the difficulty of comparing passive and active results when AEs are ascertained at different time points and by different cadres of staff. The key to improving passive AE ascertainment lies in improving participant attendance at follow-up visits, especially if a large-scale MC program relies solely on passive surveillance data for program evaluation. (At the same time, these results indicate that clients who had a complication were more likely to attend a follow-up visit than those who reported no complications.) Further, if additional means of participant interaction are implemented (e.g., the 24-hour hotline), a functional system should be implemented to monitor the care provided through these mechanisms. The most common AEs identified by both systems were bleeding (mean follow-up 6.7 days post-MC) and infection (mean follow-up 9 days post-MC). While visiting participants at their home 30–40 days post-MC allowed us to assess non-AE indicators of interest (e.g., the resumption of sexual activity following MC), it was not the most ideal time for assessing AE history, since most participants had healed and most AEs

could not be visually observed. To improve upon the findings of this study, future operations research should actively assess AEs by visually observing participants frequently and at similar time points for the first two weeks in order to observe visually for the incidence of AEs.

The results from this study should be considered along with the following limitations. Less than half of the participants returned for a follow-up visit, and since AEs are relatively rare, some cell sizes were small (less than 20 participants). Since the clinic system was passive, and the active system only monitored circumcised men, we know little about the outcomes of participants who were deferred for circumcision (e.g., did they complete treatment and were they ever circumcised). Since research staff were stationed at all facilities, the clinic system data may be of higher quality than they would be without this level of intense supervision (i.e., for a national surveillance system). The vast majority of MCs were provided by NRHS, MC-dedicated staff, who specialize in MC and provide MC services on a full-time basis; therefore, the AE rates presented here may be artificially low and not generalizable to programs using mostly government, non-MC-dedicated staff. While we attempted to enroll minors, the parental permission and assent process was logistically challenging; as a result, the sample size of minors was not adequately powered for robust analysis. Finally, we have analyzed the safety of the procedure only from the perspective of AEs; however, other data, such as sterilization supervisory checklists, could also be used to assess procedure contributions to safety.

Our findings indicate that the most important factor in reducing the AE rate during the scale-up and widespread provision of medical MC services is to ensure that providers achieve a desired level of experience before they perform unsupervised procedures. In adjusted models, providers who had performed at least 100 MCs were 63% and 39% less likely to perform an MC that resulted in an AE than less experienced providers in the clinic system

and active system respectively. This finding is especially important to programs that may use staff from multiple cadres to provide MC services. Among experienced providers who had performed more than 100 MCs, nurses and clinicians provided equivalent quality services. As medical MC programs continue to be implemented in high-HIV prevalence areas, robust AE surveillance is crucial, especially during the first year of implementation, to identify factors that may need to be addressed in order to improve the safety and efficacy of the program.

IV. FACTORS ASSOCIATED WITH THE EARLY RESUMPTION OF SEXUAL ACTIVITY FOLLOWING MEDICAL MALE CIRCUMCISION

A. Background

Approximately one-third of adult men in the world are circumcised for medical, religious, or cultural reasons (UNAIDS, 2007). More than 40 observational studies and three RCTs have established that MC reduces the risk of HIV-1 acquisition in heterosexual men by approximately 60% (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007; Weiss et al., 2008). As a result, WHO and UNAIDS have recommended MC as one component of a comprehensive HIV-prevention strategy in regions with low MC prevalence, high HIV-1 prevalence, and where heterosexual sex is the mode of transmission (WHO, 2007). The implementation of large-scale MC services has the potential to impact significantly the HIV epidemic; modeling, based on MC conferring a 60% protective effect, estimated that over a 10-year period, one HIV infection may be averted for every five to 15 MCs performed, and HIV incidence could be reduced by as much as 30%–50% over the same period (UNAIDS, 2009).

Despite these encouraging findings, there are several factors that could attenuate the protective effect of MC once large-scale programs are implemented outside of a clinical trial setting. Among them is that MC may actually increase HIV transmission and acquisition if recently circumcised men engage in sexual activity before the surgical site is healed (de Bruyn et al., 2010; Weiss et al., 2009). Current guidelines recommend that recently circumcised men abstain from sexual activity for at least 42 days, or six weeks, to promote and ensure complete healing (WHO, 2007). The RCTs each promoted an abstinence period among participants, but of slightly different durations. The Orange Farm RCT advised participants to abstain from sexual activity for six weeks; the Rakai RCT advised participants

to abstain until the wound was confirmed as healed based on visual examination by a clinician; and the Kisumu RCT advised participants to abstain for at least 30 days following MC (Mehta et al., 2009). All the RCTs reported that some participants engaged in early sexual activity. In a review of the MC RCTs, in which early sexual activity was defined as a participant engaging in sexual activity less than 42 days post-circumcision, 22.5% of Orange Farm, 5.4% of Rakai, and 3.9% of Kisumu participants reported engaging in early sex (Mehta et al., 2009).

While the RCT findings from Rakai and Kisumu were encouraging, it remained unclear whether these results would be maintained in the context of a large-scale MC program implemented outside of a clinical trial setting. In order to understand the behaviors and outcomes of participants who were circumcised in a non-RCT, resource-limited setting, we prospectively assessed the post-MC time to sexual activity and wound healing among males who voluntarily sought MC services in three districts in Nyanza Province, Kenya.

B. Methods

1. Study context

Nyanza Province is the geographic home to the Luo ethnic group. Luo men do not traditionally practice MC, and they have a high prevalence of HIV compared to the rest of the country: 21.5% of Luo men are circumcised and 17.1% are HIV-positive; by comparison, among all Kenyan males 15–49 years of age, 85.9% are circumcised and 4.6% are HIV-positive. Additionally, 2.8% of circumcised men in Kenya tested HIV-positive, while 12.9% of uncircumcised men tested HIV-positive in the same survey (Kenya National Bureau of Statistics and ICF Macro, 2010).

In response to the HIV epidemic in Kenya, the GoK launched the VMMC program in Nyanza Province in November 2008 and plans to circumcise 860,000 males by 2013

(National AIDS and STI Control Programme, 2008). At the time of this study, the national VMMC program was providing high-quality medical MC services throughout Luo districts in Nyanza Province at no cost to clients, and all procedures were performed by trained doctors and nurses.

2. Voluntary Medical Male Circumcision service provision

VMMC clients are circumcised according to the national clinical guidelines using the forceps-guided method (National AIDS and STI Control Programme, 2008). The provision of VMMC services in Kenya includes voluntary HIV testing and counseling, risk-reduction counseling, condom education and distribution, information about the risks and benefits of MC, directions about wound care, and facts demonstrating the importance of sexual abstinence for at least 42 days post-MC. In addition to verbal counseling, clients receive written instructions on how to remove the bandage, how to care for the wound, and why they should abstain from intercourse for six weeks. Clients are scheduled to return to the facility for one follow-up visit seven days post-MC procedure and they are encouraged to return any time they have a question/concern. During every interaction with a VMMC client, providers highlight the importance of the post-surgical abstinence period.

3. Participants and data collection

This prospective study monitored VMMC clients from pre-surgery through all follow-up care. Study participants included males who voluntarily sought VMMC services at a study facility between November 2008 and March 2010. All study participants were 12 years of age or older and provided signed assent/consent forms prior to participation in the study in the language of their choice (English, Dholuo, or Kiswahili). Participants were enrolled in three districts of Nyanza Province: Kisumu East, Kisumu West, and Nyando;

these districts were chosen because they had an active VMMC program, were contiguous, and represented typical urban and rural populations in Nyanza Province. Participants were informed of their right to refuse to answer any question or to terminate their enrollment at any time; however, no participant terminated his participation prematurely.

The study had two surveillance components including, first, a passive, clinic system collected and managed routine clinical data on 4,010 participants who voluntarily sought and received VMMC services at one of 16 health facilities. No compensation was offered to participants in the clinic system since research staff were managing routine, clinical-care data. Second, an active system was implemented to monitor a random sub-sample of all circumcised participants in the clinic system via a home-based, in-depth interview that was scheduled 30–40 days post-MC. Research staff attempted to establish contact with each selected participant before the 30–40-day window, but it occasionally took some time to establish contact. For this reason, some participants were interviewed outside of the recommended window, resulting in interviews being completed 28–45 days post-MC. For the active system, a target sample size of 1,449 was set to detect a 2% difference in the AE rates recorded between the two systems with an overall type-I error rate of $\alpha = .05$ and 80% power; this sample size was achieved. Each week, VMMC participants who had been circumcised were randomly selected based on a unique, participant identification number. In addition, the selected sample was proportional in size to the number of MCs provided in a given week; as a result, more participants were selected during a busy week than a less busy week. If research staff were unable to locate and/or interview a participant after three attempts, he was replaced with the next participant of similar age listed on the same health facility's weekly circumcision register (divided into the following categories based on age: 18–24, 25–30, 31–35, 36–40, and over 40 years of age). Data collected by the active system focused on the participant's circumcision experience, AE history, and sexual behavior following MC. The

data collected were a mixture of self-report (e.g., demographic information, care-seeking behavior, satisfaction, AE history, and sexual activity) and genital examination to assess healing status as well as specific AEs (e.g., problems with appearance). Participants were compensated 200 Kenya Shillings ($2.50 USD), less than the average daily wage in Kenya, for participating in the interview for the active system.

4. **Data collection and statistical analysis**

The results presented in this analysis include only participants who were part of the active system (n = 1,449) since we only collected sexual activity information from those participants. We further limited the analysis to those over 18 years of age (n = 1,346) since those participants were more likely to be sexually active; the median age at first sex among Kenyan males 20–54 years of age is 17.6 years (Kenya National Bureau of Statistics and ICF Macro, 2010). Additionally, two participants refused to report whether they had engaged in sexual activity; as a result, they were excluded from the analysis. Therefore, the number of participants included in this analysis was 1,344.

Data for the active system were collected using Dell Axim PDAs, programmed using Visual CE (Appendix C). Participants were asked questions about the following: demographic information; satisfaction with circumcision; how protected participants felt against HIV and STIs after MC; sex partner's opinions about MC; erections following MC; sexual activity and behaviors following MC; and sexual satisfaction for participant and partner (see Table VIII for questions).

Reported sexual activity was measured at 28 to 45 days post-MC; participants who reported engaging in sexual activity before 42 days were considered to have engaged in early sexual activity post-MC. Wound healing was assessed by direct observation of the wound. A wound was considered healed when it met all seven of the following criteria: wound

completely closed with the suture line intact; no sutures visible; no bleeding or signs of bleeding; no tenderness on gentle palpation; no obvious features of inflammation; no form of discharge from the incision line; and no pain reported on erection.

Data were analyzed using SAS version 9.1 (SAS Institute Inc., Cary, North Carolina). Differences between participants who engaged in early sexual activity and those who did not were assessed using Pearson's chi-square for independence. The time to onset of sexual activity following MC was assessed using the LIFETEST procedure, which accounted for censoring. The magnitude of the association between independent variables that had a significant chi-square and the outcome were assessed using bivariate logistic regression analysis and characterized with ORs, 95% CIs, and p-values. A multivariable logistic regression model, considering demographic variables and all significant variables in the univariate analysis, was developed to estimate AORs, CIs, and p-values using automated forward, backward, and score techniques. The following factors were included in the adjusted model where they were assessed for confounding, effect modification, and colinearity: age, marital status, employment status, HIV status, penile sensitivity, and attractiveness to women. Age was identified as modifying the relationship between several covariates and the outcome; therefore, adjusted model results are presented separately for younger participants (18–24 years of age) and older participants (25 years of age and older).

5. **Ethical considerations**

All research staff completed the online Collaborative Institutional Training Initiative training course on human subject protection. The study was approved by the IRB at UIC (protocol: 2007-0913), and the Kenyatta National Hospital Ethics and Research Committee in Nairobi, Kenya (protocol: P338/11/2007).

C. **Results**

Among the 1,344 participants included in the analysis, the mean age was 23.2 years (SD = 6.7 years), and the median age was 21 years (IQR: 19–25 years). Most participants were from the Luo ethnic group (97.2%); 41.7% had completed secondary school; 24.5% were married; and 76.1% were unemployed.

Table VIII

STUDY SAMPLE CHARACTERISTICS BY EARLY SEXUAL ACTIVITY[a]

	Early[b] sexual activity (N = 413) n (%)	**No early sexual activity (N = 931) n (%)**	**p-value**
Age (years)			p < .0001
18–24 years	216 (52.3%)	760 (81.6%)	
25–29 years	90 (21.8%)	92 (9.9%)	
30–34 years	62 (15%)	45 (4.8%)	
≥ 35 years	45 (10.9%)	34 (3.7%)	
Secondary School Completed			p = .44
No	247 (59.8%)	536 (57.6%)	
Yes	166 (40.2%)	395 (42.4%)	
Marital Status			p < .0001
Married / Live-in partner	216 (52.3%)	113 (12%)	
Not married / No live-in partner	197 (47.7%)	818 (88%)	
Employment Status			p < .0001
Unemployed	256 (62%)	767 (82.4%)	
Employed	157 (38%)	164 (17.6%)	
HIV Status			p = .05
HIV-positive (onsite test/self-report)	20 (4.8%)	22 (2.4%)	
HIV-negative (onsite test)	146 (35.4%)	331 (35.5%)	
Unknown (no onsite test)	247 (59.8%)	578 (62.1%)	
Attended ≥ 1 Follow-up Appointments			p = .92
No	219 (53%)	491 (52.7%)	
Yes	194 (47%)	440 (47.3%)	
Wound Healed at Interview			p = .53
No	33 (8%)	84 (9%)	
Yes	380 (92%)	847 (91%)	
Compared to before you were circumcised, how protected do you feel now against HIV?			p = .48
More	385 (93.3%)	863 (92.7%)	
About the same	20 (4.8%)	43 (4.6%)	
Less	1 (.2%)	10 (1.1%)	
Don't Know	7 (1.7%)	15 (1.6%)	
Compared to before you were circumcised, how protected do you feel now against sexually transmitted diseases, other than HIV?			p = .16
More	393 (95.2%)	872 (93.7%)	
About the same	16 (3.9%)	35 (3.7%)	
Less	0 (0%)	10 (1.1%)	
Don't Know	4 (.9%)	14 (1.5%)	

Table VIII (continued)

STUDY SAMPLE CHARACTERISTICS BY EARLY SEXUAL ACTIVITY[a]

	Early[b] sexual activity (N = 413) n (%)	**No early sexual activity (N = 931) n (%)**	**p-value**
Compared to the time before you were circumcised, how sensitive would you say your penis is now?			p < .0001
More	315 (76.3%)	612 (65.7%)	
About the same	52 (12.6%)	154 (16.5%)	
Less	41 (9.9%)	101 (10.9%)	
Don't Know	5 (1.2%)	64 (6.9%)	
Compared to before you were circumcised, how attracted are women to you?			p < .0001
More	215 (52.1%)	280 (30.1%)	
About the same	100 (24.2%)	310 (33.3%)	
Less	3 (.7%)	21 (2.2%)	
Don't Know	95 (23%)	320 (34.4%)	
How did your sex partners react to your circumcision?			p < .0001
Pleased	372 (90.1%)	482 (51.8%)	
Neutral or expressed no opinion	15 (3.6%)	43 (4.6%)	
Displeased	7 (1.7%)	12 (1.3%)	
No sex partners / Don't Know	19 (4.6%)	394 (42.3%)	

[a] (N = 1,344)

[b] Early sexual activity is defined as engaging in sexual activity < 42 days post-MC.

In this study, 30.7% of participants engaged in early sexual activity. Participants who engaged in early sexual activity were more likely to be older, employed, and married; 65.7% of married participants and 19.4% of unmarried participants reported having sexual intercourse during the recommended abstinence period ($p < .0001$). Being HIV-positive was associated with early sexual activity ($p = .05$). Less than half of the participants attended a follow-up visit at the clinic (47.5%). At the time of the interview and genital exam, 1,227 (91.3%) participants were classified as completely healed. There was no association between wound-healing status and early sexual activity ($p = .53$). Perceptions of protection against HIV and other STIs were not significantly associated with early sexual activity ($p = .48$ and $p = .16$ respectively) (Table IX).

Participants who engaged in early sexual activity were more likely to report that women were more attracted to them after MC compared to before the procedure ($p < .0001$), and that their sex partners were pleased with the circumcision ($p < .0001$) (Table IX). Participants reported several reasons to explain why their female partners were pleased with their circumcision; the most common reasons included improved penile hygiene (26.9%), protection against HIV (24.3%), protection against STIs (22.4%), improved sexual satisfaction for male partners (9.3%), and improved sexual satisfaction for themselves (7.4%) (results not shown).

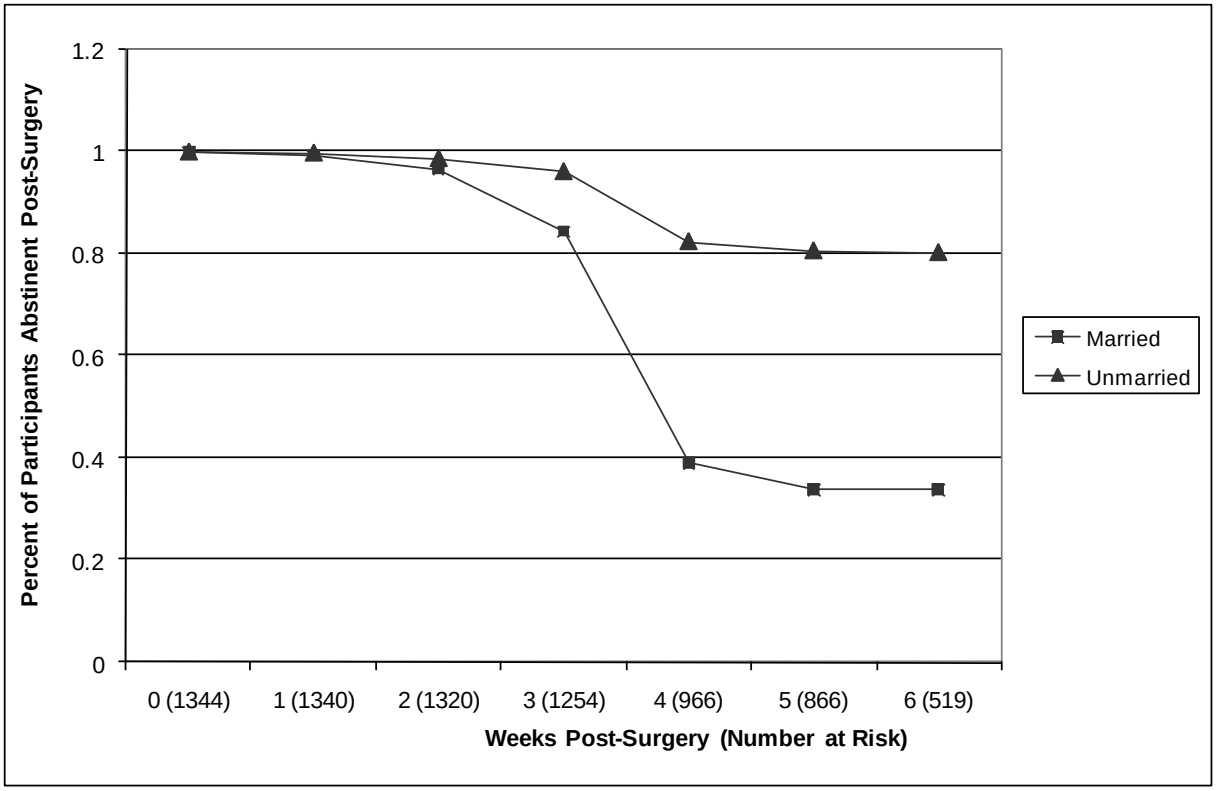

Figure 1. Percent of participants remaining abstinent post-surgery stratified by marital status*

***(n = 1,344)**

The majority of participants who engaged in early sexual activity did so between weeks three and four following the surgery (Figure 1). This analysis accounts for participants who are censored given the differences in the timing of the data collection (28–45 days post-MC) and the definition of engaging in early sexual activity (sex less than 42 days post-MC). When limiting the analysis only to participants who engaged in early sexual activity (n = 413), 90 out of 413 (21.8%) reported doing so by week three and 378 out of 413 (91.5%) by week four. Married participants were more likely to engage in early sex than unmarried participants (Wilcoxon $X^2 = 266.86$, $p < .0001$) (Figure 1). Among participants who had sexual intercourse during the recommended abstinence period, 4.4% of unmarried participants and 32.2% of married participants reported having sexual intercourse three or more times in the period between the surgery and the follow-up interview. When participants

who had engaged in sexual activity were asked, “Since the circumcision, how often have you used a condom during sexual intercourse?” 45.3% reported that they always used a condom, 10.7% reported sometimes using a condom, and 44.1 % reported never using a condom. Among the participants who reported never using a condom, 79.7% were married; and among participants who reported always using a condom, 75.9% of participants were unmarried (results not shown).

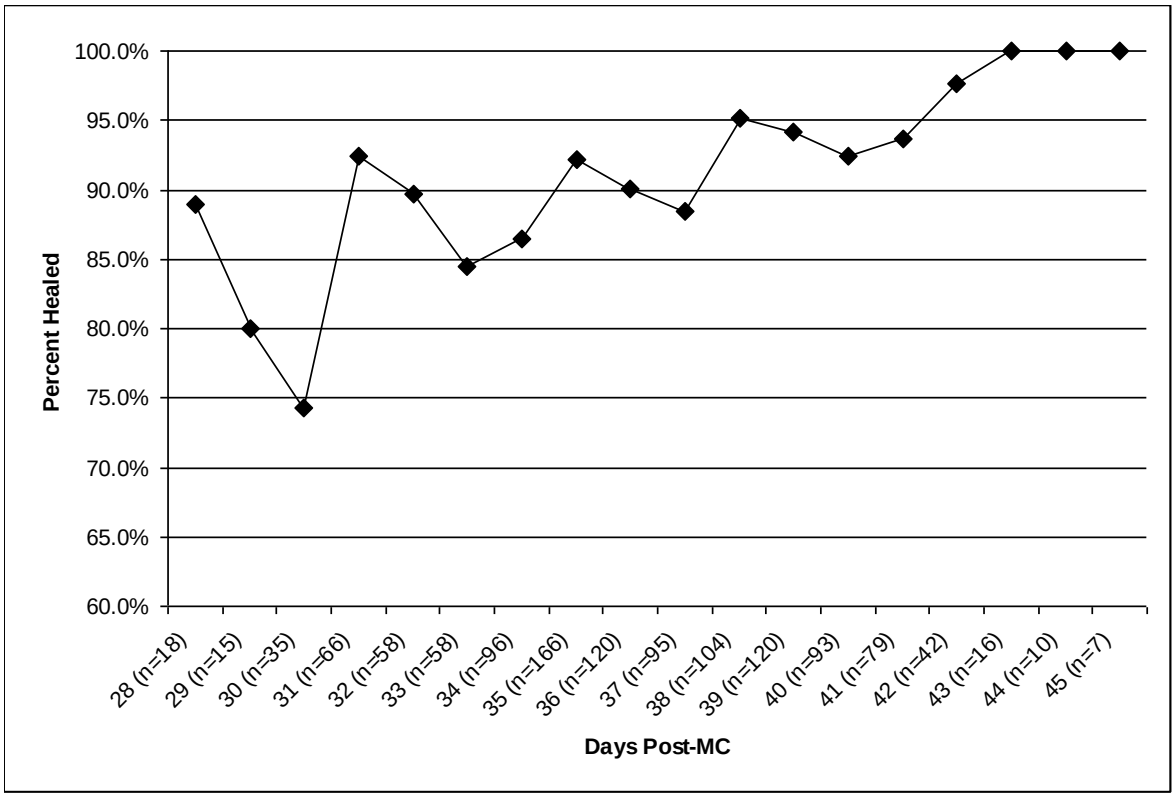

Figure 2. Percent of wounds healed 28–42 days after male circumcision[*]
[*](n=1,198[a])

[a] Some participants had an incorrect interview date recorded automatically by the PDA (n = 146); as a result, we were unable to calculate the relationship between lapsed time post-MC and wound healing for them.

The percent of participants who were classified as healed increased significantly with time post-MC (Figure 2); 84.9% of participants interviewed at 28–29 days; 88.5% at 30–35 days; 92.1% at 36–40 days; and 96.1% at 41–45 days were healed (test for trend p = .001).

TABLE IX

FACTORS ASSOCIATED WITH THE RESUMPTION OF EARLY SEXUAL ACTIVITY*

	Age 18–24 years (N = 976)		**Age ≥ 25 years (N = 368)**	
Factor	**UOR (95% CI)**	**AOR (95% CI)**	**UOR (95% CI)**	**AOR (95% CI)**
Marital Status				
Married / live-in partner	8.1 (4.7–13.9)**	7.5 (4.2–13.2)**	6.7 (3.9–11.3)**	6.4 (3.7–11.1)**
Not married / no live-in partner	*ref*	*ref*	*ref*	*ref*
Employment Status				
Employed	2.3 (1.6–3.3)**	1.9 (1.2–2.8)**	1.7 (1.1–2.6)**	1.3 (.8–2)
Unemployed	*ref*	*ref*	*ref*	*ref*
HIV-status				
HIV-positive	2.7 (.6–12)	2.3 (.4–11.8)	.8 (.4–1.6)	.8 (.4–1.7)
HIV-negative or unknown	*ref*	*ref*	*ref*	*ref*
Penile Sensitivity				
Penis “more sensitive” after MC	1.8 (1.3–2.6)**	1.7 (1.1–2.5)**	1.7 (1.1–2.7)**	1.8 (1.1–2.9)**
Same, less, or “Don’t know”	*ref*	*ref*	*ref*	*ref*
Female Attraction to Participant				
“More attractive” to women after MC	2.8 (2.1–3.9)**	2.8 (2–3.9)**	1.9 (1.2–2.8)**	1.6 (1–2.5)
Same, less, or “Don’t know”	*ref*	*ref*	*ref*	*ref*

*(N = 1,344)

**Significant at $p < .05$

Among younger men (18–24 years of age), after adjusting for other variables included in the model, being married or having a live-in partner was most associated with engaging in early sexual activity (AOR = 7.5, $p < .05$). Being employed (AOR = 1.9, $p < .05$), reporting increased penile sensitivity (AOR = 1.7, $p < .05$), and reporting being "more attractive" to females (AOR = 2.8, $p < .05$) were also significant risk factors for engaging in early sexual activity; HIV-status was not associated with the outcome.

Among older men (25 years of age or older), after adjusting for other variables included in the model, being married or having a live-in partner was most associated with engaging in early sexual activity (AOR = 6.4, $p < .05$). Reporting increased penile sensitivity post-MC was also a significant risk factor for engaging in early sexual activity (AOR = 1.8, $p < .05$). Employment status, HIV-status, and reporting being "more attractive" to women were not associated with engaging in early sexual activity.

D. **Discussion**

This study explored the time to sexual activity and wound healing following MC among participants who were circumcised in a non-RCT, resource-limited setting. Participants were interviewed and underwent a genital exam 28–45 days after their circumcision procedure. At the time of interview and genital exam, 91.3% of participants were completely healed. Additionally, 30.7% of participants reported engaging in early sexual activity following MC. Several factors were associated with engaging in early sexual activity following MC, including older age, being married or having a live-in partner, being employed, perception of increased penile sensitivity post-MC, and perceptions about how women respond to recently circumcised men.

While the RCTs provided ongoing interaction with participants, during which medical providers highlighted risk-reduction strategies and the post-MC abstinence period, this level of regular contact could not be duplicated in settings where MC is implemented on a large-scale. Although VMMC providers stressed the post-MC abstinence period via verbal counseling and written instructions, the majority of participants in this study (52.5%) interacted with providers only one time (the day of the surgery), and only 47.5% of participants attended a follow-up visit as recommended by the VMMC program. In the Kisumu RCT, early sex was reported by 3.9% of participants (Mehta et al., 2009); although the RCT was conducted in the same geographic region as our study, we recorded nearly 10 times more participants who reported engaging in early sexual activity (30.7%). In the Kisumu RCT, early sexual activity was defined as sex occurring during the first 30 days post-MC, while in this study it was defined as sex occurring before 42 days post-MC. While the variance in definition may account for some of the observed difference, most of the participants who reported resuming sex early did so three to four weeks post-MC (or 21–28 days), a period that is within the window of measurement for the RCT. A major difference between this study and the RCT is that 24.5% of participants in this study were married or had a live-in partner (n = 329) compared to only 6% in the Kisumu RCT (Bailey et al., 2007). Recently, a large-scale MC program was implemented in the former Orange Farm RCT site, and 12.5% of participants reported engaging in early sexual activity (less than 42 days) following MC; 6.5% of participants were married or co-habitating (Lissouba et al., 2010). This is nearly half the percent of participants who reported engaging in early sexual activity during the Orange Farm RCT in which 1.8% of participants were married (Auvert et al., 2005).

The results from multivariable modeling also illuminated the driving impact of being married or having a live-in partner as a risk factor for engaging in early sexual activity. Similar

to findings reported from all the RCTs, being married (or having a live-in partner) was strongly associated with engaging in early sexual activity (Mehta et al., 2009). In this study, after adjusting for covariates, older married men were 6.4 (95% CI: 3.7–11.1) times at increased odds to engage in early sexual activity than unmarried men in the same age group; this strong association between marital status and the early resumption of sex was also observed among younger men (AOR = 7.5; 95% CI: 4.2–13.2). These findings highlight the need for innovative strategies to encourage men who seek VMMC services, and who are already involved in a sexual partnership, to abstain from sexual activity during the post-MC healing time. For example, it may be useful to connect with participants when sexual activity post-MC peaks (three to four weeks). Initiatives, such as sending text messages that encourage men to abstain during this critical time, are currently being implemented and evaluated in the study area. Additionally, it is essential to reinforce the importance of female partner involvement in the MC counseling process. Because many couples do not get counseled together during the MC process, mass communication should include messages about the importance of the abstinence period since female partners may be at increased risk of acquiring HIV or STIs when the healing process is incomplete. This is especially important since 3.1% of all participants and 8.5% of married participants in this study reported being tested or were tested to be HIV-positive (results not shown). Additionally, strategies to encourage married men and their partners to abstain post-MC, such as counseling them to sleep in different beds during the abstinence period, may also be useful.

In the Kisumu RCT, 1.3% of men were not completely healed at the day-30 visit, and wound healing was defined as “no scab, open wound, swelling or redness.” In the Rakai RCT, 13.9% were not healed by day 30, and wound healing was defined as “healthy scar formation; no

scab or open wound" (Mehta et al., 2009). Based on a genital exam, 8.7% of participants in this study did not meet all seven wound healing criteria at the time of the interview. Although differences in procedure-type and wound-healing definitions complicate direct comparisons between this study and each RCT, it appears that participants circumcised in this study, as part of a large-scale MC program implementation, take approximately the same amount of time to heal as Rakai RCT participants, but perhaps longer than Kisumu RCT participants. Studies to better understand the wound-healing process are underway; however, since RCT participants were circumcised in a highly controlled trial setting, and participants in this study were circumcised in GoK facilities that are often less well equipped (Herman-Roloff et al., 2011), these results support the recommendation for a 42-day abstinence period following MC.

Among participants who engaged in early sexual activity, 45.3% reported always using a condom, 10.7% reported sometimes using a condom, and 44.1 % reported never using a condom. Condom use was related to marital status: 79.7% of participants who reported never using a condom were married, whereas 75.9% of participants who reported always using a condom were unmarried (results not shown). These results are consistent with the most recent national survey; among unmarried men, 15–24 years of age, 72.3% used a condom at last sex, and among high-risk married men (who reported two or more partners in the past 12 months), 13.9% reported using a condom at last sex (Kenya National Bureau of Statistics and ICF Macro, 2010). In the Kisumu RCT, control participants were significantly more likely to use condoms consistently than circumcised participants; however, among circumcised participants, there was a significant increase in consistent condom use from baseline (22%) through follow-up (36%) (Bailey et al., 2007). In the Rakai RCT, approximately 19% of participants used condoms consistently by the end of the study (Gray et al., 2007). Since participants in this study report using condoms

consistently more frequently than participants in the RCT, there may be a secular trend in the population toward increased condom use.

These findings should be considered along with the following limitations. Participants were recruited among all males who voluntarily sought VMMC services at a study facility; these males, who were early-adopters of VMMC services, may be different from the males in the general population in ways that are not quantifiable. Questions pertaining to sexual behavior are based on self-report; for this reason, it is possible that behaviors may be misreported. We have no information on baseline sexual behaviors. Perceptions about the reactions of female sex partners to a participant's circumcision were secondary and not collected from women. At the time that this study was conceived, there was no clear guidance regarding a 42-day abstinence period; therefore, this study evaluated participants 28–45 days post-MC, and the results presented here likely underestimate the true percent of participants engaging in early sexual activity in that the majority of participants were interviewed less than 42 days post-MC and may have engaged in early sexual activity after the interview but before completing the recommended abstinence period. Finally, while we assessed wound healing from a clinical perspective, client's perception of their wound healing was not recorded—this is an opportunity for future research. While less than 6% of participants in the Kisumu and Rakai RCTs reported engaging in early sexual activity after MC, it was unclear before this study whether these results could be replicated in a non-trial setting. The findings from this study indicate that more men engaged in early sexual activity after being circumcised as part of a large-scale program than during any of the RCTs. This result is likely due in large part to the low proportion of married RCT participants. In addition, the higher frequency of counseling provided during the RCTs may have also contributed to this result. Nevertheless, our findings indicate that it remains important for

large-scale programs to find ways to reduce the number of men engaging in early sexual activity following MC. Several strategies to reduce this behavior have been proposed in this paper, including re-energizing the effort to provide couple's counseling, implementing mass communication campaigns that target both men and women, and text-messaging programs. Future efforts should implement and evaluate strategies such as these.

V. CONCLUSION

To date, little research has been published about the uptake and outcomes of male MCs provided via a large-scale, multi-site program in a resource-limited setting. By providing clinical training and conducting operations research, UIC and NRHS, as part of the MCC, are supporting the GoK to scale-up MC services in Nyanza Province.

Specifically, UIC implemented a number of operations research studies to assess several aspects of the implementation process of MC services in Nyanza Province, and this study was one research activity. In general, this research was designed to evaluate three components of the implementation: (1) the safety of MC procedures provided by the national program; (2) the time to the onset of sexual activity; and (3) the uptake and acceptability of MC services.

First, using both passive and active surveillance systems, this study evaluated the incidence of moderate or severe AEs following medical MC provided in 16 health facilities in Nyanza Province, Kenya. Further, factors associated with the development of AEs were assessed. While most post-surgical surveillance studies have examined the incidence of infection for in-patient surgical procedures (Manniën et al., 2006), this study is one of the first to evaluate surveillance methods for multiple AEs resulting from an out-patient surgery performed in a resource-limited setting.

Second, this research assessed the time from MC to the onset of sexual activity. The results from the three RCTs indicated that some recently circumcised men would engage in sexual activity during the recommended post-surgical abstinence period. In the Orange Farm RCT, 22.5% of clients engaged in early sex, as did 5.4% in Rakai and 3.9% in Kisumu (Mehta et al., 2009). While the RCTs provided ongoing interaction with participants, during which medical

providers highlighted risk-reduction strategies and the post-MC abstinence period, this level of regular contact could not be duplicated in settings where MC was implemented on a large-scale. To this end, some were concerned that MC may actually increase HIV transmission and acquisition if recently circumcised men engaged in sexual activity before the surgical site is healed (de Bruyn et al., 2010; Weiss et al., 2009).

Finally, while more than 13 published studies indicated that MC was likely to be an acceptable HIV-prevention strategy (Westercamp and Bailey, 2007), few studies have explored revealed, non-hypothetical acceptability among uncircumcised men. Now that MC services are widely available at no cost, it is important to learn from males seeking circumcision services and uncircumcised men about the factors that influence MC uptake.

A. **Key Findings**

1. **Adverse events**

Provider experience was correlated with both safety and efficiency. Providers' first 20 procedures (having previously performed at least 20 under supervision) were completed in a mean time of 24 minutes, while those who had performed more than 200 MCs completed the procedure in a mean time of 15.5 minutes. Additionally, the most experienced clinicians recorded an AE rate of .7% in the clinic system and 4.3% in the active system—rates equivalent to the low AE rates observed in the RCT sites.

While adjusting for provider experience reduced the protective effect of a clinician providing the procedure compared to a nurse, in the adjusted clinic system analysis, an MC provided by a clinician was still at decreased odds to result in an AE than one provided by a nurse (OR = .60, $p < .05$). However, the active system did not corroborate these findings, and

when the analysis was limited to the most experienced providers, provider cadre was not significantly associated with the development of an AE.

In the adjusted active-system model, receiving a high dose of anesthesia was a risk factor for developing an AE. Anecdotally, we observed that a higher dose of anesthesia was sometimes administered by inexperienced providers, apparently because they were taking longer to complete the procedure. Additionally, if a challenge arose during the procedure (that is, a problem that was not severe enough to be documented), additional time may have been required and more anesthesia may have been given as a result.

In this study, we considered the 677 clients who completed both a follow-up visit (clinic system) and an interview for the active system. The clinic system detected 18% of AEs identified by the active system. Fifty-six clients were classified as having an AE only by the active system, the majority of whom reported either having a problem with appearance (n = 19) or other AE (n = 17). Although both of these AEs appeared on the clinic system form, problems with appearance and other AEs went nearly undetected by the clinic system, perhaps because they may not arise until several weeks after the procedure.

2. **Time to onset of sexual activity following male circumcision**

To date, our study has recorded the highest percentage of MC participants who reported engaging in sexual activity during the post-MC abstinence period (30.7%). Although VMMC providers stressed the post-MC abstinence period via verbal counseling and written instructions, the majority of participants (52.5%) only interacted with providers one time, the day of the surgery.

Similar to findings reported from all of the RCTs, being married or having a live-in partner (Mehta et al., 2009), was strongly associated with engaging in early sexual activity. After adjusting for covariates, we found that older, cohabitating men were at 6.4 times increased odds (95% CI: 3.7–11.1) to engage in early sexual activity than unmarried men in the same age group; this strong association was also observed among younger men (AOR = 7.5; 95% CI: 4.2–13.2).

Based on a genital exam, 8.7% of participants in this study did not meet all seven wound-healing criteria at the time of the interview. It appears that participants circumcised in this study, as part of a large-scale MC program implementation, took approximately the same amount of time to heal as Rakai RCT participants, but longer than Kisumu RCT participants. Among participants who engaged in early sexual activity, 45.3% reported always using a condom, 10.7% reported sometimes using a condom, and 44.1% reported never using a condom. Condom use was related to marital status—79.7% of participants who reported never using a condom were married, whereas 75.9% of participants who reported always using a condom were unmarried. These results are consistent with the most recent national survey (Kenya National Bureau of Statistics and ICF Macro, 2010).

3. **Factors that influence the uptake of male circumcision**

Most participants in FGDs identified MC as an HIV-prevention strategy without prompting. However, when asked generally about HIV-prevention methods, participants were most familiar with the ABC approach and frequently did not situate MC within their existing HIV-prevention framework—this phenomenon was especially true among young men. While older men were more aware of MC for HIV prevention, they were less likely to believe that MC was necessary, especially if a man practiced other HIV-prevention methods.

Participants reported a wide range in estimates of the protective effect afforded by MC against HIV acquisition (range: 30%–100%). Most participants did not know the exact magnitude of the protective effect, but they knew that MC was not fully protective and that other HIV-prevention methods would continue to be necessary.

These data indicate that time away from work was the most important barrier to MC acceptability, especially for men working in the informal sector (e.g., bicycle transporters) and older men. Participants expressed uncertainty about the duration of time away from work and the time required for complete healing.

Participants were aware that there is a recommended period of abstinence following MC; however, there was confusion about how long a man should abstain from sexual activity after having MC surgery. In this sample, participants believed that adolescent boys and teenagers (11–18 years of age) were best suited to go for MC. There was consensus among participants that MC services should be offered in medical settings, not in traditional settings, because they believed medical settings were safer and AEs could be handled there by medical professionals.

Participants also believed that medical MCs would clarify the purpose of the MC program—that is, a medical setting would demonstrate that the national VMMC program is not trying to change or to dilute any ethnic group's culture; instead, it is promoting the procedure for medical and health purposes.

B. **Program Implications**

1. **Safety of male circumcision service provision**

Our findings indicate that the most important factor for improving the safety of large-scale medical MC services is to ensure that providers achieve a prescribed level of clinical

expertise. In adjusted models, providers who had performed at least 100 MCs were approximately half as likely to perform an MC that resulted in an AE than was the case for less experienced providers. This finding is especially important to programs that use staff from multiple cadres and employers to provide MC services. Among experienced providers (i.e., those who had performed more than 100 MCs), nurses and clinicians provided equivalent services. Similarly, after adjusting for provider experience, GoK and NRHS providers performed equivalent services. It is essential for the organization providing MC training to ensure that providers will continue to use and improve their MC skills immediately after the training. In the study area, more than 300 GoK staff were trained to provide MC services, but only 11.5% of participants were circumcised by a GoK provider—averaging one or two MCs per provider post-training. Our results indicate that this level of service provision is not adequate to achieve (or maintain) the desired level of clinical expertise.

2. **Program efficiency**

Auvert (2008) estimated that an MC provider could perform 10 MCs per day. In our study, the most experienced providers performed MCs in a mean time of 15.5 minutes. Assuming ample client flow, our results suggest that experienced providers may have time to perform 20–30 MCs per day without compromising the safety of the procedure. Initiatives are underway to improve the efficiency of the procedure (for example, the Maximizing for Optimizing the Volume and Efficiency of MC services model [WHO, 2010]), but our results suggest that the procedure will naturally become efficient over time; therefore, efforts to improve efficiency should target other time-consuming components of the MC process (e.g., HIV counseling and testing).

3. **Male circumcision service surveillance**

As medical MC programs continue to be implemented in sub-Saharan Africa, robust AE surveillance is crucial, especially during the first year of implementation, to identify factors that may contribute to unnecessarily high rates of AEs. This study has shown, for example, that using data to evaluate provider experience was especially critical in Kenya when nurses were first approved to provide MC services in June 2009, several months after the launch of the national MC program. In Kenya, the quality of MC passive surveillance suffered because less than half (45.1%) of participants reported for a follow-up visit. Additionally, our findings suggest that there are some AEs—such as bleeding and swelling—that are best detected soon after the procedure, while other problems—such as appearance and other complaints—are not easily ascertainable until several weeks after the procedure. These findings highlight the importance of providing mechanisms for continued interaction with clients after the recommended follow-up period (e.g., an emergency call line may be used to provide post-MC counseling and to monitor AEs). Finally, it remains important to collect MC client perceptions about the process and outcomes since clients are usually the most effective mobilizers for the program.

4. **Male circumcision health communication campaign**

The results of this study may be useful for the development or improvement of an MC communication campaign both within and outside of Kenya. A national or regional communication campaign is well positioned to dispel misconceptions such as the duration of time away from work (usually a few days, but less than one week), the magnitude of the protective effect, and the recommended duration of the abstinence period. Additionally, many

participants stated that men are concerned about AEs such as pain and bleeding. Our findings suggest that neither of these AEs are common, severe, or untreatable, and this message should be disseminated widely. Some FGD participants doubted that MC really protects against HIV acquisition because they did not know the mechanisms that explained this protection, and these mechanisms can be communicated through campaign messages. Finally, results from the FGDs suggest that it is important to situate MC within the existing HIV-prevention framework (that is, alongside the ABC approach, HIV testing, home-based counseling and testing, couple's testing and counseling, and STI diagnosis and treatment) to improve the relevance of this intervention for men already practicing some HIV-prevention methods.

Results from this study also reinforce the importance of involving female partners in the MC counseling and education process. Couple's counseling should clarify the abstinence period to ensure realistic expectations for MC clients and their sex partners, and to promote wound healing among recently circumcised men. Since many couples are not counseled together during the MC process, mass communication should include messages about the importance of the abstinence period to lessen the risk of HIV acquisition by female partners during the healing process. Additionally, strategies to encourage married men and their partners to abstain from sex post-MC (e.g., counseling them to sleep in different beds during the abstinence period) may be useful.

5. **Target population for male circumcision services**

Previous research has indicated that the ideal age for MC in sub-Saharan Africa is 7–13 years (Westercamp and Bailey, 2007); participants in this study reported the ideal age to be 11–18 years. While literature has consistently shown that communities are more receptive to the

circumcision of adolescent males, several governments are targeting sexually active males during the initial "catch-up" period (Republic of Kenya, 2009; WHO, 2007) to achieve a great public health impact more quickly. Achieving program impact needs to be balanced with community opinions about the ideal age for MC. Because older men will be more likely than adolescent males to engage in early sexual activity after an MC procedure, the risk of HIV acquisition or transmission may be reduced by circumcising adolescents instead of older males.

C. **Research Opportunities**

When asked about HIV-prevention methods, FGD participants were most familiar with the ABC approach and frequently did not situate MC within their existing HIV-prevention framework—this discrepancy was especially true among young men. While most FGD groups identified MC as an HIV-prevention strategy without prompting, older men were more aware of MC for HIV prevention but less likely to believe that MC was necessary, especially if a man practiced other HIV-prevention methods. Understanding this disparity between knowledge, beliefs, and intention may be crucial to improving MC uptake and acceptability and should be explored in future research.

Despite extensive training in the study area, GoK MC providers performed few procedures in this study population. Given that the national MC training curriculum is intensive—often requiring three or four weeks to complete—it may be important to understand the characteristics of providers who go on to perform several MCs after training and the characteristics of those who go on to perform very few procedures. This may assist the partners and hospital administrators to recruit appropriate trainees and to implement systems at health facilities that will encourage providers to perform procedures.

Because few research studies have compared passive and active surveillance methods for out-patient surgeries in resource-limited settings, follow-up studies to confirm or challenge the results of this study are needed. For MC, the key to improving AE ascertainment in a passive system lies in improving participant attendance at follow-up visits, especially if a large-scale MC program relies solely on this type of surveillance data for program evaluation; strategies to improve attendance should be developed and evaluated. While visiting participants at their homes 30–40 days post-MC allowed us to assess non-AE indicators of interest (e.g., the resumption of sexual activity following MC), it was not the most ideal time for assessing AE history since most participants had healed and most AEs could not be visually observed. To improve upon the findings of this study, future research should actively assess AEs by visually observing participants more frequently and at similar time points during the first two weeks. Additionally, it would be important to assess the agreement of AE ascertainment among MC providers.

The results from this study indicate that more men engaged in early sexual activity after being circumcised as a part of this large-scale program than during any of the RCTs. Specifically, participants who reported resuming sex early did so three to four weeks post-MC. The healing process post-MC is tied to the risk of engaging in early sexual activity, and studies to understand the wound healing process more fully are underway. Ideally, these studies should compare client perceptions of healing with various cadres. Innovative strategies are needed to encourage men who seek VMMC services to abstain from sexual activity during the healing process; this encouragement is especially necessary if they are already involved in a sexual partnership. To build upon the findings of this study, strategies to improve the uptake of couple's counseling and text messaging programs should be implemented and evaluated.

D. **Limitations**

The findings reported by this study should be considered along with the following limitations. The results from this study might not be generalizable to other programs and countries since they were restricted to Nyanza Province. Participants were recruited among all males who voluntarily sought VMMC services at a study facility; these males, who were early adopters of VMMC services, may be different from males in the general population in ways that are not quantifiable. In addition, analyses pertaining to sexual behavior were based on self-reported data; as a result, it is possible that behaviors may have been misreported. Since less than half of the participants returned for a follow-up visit, and since AEs were relatively rare, some cell sizes were small (less than 20 participants). Perceptions about how female partners reacted to a participant's circumcision were secondary and not collected directly from the women themselves. At the time that this study was conceived, there was no clear guideline regarding a 42-day abstinence period; therefore, this study evaluated participants 28–45 days post-MC, and the results presented here may underestimate the true percent of participants engaging in early sexual activity since most interviews took place before the end of the abstinence period. Finally, the vast majority of MCs were provided by MC-dedicated staff who worked for NRHS. Because these staff specialized in MC only and provided MC services on a full-time basis, the AE rates presented here may be artificially low and not generalizable to programs using mostly non-MC-dedicated staff.

While purposive sampling was employed in an attempt to recruit a representative sample of uncircumcised men (based on self-reported status, as noted above) to participate in the FGDs, it is possible that this study may not have identified and described the full range of beliefs related to MC in Nyanza Province (even though saturation was achieved). Also, all participants were

uncircumcised with no plans to become circumcised; for this reason, their opinions about MC might be more negative than those in the general population. Finally, participants in FGDs provided data via self-reported opinions about community perceptions of MC; therefore, it is possible that the participants themselves did not hold these opinions and may have withheld or exaggerated information.

E. **Conclusion**

This study has evaluated the first implementation phase of a large-scale MC program in a resource-limited setting. The findings presented and discussed in this report will add to the scientific and public health literature by exploring many of the concerns associated with implementing large-scale MC programs as part of an HIV-prevention strategy in Africa. The next phase of research should focus on addressing the programmatic and research gaps identified by this study. The findings contained in this report will be shared with the GoK and implementing partners as part of a collective effort to improve the VMMC clinical training program, the health education campaign, and the national monitoring system for VMMC in Kenya.

APPENDICES

APPENDIX A

MCMES Focus Group Discussion Guide:

Uncircumcised Men

Welcome and Introduction:

Greet all the participants and welcome them to the discussion.

As a way of introduction, I would like to remind you of the purpose of the study

- The purpose of this study is to assess the implementation of male circumcision as an HIV prevention strategy in several districts in Nyanza.
- This discussion is one part of a larger study assessing the roll-out of male circumcision.
- One of the aspects we are studying is the issue of acceptability.
- That is what we would like to talk about today. You are the "experts" on this topic, and we are here to listen to your thoughts and ideas.

Each of us in the room has an important role to play in today's discussion.

- I, as the facilitator, will ask discussion questions to the group and keep the conversation on track. I may take some brief notes.
- <State the name of the note-taker> is the note-taker for this session and will record more detailed notes about our conversation, as well as assist with any logistical items, like operating the audio recording as we will be recording this session.
- You, as participants, have been invited here to share your opinions on the topic of male circumcision service provision. You all have something in common—the fact that you are uncircumcised.

Ground Rules:

We would like to propose some guiding principles for our discussion:

- We want everyone to be comfortable sharing their ideas. The aim of today's group discussion is not to reach consensus. The more opinions and perspectives we have the better our understanding will be. There are no wrong or right answers, so please feel free to openly share your views with us.
- We also hope everyone feels secure that the ideas expressed here will not be shared in a way that identifies you to others outside the discussion group here today. We want to respect the confidentiality of what is shared here. Please do not discuss what is discussed with people outside this room.
- Please take turns while talking so that we can all hear what is said clearly. We want to make sure everyone has a chance to talk.
- Please respect the opinions of others.

APPENDIX A (continued)

- You don't have to answer any questions that you don't like or don't feel comfortable talking about.
- Please switch off your mobile phone.
- Are there any other guiding principles for this discussion that you would like to suggest?
- If you don't have any further suggestions or questions, we would like to start the tape recorder now.

Start Recording Device Now

Questions:

- HIV Context (Warm-Up)

1. What are some of the words or phrases that people in this community use when talking about HIV/AIDS?
    a. Let's go around the room, and share one or two words or phrases that come to mind. (If coded words/phrases are used, please probe for their meaning.)

2. What are some things people do to protect themselves, or their sexual partner, against getting HIV?

Male Circumcision Acceptability

3. When you hear people talk about male circumcision in the community, what are some of the things they say?
    a. What are some of the ways male circumcision is described?
    b. What are some of the things that you have heard discussed about the relationship between male circumcision and HIV?

4. Imagine that two young Luo men are having a conversation about male circumcision. What are some of the things they might say?
    a. What are some of the reasons they are discussing circumcision?
    b. What are some of the things that they would say about male circumcision in the context of Luo culture?
    c. What are some of the things that they would say about circumcision and a man's health?
    d. What other things might they be discussing about circumcision?

5. Imagine that two Luo elders are having a conversation about male circumcision. What are some of the things they might say?
    a. What are some of the ways that their conversation might differ from the conversation between young Luo men?

APPENDIX A (continued)

6. A Luo man, named Onyango, is considering getting circumcised. What are some of the reasons that he might decide to get circumcised?
    a. How would hygiene impact his decision?
    b. How would sexual pleasure impact his decision?
    c. How would protection from HIV impact his decision?
    d. How would protection from STIs impact his decision?
    e. Are there any other reasons?

7. What are some of the reasons that Onyango might decide not to get circumcised?
    a. How would cost impact his decision?
    b. How would travel to and from the health facility impact his decision?
    c. How would abstinence from sex impact his decision?
    d. How would pain impact his decision?
    e. How would time off from work impact his decision?
    f. How would infection impact his decision?
    g. How would the Luo culture impact his decision?
    h. How would stigma impact his decision?
    i. Are there any other reasons?

8. If Onyango goes to a health facility for male circumcision and finds the following, how might he react:
    a. Female staff providing counseling and education on circumcision?
    b. Female staff assisting in the theater with the circumcision?
    c. Female staff performing the circumcision?
    d. Female staff attending to clients during follow-up visits?

9. To help him in his decision, Onyango decides to talk with his female sex partners about him getting circumcised. What are some of the things that these women might say?
    a. What are some of the things that the women might say to convince Onyango to get circumcised?
    b. What are some of the things that the women might say to convince Onyango not to get circumcised?
    c. What are some of the ways that women should be involved in the decision of their partners to become circumcised?

10. The Government of Kenya now recommends male circumcision for HIV prevention. What would be some of the ways to sensitize men, like Onyango, about the benefits and risks of male circumcision?
    a. What are some of the groups that should be involved in sensitizing men about male circumcision?

APPENDIX A (continued)

11. In the end, Onyango decided to get circumcised. What would his neighbors say about Onyango if they found out he was circumcised?
    a. What are some of the positive things they might say?

    b. What are some of the negative things they might say?

- Summary Question (Wrap-Up)

1. Are there any other factors pertaining to male circumcision that we missed, but should discuss?

Closing Statement:

Thank you for your active participation in this focus group discussion. Your knowledge and experiences are very important to us in our effort to try to understand views about male circumcision in this community. We sincerely appreciate the opinions that you have shared with us today.

Stop Recording Device Now

APPENDIX B

MCMES **CLINIC SYSTEM**	**FORM 1:** **DEMOGRAPHIC INFORMATION**
Date (dd/mm/yy): **____/____/____**	**Participant Number:** _____ **Site ID:**_____

Directions: Please complete the following form. If you need assistance, please speak to a health facility staff member.

1. Your surname: _____
2. Your other names: _____
3. Date of birth (dd/mm/yy): _____/_____/_____
4. How old were you at your last birthday? _____ years
5. Ethnic origin *[check one box]*:
   ☐ Luo
   ☐ Other (please specify): _____
6. What district do you currently live in? *[check one box]*
   ☐ Kisumu East
   ☐ Kisumu West
   ☐ Nyando
   ☐ Other (please specify): _____
7. Sub-location where you live:
   _____
8. Please describe places that are close to where you live (name, location, or other helpful information we could use to locate you):
   a. Church/mosque: _____
   b. School: _____
   c. Bar: _____
   d. Bus stop: _____

APPENDIX B (continued)

e. Kiosk/Duka: _____

f. Other: _____

9. Please write directions from the health facility to where you currently live:
_____

_____

10. If you have the following contact information, please list your:
    a. Phone number: _____
    b. Email: _____
    c. Name of workplace: _____

11. Contact information for a close friend or family member who can contact you:
    a. Name and popular name(s): _____
    b. Personal telephone contact number: _____
    c. Name of workplace: _____

12. What is the highest level school you completed? *[check one box]*
☐ No level completed
☐ Primary
☐ Secondary
☐ Post-Secondary

13. Are you currently employed? *[check one box]*
☐ Yes
☐ No

14. What is your occupation? *[check one box]*
☐ Unemployed
☐ Laborer
☐ Hawker/Small Business
☐ Fisherman
☐ Military/Police
☐ Professional/Managerial
☐ Student
☐ Other (specify):_____

15. What is your current marital status? *[check one box]*

APPENDIX B (continued)

☐ Not married, without a regular live-in partner
☐ Not married, with a regular live-in partner
☐ Married, not living with wife
☐ Married, living with wife
☐ Other (please specify): _____

16. What is your religion? *[check one box]*
☐ Anglican
☐ Catholic
☐ Muslim
☐ Pentecostal
☐ Nomiya
☐ 7th Day Adventist
☐ Africa Independent Churches
☐ Other (please specify):_____
☐ None / I Don't know

17. Who completed this form? *[check one box]*
☐ Patient
☐ Health facility staff member (name): _____

APPENDIX B (continued)

MCMES CLINIC SYSTEM	**FORM 2: MALE CIRCUMCISION CONSULTATION**
Date (dd/mm/yy): **____/____/____**	**Participant Number:** _____ **Site ID:**_____

General Information

1. Start time of consultation (24 hour clock): hh:mm |___|___| : |___|___|

VCT

2. Did the patient go through VCT at this site? *[check one box]*
   - ☐ 0 = No
   - ☐ 1 = Yes
   - ☐ 2 = VCT not available at this facility
   - ☐ 9 = Don't know

   a. If **YES**, result of testing (check one box):
   - ☐ 1 = HIV Positive
   - ☐ 2 = HIV Negative
   - ☐ 3 = Refuse to Answer
   - ☐ 9 = Don't know

3. Does the client know their HIV status based on the previous testing? *[check one box]*
   - ☐ 0 = No
   - ☐ 1 = Yes
   - ☐ 9 = Patient Doesn't Know

   a. If **YES**, result of testing *[check one box]*:
   - ☐ 1 = HIV Positive
   - ☐ 2 = HIV Negative
   - ☐ 3 = Refuse to Answer
   - ☐ 9 = Don't know

4. Was the client given condoms at this site today? *[check one box]*
   - ☐ 1 = Yes
   - ☐ 0 = No

Informed Consent

APPENDIX B (continued)

5. Have you, or your designee, explained the health risks and benefits of male circumcision (i.e., clinical consent)? *[check one box]*
   ☐ 1 = Yes

   ☐ 0 = No

6. Have you, or your designee, reviewed the risks and benefits of participating in the monitoring and evaluation study with the patient? *[check one box]*
   ☐ 1 = Yes
   ☐ 0 = No

7. Has the patient signed the consent form to participate in the monitoring system study? *[check one box]*
   ☐ 1 = Yes
   ☐ 0 = No

Clinical Exam

8. Patient weight (kg) : _____ kg

9. Patient height (m): _____ m

10. Patient pulse (beats/minute): _____ beats/minute

11. Patient blood pressure: |___|___|___| / |___|___|___|

[To the clinician: Examine the patient's penis.]

12. Patient's current foreskin status *[check one box]*:
    ☐ 1 = Foreskin covers one-half or more of the glans (completely uncircumcised)
    ☐ 2 = Foreskin is past the sulcus, but covers less than one-half of the glans
    ☐ 3 = Foreskin is not past the sulcus, but can be extended past the sulcus to cover one-half of the glans without compressing it
    ☐ 4 = Foreskin completely absent (completely circumcised)

13. At the present time, does the patient have any of the following medical complaints/conditions? *[check either "present" or "absent" for each complaint/condition]*

Complaints/Conditions	**Present = 1**	**Absent = 0**
a. Urethral discharge	☐	☐
b. Painless genital ulcer	☐	☐
c. Painful genital ulcer	☐	☐
d. Genital warts	☐	☐

APPENDIX B (continued)

e. Balanitis	☐	☐
f. Phimosis	☐	☐
g. Hypospadias	☐	☐
h. Pallor	☐	☐
i. Chronic wounds	☐	☐
j. Other (specify):_____	☐	☐

14. List any medications that the patient has taken in the past one month:

Name	**Dose**	**Frequency**
a.		
b.		
c.		
d.		
e.		

15. *[Ask the patient]* "Have you ever experienced excessive bleeding or bruising, or has any doctor ever told you that you are a hemophiliac?" *[check one box]*
    - ☐ 1 = Yes
    - ☐ 0 = No
    - ☐ 9 = Don't know

16. *[Ask the patient]* "During the last six months, has there ever been a period of two weeks or more when you had trouble achieving or maintaining an erection?" *[check one box]*
    - ☐ 1 = Yes
    - ☐ 0 = No
    - ☐ 2 = Refuse to Answer
    - ☐ 9 = Don't know

17. How many hours have passed since the patient last ate any food? _____ hours

    a. What food or drink did the patient consume? _____

APPENDIX B (continued)

18. *[Ask the patient]* **"What is the primary reason you decided to be circumcised?"**
[After the patient answers ask,] "**Are there any other reasons you decided to be circumcised?"**
[Check the box next to the answer(s) that the patient provides—DO NOT read the list of answers]

	Primary Reason (check one box)	**Other Reasons** (check any others)
a. HIV protection	☐	☐
b. STI protection	☐	☐
c. Cost (free)	☐	☐
d. Request of sex partner	☐	☐
e. Improve hygiene	☐	☐
f. Improve sexual experience	☐	☐
g. Peer pressure / Friends told him to circumcise	☐	☐
h. Improve cultural acceptance by other ethnic groups	☐	☐
i. Improve sexual acceptance by women from other ethnic groups	☐	☐
j. Parents made decision for their son to be circumcised	☐	☐
k. Other (please specify):_____	☐	☐
l. None	☐	☐

19. *[Ask the patient]* **"What is your primary concern or question about getting circumcised?"**
[After the patient answers ask,] **"Do you have any other concerns or questions?"**
[Check the box next to the answer(s) that the patient provides—DO NOT read the list of answers]

	Primary Concern (check one box)	**Other Concerns** (check any others)
a. Pain	☐	☐
b. Loss of ethnic identity	☐	☐
c. Family does not want patient to be circumcised	☐	☐
d. Sex partner does not want patient to be circumcised	☐	☐
e. Time off of work	☐	☐
f. Time to heal / Delayed wound healing	☐	☐
g. Time away from sex	☐	☐
h. Infection	☐	☐
i. Loss of blood	☐	☐
j. None	☐	☐

APPENDIX B (continued)

20. Is there any clinical evidence to exclude the patient from being circumcised? *[check one box]*
☐ 0 = No
☐ 1 = Yes, temporarily
☐ 2 = Yes, permanently

a. If **YES**, please specify: _____

b. If **YES**, have you prescribed treatment? *[check one box]*
☐ 1 = Yes ☐ 0 = No

21. End time of consultation (24 hour clock): hh:mm |___|___| : |___|___|

Clinician Information

22. This consultation was performed by:
☐ 1 = Staff stationed at this health facility
☐ 0 = NRHS MC Mobile Team

23. Name of person who completed the clinical consultation: _____

a. This person is a: *[check one box]*
☐ 1 = Clinical Officer
☐ 2 = Medical Officer
☐ 3 = Nurse
☐ 4 = Other (please specify): _____

24. Name of person who completed this form: _____

Clinical Notes:

APPENDIX B (continued)

MCMES CLINIC SYSTEM	**FORM 3: MALE CIRCUMCISION PROCEDURE**
Date (dd/mm/yy): **____/____/____**	**Participant Number:** _____ **Site ID:**_____

1. Start time of procedure *[24 hour clock]*: hh:mm |___|___| : |___|___|

2. What surgical method was used? *[check one box]*
   ☐ 1 = Forceps guided
   ☐ 2 = Dorsal slit
   ☐ 3 = Sleeve

3. Was the circumcision completed? *[check one box]*
   ☐ 1 = Yes ☐ 0 = No

   a. If **NO**, why not: _____ *[Stop here]*

4. Were there any complications of the procedure? *[check one box]*
   ☐ 1 = Yes ☐ 0 = No

   a. If **YES**, characterize complications *[check all that apply]*:
      ☐ 1 = Excessive bleeding, required transfusion
      ☐ 2 = Excessive skin removed
      ☐ 3 = Cosmetic problem
      ☐ 4 = Problem with anesthetic
      ☐ 5 = Excessive swelling
      ☐ 6 = Injury/abrasion of glans penis
      ☐ 7 = Required transfer to other facility (Reason: _____)
      ☐ 8 = Other (please specify):

      _____

5. What anesthesia was used? *[check one box]*
   ☐ 1 = None
   ☐ 2 = 1% lidocaine with epinephrine

APPENDIX B (continued)

☐ 3 = 1% lidocaine without epinephrine
☐ 4 = 2% lidocaine with epinephrine
☐ 5 = 2% lidocaine without epinephrine
☐ 6 = Other (please specify): _____

6. If an anesthetic was given, what quantity? *[check one box]*
   ☐ 1 = < 5 cc
   ☐ 2 = 6–10 cc
   ☐ 3 = 11–15 cc
   ☐ 4 = 16–20 cc
   ☐ 5 = 21–25 cc
   ☐ 6 = 26–30 cc
   ☐ 7 = >30 cc

7. Type of suture line: *[check one box]*
   ☐ 1 = No sutures needed
   ☐ 2 = Standard
   ☐ 3 = Running
   ☐ 4 = Running/locked

8. Type of dressing: *[check one box]*
   ☐ 1 = Standard
   ☐ 2 = Pressure
   ☐ 3 = High pressure

9. Type of pain killer: *[check one box]*
   ☐ 1 = None
   ☐ 2 = Panadol
   ☐ 3 = Other (please specify): _____

10. The patient was: *[check one box]*
    ☐ 1 = Discharged home
    ☐ 2 = Hospitalized
    ☐ 3 = Died

11. Was the patient discharged/transferred wearing tight underpants and/or with the penis strapped in an elevated position in order to reduce swelling? *[check one box]*
    ☐ 1 = Yes ☐ 0 = No ☐ 9 = Don't know

12. End time of procedure (24 hour clock): hh:mm |___|___| : |___|___|

13. This procedure was performed by:
    ☐ 1 = Staff stationed at this health facility
    ☐ 0 = NRHS MC Mobile Team

APPENDIX B (continued)

14. Name of clinician who performed the procedure: _____

15. The clinician who performed the procedure is a: *[check one box]*
    - ☐ 1 = Clinical Officer
    - ☐ 2 = Medical Officer
    - ☐ 3 = Nurse
    - ☐ 4 = Other (please specify): _____

16. Name of person who completed this form: _____

Clinical Notes:

APPENDIX B (continued)

MCMES CLINIC SYSTEM	**FORM 4: MALE CIRCUMCISION FOLLOW-UP VISIT**
Date (dd/mm/yy): **____/____/____**	**Participant Number:** _____ **Site ID:**_____

1. Start time of follow-up visit (24 hour clock): hh:mm |___|___| : |___|___|

2. Date of circumcision procedure (dd/mm/yy): _____/_____/_____

   [Clinician: Read the following adverse event definitions and inspect the participant's penis.]
   Adverse Event Definitions:
   - Normal Range: Symptoms that do not require treatment, and are expected following the male circumcision procedure
   - Moderate: Notable symptoms requiring modification of activity, but not resulting in loss of work or hospitalization
   - Severe: Incapacitating symptoms requiring bed rest, loss of work, or hospitalization

3. Is the client currently experiencing an adverse event?
   ☐ 1 = Yes, at least one moderate or severe adverse event is present [*Go to Question*
   ☐ 0 = No, the healing and symptoms are within the normal range following male circumcision [*Go to Question 4*]
      a. If **YES**, complete the following table for each moderate or severe adverse event that is present.

	AE Status *[check one]*	**Severity** *[check one]*	**AE Clinical Notes**
a. Excessive pain	☐ New ☐ Existing	☐ Moderate ☐ Severe	
b. Excessive swelling	☐ New ☐ Existing	☐ Moderate ☐ Severe	
c. Hematoma	☐ New ☐ Existing	☐ Moderate ☐ Severe	
d. Bleeding	☐ New ☐ Existing	☐ Moderate ☐ Severe	

APPENDIX B (continued)

	AE Status *[check one]*	**Severity** *[check one]*	**AE Clinical Notes**
e. Infection	☐ New ☐ Existing	☐ Moderate ☐ Severe	
f. Difficulty urinating	☐ New ☐ Existing	☐ Moderate ☐ Severe	
g. Wound disruption / Delayed healing	☐ New ☐ Existing	☐ Moderate ☐ Severe	
h. Problems with appearance	☐ New ☐ Existing	☐ Moderate ☐ Severe	
i. Injury to the glans	☐ New ☐ Existing	☐ Moderate ☐ Severe	
j. Other (specify): _____	☐ New ☐ Existing	☐ Moderate ☐ Severe	

4. Has the patient performed normal activities or work since the circumcision? *[check one box]*
   - ☐ 1 = Yes
   - ☐ 0 = No

5. How many days after the circumcision did the patient resume normal activities or work? _____days

6. Has the patient had an erection since the circumcision? *[check one box]*
   - ☐ 1 = Yes
   - ☐ 0 = No
   - ☐ 2 = Refuse to answer
   - ☐ 9 = Don't know

   a. If **YES**, did the erection cause any of the following: [*check all that apply]*
      - ☐ 1 = Pain
      - ☐ 2 = Bleeding
      - ☐ 3 = Opening up of the wound
      - ☐ 4 = Weak erection
      - ☐ 5 = No problem
      - ☐ 6 = Other problem (specify): _____

APPENDIX B (continued)

7. Has the patient had sexual intercourse since the circumcision? *[check one box]*
   ☐ 1 = Yes
   ☐ 0 = No
   ☐ 2 = Refuse to answer

   b. If **YES**, how often has the patient used a condom during sexual intercourse since the circumcision? *[check one box]*
      ☐ 1 = Always
      ☐ 2 = Sometimes
      ☐ 0 = Never
      ☐ 3 = Refuse to answer

8. [Ask the patient] "So far, how satisfied or dissatisfied are you with the circumcision?" *[check one box]*
   ☐ 1 = Very satisfied
   ☐ 2 = Somewhat satisfied
   ☐ 3 = Somewhat dissatisfied
   ☐ 4 = Very dissatisfied

   a. If **SOMEWHAT DISSATISFIED** or **VERY DISSATISFIED**, what would make you more satisfied?

   _____

9. Any treatment provided for adverse events? *[check one box]*
   ☐ 1 = Yes
   ☐ 0 = No

   a. If **YES**, describe _____

10. This follow-up examination was conducted by:
   ☐ 1 = Staff stationed at this health facility
   ☐ 0 = NRHS MC Mobile Team

11. Name of person conducting follow-up examination: _____

12. The person conducting this examination is a *[check one box]:*
   ☐ 1 = Clinical Officer
   ☐ 2 = Medical Officer
   ☐ 3 = Nurse
   ☐ 4 = Community Health Worker
   ☐ 5 = Other (specify): _____

APPENDIX B (continued)

13. Name of person completing form: _____

14. End time of follow-up visit (24 hour clock): hh:mm |___|___| : |___|___|

Clinical Notes:

APPENDIX C

MCMES **ACTIVE SYSTEM**	**FORM 5: (PDA)** **MALE CIRCUMCISION ACTIVE FOLLOW-UP VISIT**
Date (dd/mm/yy): **____/____/____**	**Participant Number:** _____

1. Start time of interview (24 hour clock): hh:mm |___|___| : |___|___|

2. Patient was circumcised at site (site ID): _____

Demographic Information

3. How old were you at your last birthday (years)? _____

4. What is your current employment status? *[check one box]*
   ☐ 1 = Currently unemployed
   ☐ 2 = Currently employed, but not returned to work yet after circumcision
   ☐ 3 = Currently employed and working

   a. If **NOT RETURNED TO WORK YET**, why not? *[check one box]*
      ☐ 1 = Experiencing adverse event
      ☐ 2 = Taking annual leave / time off of work
      ☐ 3 = Other

   b. If **EMPLOYED AND WORKING**, how many days after circumcision were you able to return to work? |___|___|___|

5. What is your current marital status? *[check one box]*
   ☐ 1 = Not married, without a regular live-in partner
   ☐ 2 = Not married, with a regular live-in partner
   ☐ 3 = Married, not living with wife
   ☐ 4 = Married, living with wife

6. What is your religion? *[check one box]*
   ☐ 1 = Anglican
   ☐ 2 = Catholic
   ☐ 3 = Muslim
   ☐ 4 = Pentecostal
   ☐ 5 = Nomiya
   ☐ 6 = 7th Day Adventist
   ☐ 7 = Africa Independent Churches

APPENDIX C (continued)

☐ 8 = Other (please specify):_____
☐ 9 = None / I don't know

7. In the past month, how many shillings have you earned from all sources? *[check one box]*
   ☐ 1 = None
   ☐ 2 = < 2000
   ☐ 3 = 2000–4999
   ☐ 4 = 5000–9999
   ☐ 5 = 10000–25000
   ☐ 6 = > 25000

Residential Information

8. What is your current housing arrangement? *[check one box]*
   ☐ 1 = Own my own house
   ☐ 2 = Renting/contributing rent
   ☐ 3 = Paying no rent
   ☐ 4 = Other

9. How long does it take you to walk from your home to get transport (e.g., matatu) to the nearest town? *[check one box]*
   ☐ 1 = < 5 minutes
   ☐ 2 = 5–15 minutes
   ☐ 3 = 15 minutes–30 minutes
   ☐ 4 = ≥ 30 minutes

10. How long did it take you to get from the health facility to your home on the day you were circumcised (one-way)? *[check one box]*
    ☐ 1 = < 15 minutes
    ☐ 2 = 15–30 minutes
    ☐ 3 = 30 minutes–1 hour
    ☐ 4 = 1–2 hours
    ☐ 5 = >2 hours

11. What modes of transportation did you take from the health facility to your home on the day you were circumcised? *[check all that apply]*
    ☐ 1 = Walking (< 1 kilometers)
    ☐ 2 = Walking (≥ 1 kilometers)
    ☐ 3 = Bicycle / Boda-boda / Motorcycle
    ☐ 4 = Matatu / Bus
    ☐ 5 = Personal or family automobile
    ☐ 6 = Friend gave you a ride in their automobile

Hygiene

APPENDIX C (continued)

12. Where is the water source for your home? *[check one box]*
    - ☐ 1 = Water is available/flowing inside the house (indoor plumbing)
    - ☐ 2 = Water is available outside the house, but inside the compound (< 20 meters)
    - ☐ 3 = Water is available within a short distance from the house (≤ 200 meters)
    - ☐ 4 = Water is not available near the house (> 200 meters)

13. About how often do you normally bathe? *[check one box]*
    - ☐ 1 = Once per week, or less
    - ☐ 2 = Twice per week
    - ☐ 3 = Every two days
    - ☐ 4 = At least once per day
    - ☐ 9 = Refuse to answer

14. About how often do you put on clean underpants? *[check one box]*
    - ☐ 1 = Never / I don't wear underpants
    - ☐ 2 = Once per week, or less
    - ☐ 3 = Twice per week
    - ☐ 4 = Every two days
    - ☐ 5 = At least once per day
    - ☐ 9 = Refuse to answer

General Acceptability

15. Overall, how satisfied or dissatisfied are you with the circumcision? *[check one box]*
    - ☐ 1 = Very satisfied
    - ☐ 2 = Somewhat satisfied
    - ☐ 3 = Somewhat dissatisfied
    - ☐ 4 = Very dissatisfied

    a. If **SOMEWHAT DISSATISFIED** or **VERY DISSATISFIED**, what were the reasons? *[check all that apply]*
       - ☐ 1 = Problems with penile appearance
       - ☐ 2 = Problems with penile function
       - ☐ 3 = Problems with treatment provided at health facility
       - ☐ 4 = Social rejection from family, friends, or sex partners
       - ☐ 5 = Other (specify): _____

16. If you could go back in time and change things, would you choose to be circumcised or remain uncircumcised? *[check one box]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = Unsure

APPENDIX C (continued)

17. How satisfied or dissatisfied are you with the services (circumcision and follow-up) provided to you by the health facility? *[check one box]*
    - ☐ 1 = Very satisfied
    - ☐ 2 = Somewhat satisfied
    - ☐ 3 = Somewhat dissatisfied
    - ☐ 4 = Very dissatisfied

18. Compared to before you were circumcised, how protected do you feel now against HIV? *[check one box]*
    - ☐ 1 = Much more
    - ☐ 2 = Somewhat more
    - ☐ 3 = About the same
    - ☐ 4 = Somewhat less
    - ☐ 5 = Much less
    - ☐ 9 = Don't know

19. Compared to before you were circumcised, how protected do you feel now against sexually transmitted diseases, other than HIV? *[check one box]*
    - ☐ 1 = Much more
    - ☐ 2 = Somewhat more
    - ☐ 3 = About the same
    - ☐ 4 = Somewhat less
    - ☐ 5 = Much less
    - ☐ 9 = Don't know

20. How satisfied or dissatisfied are you with the appearance of your penis now, following circumcision? *[check one box]*
    - ☐ 1 = Very satisfied
    - ☐ 2 = Somewhat satisfied
    - ☐ 3 = Somewhat dissatisfied
    - ☐ 4 = Very dissatisfied

21. Compared to the time before you were circumcised, how sensitive would you say your penis is now? *[check one box]*
    - ☐ 1 = Much more
    - ☐ 2 = Somewhat more
    - ☐ 3 = About the same
    - ☐ 4 = Somewhat less
    - ☐ 5 = Much less
    - ☐ 9 = Don't know

22. Since the circumcision, have any men asked you your opinion about circumcision? *[check one box]*

APPENDIX C (continued)

☐ 1 = Yes ☐ 0 = No

a. If **YES**, have you recommended circumcision to other men? *[check one box]*
- ☐ 1 = Yes
- ☐ 0 = No
- ☐ 2 = Refuse to answer
- ☐ 9 = Don't know

b. If **YES**, what is the primary reason that you recommended circumcision to other men? *[DO NOT read responses—check one box]*
- ☐ 1 = Protection against STI
- ☐ 2 = Protection against HIV
- ☐ 3 = Penile hygiene
- ☐ 4 = Going against cultural tradition
- ☐ 5 = Improved sexual pleasure for you
- ☐ 6 = Diminished sexual pleasure for you
- ☐ 7 = Improved sexual pleasure for your sex partners
- ☐ 8 = Diminished sexual pleasure for your sex partners
- ☐ 9 = Improved ethnic mixing
- ☐ 10 = No primary reason
- ☐ 11 = Other (specify): _____

c. If **YES**, are there other reasons that you recommended circumcision to other men? *[DO NOT read responses—check all that apply]*\
- ☐ 1 = Protection against STI
- ☐ 2 = Protection against HIV
- ☐ 3 = Penile hygiene
- ☐ 4 = Going against cultural tradition
- ☐ 5 = Improved sexual pleasure for you
- ☐ 6 = Diminished sexual pleasure for you
- ☐ 7 = Improved sexual pleasure for your sex partners
- ☐ 8 = Diminished sexual pleasure for your sex partners
- ☐ 9 = Improved ethnic mixing
- ☐ 10 = No other reasons
- ☐ 11 = Other (specify): _____

23. Compared to before you were circumcised, how attracted are women to you? *[check one box]*
- ☐ 1 = Much more attracted
- ☐ 2 = Somewhat more attracted
- ☐ 3 = About the same
- ☐ 4 = Somewhat less attracted

APPENDIX C (continued)

☐ 5 = Much less attracted
☐ 9 = Don't know

24. Do your sex partners know that you have been circumcised? *[check one box]*
☐ 1 = Yes
☐ 0 = No
☐ 2 = Refuse to answer
☐ 9 = Don't know

a. If **YES**, overall what were their reactions? *[check all that apply]*
☐ 1 = Very pleased
☐ 2 = Somewhat pleased
☐ 3 = Neutral or expressed no opinion
☐ 4 = Somewhat displeased
☐ 5 = Very displeased
☐ 9 = Don't know

b. If **YES,** what reasons have they given for their opinion?
[DO NOT read responses—check all that apply]
☐ 1 = Protection against STI
☐ 2 = Protection against HIV
☐ 3 = Penile hygiene
☐ 4 = Going against cultural tradition
☐ 5 = Improved sexual pleasure for you
☐ 6 = Diminished sexual pleasure for you
☐ 7 = Improved sexual pleasure for your sex partners
☐ 8 = Erectile dysfunction
☐ 9 = Diminished sexual pleasure for your sex partners
☐ 10 = Improved ethnic mixing
☐ 11 = Other
☐ 12 = No reason given

25. Other than your sex partners, does anyone in your family know that you have been circumcised? *[check one box]*
☐ 1 = Yes
☐ 0 = No
☐ 2 = Refuse to answer
☐ 9 = Don't know

a. If **YES**, overall what were their reactions? *[check all that apply]*
☐ 1 = Very pleased
☐ 2 = Somewhat pleased
☐ 3 = Neutral or expressed no opinion

APPENDIX C (continued)

☐ 4 = Somewhat displeased
☐ 5 = Very displeased
☐ 9 = Don't know

b. If **YES**, what reasons have they given for their opinion? *[check all that apply]*
☐ 1 = Protection against STI
☐ 2 = Protection against HIV
☐ 3 = Penile hygiene
☐ 4 = Going against cultural tradition
☐ 5 = Improved sexual pleasure for you
☐ 6 = Diminished sexual pleasure for you
☐ 7 = Improved sexual pleasure for your sex partners
☐ 8 = Erectile dysfunction
☐ 9 = Diminished sexual pleasure for your sex partners
☐ 10 = Improved ethnic mixing
☐ 11 = Other
☐ 12 = No reason given

General Health

26. Have you returned to normal, general activities now? *[check one box]*
☐ 1 = Yes ☐ 0 = No

a. If **YES**, how long did it take you after circumcision to return to normal general activities?
Weeks |___|___| OR Days |___|___|

Sexual Health

27. Have you had an erection since the circumcision? *[check one box]*
☐ 1 = Yes
☐ 0 = No
☐ 2 = Refuse to answer
☐ 9 = Don't know

a. If **YES**, compared to before your circumcision, how do your erections feel? *[DO NOT read list of answers—check all that apply]*
☐ 1 = Normal / About the same
☐ 2 = Harder
☐ 3 = Less hard
☐ 4 = It hurts now
☐ 5 = It bleeds now
☐ 6 = It feels tight/stretched now
☐ 7 = It feels itchy now
☐ 8 = Refuse to answer

APPENDIX C (continued)

☐ 9 = Don't know

28. Since the circumcision, have you had trouble achieving or maintaining an erection? *[check one box]*
    ☐ 1 = Yes
    ☐ 0 = No
    ☐ 2 = Refuse to answer
    ☐ 9 = Don't know

29. Have you had sexual intercourse since the circumcision? *[check one box]*
    ☐ 1 = Yes
    ☐ 0 = No
    ☐ 2 = Refuse to answer
    ☐ 9 = Don't know

    If YES:

    a. How soon after the circumcision did you start having sexual intercourse? *[check and complete one box]*
    ☐ ____ Hours (less than one day)
    ☐ ____ Days (less than one week)
    ☐ ____ Weeks (less than one month)
    ☐ ____ Months (number of months)
    ☐ 9 = Refuse to answer

    b. Since the circumcision, how many times have you had sexual intercourse? *[check one box]*
    ☐ 1 ☐ 2 ☐ 3 ☐ 4
    ☐ 5 ☐ 6 ☐ 7 ☐ ≥ 8 ☐ Refuse to answer

    c. Since the circumcision, how often have you used a condom during sexual intercourse? *[check one box]*
    ☐ 1 = Always
    ☐ 2 = Sometimes
    ☐ 3 = Never
    ☐ 9 = Refuse to answer

    d. Overall, how satisfied or dissatisfied are you with sexual intercourse since you were circumcised? *[check one box]*
    ☐ 1 = Very satisfied
    ☐ 2 = Somewhat satisfied
    ☐ 3 = Somewhat dissatisfied
    ☐ 4 = Very dissatisfied

APPENDIX C (continued)

e. Compared to before you were circumcised, how enjoyable is sex? *[check one box]*
☐ 1 = More enjoyable before MC
☐ 2 = No difference
☐ 3 = More enjoyable after MC
☐ 4 = Refuse to answer

f. Did your sex partner express any opinion about sexual satisfaction since your circumcision? *[check one box]*
☐ 1 = Yes
☐ 0 = No
☐ 2 = Refuse to answer
☐ 9 = Don't know

g. If **YES**, how sexually satisfied or dissatisfied is your partner since circumcision? *[check one box]*
☐ 1 = Very satisfied
☐ 2 = Somewhat satisfied
☐ 3 = Somewhat dissatisfied
☐ 4 = Very dissatisfied

Physical Exam and Adverse Events

30. Did you attend one follow-up appointment at the study health facility 7 to 12 days after circumcision? *[check one box]*
☐ 1 = Yes
☐ 2 = Yes, but fewer than 7 days after surgery
☐ 3 = Yes, but more than 12 days after surgery
☐ 4 = No

31. Amount of skin removed: *[check one box]*
☐ 1 = Right amount ☐ 2 = Too much ☐ 3 = Too little

32. Is the wound completely healed? *[check one box]*
☐ 1 = Yes ☐ 2 = No

33. Is there any sign of infection? *[check one box]*
☐ 1 = Yes ☐ 2 = No

a. If **YES**, describe: *[check all that apply]*
☐ 1 = Erythema at incision line
☐ 2 = Purulence/discharge at incision site
☐ 3 = Cellulitis, wound necrosis
☐ 4 = Other (describe): _____

APPENDIX C (continued)

34. Is there torsion of the penis? *[check one box]*
    ☐ 1 = Yes ☐ 2 = No

[Questions 35–38 will be asked for each of the following AEs]:

a. Abnormal pain
b. Excessive swelling
c. Hematoma
d. Bleeding
e. Infection
f. Difficulty urinating
g. Delayed wound healing
h. Problems with appearance
i. Injury to glans
j. Erectile dysfunction
k. Other (specify):_____

35. Did you experience < insert one AE from list > as a result of the circumcision procedure? *[check one box]*
    ☐ 0 = Patient never had this AE since circumcision (go to next AE in list)
    ☐ 1 = AE currently present
    ☐ 2 = Patient had this AE, but it has resolved

36. How severe was/is this AE? *[check one box]*
    ☐ 1 = Within the normal range
    ☐ 2 = Moderate
    ☐ 3 = Severe

37. Was this AE examined at the study health facility? *[check one box]*
    ☐ 1 = Yes ☐ 0 = No

38. How did this AE resolve? *[check all that apply]*
    ☐ 1 = Care and treatment was provided at the study health facility
    ☐ 2 = AE resolved without treatment
    ☐ 3 = Patient self-treated AE
    ☐ 4 = Patient received treatment at a non-study facility
    ☐ 5 = Patient received treatment from a pharmacist (did not see clinician)
    ☐ 6 = Patient received treatment from a traditional healer
    ☐ 7 = AE not currently resolved

39. Do you (the Research Assistant) think that it is necessary for the patient to return to the health facility for follow-up evaluation and/or treatment? *[check one box]*
    ☐ 1 = Yes ☐ 0 = No

APPENDIX C (continued)

a. **If YES**, have you encouraged the patient to return to the health facility for follow-up care? *[check one box – if you have questions about this, please call the Project Coordinator or the Field Supervisor]*
☐ 1 = Yes ☐ 0 = No

40. End time of interview (24 hour clock): hh:mm |___|___| : |___|___|

41. Name of Research Assistant: _____

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VITA

NAME: Amy Kate Noel Herman-Roloff

EDUCATION: B.A., Physics and English Literature and Writing, Bethel College, St. Paul, Minnesota, 2000

M.P.H., Epidemiology, University of Minnesota, Minneapolis, Minnesota, 2003

Ph.D., Epidemiology, University of Illinois at Chicago, Chicago, Illinois, 2011

PROFESSIONAL EXPERIENCE:

East Africa Regional Researcher
Population Services International, Nairobi, Kenya: 12/2010–present

- Assisting with research and monitoring and evaluation activities in eight countries, including study design development, questionnaire development, analysis, and dissemination.
- Building capacity among country-level researchers in the region to design studies, oversee data collection, and analyze/interpret results.
- Collaborating with country-level researchers to develop annual research portfolios and manage local research subcontractors.
- Analyzing study data, writing reports, and disseminating results through manuscripts, conferences, and presentations.

Research Project Coordinator–Department of Epidemiology
A collaboration between the University of Illinois at Chicago and the Nyanza Reproductive Health Society, Kisumu, Kenya: 10/2007–11/2010

- Principal Investigator for a research study assessing the safety and acceptability of the roll-out of male circumcision (MC) as an HIV prevention strategy in 16 health facilities in Nyanza Province, Kenya ($n \approx 4{,}000$ participants).
- Developed data collection instruments for the study (qualitative and quantitative).

VITA (continued)

- Developed technical infrastructure for the study, including database development and PDA programming.
- Supervised 12 research staff.
- Provided technical assistance to the national and provincial MC task forces to standardize monitoring and evaluation practices between partner organizations and the Government of Kenya.
- Analyzed qualitative and quantitative data.
- Disseminated findings through publications and at national and international conferences.
- Developed research capacity through intense mentorship of three Kenyan national staff members.

Project Director–Department of Epidemiology
University of Illinois Chicago, Chicago, IL: 1/2005–9/2007

- Managed the daily operations of the "Evaluation of MCH Epidemiology in State Health Agencies" cooperative agreement, co-funded by CDC and ASPH.
- Contributed to the data analysis of MCH structures, processes, and outputs that collectively lead to effective MCH epidemiology in state health agencies.
- Lead the primary data collection (50 states) and the secondary data acquisition and management efforts.
- Authored reports, presentations, and a manuscript.
- Organized and facilitated strategic discussions with the project's national Advisory Committee.
- Supervised support staff.

Public Health Consultant
Marie Stopes Kenya: 8/2008–12/2008

- Provided technical guidance for a study conducted by MSK assessing adverse events following medical male circumcision in terms of data collection and analysis.

Northern Illinois Public Health Consortium (NIPHC): 5/2005–9/2007

- Edited and authored the Project Public Health Ready Infectious Disease Annex for Illinois' northern 11 jurisdictions, as well as the Infectious Disease Committee's communication plan.
- Co-founded and facilitated the regional geographic information system (GIS) group.
- Facilitated over 15 tabletop exercises and strategic planning discussions.

VITA (continued)

Cook County Department of Public Health: 2/2005–8/2005

- Presented the details of the ESSENCE syndromic surveillance system to health partners (e.g., hospitals, local health departments, Illinois Bioterrorism Summit session, etc.).
- Implemented the first phase of the ESSENCE surveillance system including signing data sharing agreements with hospitals, customizing a user interface, and importing data into the system.
- Secured additional funding for the roll-out and expansion of the ESSENCE surveillance system.

Assistant Director–Enhanced Surveillance Unit
Cook County Department of Public Health (CCDPH), Oak Park, IL: 2/2004–1/2005

- Created and supervised the Enhanced Surveillance Unit from its inception, including strategic planning, hiring and personnel management.
- Developed and utilized databases and GIS techniques to monitor infectious disease trends.
- Facilitated the planning process for the infectious disease components of CCDPH response plans (e.g., West Nile Virus, SARS, and federal BioNet initiative response plans), and participated in the Incident Command structure for response.
- Implemented a syndromic surveillance system including securing data from healthcare providers, laboratories, pharmacies, retail outlets, and schools.
- Wrote and disseminated surveillance reports, newsletters and website updates.

Public Health Specialist–CDC Quarantine Station, O'Hare Airport
Constella Group Inc., Chicago, IL: 8/2003–1/2004

- Enforced CDC's communicable disease control and surveillance practices at an international port.
- Designed and improved multiple Microsoft Access databases.
- Facilitated agreements with hospitals in the Midwest for emergency preparedness purposes.

Program Manager–The Nevirapine Program
Selian Lutheran Hospital, Arusha, Tanzania: 2002

- Designed the protocol and implemented the program through the hospital's Maternal and Child Health Clinic.
- Trained hospital staff and over 300 community leaders about the program.

VITA (continued)

- Coordinated 12 hospital staff members
- Authored a successful grant application.

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Research Assistant–Department of Epidemiology
University of Minnesota, Minneapolis, MN: 2001–2003

Project Northland Chicago–a group randomized trial to reduce under-age alcohol consumption in Chicago, Illinois

- Developed a data collection protocol to survey alcohol signage around 65 project schools.
- Evaluated pilot data to assess the data collection protocol.
- Supervised project staff (drafting protocol, training, pilot testing, etc.).
- Participated in school-based training and focus group evaluation.

Project on Neighborhood Effects in Community Trials for Cardiovascular Disease (CVD)

- Utilized GIS analysis to evaluate the Pawtucket Heart Health Program data to identify and quantify community-level social predictors of cardiovascular disease.
- Conducted literature reviews for journal articles and grant applications.

Scientist–Famine Early Warning System (FEWS Net)
EROS Data Center, Sioux Falls, SD: 2000–2001

- Utilized GIS to monitor identified causes of famine in Africa (disease, climate, economy, etc.).

PUBLICATIONS: Welter, C., Herman-Roloff, A. "The Public Health Planning Process." Presented at the Illinois Bioterrorism Summit in Oakbrook, IL, 2004.

Herman-Roloff, A. "ESSENCE Syndromic Surveillance System." Presented at the Illinois Bioterrorism Summit in St. Charles, IL on July 19, 2005.

VITA (continued)

Herman-Roloff, A., Llewellyn, E., Agot, K., and Bailey, R. C. "Using Health Facility Assessment Data to Strategically Roll-Out Male Circumcision in Nyanza Province, Kenya: A Mixed Method Approach." Poster and presentation at the International AIDS Society conference, Cape Town, South Africa, 19–22 July 2009.

Herman-Roloff, A., Agot, K., Ndinya-Achola, J., and Bailey, R. C. "Medical Male Circumcision for HIV Prevention in Kenya: A Study of Service Provision and Adverse Events." Poster presented at the International AIDS Society conference, Vienna, Austria, 18–23 July 2010.

Rosenberg, D., Herman-Roloff, A**.**, Kennelly, J., and Handler, A. "Factors Associated with Improved MCH Epidemiology Functioning in State Health Agencies." *Maternal and Child Health Journal* September 17, 2010. (Epub ahead of print).

Herman-Roloff, A., Agot, K., and Bailey, R. C. "Factors Associated with the Early Resumption of Sexual Activity Following Medical Male Circumcision in Nyanza Province, Kenya." Presented at the University of Nairobi Collaborative STI/HIV Conference, Kenya, January 20, 2011.

Herman-Roloff, A., Llewellyn, E., Obiero, W., Agot, K., Ndinya-Achola, J., Muraguri, N., and Bailey, R. C. "Implementing Voluntary Medical Male Circumcision for HIV Prevention in Nyanza Province, Kenya: Lessons Learned During the First Year." 2011. *PLos ONE* 6 (4): e18299. doi:10.1371/journal.pone.0018299.

Herman-Roloff, A., Otieno, N., Agot, K., Ndinya-Achola, J., and Bailey, R. C. 2011. "Acceptability of Medical Male Circumcision Among Uncircumcised Men in Kenya One Year After the Launch of the National Male Circumcision Program." *PLoS ONE* 6 (5): e19814. doi:10.1371/journal.pone.0019814.)

AWARDS:

- U.S. State Department, National Security Education Program Scholarship, Kenya, 1999–2000
- Volunteer of the Year for Lutheran Social Services' refugee resettlement program, 2000
- Walter Judd Fellowship and Cecilia Goetz Scholarship, Tanzania, 2002

VITA (continued)

TRAINING
AND
COURSEWORK:

- Epidemiology: Infectious Disease, Surveillance, and HIV (5 courses)
- Epidemiology Methods (6 courses)
- Biostatistics (4 courses)
- SAS and STATA Analysis
- Sampling and Data Collection Methods (2 courses)
- Group Facilitation Methods
- UIC Student Epidemiology Corps (2005–present)