Sexual Behavior, Health, And Medical Male Circumcision

In Nyanza Province, Kenya

BY

NELLI WESTERCAMP
BS, Academy of Economic Studies, Moldova, 1998
BA, University of Nebraska at Omaha, 1999
MBA, University of Illinois at Chicago, 2006
MPH, University of Illinois at Chicago, 2006

THESIS

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Defense Committee:

Robert C. Bailey, Chair and Advisor
Richard Campbell
Ronald Hershow
Supriya Mehta
Christine Mattson, CDC

To Matthew, who keeps me grounded.

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ACASI	Audio Computer-Assisted Self-Interview
AIDS	Acquired Immune Deficiency Virus
AR(1)	Autoregressive covariance model of order 1
CI	Confidence Intervals
GUD	Genital Ulcer Disease
MC	Male Circumcision
OR	Odds Ratio
RCT	Randomized Controlled Trial
SHABS	Sexual Health, Attitudes and Behavior Study
STI	Sexually Transmitted Infections
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary Counseling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organizations

SUMMARY

Three randomized controlled trials (RCTs) in Africa have demonstrated the efficacy of male circumcision (MC) in reducing the risk of female-to-male HIV transmission by approximately 60%. Following these results, the United Nations Joint Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) recommended MC as an important additional strategy for the prevention of heterosexually acquired HIV infection in men. Kenya was one of the first priority countries to initiate national male circumcision scale-up.

However, questions remain about whether the promotion of MC as an HIV prevention intervention will translate into a decline in HIV incidence in the general population. Risk compensation—defined as an increase in risky behavior in response to the perceived risk reduction following an intervention—is one important possible mechanism that could negatively impact the effectiveness of MC programs.

To assess the concerns about risk compensation, we conducted a prospective observational study to monitor the sexual risk behavior of circumcised men before and after circumcision and compare it to the behavior of uncircumcised controls over 24 months of follow-up. As a secondary objective, we also aimed to evaluate the impact of circumcision on sexual health, function, and satisfaction. Finally, we sought to conduct an in-depth investigation of one of the least understood HIV risk behaviors—sexual partner concurrency—among circumcised and uncircumcised men, based on an earlier study of risk compensation embedded in the MC RTC in Kisumu, Kenya.

Designed to complement operations research accompanying the scale-up of the national MC program in Kenya, our study produced results that enabled policy makers throughout the region to make evidence-based decisions about MC implementation.

I. INTRODUCTION

A. Background

By the end of 2011 approximately 34 million people were living with HIV/AIDS, 69% of who lived in sub-Saharan Africa (UNAIDS/WHO, 2011). Sub-Saharan Africa represents a large and varied geographic area and is home to over 800 million people representing the most culturally diverse region in the world (Fearon, 2003). Challenging economic conditions, unstable political climates, and a relative lack of infrastructure and associated resources are interwoven with a set of health issues that often unifies the region in international perception and public health understanding. Foremost of these health issues is the region's disproportionate burden of HIV.

Ending in 2007, three RCTs proved that VMMC reduces the risk of female-to-male HIV transmission by as much as 60% (WHO/UNAIDS, 2007; Gray et al., 2007a; Bailey et al., 2007; Auvert et al., 2005). This finding, that a relatively simple and inexpensive procedure could reduce (UNAIDS/WHO/SACEMA, 2009), if not end (Nagelkerke et al., 2007), many generalized epidemics was a watershed in the fight against HIV. Fourteen priority countries, all in sub-Saharan Africa, were identified and international funding secured to facilitate the rapid scale-up of VMMC programs with the goal of providing circumcision services to almost 21 million men, as reported by USAID (2009). As of the end of 2011, just 7% of that goal had been met (WHO, 2011, 2012).

Despite the findings from the RCTs, the set of observational studies acting as their foundation (Bailey et al., 2001; Weiss et al., 2000), and the subsequent mathematic models addressing impact (UNAIDS/WHO/SACEMA, 2009), questions of real-world effectiveness of planned VMMC programs has stirred debate and slowed scale-up (Green et al., 2010). One of the main issues raised is fear that men will increase their HIV risk behaviors after VMMC, offsetting protection for them and putting their partners at risk (Eaton and Kalichman, 2009; Kalichman et al., 2007b; Eaton and Kalichman, 2007; Cassell et al., 2006). Termed "risk compensation," this unintended consequence of the reduction of personal perceived risk has been described in relation to interventions ranging from mandatory seat-belt laws to the provision of highly active anti-retroviral therapy (Adams, 1994; Pinkerton, 2001; Stolte et al., 2001).

Data on risk compensation reported in the three RCTs was promising: in the Kenyan trial, declines in risk behaviors were noted in both study arms, which were less dramatic in the circumcised group (Mattson et al., 2008; Bailey et al., 2007). In the Ugandan trial, a slight difference (37% in circumcised and 31% in uncircumcised) was observed in inconsistent condom use at six-months follow-up, which equalized by 24-months (Gray et al., 2007a). The most worrisome result was reported by the Orange Farm trial, where the difference between newly circumcised and uncircumcised men in mean number of recent casual partners was quite large (5.9 versus 5.0); other behaviors did not differ significantly (Auvert et al., 2005). These favorable findings are often questioned in light of assumptions that the rigorous and structured risk reduction counseling of the RCTs is infeasible when VMMC is provided at scale (Kalichman et al., 2007b). Regardless, mathematical modeling studies suggest that only extreme levels of increased risk behavior will offset the protection provided to circumcised men (Alsallaq et al., 2009; Andersson et al., 2011; Dushoff et al., 2011; Gray et al., 2007b; Hallett et al., 2011; Hallett et al.,

2008; Kahn et al., 2006; Nagelkerke et al., 2007; White et al., 2008; Njeuhmeli et al., 2011). More moderate levels of risk compensation, however, could result in increased female partner risk—especially in the short term (Andersson et al., 2011; Alsallaq et al., 2009; Dushoff et al., 2011; Hallett et al., 2008). This concern is exacerbated by the often exclusive male focus of VMMC initiatives and the fear that men circumcised for HIV prevention will be less willing to use condoms (Hankins, 2007).

Mild injury to the penis during intercourse may be an underappreciated source of sexual discomfort and possible dysfunction in men (Alanis and Lucidi, 2004), especially in populations where natural lubrication is not promoted or is actively discouraged (Scorgie et al., 2009; Mbikusita-Lewanika et al., 2009; Brown et al., 1993). While there is little systematically collected information available on prevalence, what little information is available suggests penile scratches, tears, and abrasions sustained during sex may be more prevalent than widely believed, and more common in uncircumcised men (Mehta et al., 2010). Several qualitative studies also have noted the perception of increased sexual satisfaction as a motivating factor to becoming circumcised, with “decreased discomfort” and “less soreness” often sited as aspects of sexual enhancement (Plotkin et al., 2011; Tarimo et al., 2012; Ssekubugu et al., 2013). If penile coital trauma is more common in uncircumcised men and sufficiently prevalent, the portal of entry this represents may be one important pathway by which MC lowers the risk of HIV infection in men and a motivation to become circumcised (Szabo and Short, 2000; Morris and Wamai, 2012; Dinh et al., 2011).

Defined as overlapping sexual partnerships in which sexual intercourse with one partner occurs between two acts of intercourse with another partner (UNAIDS Reference Group on Estimates, 2009), concurrent sexual partnerships have been suggested, and contested (Sawers and Stillwaggon, 2010), as a significant contributor to the unparalleled spread of HIV in the

general population of sub-Saharan Africa (Mah and Halperin, 2010; Hunter, 1993). Sexual concurrency is thought to increase HIV transmission by removing the protective effect of partner sequence and reducing the time to secondary transmissions in acutely infected individuals (Epstein and Morris, 2011). The potential impact of this, as well as the concomitant increase in sexual network density, has been described in multiple mathematical models (Goodreau, 2011). However, operationalizing the definition of sexual concurrency for comparative analyses has proven a fundamental limitation to empirical study. This issue was partially resolved with the 2010 UNAIDS consensus concurrency indicators (UNAIDS Reference Group on Measurement and Modeling, 2010); however, the impact of this definition in relation to previous measures has not been completely explored (Eaton, McGarth, and Newell, 2012). Further, due to the detailed and complex sexual history required, information on the actual prevalence and predictors of sexual concurrency in high-risk populations are limited.

There has been growing recognition that en lieu of a single "magic bullet" for HIV prevention, the reduction of HIV transmission below the reproductive rate needed to sustain the epidemic may require the strategic, simultaneous use of different classes of prevention activities (biomedical, behavioral, social-structural) (Kurth et al., 2011; Piot et al., 2008). Combination prevention strategies have been recognized by UNAIDS and the National Institutes of Health as important avenues of prevention study. As one of the few proven biomedical interventions, MC has been highlighted as an important component of comprehensive prevention (The Joint United Nations Programme on HIV/AIDS [UNAIDS], 2009). Sexual concurrency is a behavioral risk factor possibly driving HIV transmission in many VMMC priority countries, and the integration of targeted concurrency mitigation with VMMC risk reduction counseling may offer an example of a natural prevention synergy.

B. Purpose of the Study

Given continued concerns regarding risk compensation in men circumcised through widely implemented VMMC programs and the potential impact of these programs in HIV prevention, the primary aim of this thesis is to assess changes in risk behavior in men circumcised through an established and successful VMMC initiative before and after the procedure and to compare their behavior to those of uncircumcised men longitudinally. In addition, we use the detailed sexual histories obtained to determine prevalence and correlates of penile trauma in a general population of men living in a high-prevalence generalized HIV epidemic. Lastly, we will perform a detailed analysis of sexual concurrency based on a unique lifetime sexual partnership history from a nested cohort of men participating in the Kenyan RCT.

To determine if men circumcised through a community based VMMC program significantly change their behavior following the procedure, we first present the primary analysis of the Sexual Health, Attitudes, and Behaviors Study (SHABS). This analysis will compare the perceptions and behaviors of a self-selected cohort of men before and up to 24 months after they choose to become circumcised. To account for secular changes, newly circumcised men are also compared to age matched controls, from the same community, who chose not to become circumcised (chapter III).

Next we will determine the prevalence of penile coital injuries/trauma in the SHABS circumcised and uncircumcised cohorts. Using baseline sexual histories we will describe the experience regarding men's penile health before and after the procedure and identify factors associated with penile pain, scratches, cuts, abrasions, and bleeding following intercourse (chapter IV).

To conclude we utilize a set of detailed sexual histories collected from men screened for the Kenyan RCT as part of a risk compensation sub-study of trial participants. These data were unique

in that it allowed the assessment of both personal and partnership characteristics at a high level of detail. In this analysis we compare multiple operational definitions of sexual concurrency, observe changes of concurrency over time, and define the prevalence and correlates of concurrency for a well described high-risk population (chapter V).

II. MATERIALS AND METHODS

A. Overview of Study Setting and Design

The SHABS cohorts were selected from the populations of two rural and one urban district of Nyanza Province. Study activities were coordinated from nine study centers located at governmental district and sub-district hospitals and health centers participating in the VMMC scale up (Figure 1). The predominant ethnic group in all three districts is the Luo who, unlike the majority of ethnic groups in Kenya, do not traditionally circumcise. These populations were selected because they have the highest prevalence of HIV in Nyanza Province, which in turn has the highest HIV prevalence in Kenya (16.0% in women and 11.4% in men) (Kenya National Bureau of Statistics [KNBS] and ICF Macro, 2010).

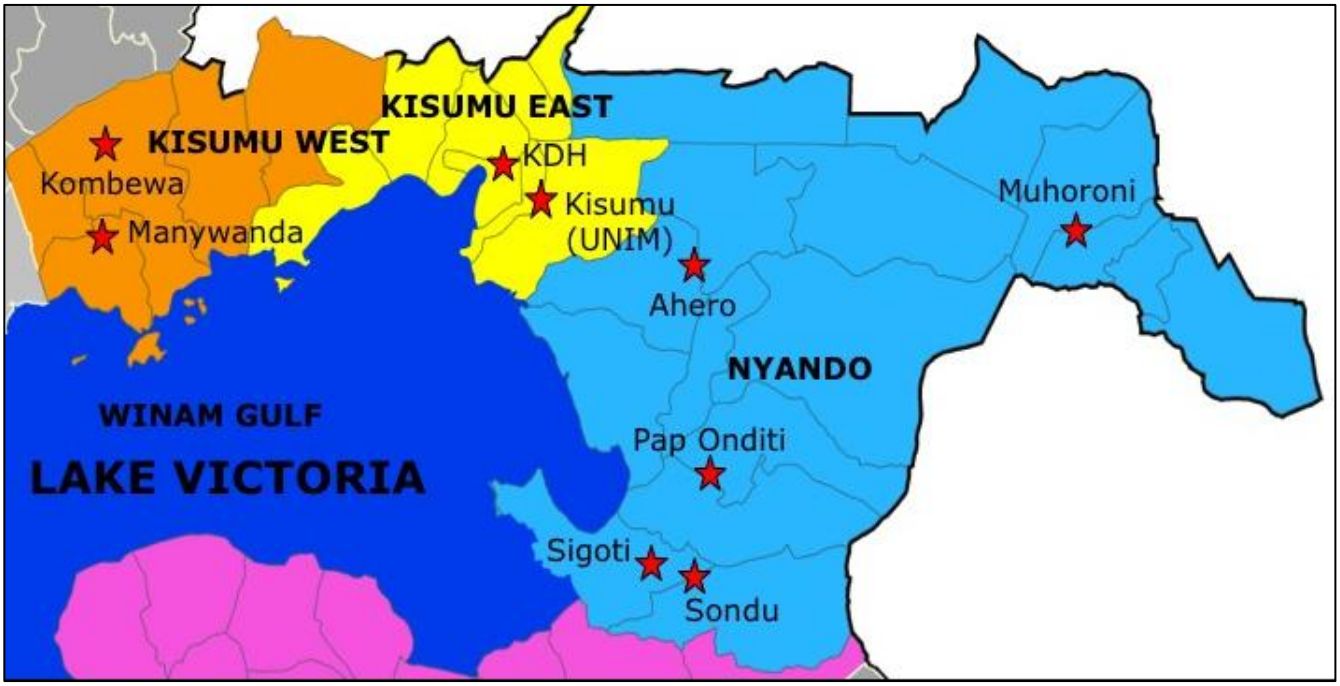

Figure 1: Geographical location of study sites

Men were eligible for study participation if: (1) they were between 18 and 35 years of age, (2) were able to provide informed consent, (3) had no plans to move outside the study area within the next two years, and either (4a) had scheduled a circumcision procedure (circumcised/ intervention group) or (4b) were uncircumcised, but eligible for the procedure, with no immediate plans to become circumcised (uncircumcised/control group). During recruitment, men presenting for circumcision were informed about the study by risk reduction counselors or other VMMC staff at participating facilities. If interested, study staff assessed eligibility, obtained written informed consent, and administered the baseline demographic and behavioral questionnaires in the language of their choice (Dholuo, Kiswahili, or English). The complete SHABS study instrument is provided as Appendix A. Following the baseline study procedures, circumcision group participants proceeded through a normal VMMC flow, including screening, risk-reduction counseling and HIV testing, counseling on partial protection provided by MC against HIV, consent for the surgery, and the circumcision procedure itself.

Uncircumcised controls were recruited VMMC provider, including training on the determination of lack of circumcision (prepuce covering the glans), definite circumcision (complete absence of prepuce), and indeterminate circumcision (residual foreskin, likely a result of traditional circumcision). Men were excluded from participation in the study if complete or partial absence of foreskin was detected.

Participants returned for follow-up visits at six, 12, 18, and 24 months after enrollment. At each visit, men were requested to undergo a visual exam to confirm circumcision status. Participants that did crossover continued participation in the study. Study participants were offered a referral to the nearest voluntary counseling and testing (VCT) center for risk reduction counseling and HIV testing at each visit. Uptake of such referrals was not measured. Study

participants were exposed to HIV educational videos playing at the waiting bay adjacent to the study office at each health facility.

Follow-up visits were scheduled six months from the previous visit, with an allowed window period for completing the visit of plus-or-minus three months. Participants who missed follow-up appointments by one week or more were actively traced in the community, following the detailed locator information collected and updated at each study visit. Every attempt was made to locate the defaulting participant, from phone calls to physical tracing in the community, including traveling outside of the research area in cases of participant relocation. To maximize the outcomes of the physical tracing efforts, follow-up interviews were conducted at the client's location, whenever it was not possible for him to return to the study office. When it was impossible to locate or interview participants within the window period, that follow-up visit was considered missed. Those missing a visit were allowed to continue participation at subsequent visits.

For our concurrency analysis, sub-study participants were recruited from the parent RCT of male circumcision for HIV prevention between March 2004 and September 2005. Men were eligible for participation in the sub-study if either: (1) they enrolled in the RCT of MC and thus, were HIV negative, uncircumcised, aged 18–24, residents of Kisumu district and reported sexual intercourse within the last 12 months; or (2) were excluded from enrolling in the RCT only because they tested positive for HIV, but met all other inclusion criteria.

The SHABS study questionnaires were administered through audio computer-assisted self-interview (ACASI) modules. An equivalent paper-based questionnaire was used at participant request or in cases of power outage at study facilities, and approximately 75% were double-entered for quality control with discrepancies resolved based on the original questionnaire. The

study database was maintained with QDS Data Warehouse Manager v2.5 (NOVA Research Company, 2007). The RCT sub-study data was entered by interviewers at the study site in Kisumu with 30% double-entered to evaluate accuracy (error rate less than 1%). The sub-study principal investigator provided the final dataset for the concurrency analysis.

B. Overview of Analytic Methods

1. Sample size calculation

Sample size calculation (n for each study arm) for primary objectives was performed for cross-sectional comparisons (Table I) of risk behaviors between circumcised and uncircumcised men at any visit for a range of proportions with the low value obtained from Kenya Demographic and Health Survey and the high value based on preliminary findings of the MC RCT in Kisumu, Kenya. Table I is also suitable for sample size calculation for HIV risk perception. Additionally, sample size calculation for each study arm was carried out considering longitudinal design exploring group effect (Table II).

Based on our sample size estimation, as well as operational and budgetary considerations, we aimed for a sample size of 1600 of circumcised and 1600 uncircumcised men for all study sites or a total of 3200 participants. This sample size enabled us to detect an odds ratio (OR) of 1.23 (α 0.05 and 80% power) between study groups in various behaviors (e.g., consistent condom use, sex for money, or gifts) that ranged in frequency in the comparison group between 20% and 45%. Longitudinally, this sample size allowed us to detect small size effects (0.1–0.2) corresponding to 5%–10% difference in proportions of the two study groups endorsing various behaviors under different time trend scenarios, accounting for 10% attrition at each follow-up and assuming repeated measured correlation coefficient of 0.5–0.7, two-tailed α of 0.05, 80% power and autoregressive covariance AR(1) (Hedeker and Barlas, 1999; Hedeker et al., 1999).

TABLE I. SAMPLE SIZE CALCULATION BASED ON CROSS-SECTIONAL DESIGN

Proportion (%) in uncircumcised	Proportion (%) in circumcised	Difference (%)	OR	Alpha	Power	N in each group	Effect Size
Greater than one sexual partner (range based on DHS and Kisumu RCT)							
25	30	5	1.28	0.05	80	1300	0.11
25	33	8	1.5	0.05	80	500	0.18
25	35	10	1.6	0.05	80	350	0.18
30	35	5	1.25	0.05	80	1450	0.11
30	38	8	1.42	0.05	80	580	0.17
30	40	10	1.54	0.05	80	380	0.21
35	40	5	1.24	0.05	80	1540	0.10
35	43	8	1.4	0.05	80	600	0.16
35	45	10	1.5	0.05	80	400	0.21
40	45	5	1.23	0.05	80.7	1600	0.10
40	48	8	1.38	0.05	80	630	0.16
40	50	10	1.49	0.05	80	410	0.20
45	50	5	1.22	0.05	80	1620	0.10
45	53	8	1.37	0.05	80	640	0.16
45	55	10	1.48	0.05	80	420	0.20
Condom use at last sexual encounter (range based on DHS and Kisumu RCT)							
47	39	8	1.38	0.05	80	630	0.16
47	37	10	1.5	0.05	80	410	0.20
40	32	8	1.4	0.05	80	590	0.17
40	30	10	1.53	0.05	80	380	0.21

TABLE II. SAMPLE SIZE REQUIRED FOR THE FIRST TIME POINT; CALCULATION BASED ON LONGITUDINAL DESIGN WITH 10% ATTRITION AT EACH VISIT

ρ=.5				**ρ=.6**				**ρ=.7**			
Size of Effect				**Size of Effect**				**Size of Effect**			
0.1	0.15	0.2	0.3	0.1	0.15	0.2	0.3	0.1	0.15	0.2	0.3
Compound symmetry: Constant group across time effect											
1154	513	289	128	1292	574	323	144	1431	636	358	159
Compound symmetry: Between group linear trend effect											
1697	754	424	189	1367	607	342	152	1037	461	259	115
AR(1): Constant group across time effect											
953	424	238	106	1094	486	273	122	1252	556	313	139
AR(1): Between group linear trend effect											
3312	1472	828	368	2988	1328	747	332	2518	1119	629	230

2. Statistical analysis

Outcomes of interest were assessed in longitudinal analyses with random intercept mixed-effect models. Behavioral outcomes included: having sex in the past six months, condom use at last sex, last sex with a casual partner, condom use at last sex if it was with a casual partner, multiple sexual partners (more than one) in the past six months, multiple (more than one) partners within the same 30-day period, and exchanging sex for money or gifts in the past six months. Self-assessed risk perception was determined by asking: "What do you think are your chances of getting HIV/AIDS?" Men choosing "moderate" or "great" were categorized as having high HIV risk perception. Outcomes on penile coital injuries in the past six months included: soreness during sex; cuts, scratches and abrasions during sex; and penile bleeding during or after sex. Self-reported genital sores were assessed in their relationship with penile coital injuries and male circumcision.

All outcomes were binary, and each outcome model included the sequential visit number (time), circumcision status (group) and the interaction of time and group. Circumcision status at each study visit was treated as time-variant covariate, with baseline status set according to self-selected group assignment at enrollment. Demographic and behavioral covariates were included in mixed-effect models to allow consideration of baseline adjustments to the group effect and to be considered independently for association with the outcomes of interest. Final model selection was done using backwards elimination, with retention of time, group effect and age in the model regardless of statistical significance and adjustment for other independent predictors if significant at $p<.05$.

We used Pearson χ^2 tests for categorical variables and Kolmogorov-Smirnov two-sample test for non-normally distributed continuous variables to detect baseline differences between

circumcision and control group participants, between men who did and did not return for follow-up after the baseline visit, and between crossovers and non-crossovers.

In the sexual partner concurrency analysis, we evaluated factors associated with concurrency on two levels: the respondent level and the partnership level. At the respondent level, χ^2 tests were used to assess differences in categorical factors, and logistic regression was used in the analysis of point prevalence to adjust for multiple correlates of interest. Mixed-effect models were used at the partnership level to correct for correlation between the multiple reports provided by each respondent. Separate analyses were carried out for regular/spousal and casual partnerships. Variables were selected for inclusion in multivariable models based on significance in univariate analyses ($p<.10$) and previous literature.

To ensure the comparability of our results with those from studies that analyzed partnership data without accounting for multiple reports, population-averaged ORs were calculated by transforming our subject-specific regression estimates as described by Hu et al. (Hu et al., 1998) Statistical analysis was performed using SAS v9.2 (SAS Institute Inc, 2008) with the NLMIXED procedure for mixed-effect modeling for binary outcomes.

III. RISK COMPENSATION FOLLOWING MALE CIRCUMCISION: A LONGITUDINAL STUDY OF RECENTLY CIRCUMCISED AND UNCIRCUMCISED MEN DURING THE KENYA NATIONAL SCALE-UP PROGRAM OF MEDICAL CIRCUMCISION FOR HIV PREVENTION

A. Introduction

Three RCTs in sub-Saharan populations have demonstrated the efficacy of MC in reducing the risk of female-to-male HIV transmission by approximately 60% (Bailey et al., 2007; Gray et al., 2007a; Auvert et al., 2005; WHO/UNAIDS, 2007). Following these results, UNAIDS and the WHO recommended MC as an important additional strategy for the prevention of heterosexually acquired HIV infection in men, and 14 countries in eastern and southern Africa, including Kenya, with high HIV prevalence and low levels of MC were set as priority areas for MC scale-up (WHO/ UNAIDS, 2007).

Circumcision, when performed by trained practitioners, has been shown to be safe, cost-effective, and acceptable in a variety of non-circumcising communities across Africa (Bailey et al., 2007; Gray et al., 2007a; Auvert et al., 2005; Weiss et al., 2010; Kahn et al., 2006; Westercamp and Bailey, 2007). Several modeling studies found that the long-term population-level impact of widespread implementation and scale-up of VMMC services will result in substantial reductions in HIV incidence for both men and women (Bollinger et al., 2009; Gray et al., 2007b; Nagelkerke et al., 2007; UNAIDS/WHO/SACEMA, 2009; Williams et al., 2006).

As a result, ten of the fourteen high-priority countries are actively engaged in national VMMC program scale-up (de Bruyn et al., 2010; Hankins et al., 2011; WHO, 2012). However, questions remain about whether the promotion of VMMC as an HIV prevention intervention will translate into a decline in HIV incidence in the general population. Risk compensation, also sometimes referred to as behavioral disinhibition (Hogben and Liddon, 2008), is defined as an increase in risky behavior in response to the perceived risk reduction following an intervention. Risk compensation is an important possible mechanism that could negatively impact the effectiveness of VMMC programs (Cassell et al., 2006; Kalichman et al., 2007b). If operating, risk compensation could reduce the protective effect of circumcision against HIV and, if of sufficient magnitude, completely negate the protection (White et al., 2008). Epidemiological modeling studies suggest that, at the population level, only extreme levels of increased risk behavior will offset the protection offered by circumcision to men (Alsallaq et al., 2009; Andersson et al., 2011; Dushoff et al., 2011; Gray et al., 2007b; Hallett et al., 2011; Hallett et al., 2008; Kahn et al., 2006; Nagelkerke et al., 2007; White et al., 2008; Njeuhmeli et al., 2011); however, only moderate levels of risk compensation in men could result in increased HIV risk for women, especially in the short term (Andersson et al., 2011; Alsallaq et al., 2009; Dushoff et al., 2011; Hallett et al., 2008).

The current evidence of risk compensation following MC is limited to hypothetical models and behavioral evaluations and extended follow-up in the RCT populations (Agot et al., 2007; Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007a; Kong et al., 2012; Mattson et al., 2008). In the analysis of behavioral change before the procedure and throughout follow-up in circumcision and control groups, the Rakai trial found no consistent evidence of risk compensation (Gray et al., 2007a). Extended follow-up confirmed the lack of risk compensation over a longer period of observation, as well as in newly circumcised control participants (Gray et al., 2012). In Orange

Farm, circumcised participants reported a higher mean number of sexual contacts during 4–12 months and 13–21 months of follow up (Auvert et al., 2005). Despite this higher risk behavior, the protective effect of circumcision was not changed after adjustment for sex behavior and was remarkably consistent with results of the two other trials (Siegfried et al., 2009). In Kisumu, risky behaviors declined in both circumcised and uncircumcised men over time, but differences in the rate of the decline were observed (Bailey et al., 2007). Most notably, the proportion of men reporting two or more sex partners declined steadily in the uncircumcised controls, but declined and stabilized after six months in circumcised participants. A unique in-depth study specifically addressing risk compensation in a sub-set of Kisumu trial participants found no evidence of increase in sexual risk behavior over one year of follow-up based on two measures: a composite scale of 18 risk behaviors and laboratory diagnosed sexually transmitted infections (STIs) (Mattson et al., 2008). Lastly, an independent non-randomized prospective cohort study conducted in a rural community near Kisumu before trial results were available also found no evidence of risk compensation up to one year after the procedure (Agot et al., 2007).

The lack of risk compensation reported by these studies is encouraging, but should be interpreted with caution. The perception of HIV risk and associated behavior modification could change considerably in the context of large-scale VMMC implementation in which counseling and follow-up are less intense and promotional messages are designed to increase demand. The assessment of risk compensation outside the experimental setting has been set as an operations research priority (Weiss et al., 2010; WHO, 2011). However, due to slower than anticipated scale-up, little empirical data on risk compensation related to a wide-scale VMMC implementation has been available to date.

Here we report the results of the first large prospective observational study of risk compensation following male circumcision in the context of a successful national VMMC initiative. Our main study objective was to assess change in HIV risk perception and sexual risk behavior in men before and after being circumcised, and to compare these newly circumcised men to uncircumcised controls over 24 months of follow-up.

B. Methods

1. Participants

By all measures, Kenya's VMMC program for HIV prevention is the world's most successful (Weiss et al., 2010; WHO, 2011). Started in 2008, the VMMC program was initially focused on the non-circumcising Luo population of Nyanza Province. Nyanza suffers the highest HIV prevalence in Kenya, and contributes approximately one-third of the nation's new infections (NACC and NASCOP, 2012). Following just two years of program activity over 390,000 circumcisions were performed, 82% of which were done in Nyanza province alone. As a result, the prevalence of circumcised Luo males in Kisumu, the urban center of the province, rose from just 11% in 2006 to 38% in 2011 ("Progress in voluntary medical male circumcision service provision—Kenya, 2008–2011," 2012; Westercamp et al., 2011; Westercamp et al., 2010).

The current study took place in two rural (Nyando, Kisumu West) and one urban (Kisumu East) districts of Nyanza Province. Study information was distributed as posters at nine participating governmental health facilities, by word of mouth, in community outreach, and by community sensitization through chief's barazas (community meetings) and other local meetings. Men seeking VMMC services at study health facilities were recruited into the circumcision (intervention) group and went through screening, consent, enrollment and baseline visit procedures before circumcision. Following baseline study procedures, men proceeded through the

normal VMMC process, including clinical informed consent for the procedure, risk-reduction counseling, and the circumcision procedure itself carried out by specialized VMMC surgical teams operating at the respective health facilities. Uncircumcised controls were recruited mainly through community outreach, and were offered the procedure but decided to remain uncircumcised. Controls were frequency-matched on age and residence (community) to circumcision group participants. To be eligible for participation in either group, men had to be 18 to 35 years of age, be uncircumcised at enrollment, and reside within the study area with no plans to relocate within the next two years. Eligibility was not restricted by HIV status or level of sexual activity. For controls, intention to become circumcised was assessed. If a participant expressed intent to become circumcised within the next six months, he was encouraged not to enroll but to join the circumcision group when scheduled for the procedure. Any participant who crossed over from one study group to the other was requested to continue active participation in the study.

Recruitment began in late November 2008, concurrent with the launch of the VMMC program, and ended in April 2010. Participants were consented in their language of choice (English, Dholuo, or Kiswahili) by male research assistants certified in ethical research conduct and trained in ascertainment of MC status through visual examination. Participants received travel/income reimbursement of 200 Kenyan shillings (about $2.50) for each completed study visit. Study follow-up was finished in January of 2012.

Ethical approval was obtained from the Kenyatta National Hospital Ethics and Research Committee and the University of Illinois at Chicago Institutional Review Board #3.

2. **Procedures**

Study participants were asked to return for follow-up at six, 12, 18, and 24 months after enrollment. At all study visits participants underwent visual examination to confirm

circumcision status, completed the study questionnaire, were offered HIV risk reduction counseling available at each health facility, and were exposed to HIV educational videos playing in the study waiting bay. The window period for each follow-up was plus-or-minus three months with visits considered missed three months after the scheduled study visit date. Tracing procedures were initiated for any participant more than one week late for a follow-up visit.

Study questionnaires were administered through ACASI modules, developed in three languages (English, Dholuo, and Kiswahili). An equivalent paper-based questionnaire was used at participant request or in cases of power outage at study facilities. In total, 30% of questionnaires were completed on paper requiring database entry, and approximately 75% of these were double-entered for quality control. The study questionnaire included sections assessing sociodemographic characteristics, beliefs, and attitudes toward MC; sexual behavior; HIV risk perception; history of STIs; and sexual health, function, and satisfaction. Circumcised men completed an additional set of questions regarding their experiences after circumcision.

3. **Statistical analyses**

Our targeted sample size of 3,200 (1,600 in each group) allowed for the detection of effect sizes between 0.1 and 0.2, corresponding to 5%–10% difference in sexual behaviors between groups. This assumes two years of follow-up under constant group effect and under group by linear time interaction scenarios. We allowed for 10% attrition at each follow-up, 20% crossover (non-adherence to group self-assignment), and repeated measures correlation of 0.5–0.7 (Hedeker et al., 1999). Significance was considered at $p \leq .05$ with 80% power and the covariance structure was assumed constant. Sample size and power calculations were done in RMASS2 statistical power analysis program (Hedeker and Barlas, 1999).

Behavioral outcomes were assessed in longitudinal analyses with random intercept mixed-effect models and included: having sex in the past six months, condom use at last sex, last sex with a casual partner, condom use at last sex if it was with a casual partner, multiple sexual partners (more than one) in the past six months, multiple (more than one) partners within the same 30-day period, and exchanging sex for money or gifts (transactional sex) in the past six months. Self-assessed risk perception was determined by asking: "What do you think are your chances of getting HIV/AIDS?" Men choosing "moderate" or "great" were categorized as having high HIV risk perception.

All outcomes were binary, and each outcome model included the sequential visit number (treated as continuous time), circumcision status (group) and the interaction of time and group. Circumcision status at each study visit was treated as time-variant covariate, with baseline status set according to self-selected group assignment at enrollment. Men enrolled in the control group that became circumcised during their study participation were considered crossovers to the circumcision group (i.e., circumcised crossovers). Men who were enrolled in the circumcision group, but did not undergo MC during their time in the study were considered crossovers to the control group (i.e., uncircumcised crossovers). Circumcision was assumed to have occurred within the six months prior to the first visit the participant was confirmed as circumcised.

We used Pearson $\chi 2$ tests for categorical variables and Kolmogorov-Smirnov two-sample test for non-normally distributed continuous variables to detect baseline differences between circumcision and control group participants, between men who did and did not return for follow-up after the baseline visit, and between crossovers and non-crossovers. Sensitivity analyses to determine the effect of missed visits on behavioral outcomes were performed through Poisson and logistic regressions modeling the predictors of missingness, as well as pattern-mixture mixed-

effect models to assess differences in outcomes by groups with different missed visit patterns, compared to men with complete follow-up. Fixed covariates were included in mixed-effect models to allow consideration of baseline adjustments to the group effect. Age and demographic variables that significantly differed by study group (i.e., marital status, education, income, ethnicity, and employment status) were considered independently for association with sexual behaviors, as well as adjustments to the group effect. Final model selection was done using backward elimination, with retention of time, group effect, and age in the model regardless of statistical significance and adjustment for other independent predictors if significant at $p<.05$. All analyses were done in SAS version 9.2 using PROC NLMIXED for binary mixed-effect models (SAS Institute Inc, 2008).

C. **Results**

Of the 3,627 men who presented for screening, 91% (3,299 out of the total 3,627 men; noted as 3,299/3,627 from here on) were eligible for participation and 97% (3,186/3,299) agreed to participate. By design, our study groups were balanced with 1,588 men initially self-selecting into the intervention (circumcision) group and 1,598 enrolling as controls (Figure 2).

Approximately 5% of each group interviewed at baseline (intervention: 79/1,588, control: 74/1,598) were lost to follow-up prior to any follow-up visit and were excluded from longitudinal analysis. Those initially lost to follow-up were less likely to be Luo ($p=.03$), to have ever had sex ($p=.01$), and to have been sexually active in the six months prior to interview ($p=.02$) compared to men returning for at least one follow-up visit. Participants missing a study visit could continue study participation at a subsequent visit resulting in a complex study flow (Figure 2). Basic follow-up rates by study visit were 70% (6 months), 81% (12 months), 82% (18 months), and 84% (24 months).

Among men enrolled in the control group, 21% (332/1,598) chose to become circumcised during study follow-up (circumcised crossovers). Among the intervention group, 8%(133/1,588) did not become circumcised (uncircumcised crossovers). The comparison of men initially selecting into the intervention group and men initially refusing, but later accepting circumcision, offers a comparison between VMMC program early and later adopters. Sixty-five percent of later adopters became circumcised within 12 months of enrollment in the study. Compared to early adopters, later adopters tended to be younger (median age 19 versus 20, p=.001), perceive themselves at less risk of HIV (26% versus 32%: moderate/high risk, p=.04), were more likely to have used a condom at last sex (57% versus 47%, p=.005), and were more likely to have sex that was transactional (30% versus 22%, p=.03).

A sensitivity analysis comparing models restricting crossovers from consideration showed no significant differences with analyses using the full dataset. All models presented here are based on the full sample with circumcision treated as at time-varying covariate. Additional sensitivity analyses showed that controlling for patterns of missed study visits did not change the magnitude or the significance of association between circumcision and behavioral outcomes.

Demographically, men choosing not to become circumcised (controls) at baseline were significantly more likely to be Luo (p<.001), less educated (p<.001), and more likely to be currently employed (p<.001) and married (p<.001) (Table III). Men who chose to become circumcised at the time of enrollment considered themselves at higher personal risk of HIV (p=.008); however, the two groups did not significantly differ in any measure of sexual history or HIV risk behavior.

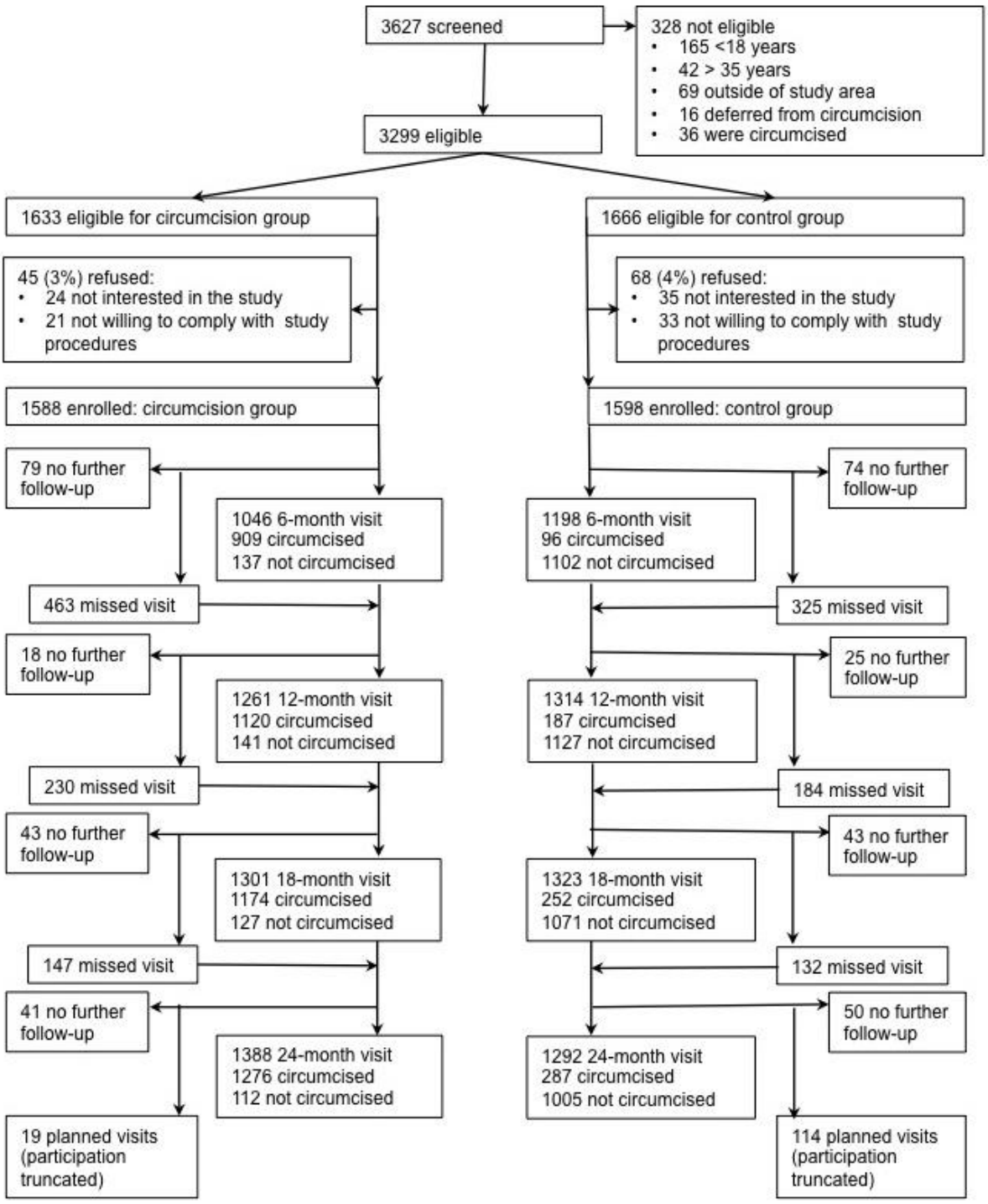

Figure 2: Study profile[a]

[a] Note: For each follow-up visit, participants were classified as "no further follow-up" if they were eligible for that study visit but passed the window period and did not return for any subsequent visit. Participants were classified as "missed visit" if they passed the window period for that visit, but returned for later follow-up visits. Participants who were expected for the last study visit, but were unable to return for follow-up due to the termination of the data collection were classified under "truncated participation."

TABLE III. ENROLLMENT CHARACTERISTICS OF STUDY PARTICIPANTS

	Circumcision group [a, b]	Control group [a,b]	p< [c]
Demographic characteristics			
Age in (years (IQR; range; N))	20 (19–24; 18–35; 1588)	20 (19–24; 18–35; 1598)	0.08
Ethnic group			0.001
Luo	1547 (97%)	1585 (99%)	
Other	41 (3%)	13 (1%)	
Educational level			0.001
Primary and less	367 (23%)	510 (32%)	
Any secondary or higher	1221(77%)	1088 (68%)	
Employment status			0.001
Employed	421 (27%)	584 (37%)	
Unemployed	1167 (73%)	1014 (63%)	
Marital status			0.001
Single	1097 (69%)	994 (62%)	
Married or living as married	491 (31%)	604 (38%)	
Sexual history with women			
Ever had sex			0.13
Yes	1382 (87%)	1419 (89%)	
No	206 (13%)	179 (11%)	
Age at first sex (years)	16 (15–18; 9–30; 1380)	16 (15–18; 9–29; 1417)	0.66
Sexual intercourse in past 6 months (ever sexually active only)			0.54
Yes	1032 (75%)	1074 (76%)	
No	350 (25%)	345 (24%)	
Number of partners in past 6 months (ever sexually active only)			0.13
None	350 (25%)	345 (24%)	
One	502 (36%)	564 (40%)	
2+	393 (29%)	398 (28%)	
Unsure / Refused to answer	137 (10%)	112 (8%)	
Number of partners lifetime	3 (2–6; 1–123 1193)	3 (2–6; 1–122; 1270)	0.73
Gave gifts or money to a woman in exchange for sex in the past 6 months			0.14
Yes	246 (24%)	284 (26%)	
No	784 (76%)	790 (74%)	
Refused to answer	2 (0%)	0 (0%)	
Had sex with 2 or more partners in the same 30-day period in the past 6 months			0.36
Yes	279 (27%)	261 (24%)	
No	750 (73%)	810 (76%)	
Refused to answer	3 (0%)	3 (0%)	
Drank alcohol at last time having sexual intercourse (ever sexually active only)			0.43
Yes	186 (13%)	211 (15%)	
No	1129 (82%)	1154 (81%)	
Unsure / Refused to answer	67 (5%)	51 (4%)	
Used condom at last time having sexual intercourse (ever sexually active only)			0.52
Yes	613 (44%)	660 (47%)	
No	693 (50%)	694 (49%)	
Unsure / Refused to answer	75 (6%)	65 (4%)	

ENROLLMENT CHARACTERISTICS OF STUDY PARTICIPANTS

	Circumcision group	Control group	p<
Last sexual intercourse was with regular partner (ever sexually active only)			0.10
Yes	1014 (73%)	1082 (76%)	
No	282 (20%)	271 (19%)	
Unsure / Refused to answer	86 (5%)	66 (5%)	
Sexual history with men			
Ever had sexual relations with a boy or man			0.41
Yes	43 (3%)	35 (2%)	
No	1542 (97%)	1558 (98%)	
Refused to answer	3 (0%)	5 (0%)	
Perception of HIV risk			
Self-perceived chances of getting HIV			0.001
No chance or small chance	1118 (70%)	1209 (76%)	
Moderate or great chance	470 (30%)	389 (24%)	
Sexually transmitted infections			
Ever treated for STI (sexually active only)			0.43
Yes	216 (16%)	222 (16%)	
No	1059 (77%)	1105 (78%)	
Refused to answer	107 (8%)	92 (6%)	
Ever tested for HIV			0.99
Yes	948 (60%)	956 (60%)	
No	636 (40%)	638 (40%)	
Refused to answer	4 (0%)	4 (0%)	

[a] Sample sizes vary in questions based on past or recent sexual activity.

[b] Data are median (IQR; range) for continuous data, or n (%) for categorical data.

[c] P values are based on Kolmogorov-Smirnov two-sample test for non-normally distributed continuous data and Pearson's $\chi 2$ test for categorical data for comparison of circumcision and control group.

The proportion of men reporting sexual activity in the past six months increased equally in both the intervention and control groups over the follow-up period (group effect$_{adj}$ p=.86, Table IV, Figure 3a). However, a significant interaction of study group and age (p=.02; Table IV) indicated possible differences in this relationship by age group. Stratifying by age (groups: 18–24 years, 25–29 years, and 30–35 years) and controlling for marriage and employment, we note an equivalent (group p_{adj}=.13) increase (p_{adj}<.001) in sexual activity in the youngest group, no significant change (p_{adj}=.29) in 25- to 29-year olds, and an increase in sexual activity for circumcised men only (group p_{adj}=.01, time p_{adj}=.03) in the oldest, 30- to 35-year-old, group (Figure 3b–3d).

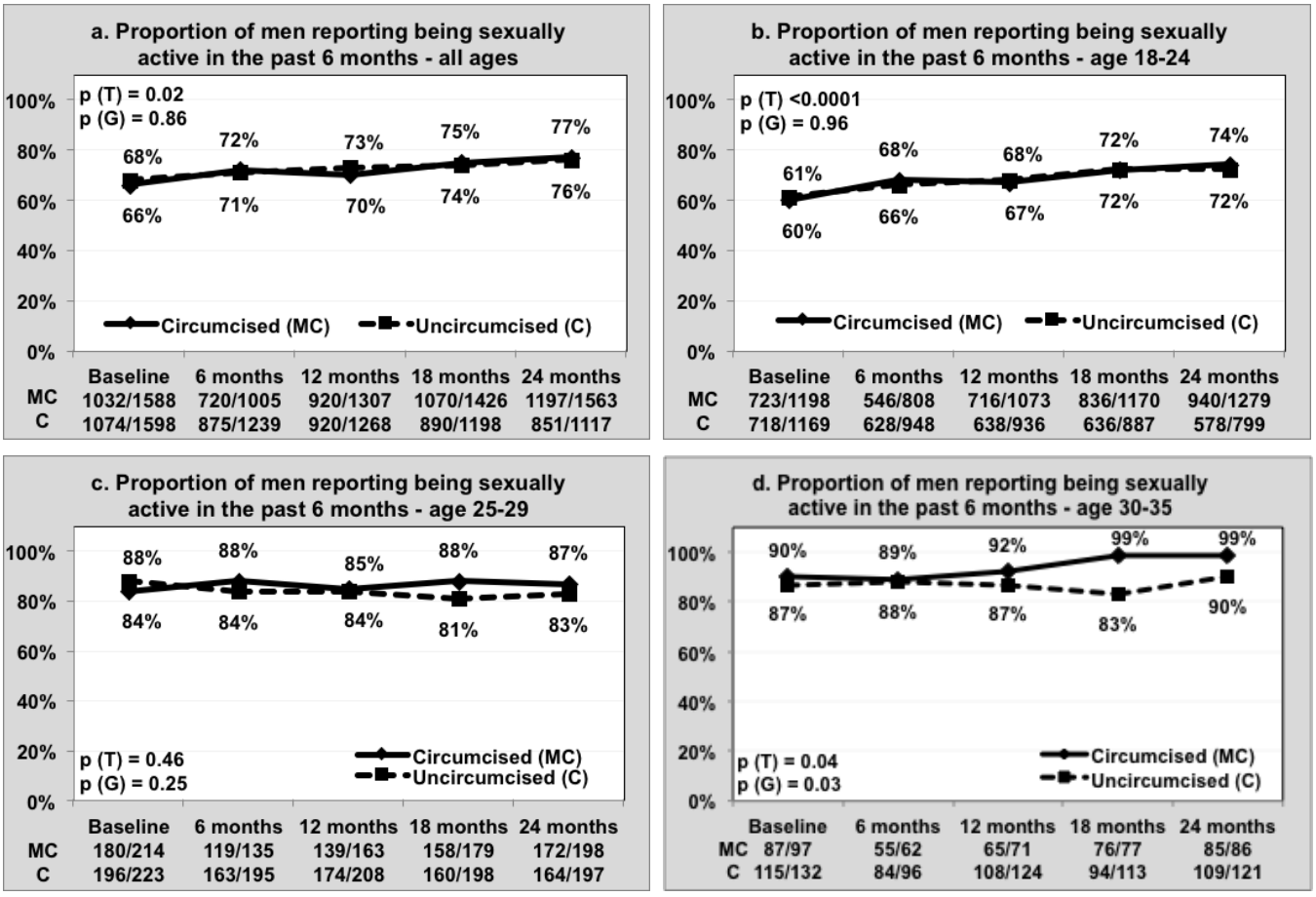

Figure 3. Observed proportions of men reporting sexual activity in the past six months over 24 months of follow-up, by circumcision and age[a]

[a] Note: p(T) is the p value for the linear time trend; p(G) is the p value for the group effect (overall difference between the circumcised and uncircumcised men); and p(GxT) is the p value for the group by time interaction, when applicable. All p values are based on unadjusted analysis. Below the horizontal axis labels are the raw numbers corresponding to the graphically represented proportions (MC – circumcised men; C – uncircumcised men or controls reporting behavior).

TABLE IV. CHANGE IN HIV RISK PERCEPTION AND SEXUAL BEHAVIOR AMONG CIRCUMCISED AND UNCIRCUMCISED MEN OVER 24 MONTHS OF FOLLOW-UP: RESULTS OF ADJUSTED MIXED-EFFECT MODELS

Covariates	Estimate	SE	p ≤
Self-perception of high or moderate chance of acquiring HIV			
Time (visit number)	-0.054	0.025	0.032
Group (circumcision status)	0.477	0.121	0.001
Time by group interaction	-0.231	0.036	0.001
Age (continuous)	0.033	0.010	0.001
Employment (yes / no)	-0.204	0.067	0.002
Marriage (yes / no)	0.159	0.067	0.017
Sexually active in the past 6 months			
Time (visit number)	0.133	0.017	0.001
Group (circumcision status)	-0.799	0.431	0.064
Age (continuous)	0.094	0.015	0.001
Age by group interaction	0.047	0.020	0.020
Employment (yes / no)	0.797	0.070	0.001
Marriage (yes / no)	1.381	0.072	0.001
Used condoms last time had sex (sexually active men only)			
Time (visit number)	0.102	0.024	0.001
Group (circumcision status)	-0.376	0.120	0.002
Time by group interaction	0.140	0.034	0.001
Age (continuous)	-0.101	0.010	0.001
Education (any secondary or above)	0.696	0.085	0.001
Employment (yes / no)	-0.424	0.062	0.001
Marriage (yes / no)	-1.036	0.062	0.001
Last sex was with a casual partner (sexually active men only)			
Time (visit number)	-0.152	0.020	0.001
Group (circumcision status)	0.107	0.071	0.131
Age (continuous)	-0.023	0.010	0.027
Marriage (yes / no)	-1.295	0.079	0.001
Used a condom during last sex with a casual partner			
Time (visit number)	0.275	0.047	0.001
Group (circumcision status)	-0.175	0.147	0.234
Age (continuous)	0.094	0.024	0.001
Education (any secondary or above)	0.740	0.181	0.001
Sex with ≥2 partners in the same 30-day period in the past 6 months			
Time (visit number)	-0.176	0.021	0.001
Group (circumcision status)	0.108	0.077	0.163
Age (continuous)	0.016	0.010	0.098
Exchanging money or gifts for sex in the past 6 months			
Time (visit number)	-0.285	0.023	0.001
Group (circumcision status)	-0.100	0.085	0.237
Age (continuous)	-0.005	0.012	0.664
Education (any secondary or above)	-0.575	0.103	0.001
Employment (yes / no)	0.298	0.081	0.001
Marriage (yes / no)	-0.258	0.082	0.002
Two or more partners in the past 6 months			
Time (visit number)	-0.141	0.018	0.001
Group (circumcision status)	-0.073	0.068	0.285
Age (continuous)	-0.017	0.009	0.059
Education (any secondary or above)	-0.222	0.081	0.006

Despite this overall increase in sexual activity, all other sexual risk behaviors declined (Figures 4b, 4d, 4e, and 4f) and condom use increased (Figures 4a and 4c) over 24 months of follow-up. The most dramatic declines were observed in transactional sex in the last six months (26% to 12%), most recent sex with a casual partner (20% to 12%), and having multiple sex partners (within a 30-day window) in the last six months (26% to 16%). These declines were not associated with circumcision status (Table IV). Overall condom use at last sex, regardless of partner type, increased significantly in both circumcised and uncircumcised groups (Figure 4a), but showed more pronounced gains in those circumcised (relative increase of 30% in circumcised versus 6% in uncircumcised; group by time interaction $p<.001$). This increase was more pronounced when restricted to condom use with casual partners, but did not differ by study group (Figure 4c, Table IV).

The proportion of men reporting last sex with a casual partner decreased over time in both groups (Figure 4b, Table IV). Reflecting the relative youth of study participants, the proportion of men becoming married increased significantly over the follow-up period. Adjusted for age, circumcised men had relatively greater increase in proportion married (26% versus 21% increase; $p<.001$), but gains in both groups were significant.

At baseline, men seeking circumcision services (intervention group), considered themselves at higher risk of HIV than men in the control group (30% versus 24%; $p=.001$, Table III). Over the two years of follow-up, uncircumcised men had relatively stable self-perception of HIV risk (Figure 5). Men who became circumcised, however, had a precipitous decline in perceived risk from 30% considering themselves at high risk to just 14% by study exit (group by time interaction $p=.001$: Table IV).

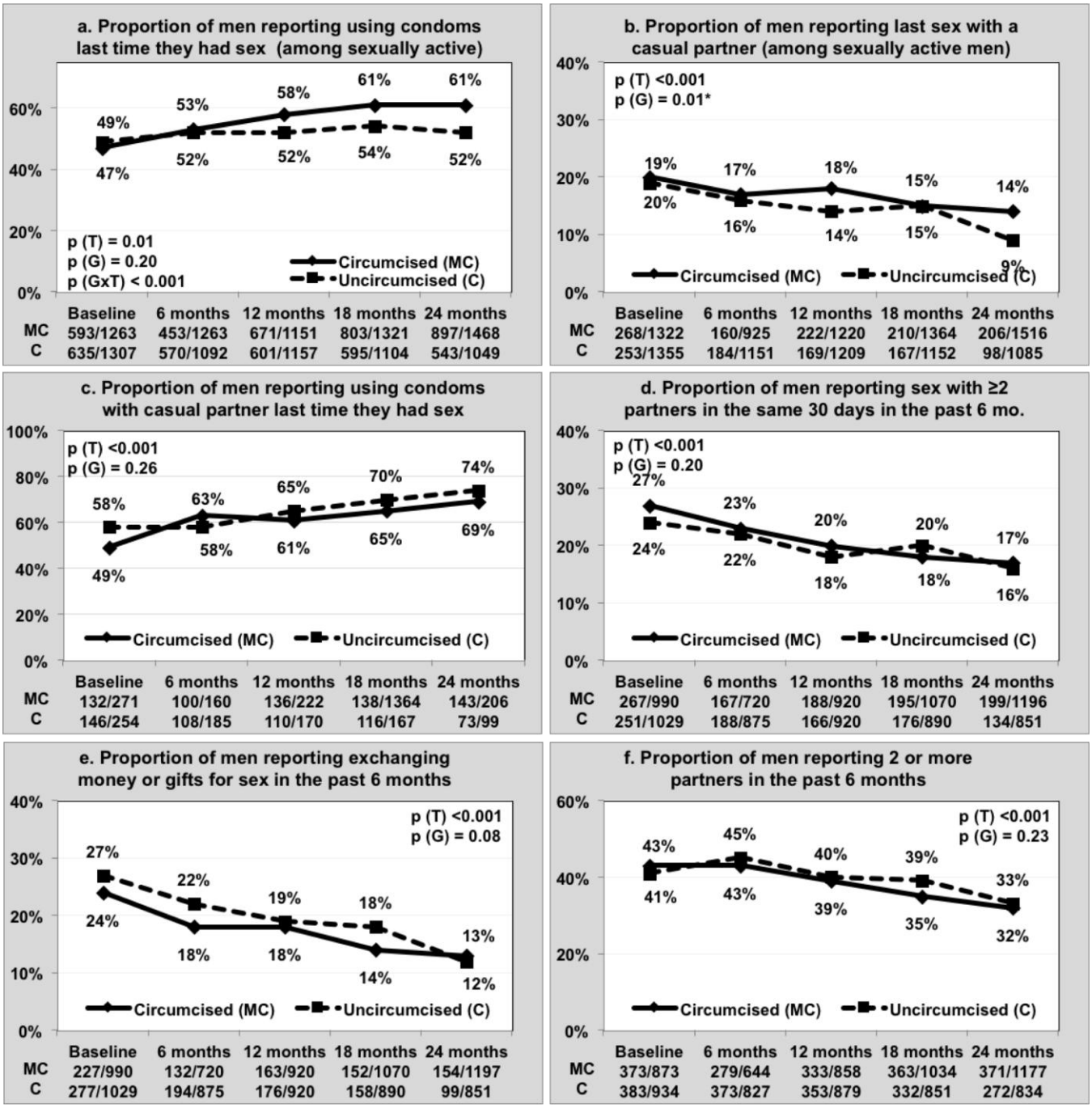

Figure 4. Observed trends of examined behavioral variables by circumcision status over 24 months of follow-up [a]

[a] Note: p(T) is the p value for the linear time trend; p(G) is the p value for the group effect (overall difference between the circumcised and uncircumcised men); and p(GxT) is the p value for the group by time interaction, when applicable. All p values are based on unadjusted analysis (* p value that is no longer significant in the adjusted analysis). Below the horizontal axis labels are the raw numbers corresponding to the graphically represented proportions (MC – circumcised men; C – uncircumcised men or controls reporting behavior).

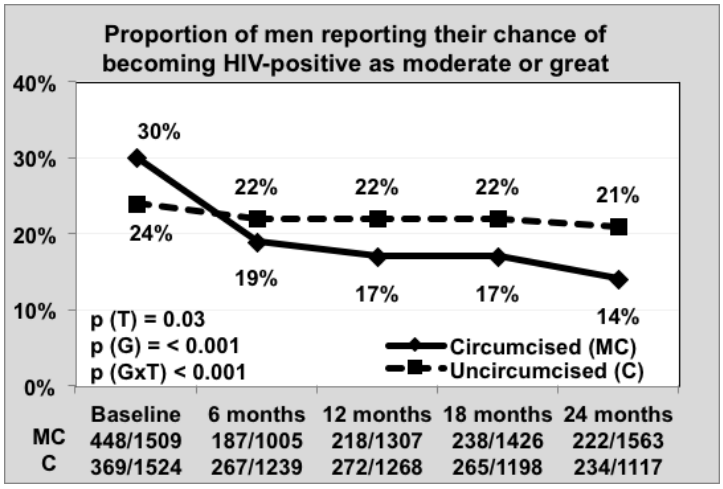

Figure 5. Observed change in risk perception by circumcision status over 24 months of follow-up[a]

[a] Note: p(T) is the p value for the linear time trend; p(G) is the p value for the group effect (overall difference between the circumcised and uncircumcised men); and p(GxT) is the p value for the group by time interaction. All p values are based on unadjusted analysis. Below the horizontal axis labels are the raw numbers corresponding to the graphically represented proportions (MC – circumcised men; C – uncircumcised men or controls reporting behavior).

D. **Discussion**

Risk compensation could significantly reduce the impact of VMMC programs (Cassell et al., 2006; Kalichman et al., 2007b) and, if of sufficient magnitude, has the potential to completely negate the protective effect of circumcision against HIV (White et al., 2008). Research designed to monitor post-circumcision risk compensation over time, in the context of active promotion of VMMC as an HIV prevention strategy, has been set as a high priority (Weiss et al., 2010; White et al., 2008). This is the first study of longitudinal change in HIV-associated risk behaviors in men before and after circumcision in the context of a large population-level VMMC program. We observed no evidence of behavioral risk compensation over 24 months of follow-up. Further, there

is evidence that men exposed to the VMMC program, both as circumcised clients and through informational messages as study controls, meaningfully shifted towards safer behaviors. This behavioral reduction in risk was noted in all sexual risk behaviors examined, including increased condom use. The only behavior that showed an increase over time was sexual activity in the past six months, largely driven by the youngest age group (18–24) that had similar increases in both circumcised and uncircumcised men.

That men are likely to increase their risk-taking behavior in response to a perceived reduction in risk following circumcision has formed a prevalent assumption for a wide variety of stakeholders. In addition to the HIV prevention community (Cassell et al., 2006; Kalichman et al., 2007b; Kalichman et al., 2007a; WHO/UNAIDS, 2007), the potential dangers of risk compensation have been expressed by politicians ("Mad rush to be circumcised," 2008), healthcare providers (Milford et al., 2012), those involved with international VMMC organizations (Reed et al., 2012), and HIV advocacy groups (AIDS Vaccine Advocacy Coalition, 2007). At the community level, MC acceptability and feasibility studies often noted that concerns of risk compensation (expressed as the fear that circumcision will lead to sexual promiscuity, adultery, and decrease gains in condom use) could act as a barrier to community acceptance of the intervention (Bailey et al., 2002; Kelly et al., 2012; Ngalande et al., 2006; Rain-Taljaard et al., 2003). The results of our study are not consistent with these concerns or with assumptions of moderate-to-high risk compensation used in the modeling studies projecting the long-term effect of VMMC on HIV at the population level (Alsallaq and Abu-Raddad, 2008; Gray et al., 2007b; Hallett et al., 2008; Nagelkerke et al., 2007; Njeuhmeli et al., 2011; White et al., 2008).

Our results do, however, strongly support previous empirical findings of a lack of risk compensation or even the reduction in risky behaviors in men circumcised for HIV/STI

prevention. Previous research includes information collected during the RCTs (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007a), more detailed evaluation of sexual behaviors in trial participant subgroups (Mattson et al., 2008), in extended trial follow-up (Kong et al., 2012), and in a non-randomized study before trial conclusion (Agot et al., 2007). The consistent lack of risk compensation found up to date has been discounted as inconclusive due to the following limitations: (1) trial participants were provided with continuous and rigorous risk-reduction counseling as part of the trial design that could be responsible for the observed behavioral changes; and (2) due to the timing of this study, participants could not be certain whether circumcision was protective against HIV. Our findings are not subject to these limitations, and confirm and decisively the lack of significant HIV risk behavior increases in newly circumcised men in the context of a promoted and visible VMMC program.

To our knowledge, this is the first study to assess risk compensation associated with MC in a setting of generalized VMMC scale-up. Information about the benefits and risks of circumcision was widely available, and men enrolled in the study were allowed to make the personal decision to become or not to become circumcised without impacting study participation. This is in contrast to previous studies assessing MC-related risk compensation using hypothetical scenarios or the perception of change only after men have become circumcised (Andersson and Cockcroft, 2012; Lissouba et al., 2011; Westercamp et al., 2012a; Westercamp and Bailey, 2007).

Decline in condom use is the most consistently expressed concern regarding VMMC promotion and uptake. Specifically, the perception is that circumcised men, considering themselves armed with an “invisible condom” will be less inclined to, and women less able to negotiate, condom use (Andersson et al.,, 2011; Crosby et al., 2012; Hankins, 2007; Kalichman et al., 2007b). In contrast, qualitative research in newly circumcised men has repeatedly revealed the

view that circumcised men find condoms easier and more comfortable to use once the foreskin has been removed (Riess et al., 2010), and a modest increase in condom use was observed in the Kisumu trial (Bailey et al., 2007). No changes in condom use were noted in other newly circumcised cohorts (Agot et al., 2007; Gray et al., 2012; Gray et al., 2007a; Kong et al., 2012). In our study, we observed that both newly circumcised men and uncircumcised controls increased their condom use as the study progressed, with moderately more significant increase in those circumcised. This suggests that men circumcised through the VMMC program were no less likely, and perhaps more likely, to use a condom when compared to age-matched uncircumcised controls from the same community.

Two cross-sectional random-household surveys completed in 2008 and 2011 assessed population-level impacts of the VMMC program in Kisumu. At the population level, HIV-related risk behaviors showed no significant increase, and measures of condom use did increase between 2008 and 2011 (Westercamp et al., 2011). These results are remarkably consistent with our findings and suggest that a wider secular change may explain in part the patterns of decreased risk behaviors found in our study. Additionally, surveys found no association between VMMC uptake and HIV high-risk behaviors, also consistent with our findings.

More than 20% of men initially declining circumcision (control group) did ultimately become circumcised during the two years of study follow-up. This expected crossover phenomenon was built into our study design, and can be seen as a reflection of secular increases in VMMC mobilization efforts and overall program success during the course of the study. Compared to crossovers, the earliest adopters tended to be older and perceive themselves at higher risk of HIV, consistent with another study in this region (Agot et al., 2004). This suggests that men motivated to early adoption of VMMC may represent a higher-risk group. Planners and

implementers of VMMC programs should anticipate this and ensure that high-quality HIV counseling is a priority throughout the commencement and often-rapid initial scale-up of services in each population.

Drawing conclusions regarding the mechanisms responsible for our findings is outside of the scope of this study. However, several possibilities can be suggested. Decreases in high-risk behaviors may relate directly to the VMMC counseling provided to clients as part of the integrated HIV prevention package (Republic of Kenya Ministry of Public Health & Sanitation, 2009). This would primarily apply to the circumcised men; however, all participants in our study were exposed to some HIV risk-reduction education through their participation. A high acceptance (nearly 90% in 2012) of HIV counseling and testing services among men undergoing circumcision in Kenya ("Progress in voluntary medical male circumcision service provision—Kenya, 2008–2011," 2012) demonstrates the VMMC programs represent a potential avenue to increase access and uptake of VCT, as well as linking those who are HIV-positive to care, in male populations known for low utilization of VCT services (NACC and NASCOP, 2012; National AIDS and STI Control Programme, 2008). This may be an important additional benefit of VMMC programs in light of growing evidence that VCT can reduce HIV risk (Fonner et al., 2012).

It is also possible that the behavioral changes observed in circumcised men may reflect a form of cognitive dissonance (Festinger, 1962)—the psychological state of conflict between attitudes, beliefs, or behaviors resulting in realignment to decrease discomfort caused by the conflict—in which men reevaluate their behaviors in light of the personal investment involved in getting circumcised. These ideas have been noted in qualitative interviews with newly circumcised men (Grund and Hennink, 2012; Riess et al., 2010), and may have value in leveraging further engagement of newly circumcised men in their sexual/ reproductive health. Additional analysis

evaluating the relationship between risk perception and behaviors (results not shown) indicated that perception of HIV risk is driven by the self-evaluation of risky behaviors (i.e., in our study men engaging in higher-risk behaviors perceived themselves at higher risk and men engaging in lower-risk behaviors perceived themselves at lower risk) as opposed to perception of risk leading to change in behaviors (e.g., men perceiving themselves at higher risk changed their behaviors towards a safer direction).

The decrease in sexual risk behaviors in uncircumcised participants that did not benefit from the counseling provided during the VMMC procedure and did not receive the intervention may reflect a secular change in the population generally exposed to the VMMC campaign. Such persistent and repeated HIV-related messaging designed for VMMC promotion may act to bring HIV back to the fore and reinvigorate the risk reduction efforts in population as a whole. Other factors that could have influenced the behavioral change at the community level are increased efforts to provide HIV counseling and testing in this population, leading to greater exposure to behavioral risk reduction information and increased enrollment in HIV care.

There are a number of limitations in this study that should be considered. Both circumcision and control group participants were self-selected to enroll in the study. While we utilized age and residence matching to enhance the comparability of the two groups, it is possible that the motivation to become circumcised represents fundamental differences between our study groups, limiting comparability. We found that at baseline the two groups differed in several ways (i.e., in several demographic characteristics, but not in sexual risk behaviors). However, because we interviewed men before and after the procedure, we were able to temporally compare men to themselves. Our study started concurrently with the initiation of the VMMC scale-up in Kenya, with study enrollment taking place only during the first year of program activities. Therefore, the

circumcised men are likely to be representative of relatively early adopters of MC in Nyanza and may not reflect the experiences of men circumcised later. Given our analysis of study group crossovers, it may be that the HIV risk profile of participants will differ as the VMMC program matures and strives to reach broader participation. All behavior and sexual history information were by self-report, and were subject to social desirability and recall biases. We attempted to limit these biases through the use of computer assisted self-interviewing and study staff trained in sensitive face-to-face interview techniques (Langhaug et al., 2010; Mensch et al., 2003; Phillips et al., 2010; Vu et al., 2012). Lastly, men were followed for two years after circumcision/enrollment; longer-term behavior changes were not assessed.

E. **Conclusion**

Our large prospective study carried out concurrently with the scale-up of the Kenya national VMMC program found no evidence of risk compensation in circumcised men. To the contrary, both circumcised and uncircumcised men significantly reduced their HIV risk behaviors over 24 months of follow-up. In light of our results and those of previous studies in varying populations, concerns about risk compensation in the context of VMMC programs for HIV prevention should not impede the widespread scale-up of the VMMC services (Agot et al., 2007; Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007a; Kong et al., 2012; Mattson et al., 2008; Westercamp et al., 2011). Previously, modeling of the impact of widespread VMMC programs has included sensitivity analyses of the hypothetical effect of only increases in risk behaviors after circumcision (Alsallaq et al., 2009; Andersson et al., 2011; Dushoff et al., 2011; Gray et al., 2007b; Hallett et al., 2011; Hallett et al., 2008; Kahn et al., 2006; Nagelkerke et al., 2007; Njeuhmeli et al., 2011; White et al., 2008; Williams et al., 2006; UNAIDS/WHO/SACEMA, 2009). It would now be most prudent for models to include scenarios of safer sexual behaviors occurring in the context of

VMMC programs, as modeling often drives national policy debate and funding projections (Njeuhmeli et al., 2011; UNAIDS/WHO/SACEMA, 2009). However, in VMMC promotion, as with any partially protective intervention, the educational messages about the effectiveness of the intervention must be carefully balanced with emphasis on continuing overall risk reducing practices.

IV. PENILE COITAL INJURIES DECLINE AFTER MALE CIRCUMCISION: RESULTS FROM A PROSPECTIVE STUDY OF RECENTLY CIRCUMCISED AND UNCIRCUMCISED MEN IN WESTERN KENYA

A. Introduction

The protective effect of circumcision against viral STIs has been well appreciated for more than five decades (Taylor and Rodin, 1975; Barile et al., 1962). The role of the penile foreskin in the transmission of HIV was suggested early (Fink, 1986), just three years after the virus was recognized as the cause of AIDS, and supportive evidence has been accruing since (Simonsen et al., 1988; Siegfried et al., 2005). This inquiry culminated almost 20 years after the initial hypothesis was raised, with the final results of three RCTs of MC for HIV prevention in Kenya (Bailey et al., 2007), Uganda (Gray et al., 2007a), and South Africa (Auvert et al., 2005), demonstrating the protective effect of MC on female-to-male transmission of HIV beyond any reasonable doubt (Siegfried et al., 2009; WHO/UNAIDS, 2007).

While the exact biological mechanism by which MC affords this protection is not known (Dinh et al., 2011), there are a number of plausible explanations based on the cellular composition and environment of the inner foreskin. The earliest hypotheses concerned the gross anatomy of the uncircumcised penis, including the feasibility of potentially infectious secretions being trapped in facilitating conditions beneath the foreskin (Siegfried et al., 2009; Cameron et al., 1989) and the increased surface area of the inner foreskin (Fink, 1986; Kigozi et al., 2009). With the recognition that ulcerative STIs and other causes of genital tract inflammation increase the risk of HIV infection (Freeman et al., 2006; Mayer and Venkatesh, 2011), the association between these infections and circumcision offers additional possible explanation (Gray et al., 2009; Weiss et al., 2006; Porter and Bunker, 2001).

Histologic examination and specific immune responses of the foreskin, and differences in the penile microbiome of circumcised and uncircumcised men offers another set of mechanisms (Price et al., 2010; Fahrbach et al., 2010; Ganor et al., 2010; Zhou et al., 2011). Like most biologic mechanisms, the protective effect of circumcision almost certainly represents a complex system incorporating multiple explanatory factors (Desai et al., 2006; Boily et al., 2008; Anderson et al., 2011; Morris et al., 2012).

One possible foreskin-associated HIV risk factor that is often mentioned, but that has not received attention in empirical research, is the perception that preputial mucosa is comparatively fragile and prone to injury during intercourse (Fink, 1986; Cameron et al., 1989; Simonsen et al., 1988; Stone et al., 1986; Szabo and Short, 2000). One difficulty in determining the role of intercourse-associated mechanical injury to the penis in HIV infection is a lack of consistent terminology or operational assessment. When discussed, mechanical penile injuries are often referred to as minor epithelial disruptions, mild penile trauma, traumatic lesions, or most recently as penile coital injuries, clarifying the integral sexual component (Cameron et al., 1989; Gray et al., 2009; Halperin and Bailey, 1999; Mehta et al., 2010; Mehta et al., 2012b; Szabo and Short, 2000).

Recent research in men participating in the Kenya RCT has shown that penile coital injuries are more commonly reported among uncircumcised men (Mehta et al., 2010), may be an important non-STI cause of genital ulcer disease (GUD) (Mehta et al., 2012a), and increase the risk of *Neisseria gonorrhoeae* (Mehta et al., 2009). Outside of this RCT population there is little information available on coital injury prevalence, associated factors, or related disease susceptibilities.

To increase the understanding of the prevalence and correlates of penile coital injuries in a more general population, we evaluate three types of self-reported penile coital injuries in a

longitudinal community-based cohort of newly circumcised and uncircumcised men in Nyanza Province, Kenya. The objectives of this analysis were (1) to assess the changes in prevalence of penile coital injuries over time and their association with MC; (2) to evaluate the relationship between penile coital injuries and genital sores; and (3) to describe factors associated with penile coital injuries.

B. Methods

1. Study design and participants

The study took place between November 2008 and January 2012 in two rural (Nyando, Kisumu West) and one urban (Kisumu East) district of Nyanza Province, with an objective to examine the sexual health, attitudes, and behaviors of men circumcised through Kenya's national VMMC program. Using a longitudinal cohort design, newly circumcised men were compared to themselves before becoming circumcised and to a matched set of community controls choosing not to become circumcised. Briefly, to participate, men had to be uncircumcised, between the ages of 18 and 35 years old, live within the study area, and have no plans to relocate within the next two years. Eligible men self-selected into the intervention cohort by seeking circumcision services at a VMMC clinic within the study area, and were recruited at the point of circumcision before risk-reduction counseling or the circumcision procedure itself were completed. A control group of eligible men was recruited from the community surrounding each VMMC clinic site and frequency-matched to age and residence (community) of intervention cohort. The controls were given the opportunity to become circumcised before enrollment in the study, but declined.

Participants provided written informed consented in their language of choice (English, Dholuo, or Kiswahili) and were offered 200 Kenyan shillings (about $2.50) for each study visit to

cover travel expenses and loss of income. Ethical approval was obtained from the Kenyatta National Hospital Ethics and Research Committee and the Institutional Review Board of the University of Illinois at Chicago.

2. **Study procedures**

Study participants completed a detailed sexual history and behavioral questionnaire and had their circumcision status visually confirmed by specially trained research assistants at each study encounter: baseline, and six, 12, 18, and 24-month follow-up visits. All participants were uncircumcised at baseline interview. Men who intended to become circumcised were placed in the intervention cohort and proceeded through the normal VMMC clinic flow following baseline study procedures. This VMMC process was independent of the study and followed the Kenyan government VMMC guidelines, including clinical informed consent for the procedure, risk-reduction counseling, HIV testing, and the surgical procedure itself. All study participants were exposed to educational videos containing risk-reduction messages when presenting at one of the central research sites located throughout the three study districts.

Study questionnaires were administered through ACASI modules, developed in English, Dholuo, and Kiswahili. An equivalent paper-based questionnaire was used at participant request or in cases of power outage at study facilities (about 30% of all questionnaires). The questionnaire instrument included items related to sociodemographic characteristics, sexual behaviors, history of STIs, general reproductive health, and sexual function and satisfaction including a set of question addressing penile coital injuries. All data were self-reported and no biological samples were taken.

3. **Statistical analyses**

Self-reported penile coital injuries were determined by asking men, "In the past six months . . . (1) how often during sex did your penis get sore? (2) how often during sex did the skin of your penis get scratches, cuts, or abrasions? and (3) how often during or after sex did the skin of your penis bleed?" The response set was dichotomized for analysis as ever (by grouping always, often, sometimes or rarely) versus never. To facilitate comparison, the penile injury assessment was the same as used by Mehta et al. in their evaluation of penile coital injuries in the Kenyan RCT and, to the extent possible, variables selected for analysis were kept consistent (Mehta et al., 2010). These variables included: condom use at last sex, preference for dry sex, applying substances on penis before sex, self-reported STIs in the past six months, genital hygiene after sex and circumcision status. Demographic (i.e., age, marital status, education, employment, and ethnicity) and behavioral (i.e., number of partners in the past six months) variables were also included.

Circumcision status at baseline was based on the self-selected group at enrollment. Sensitivity analysis excluded all crossovers (men enrolled as controls that later became circumcised or men enrolled in the intervention/circumcision group that did not become circumcised) from our coital injury models and showed no relative difference greater than 10% in effect estimates (i.e., ORs) compared to analysis including crossovers. Thus, crossovers were retained with any impact from misclassification controlled for by treating circumcision status as a time-varying covariate. Pearson $\chi 2$ tests for categorical variables and Kolmogorov-Smirnov two-sample test for non-normally distributed continuous variables were used to detect baseline differences between circumcision and control group participants.

Because reports of abrasions, scratches, or cuts to the penis may represent a misclassification of genital ulcers related to infectious etiologies, we identified men with more chronic GUD symptoms by asking, “Have you experienced any sores on or around genitals in the past six months?” A visual genital exam was done to confirm circumcision status, but did not assess genital health or STI symptomology.

We compared penile coital injuries reported by circumcised and uncircumcised participants using random intercept mixed-effect models for binary outcomes to account for within-subject correlation due to repeated measures. Penile coital injuries were modeled for each participant as the linear slope over time assessed in six-month intervals between the baseline and the 24-month follow-up time. The model included circumcision group (intervention) as a binary variable (0 for control, 1 for circumcision) and a group by time interaction to allow for varying trajectories between the two groups over time. Study time was tested for both linear and quadratic trends. Individual participant intercepts were treated as a normally distributed random effect. To quantify the differences between circumcised and uncircumcised men over the baseline to 24-month interval, we estimated ORs for group effect though mixed-effect models by excluding the circumcision by time interaction. Time was considered as a categorical factor in such models.

All analyses were restricted to men sexually active in the six months preceding the interview. In addition to group and time effect, several covariates were considered in each model. Variables were selected for inclusion in multivariable models based on univariate analyses ($p<.05$) and previous literature. All variables, except for age, education, and ethnicity, were time-variant covariates. Final model selection was done using backwards elimination with study time (visit) and age forced into all models.

To ensure the comparability of our results with studies using other modeling approaches, population-averaged ORs were calculated by transforming our subject-specific regression estimates as described by Hu et al. (Hu et al., 1998). All presented odds ratios are population-averaged. Statistical analysis was performed using SAS v9.2 (SAS Institute Inc, 2008) with the NLMIXED procedure for mixed-effect modeling.

C. Results

1. Sample description

Between November 2008 and April 2010, 3,186 participants agreed to take part in the study representing 97% of the eligible men presenting for participation. By design, study groups were equal (1,588 circumcision group; 1,598 control group). Approximately 5% of both groups (79/1588: intervention and 74/1598: controls) were lost to follow-up after the baseline assessment and were excluded from longitudinal analyses. More than half of the sample (51%; 1639/3186) completed all five visits, 29% (914/3186) returned for four visits, 11% (346/3186) came back for three visits, and 4% (133/3186) completed only two follow-up visits, with attendance patterns similar in both groups. Men not returning for any follow-up were less likely to be Luo (p=.03) and less likely to have ever had sex (p=.01). Follow-up rates were 70% (six months), 81% (12 months), 82% (18 months), and 84% (24 months), with similar loss to follow-up for the two groups.

Our self-selected cohorts represented slightly different populations, with men in the intervention (circumcision) cohort more likely to have a secondary or higher education, be unemployed, and single than the control cohort (Table V). As expected, due to matching, age did not differ by enrollment group. No significant difference between groups was noted in sexual history: with equivalency noted in lifetime number of sexual partners, number of partners in the

last six months, age at sexual debut, and condom use at last sex. Men selecting into the intervention cohort perceived their risk of HIV as greater than men in the control (not circumcising) cohort.

2. **Baseline penile coital injuries**

Among the 2,106 (66%) participants sexually active in the six months prior to baseline, 2,048 (97%) answered the question set regarding penile coital injuries. In total, 1,080 (53%) reported any penile injury, including 905/2,046 (44%) cuts, scratches, or abrasions; 664/2,046 (32%) soreness; and 445/2,042 (22%) bleeding from penile tissues (see Figure 6 for distribution of responses before dichotomization). Among men who reported cuts, scratches, or abrasions at baseline, 408 (45%) also reported bleeding, 510 (56%) complained of soreness, and 29% (259/905) reported both soreness and bleeding. Overall, 259/2,048 (13%) of men reported all three coital injuries, 413/2,048 (20%) two types, and 408/2,048 (20%) reported a single type of penile coital injury. The Venn diagram in Figure 7 shows the overlap between the reports of abrasions, bleeding and pain at baseline.

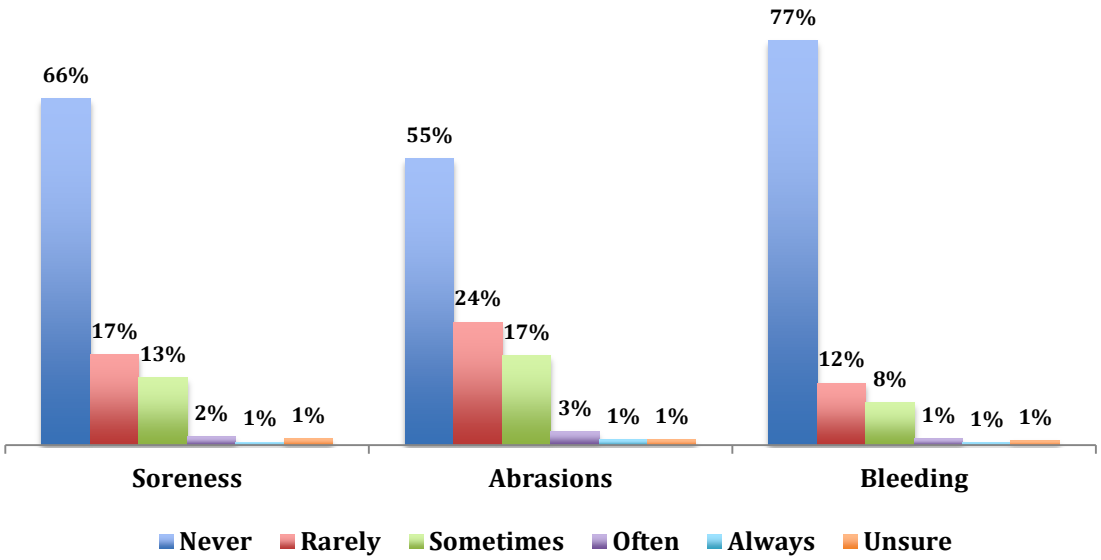

Figure 6. Distribution of responses provided by study participants for the three types of penile coital injuries at baseline.

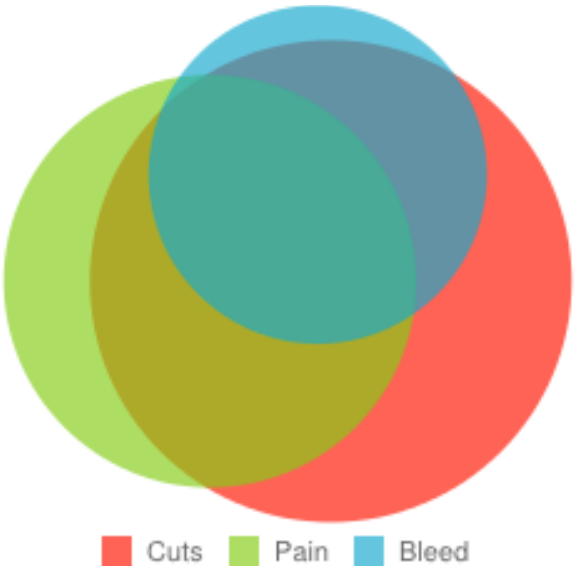

Figure 7. Venn diagram of overlap between penile coital injuries reported at baseline.

At baseline, men who selected circumcision (early VMMC adaptors) were significantly more likely to report a recent history of penile coital scratches, cuts, or abrasions compared to men who were not initially planning to become circumcised (47% versus 41%, p=.007). Reports of coital-related soreness and bleeding did not differ by circumcision intent at baseline (Table V). Combined, a greater proportion of the early VMMC adopters reported at least one type of penile coital injury compared to those not initially selecting circumcision (56% versus 50%; p=.009).

3. **Penile coital injuries by circumcision status**

Over 24 months of follow-up, reports of any penile coital injuries in newly circumcised men declined by 73%: from 56% of men before the procedure to just 15% at 24-months post circumcision. Significant decline was noted for each component individually: cuts, scratches, abrasions (81% decrease); soreness (71% decrease); and bleeding (87% decrease). All declines were evident at six-months post-procedure and sustained throughout the follow-up period (Figure 8). Among the uncircumcised cohort, no decline was noted in cuts, scratches, abrasions, or post-coital penile soreness, while a modest 25% decline in coital penile bleeding from 20% of men at enrollment to 15% at 24 months was observed.

TABLE V. BASELINE CHARACTERISTICS OF STUDY PARTICIPANTS

	Circumcision group [a, b]	Control group [a, b]	p-value [c]
Demographic characteristics			
Age (years)	20 (19–24; 18–35; 1588)	20 (19–24; 18–35; 1598)	0.08
Ethnic group			0.001
Luo	1547 (97%)	1585 (99%)	
Other	41 (3%)	13 (1%)	
Educational level			0.001
Primary and less	354 (22%)	488 (31%)	
Any secondary	955 (60%)	882 (55%)	
Any post-secondary	266 (17%)	306 (13%)	
Unsure / Refused to answer	13 (1%)	22 (1%)	
Employment status			0.001
Employed	421 (27%)	584 (37%)	
Unemployed	1167 (73%)	1014 (63%)	
Marital status			0.001
Single, without live-in partner	1055 (66%)	956 (60%)	
Single, with live-in partner	220 (14%)	203 (13%)	
Married, living with wife	271 (17%)	401 (25%)	
Married, not living with wife	42 (3%)	38 (2%)	
Sexual history			
Ever had sex			0.13
Yes	1382 (87%)	1419 (89%)	
No	206 (13%)	179 (11%)	
Age at first sex (years)	16 (15–18; 9–30; 1380)	16 (15–18; 9–29; 1417)	0.66
Sexual intercourse in past 6 months (sexually active only)			0.54
Yes	1032 (75%)	1074 (76%)	
No	350 (25%)	345 (24%)	
Number of partners in past 6 months (sexually active only)			0.13
None	350 (25%)	345 (24%)	
One	502 (36%)	564 (40%)	
2+	393 (29%)	398 (28%)	
Unsure / Refused to answer	137 (10%)	112 (8%)	
Lifetime number of partners	3 (2–6; 1–552; 1193)	3 (2–6; 1–122; 1270)	0.73
Penile coital injuries in the past 6 months (sexually active in last 6 months, N=2,048)			
Reported penile coital injuries in the past 6 months:			
Pain/soreness	343 (34%)	321 (31%)	0.15
Scratches/cuts/abrasions	477 (47%)	428 (41%)	0.007
Blood from penile tissue	234 (23%)	211 (20%)	0.12
Any penile coital injury	562 (56%)	518 (50%)	0.009

[a] Sample sizes vary in questions based on past or recent sexual activity.

[b] Data are median (IQR; range; n) for continuous data, or n (%) for categorical data.

[c] P values are based on Kolmogorov-Smirnov two-sample test for non-normally distributed continuous data and chi-square for categorical data.

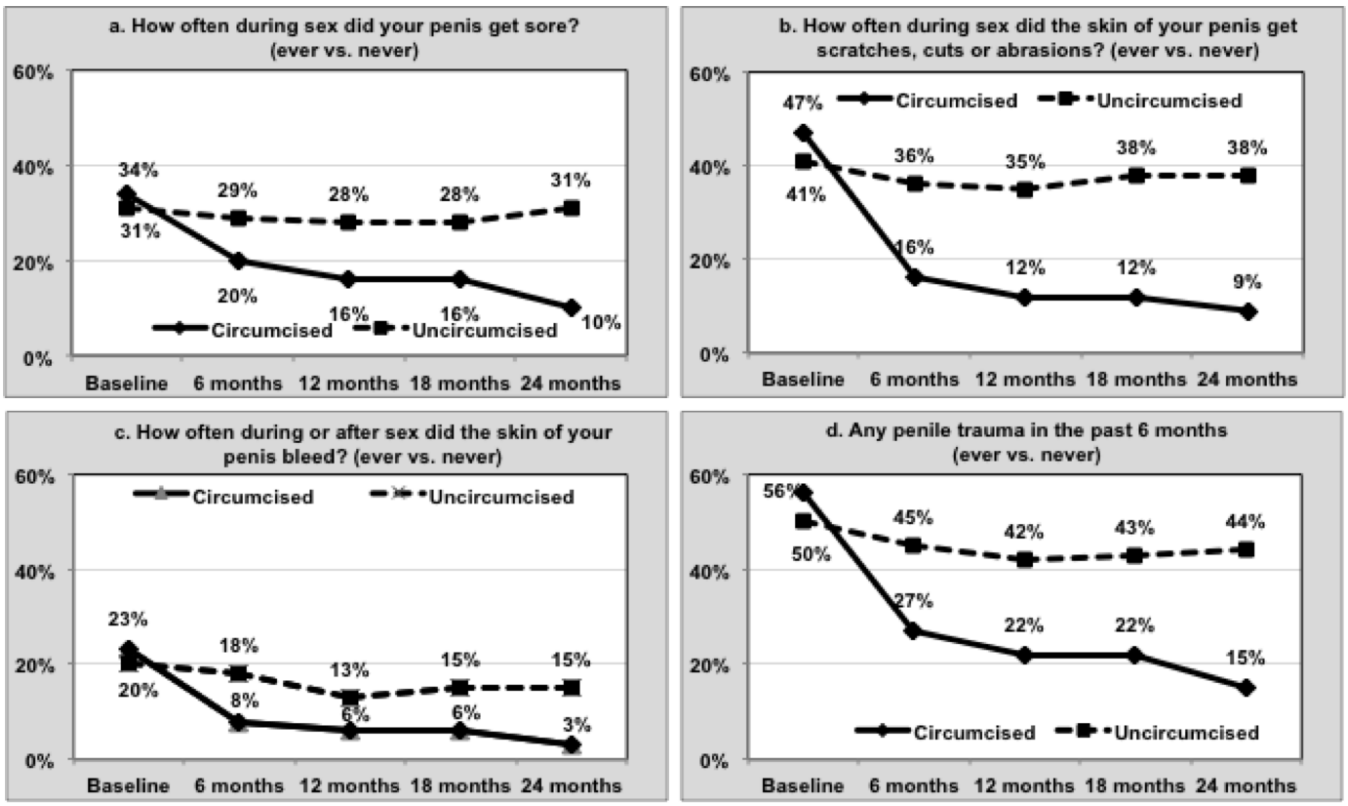

Figure 8. Observed self-reported penile coital injury by circumcision status over time.[a]

[a] Note: Group by time interaction was significant for all four outcomes (p<.0001). When stratified, decline over time was significant for both groups (p<.0001) for bleeding during or after sex and for any coital injuries, while there a significant decline over time was observed for circumcised men (p<.0001), but not for controls reporting sore penis and cuts, scratches, abrasions over time (p=.63 and p=.25, respectively). (a) Univariate OR 0.59 (0.52–0.66); (b) Univariate OR 0.41 (0.37–0.47); (c) Univariate OR 0.54 (0.47–0.62); (d) Univariate OR 0.49 (0.44–0.55).

Longitudinal analysis using mixed-effect models revealed the presence of group by time interaction for all measures of penile coital injuries indicating different patterns of change in injuries over time for circumcised and uncircumcised men (Table VI). When stratified by circumcision status, decline over time was significant for circumcised men across all types of coital injuries. For uncircumcised men, statistically significant decline was observed only for bleeding

and for the combined measure of any coital injury. The magnitude of this decline was modest when compared to circumcised men.

Removing the group by time interaction from the model, the unadjusted OR comparing circumcised to uncircumcised men over 24 months of follow-up was 0.49 (95% CI: 0.44–0.55) for any penile coital injury. By type, ORs were 0.59 (95% CI: 0.52–0.66) for soreness, 0.54 (95% CI: 0.47–0.62), bleeding, and 0.41 (95% CI: 0.37–0.47) for scratches, cuts, and abrasions.

TABLE VI. LONGITUDINAL CHANGES IN PENILE COITAL INJURIES OVER 24 MONTHS OF FOLLOW-UP BY CIRCUMCISION STATUS: THE RESULTS OF UNADJUSTED MIXED-EFFECT MODELS

				Stratified analysis					
				Circumcised			Uncircumcised		
	Estimate	**SE**	**p <**	**Estimate**	**SE**	**p <**	**Estimate**	**SE**	**p <**
Cuts, scratches, and abrasions									
Time (visit #)	-0.026	0.026	0.317	-0.719	0.037	0.001	-0.031	0.026	0.239
Group (MC status)	0.778	0.136	0.001						
Group x time	-0.689	0.043	0.001						
Soreness									
Time (visit #)	-0.011	0.027	0.687	-0.451	0.032	0.001	-0.015	0.027	0.575
Group (MC status)	0.518	0.137	0.001						
Group x time	-0.423	0.041	0.001						
Bleeding									
Time (visit #)	-0.120	0.033	0.001	-0.717	0.050	0.001	-0.121	0.032	0.001
Group (MC status)	0.685	0.163	0.001						
Group x time	-0.571	0.056	0.001						
Any penile injuries									
Time (visit #)	-0.081	0.025	0.002	-0.609	0.031	0.001	-0.082	0.025	0.001
Group (MC status)	0.588	0.129	0.001						
Group x time	-0.520	0.039	0.001						

4. **Penile coital injuries and genital sores**

At baseline, 194 (9%) of sexually active men reported genital sores in the past six months. Compared to men not reporting sores, a higher proportion of men with genital sores were seeking circumcision, had only primary education, were employed, married, had multiple partners in the past six months, had unprotected sex, preferred dry sex, and reported STIs in the past six months. In the intervention cohort, the proportion of men reporting genital sores declined from 11% before circumcision to 2% at 24 months. Among the control group, no change in the prevalence of genital sores was observed: 8% at baseline to 8% at 24 months. At baseline, 14% of men reporting penile coital injuries also reported genital sores, including 19% of men reporting pain, 14% of men with scratches, cuts, or abrasions, and 14% with bleeding. Conversely, more than 81% of men reporting a genital sore at baseline also reported a concomitant penile coital injury (Table VII), including 34% with bleeding; 68% with cuts, scratches, or abrasions; and 66% reported coital-related soreness.

In newly circumcised reporting genital sores, concurrent report of any penile coital injuries did not significantly decline over follow-up (baseline 81% to 72% at 24 months; p=.22). In circumcised men with no history of genital sores, however, reports of penile coital injuries declined almost 80% from 59% to 14% (p<.001) over the 24 months of follow-up. Therefore, following circumcision we observe a decline in reports of recent genital sores and decline in penile coital injuries, but the later only when men have not also experienced penile sores (sores by time interaction p=.0018, among circumcised men).

Considering any report of genital sores separately from that of penile coital injuries, the protective effect of circumcision on both is evident (Figure 9). Unadjusted ORs over the duration of follow-up were 0.67 (95% CI: 0.56–0.79) for recent history of genital sores and 0.50 (95% CI:

0.45–0.56) for penile coital injuries. By type of coital injury, excluding those with genital sores, ORs by circumcision status were 0.43 (95% CI: 0.38–0.48) for cuts and abrasions, 0.61 (95% CI: 0.54–0.69) for soreness, and 0.58 (95% CI: 0.50–0.67) for post-coital bleeding. The sensitivity analysis of the effect of male circumcision on penile coital injuries showed that excluding men with sores did not greatly change (less than 10%) the magnitude of the association, therefore our multivariable analyses included men with and without genital sores and reports of genital sores were evaluated as a covariate for each type of penile coital injuries.

TABLE VII. COITAL INJURY AMONG CIRCUMCISED AND UNCIRCUMCISED MEN BY TIME-VARYING COVARIATES OVER TIME

	Baseline, n(%)	6 months, n(%)	12 months, n(%)	18 months, n(%)	24 months, n(%)
Circumcision status*					
Circumcised	562/1008(56%)	200/732 (27%)	202/929(22%)	238/1071(22%)	180/1199(15%)
Uncircumcised	518/1037(50%)	401/888(45%)	390/920(42%)	386/892(43%)	375/848 (44%)
Marital status *					
Single	569/1143(50%)	270/852(32%)	295/976(30%)	271/1001(27%)	1236/1008(23%)
Married or cohabitating	511/902(57%)	331/768(43%)	297/873(34%)	353/962(37%)	319/1039(31%)
Condom use at last sex *					
No condom used	572/1001(57%)	321/736(44%)	324/861(38%)	321/861(37%)	280/912(31%)
Condom used	435/892(49%)	252/800(32%)	243/917(27%)	290/1064(27%)	263/1106(24%)
Number of partners in the past 6 months *					
One	444/1012(44%)	257/804(32%)	276/1030(27%)	311/1171(27%)	328/1353(24%)
Two or more	501/756(66%)	294/652(45%)	275/686(40%)	279/695(40%)	214/643(33%)
How long until washed penis after last time had sex *					
One hour or less	383/783(49%)	232/662(35%)	236/798(30%)	261/917(29%)	275/1085(25%)
More than one hour	697/1262(55%)	369/958(39%)	356/1051(34%)	363/1047(35%)	280/962(29%)
Applied substances to penis before sex in the past 6 months *					
No	885/1719(52%)	516/1407(37%)	507/1653(31%)	543/1776(31%)	493/1874(26%)
Yes	85/114(75%)	46/89(52%)	45/75(60%)	43/79(54%)	37/83(45%)
Sex with a partner who applied substances to her vagina before sex in the past 6 months *					
No	903/1738(52%)	526/1429(37%)	523/1670(31%)	553/1794(31%)	505/1904(27%)
Yes	67/95(71%)	36/67(54%)	29/57(51%)	32/60(53%)	24/52(46%)
Preference for dry sex					
Prefers dry sex	395/749(53%)	231/614(38%)	232/662(35%)	260/727(36%)	219/695(36%)
Prefers wet sex or no opinion	575/1084(53%)	331/881(38%)	320/1066(30%)	326/1128(29%)	311/1262(25%)
STIs in the past 6 months *					
No	885/1715(52%)	525/1440(37%)	519/1675(31%)	548/1799(31%)	500/1909(26%)
Yes	88/118(75%)	38/56(68%)	33/49(67%)	37/54(69%)	29/45(64%)
Genital sores in the past 6 months *					
No	930/1859(50%)	532/1533(35%)	519/1750(30%)	540/1860(29%)	478/1950(25%)
Yes	150/186(81%)	69/87(79%)	73/99(74%)	84/104(81%)	77/97(79%)

* Significant baseline difference ($p<.05$)

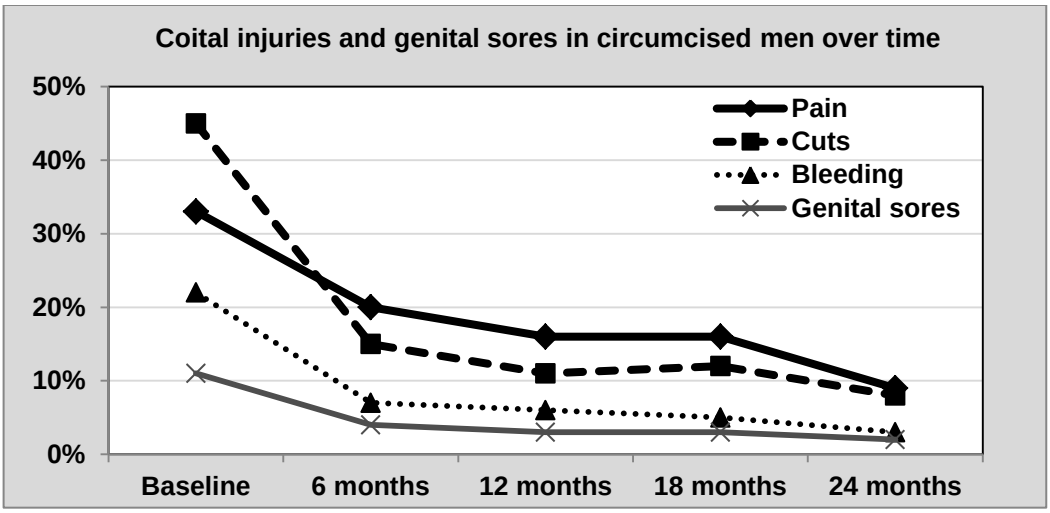

Figure 9. Observed prevalence of self-reported genital sores (men with genital sores) and penile coital injuries (men without genital sores) in circumcised men.[a]

[a] Note: The results are presented in circumcised men only, stratified by reports of genital sores (i.e., prevalence of pain, cuts, and bleeding among men without genital sores vs. prevalence of genital sores). Based on the univariate analysis, circumcised men were less likely to report genital sores—OR 0.67 (0.56–0.79). When restricted to men without genital sores, circumcised men were less likely to report soreness during intercourse (OR=0.61, 95% CI 0.54–0.69); cuts, scratches or abrasions (OR=0.43, 95% CI 0.38–0.48); bleeding during sex (OR=0.58, 95% CI 0.50–0.67); or any penile coital injuries (OR=0.50, 95% CI 0.45–0.56), compared to uncircumcised men over time.

5. **Other covariates and multivariable models**

Increased penile coital injury was observed in the 5% of men who applied substances to their penis before sex. The type of substances used specified by participants (e.g., petroleum jelly, oil, fat, and water-based products) suggests that most were used as lubricants. Penile coital injuries were higher among married men and those with more than two partners in the past six months, and lower among men who practiced condom use and genital washing within one hour of intercourse, which was found to be protective. History of a recent STI was associated with increased reports of penile coital injury (Table VII).

In multivariable modeling, circumcised men were more than 50% less likely than those uncircumcised to report any penile coital injury in the last six months (aOR=.47; 95% CI 0.42–0.53). This protection was greatest for penile cuts, scratches, or abrasions injury in which the difference reached 60% (OR=.39; 95% CI 0.34–0.44; Table VIII). Factors independently associated with increased risk of penile coital injury were the application of substances (lubricants) to the penis before sex (aOR=1.94 to 2.29), increasing age (aOR=1.03 for each added year), history of STI in the last six months (aOR=1.66 to 2.48), reporting genital sores in the last six months (aOR=2.60 to 4.27), and multiple partners in last six-months (aOR=1.38 to 1.58). Condom use (aOR=.73 to .75) remained protective for penile coital injuries. Education, employment, marriage, ethnicity, post-coital hygiene, and preference for dry sex were not associated with any of penile coital injury measures.

6. **Penile coital injuries and sexual satisfaction**

At baseline, the proportion of men reporting being satisfied with sexual intercourse was lower among men with penile coital injuries compared to those not reporting coital injuries: 67% of men with coital abrasions were satisfied with intercourse compared to 74% without abrasions (p=.001), 65% with coital soreness versus 74% without soreness (p<.0001), and 61% with coital bleeding versus 74% without bleeding (p<.0001). Adjusting for time, circumcision status, age, education, employment, number of partners in the past six months, and reports of genital sores and STIs in the past six months, penile coital injuries remained significantly associated with lower levels of sexual satisfaction in longitudinal analyses (abrasions: aOR=.87, 95% CI: 0.76–0.98; soreness: aOR=.82, 95% CI: 0.72–0.93; and bleeding: aOR=.65, 95% CI: 0.55–0.76).

TABLE VIII. RESULTS OF THE MULTIVARIABLE MIXED-EFFECT MODELS FOR RISKS OF PENILE COITAL INJURY OVER TIME (N=2781)

	Cuts/scratches/abrasions OR (95% CI)	Soreness OR (95% CI)	Bleeding OR (95% CI)
Circumcision status [a]			
Uncircumcised	Reference	Reference	Reference
Circumcised	0.39 (0.34–0.44)	0.58 (0.51–0.65)	0.53 (0.46–0.62)
Age (continuous) [b]	1.03 (1.02–1.05)	1.03 (1.01–1.04)	1.02 (1.00–1.04)
Condom use at last sex			
No condom used	Reference	Reference	Reference
Condom used	0.74 (0.67–0.83)	0.73 (0.65–0.81)	0.75 (0.65–0.86)
Number of partners in the past 6 months			
One	Reference	Reference	Reference
Two or more	1.48 (1.35–1.63)	1.38 (1.26–1.52)	1.58 (1.41–1.78)
Ever applied substances to penis before sex			
No	Reference	Reference	Reference
Yes	1.94 (1.55–2.42)	2.08 (1.66–2.60)	2.29 (1.79–2.93)
Self–reported genital sores in the past 6 months			
No	Reference	Reference	Reference
Yes	3.65 (2.99–4.46)	4.27 (5.09–6.39)	2.60 (2.10–3.20)
Self–reported STIs in the past 6 months			
No	Reference	Reference	Reference
Yes	1.66 (1.29–2.15)	2.48 (1.92–3.20)	2.16 (1.65–3.84)
Visit			
Baseline	Reference	Reference	Reference
6 months	0.43 (0.37–0.49)	0.77 (0.66–0.89)	0.60 (0.50–0.71)
12 months	0.38 (0.32–0.44)	0.67 (0.57–0.78)	0.45 (0.37–0.54)
18 months	0.43 (0.37– 0.49)	0.66 (0.57–0.76)	0.48 (0.40–0.58)
24 months	0.39 (0.34–0.45)	0.59 (0.51–0.69)	0.39 (0.33–0.48)

[a] Circumcision status at baseline is by enrollment group; at follow up by actual status.
[b] All variables are time varying, except for age at baseline.

D. **Discussion**

In our study of recently circumcised men in Nyanza province, we confirm previous observations that circumcised men are less likely to report penile coital injuries, with significantly decreased risk as early as six months after surgery (Mehta et al., 2010). Other factors associated with penile coital injury were also consistent and included increasing age, increasing number of sexual partners, the application of substances to the penis before sex, and self-reported history of STIs. Because the majority of substances applied to the penis were described as lubricants, it is possible that this association represents palliative self-treatment by men with recognized coital discomfort. Condom use, protective against coital injuries, was likely acting as a barrier and could also reduce friction if lubricated.

At baseline, we found that coital-related scratches, cuts, and abrasions to the penis among young, uncircumcised, sexually active men in Nyanza province, Kenya were common (44%). This prevalence is comparable to the 48% observed by Mehta and colleagues in this same geographical area (Mehta et al., 2010), but higher than findings from 1997 cross-sectional study in eastern Uganda (Bailey et al., 1999). In the Ugandan study, the prevalence of penile scratches and abrasions sustained during intercourse was 36% among traditionally circumcised and 31% among uncircumcised men, and unlike both Nyanza-based samples, had no association with circumcision status (Bailey et al., 1999). Several explanations for these differences are possible including: differences in the behavioral risk profile of the study samples, culturally specific sexual practices that increase the risk of coital injuries, circumcision status misclassification, misclassification of GUD and injuries, and residual foreskin associated with some traditional circumcision practices.

Reduction in GUD is a probable mechanism for at least some portion of the protective effect of male circumcision against HIV (O'Farrell, 1993; Szabo and Short, 2000), with a 41%–48% reduction in GUD following the procedure observed in recent studies (Gray et al., 2009; Mehta et al., 2012b). While not directly comparable due to methodological differences in the assessment of penile sores and genital ulcers, the 33% decline in the likelihood of self-reported genital sores with circumcision observed in our study is within the lower range of effect sizes reported. Moreover, men reporting genital sores were more likely to report penile coital injuries, suggesting an additional risk of injury with genital sores or some overlap between the symptoms of genital sores and of penile coital injuries. Unlike other studies, we found no significant reductions (p=.22) in penile injuries over time among men reporting genital sores after becoming circumcised. This finding could be affected by a small sample size or unadjusted confounding due to the ambiguity in our measurements of genital sores and should be further evaluated in other studies.

Recent research has observed that approximately 40% to 60% of genital ulcers were not explained by STI etiologies (Gray et al., 2009; Mehta et al., 2012a; Mehta et al., 2012b). Therefore, it was suggested that coital injuries may play a role in the formation of these unexplained ulcers through facilitating infections by other, non-sexually transmitted, pathogens (Gray et al., 2009; Mehta et al., 2012a; Mehta et al., 2012b; O'Farrell, 1993). In stratified analysis aimed to evaluate to what extent the reduction in genital sores may confound our findings on changes in prevalence of coital injuries, we observed that recent genital sores were reported by, at most, 14% of men with penile coital injuries. This leaves a great majority of penile coital injuries that likely relate principally to mechanical disruption or factors unrelated to preexisting GUD. Future studies should include questions designed to differentiate between coital injuries and GUD or include clinical examination to confirm current injuries or sores.

Our study findings are subject to several limitations. Data on penile coital injuries, genital sores, and STIs were based on self-report with no corresponding clinical exam, limiting comparability to studies able to augment self-report with clinical observations. However, similarities between our results and findings from the RCT of MC in Kisumu could advocate for the generalizability of our results: we used the same questions as the trial in a sample different in demographic, geographic, and other aspects. Because study participants self-selected for enrollment and group assignment, it is possible that the motivation to become circumcised represents fundamental differences between study groups, limiting comparability. The two groups differed in several demographic characteristics, as well as higher reports of coital scratches, cuts, and abrasions among men self-selecting into the circumcision group. We attempted to control the degree of incomparability through age and residence matching and through control selection that allowed for becoming circumcised during study participation. Additionally, the differences between the groups were controlled for in the analysis stage. Because behavior and sexual history were self-reported, they are subject to social desirability and recall biases, although we have limited these biases through the use of computer assisted self-interviewing and study staff with training in sensitive face-to-face interview techniques (Langhaug et al., 2010; Mensch et al., 2003; Phillips et al., 2010; Vu et al., 2012). Lastly, our study did not assess the likely mechanisms leading to coital injuries. This is an important aspect in determining how circumcision may be protecting men and ultimately in developing appropriate interventions and messaging.

E. **Conclusion**

Penile coital injuries have intuitive and observable association with increased risk of HIV and STIs (Figueroa et al., 1994; Fleming and Wasserheit, 1999; O'Farrell, 1993; Szabo and Short, 2000). While their prevention may be important in that regard alone, the potential motivational

force for circumcision may also be of value. In our study we found that men reporting penile coital injuries were more likely to be among the earliest adopters of VMMC and observed a significant decline in coital injuries following circumcision. Further, measures of sexual satisfaction in this study population indicated that men seeking circumcision services had consistently lower levels of pre-procedure sexual satisfaction across metrics (Westercamp et al., 2012) and that penile coital injuries were associated with lower levels of sexual satisfaction both at the baseline and across follow-up. This potentially justifiable role of circumcision in improvement of the sexual experience, through the removal of a potential source of sexual discomfort associated with penile coital injuries, may resonate with a significant portion of men targeted for VMMC (Figueroa et al., 1994; Fleming and Wasserheit, 1999; O'Farrell, 1993; Szabo and Short, 2000; Layer et al., 2012). The role of penile coital injuries in motivation for seeking VMMC services should be explored further.

Very little information on prevalence of coital injuries anywhere in the world is available to date. Our study shows such injuries may be more common than is generally recognized. Future studies should assess the prevalence and correlates of penile coital injuries across different geographical areas, explore potential mechanisms of injury acquisition, identify ways to prevent coital injuries (e.g., MC, lubricants, genital hygiene), and qualify the relationship between coital injuries and HIV acquisition.

V. MEASURING PREVALENCE AND CORRELATES OF CONCURRENT SEXUAL PARTNERSHIPS AMONG YOUNG SEXUALLY ACTIVE MEN IN KISUMU, KENYA

A. Introduction

The significance of sexual partner concurrency in explaining the severity of the HIV epidemic in sub-Saharan Africa is a subject of considerable debate (Epstein and Morris, 2011; Lurie et al., 2009; Lurie and Rosenthal, 2010b, 2010a; Epstein, 2010; Morris, 2010; Mah and Halperin, 2010; Kalichman and Grebler, 2010). Mathematical models have consistently illustrated that compared to serial monogamy, concurrent partnerships increase the magnitude, spread, and persistence of the HIV epidemic (Watts and May, 1992; Kretzschmar and Morris, 1996; Morris and Kretzschmar, 1997). When there are high levels of concurrency, a significant proportion of new infections is likely to occur due to increased exposures during the primary phase of infection (Eaton et al., 2011; Powers et al., 2011). Due to methodological challenges, however, few empirical studies have documented an association between concurrency and HIV incidence (Mermin et al., 2008; Koumans et al., 2001; Potterat et al., 1999; Morris, Epstein, and Wawer, 2010) and some studies have argued that it is simply the total number of partners that matters, regardless of their overlap in time (Tanser et al., 2011).

Multiple studies have assessed the prevalence of concurrent partnerships in Sub-Saharan Africa (Morris et al., 2010; Ferry et al., 2001; Kwena et al., 2010; Kenyon et al., 2010; Carter et al., 2007) and found large differences both between (from 6% of urban men in Zambia (Sandoyet al., 2010) to 21% of urban men in Uganda (Kajubi et al., 2011)) and within (from 16% in South Africa nationally (Steffenson et al., 2011) to 38% in Kwa-Zulu Natal (Harrison, Cleland, and Frohlich, 2008)) countries, as well as across time (from 13% in 1998 to 8% in 2003 in rural Zambian men (Sandoy et al., 2010)).

Comparing such results, however, is difficult due to variation in the operational definitions and measurement methods used (Lurie and Rosenthal, 2010b; Mah and Halperin, 2010). The most common operational definitions of concurrency are based on extrapolated overlap determined by provided relationship start and end dates or by asking directly about sex with other partners during each reported partnership. Measurement of concurrency prevalence has been principally reported as point prevalence (at interview or at some specified time-point) (Sandoy et al., 2010; Xu et al., 2010; Voeten et al., 2004; Ferry et al., 2001; Morris et al., 2010; Kajubi et al., 2011; Steffenson et al., 2011; Harrison et al., 2008), as cumulative prevalence (Carter et al., 2007; Kwena et al., 2010; Morris et al., 2010; Steffenson et al., 2011; Kenyon et al., 2010; Xu et al., 2010), and as a proportion of all partnerships (Lagarde et al., 2001; Clark et al., 2010). Additionally, there are often meaningful differences in the denominators chosen to express these measures. To facilitate consensus, the UNAIDS Reference Group on Estimates, Modeling and Projections recently issued a recommendation on standard indicators of concurrency (UNAIDS Reference Group on Measurement and Modeling, 2010). While these indicators should facilitate more meaningful comparisons in the future, other measures that take into account the diversity of sexual concurrency and provide greater emphasis on associated characteristics may offer additional insights. Few studies to date have focused on the complexity of measuring concurrency in practice and the impact that different measurement methods have on the magnitude of concurrency prevalence estimates (Glynn et al., 2012; Helleringer et al., 2011; Maughan-Brown and Venkataramani, 2011; Nelson et al., 2007).

In this analysis, we used data from a sub-study of the RCT of MC in Kisumu, Kenya, to explore and compare different measures of concurrency, including the UNAIDS-recommended indicator (Bailey et al., 2007). In addition, we assessed prevalence and correlates of concurrency

in our sample of young, sexually active men; defined characteristics that differed between concurrent and non-concurrent sexual partnerships; and examined to what extent the number of partners reported by men is related to the proportion of all their partnerships that are concurrent.

B. Methods

1. Participants

Data for this analysis were collected as part of a study evaluating sexual risk behavior during the RCT of male circumcision to reduce HIV incidence in Kisumu, Kenya (Bailey et al., 2007). Detailed description of study methodology and the sample has been provided elsewhere (Mattson et al., 2007; Mattson et al., 2008; Mattson et al., 2010; Westercamp et al., 2010). In brief, RCT participants were volunteers recruited between February 2002 and September 2005 through newspapers, community theater, radio, fliers, STI clinics, youth groups, and peer outreach (Bailey et al., 2007). Trial participants were followed every six months for two years with risk reduction counseling, a brief questionnaire, biologic sample collection and health examination taking place at each visit. Men enrolled in the present study were self-selected from either: (1) men enrolled in the RCT of MC and were HIV negative, uncircumcised, 18–24 years old, residents of Kisumu district, and sexually active within the past 12 months; or (2) men excluded from enrolling in the RCT only based on their positive HIV status, but otherwise met all other trial inclusion criteria. Eligible men were informed about the present study by the RCT clinic receptionists, clinicians, or nurse counselor and referred to the study office, where our research staff verified their eligibility. Participants provided signed informed consent in their language of choice (English, Kiswahili, or Dholuo), and ethical approval was obtained from the Kenyatta National Hospital Ethics and Research Committee, the Institutional Review Board of University of Illinois at Chicago, and the University of Manitoba Biomedical Research Ethics Board.

2. **Measures**

Face-to-face, structured interviews were conducted at baseline, and at six and 12 months after enrollment. The interview included demographic and behavioral characteristics, lifetime sexual behavior and STI history, and detailed partnership characteristics for the most recent 12 sexual partners. The validated Timeline Followback (TLFB) approach was used to enhance memory recall (Carey et al., 2001). Variables collected for each sexual partner and examined in the concurrency analysis included: partner's age, gender, type (wife, regular or steady partner, casual partner, or commercial sex worker), length of time knowing partner prior to sex, approximate number of sexual encounters (once, 2–5, 6–10, more than 10), sexual practices (oral, vaginal, anal, sex during menstruation), transactional sex, condom use (ever, first encounter, last encounter, every encounter), perception that the partner had other partners at the time of the relationship, and beliefs about the partner's HIV/AIDS status.

At each study visit, participants provided "month and year the sexual relationship began" and "month and year the sexual relationship ended," as well as whether they considered the relationship as formally ended, for each reported partner. Partnerships were considered concurrent if there was any overlap, by month, of the start and end dates of any two partnerships. For example, if one partnership began in September and ended in December, and another began that same December and ended in February, those partnerships were considered concurrent. Because partnership start and end dates were limited to the month and year, it is possible that partnerships reported in the same month may not have overlapped at the day level. To evaluate the impact of this potential misclassification, we did a sensitivity analysis assuming all partnerships that overlapped by one month were not concurrent.

We calculated five different measures of concurrency: (1) the UNAIDS-recommended point prevalence measure: the proportion of men with at least two ongoing partnerships at six months before interview (UNAIDS Reference Group on Measurement and Modeling, 2010); (2) point prevalence at three months before interview; (3) point prevalence at the time of the interview; (4) cumulative prevalence in the past six months; and (5) lifetime cumulative prevalence at the beginning and the end of the study. Longitudinally, each of the first four measures was calculated at baseline, six-, and 12-month follow-up visits. Point prevalence at six months before interview was estimated for the entire sample at baseline; however, some men were unable to provide six-month sexual history at follow-up due to returning before six months had passed, but within the study allowed follow-up window of plus or minus three months. Therefore, the denominator for the UNAIDS indicator is limited to 521 men at six-month and 539 men at 12-month follow-up. Our other recall time points, three months and at the time of the interview, were not subject to this limitation.

Complete sexual histories were not collected on 14% of men due to greater than 12 lifetime sexual partners at baseline. This had no effect on lifetime concurrency (all had concurrent partnerships) and likely had minimal effect on six-month cumulative prevalence and point prevalence due to those measures' focus on recent sexual partners.

3. **Statistical analyses**

We evaluated factors associated with concurrency on two levels: the respondent level and the partnership level. The respondent level refers to the characteristics of men practicing concurrency in this study—the unit of analysis is men. The partnership level refers to the characteristics of partnerships that are concurrent—the unit of analysis is partnerships. At the respondent level, χ^2 tests were used to assess differences in categorical factors, and logistic

regression was used in the analysis of point prevalence to adjust for multiple correlates of interest. Mixed-effect models were used at the partnership level to correct for correlation between the multiple reports provided by each respondent. Separate analyses were carried out for regular/spousal and casual partnerships. Variables were selected for inclusion in multivariable models based on significance in univariate analyses ($p<.10$) and previous literature.

To ensure the comparability of our results with those from studies that analyzed partnership data without accounting for multiple reports, population-averaged ORs were calculated by transforming our subject-specific regression estimates as described by Hu et al. (Hu et al., 1998). All presented ORs are population-averaged. Statistical analysis was performed using SAS v9.2 (SAS Institute Inc, 2008) with the NLMIXED procedure for mixed-effect modeling.

C. Results

1. Study sample

We enrolled 1,393 men who expressed interest in the study, out of the 2,059 men who were screened for participation in the RCT between March 2004 and September 2005 and had a chance to receive information about the study. Information from 25 enrolled participants was excluded for incomplete (n=20) and unreliable (n=5) data. Of 1,368 men included in the analysis, 1,032 (75%) returned for the six-month follow-up and 1,041 (76%) returned at 12 months.

Information was available on 11,066 partnerships (7,977 reported by 1368 men at baseline, 1,561 reported by 852 men at six months, and 1,528 reported by 860 men at 12 months). Of these, 159 were excluded: 66 for missing the start and/or end date, 85 for missing data on key partnership-level variables, and eight for involving same-gender partners, for a final partnership

sample size of 10,907 (99%). The small number (n=8) of same-gender partnerships reported by four men precluded meaningful comparison and they were excluded from the analysis.

2. **Participant characteristics**

Study participants were predominantly single (92%), comparatively well educated (more than 70% had at least a secondary education), and self-identified as belonging to the Luo ethnic group (99%). Median participant age was 20 years and the median age at sexual debut was 15 years. Despite our relatively young sample, 57% reported five or more partners since their sexual initiation, and only 67 (5%) reported having a single lifetime partner. Most men (83%) had a casual partner at some time in their lives; 14% had sex with a sex worker; and 41% had intercourse with a woman the same day they met. Few respondents (7%) consistently used condoms, 74% reported some condom use, and 19% never used condoms. Twenty-one percent reported history of treatment for an STI.

3. **Prevalence of concurrency**

Table IX provides the comparison of three point prevalence measures of concurrency (at six-month recall UNAIDS-recommended indicator, at three-months recall, and at interview) and a six-month cumulative prevalence. The UNAIDS-recommended indicator was consistently the most conservative point prevalence estimate. Calculations based on three-month recall produced slightly higher estimates, but lower than point prevalence at interview. As expected, estimates of concurrency were consistently lower when one-month overlap was excluded with 3% to 9% decrease observed in both cumulative and point prevalence. We noted a decrease in prevalence over time, with a considerable drop following the baseline interview with relative stabilization across follow-up visits. Cumulative lifetime prevalence of concurrency was

71% (65% excluding one-month overlap) and 77% (71% excluding one-month overlap) at the beginning and end of the study, respectively.

4. **Partnership-level concurrency and duration of overlap**

Sixty-one percent of all partnerships in our sample were concurrent. Concurrency was present during 58% of regular or spousal partnerships, 63% of casual partnerships and 76% of partnerships with sex workers. Excluding one-month overlap, 958 of the 6,700 originally concurrent partnerships were no longer defined as concurrent, reducing partnership concurrency to 52%. These 958 partnerships were characterized by short duration (one month—57%), few sexual encounters (one—40%; 2 to 5—38%), belief that this partner had other partners at the time of relationship (47%), and always using condom with the partner (46%).

Duration of overlap ranged from one month to 107 months (8.92 years), with a mean of 4.92 months and a median of two months. Considerable variability by partnership type was noted with regular/spousal partnerships having a mean overlap with other partnerships of 6.72 months (median: three months, range: 1–107 months), casual partnerships 3.45 months (median: one month, range: 1–99 months), and sex workers 2.11 months (median: one month, range: 1 to 31 months).

TABLE IX. PREVALENCE OF SEXUAL PARTNER CONCURRENCY MEASURED BY OVERLAPPING DATES OVER DIFFERENT RECALL PERIODS AND WITH INCLUSION AND EXCLUSION OF ONE-MONTH OVERLAP

Concurrency measure [a]	**Baseline n (%) N=1,368**	**6-month visit n (%) N=1,032**	**12-month visit n (%) N=1,041**
Excluding one-month overlap			
Point prevalence at 6 months prior to interview (UNAIDS)	252 (18.4)	36 (6.7)	51 (9.8)
Point prevalence at 3 months prior to interview	283 (20.7)	97 (9.4)	110 (10.6)
Point prevalence at the time of the interview	345 (25.2)	171 (16.6)	175 (16.8)
Cumulative prevalence, 6 months	716 (52.3)	275 (26.6)	277 (26.6)
Including one-month overlap			
Point prevalence at 6 months prior to interview	344 (25.2)	58 (11.1)	83 (15.4)
Point prevalence at 3 months prior to interview	388 (28.4)	188 (18.2)	186 (17.9)
Point prevalence at the time of the interview	382 (27.9)	222 (21.5)	217 (20.8)
Cumulative prevalence, 6 months	786 (57.5)	321 (31.1)	326 (31.3)

[a] Note: denominators used for calculation of point prevalence six months prior to the interview reflect only men who returned for follow-up ≥ six months after the preceding study visit. For men who returned for follow-up earlier than six months, point prevalence at six months prior to the visit was not possible to calculate. Therefore, for six-month follow-up, the denominator included n=521; for 12-month follow-up, the denominator included n=539. For further details see methods.

5. **Participant characteristics associated with concurrency**

In univariate analyses, the only respondent-level demographic factor significantly associated with having concurrent partnerships was higher income (OR=1.37; 95% CI 1.07–1.75) (Table X). Based on unadjusted analyses, behavioral factors more prevalent among participants who had concurrent partners were: younger age at sexual debut (15 years or younger versus older than 15 years: OR=2.11; 95% CI 1.67–2.68), higher number of lifetime sexual partners (more than 4 versus 2–4: OR=7.29; 95% CI 5.51–9.66), and any history of condom use (OR=2.16; 95% CI 1.61–2.90). While HIV status and HIV testing history were not associated with concurrency, ever being treated for an STI was more common (OR=1.46; 95% CI 1.08–1.98) among men having concurrent sexual partnerships. Circumcision status was not associated with having concurrent partners at baseline or during follow up (data not shown).

6. **Correlates of concurrency by partnership type**

The likelihood of concurrency was higher when a respondent was in a relationship with a casual partner (OR=1.11; 95% CI 1.03–1.20) or a sex worker (OR=1.59; 95% CI 1.27–1.99) than with a regular/spousal partner. In mixed-effect modeling of regular/spousal partnerships, older age of the man, greater lifetime number of partners, longer duration of the partnership, shorter time knowing the partner before first sex, belief that the partner has other partners, fellatio, and exchanging gifts or money for sex were independently associated with concurrency (Table XI). For casual partnerships, older age of the man at the time of partnership, greater number of lifetime partners, longer duration of partnership, consistent condom use with this partner, believing that the partner is HIV-positive, and the perception that the partner has other partners were associated with the partnership being concurrent (Table XI).

TABLE X. INDIVIDUAL PARTICIPANT CHARACTERISTICS: COMPARISON OF 18–24 YEAR OLD SEXUALLY ACTIVE MEN WITH AND WITHOUT CONCURRENT LIFETIME PARTNERS AT BASELINE (N=1368)

	With concurrent partners	Without concurrent partners	p[c]
Total [a]	**965 (71%)**	**403 (29%)**	
Age at the time of interview			0.07
21–24	468 (48%)	174 (43%)	
18–20	497 (52%)	229 (57%)	
Education			0.12
Primary school or less	202 (21%)	70 (17%)	
Secondary school	547 (57%)	225 (56%)	
Post-secondary school	216 (22%)	108 (27%)	
Employment status			0.31
Employed	203 (21%)	75 (19%)	
Not employed	762 (79%)	328 (81%)	
Income			**0.01**
>2,500 KSH/month	384 (40%)	131 (33%)	
≤2,500 KSH/month	581 (60%)	272 (67%)	
Marital status			0.24
Married or cohabitating	86 (9%)	28 (7%)	
Single	879 (91%)	374 (93%)	
Assigned circumcision group			0.41
Circumcised	429 (44%)	189 (47%)	
Uncircumcised	536 (56%)	214 (53%)	
Age at sexual debut			**<0.001**
≤ 15 years	639 (66%)	194 (48%)	
> 15 years	326 (34%)	209 (52%)	
Lifetime number of sexual partners [b]			**<0.001**
5 or more partners	696 (72%)	88 (22%)	
2–4 partners	269 (28%)	248 (62%)	
1 partner	0 (0%)	67 (17%)	
Ever used condoms with any partners			**<0.001**
Yes	840 (87%)	305 (76%)	
No	125 (13%)	98 (24%)	
HIV status at baseline			0.28
HIV-positive	49 (5%)	15 (4%)	
HIV-negative	916 (95%)	388 (96%)	
Ever tested for HIV outside of the study clinic			0.47
Yes	311 (32%)	122 (30%)	
No	653 (68%)	281 (70%)	
Ever treated for an STI			**0.01**
Yes	222 (23%)	69 (17%)	
No	734 (77%)	334 (83%)	

[a] At baseline, variables refer to the lifetime sexual experience.

[b] Participants reporting one partner were not included in this analysis.

[c] P value from χ^2 test of overall association between having concurrent partners and participant characteristics.

TABLE XI. UNADJUSTED AND ADJUSTED ODDS RATIOS FOR PARTICIPANT AND PARTNERSHIP CHARACTERISTICS ASSOCIATED WITH CONCURRENCY IN REGULAR/SPOUSAL AND CASUAL PARTNERSHIPS: RESULTS OF THE MIXED-EFFECT MODELING

	Regular partnerships (n=5348)		**Casual partnerships (n=5183)**	
	Unadjusted OR (95% CI)	**Adjusted OR (95% CI)**	**Unadjusted OR (95% CI)**	**Adjusted OR (95% CI)**
Duration of partnership: ≥ 1year	1.98 (1.77; 2.22)[b]	2.29 (2.03; 2.59)[b]	1.66 (1.41; 1.95)[b]	2.50 (2.09; 3.00)[b]
Time knowing partner before 1st sex: <6 months	1.31 (1.17; 1.46)[b]	1.24 (1.10; 1.40)[a]	1.30 (1.16; 1.46)[b]	-
Single sexual encounter with this partner	0.68 (0.57; 0.81)[b]	-	0.83 (0.74; 0.93)[a]	-
Partner ≥5 years younger	1.03 (0.89; 1.20)	-	1.76 (1.47; 2.11)[b]	-
Sex during menstruation with this partner	1.33 (1.09; 1.61)[a]	-	1.03 (0.78; 1.37)	-
Receptive oral sex with this partner	2.04 (1.41; 2.96)[b]	1.85 (1.26; 2.72)[a]	1.47 (0.92; 2.37)	-
Exchange of money/gifts for sex with partner	1.39 (1.12; 1.73)[a]	1.27 (1.01; 1.59)[a]	1.22 (1.02; 1.46)[a]	-
Consistent condom use with this partner	0.77 (0.68; 0.88)[b]	-	1.76 (1.56; 1.99)[b]	1.33 (1.16; 1.53)[b]
Belief that partner is HIV-positive	2.26 (1.04; 4.89)[a]	-	2.30 (1.47; 3.58)[b]	1.81 (1.14; 2.88)[a]
Uncertainty of partner's HIV status	0.93 (0.77; 1.11)	-	1.35 (1.15; 1.59)[b]	1.04 (0.88; 1.25)
Belief that partner has other partners	1.51 (1.32; 1.72)[b]	1.48 (1.29; 1.70)[b]	1.35 (1.20; 1.52)[b]	1.22 (1.07; 1.38)[a]
Man's age at the time of partnership: ≥17	1.09 (0.96; 1.24)	1.40 (1.21; 1.62)[b]	2.70 (2.36; 3.08)[b]	2.91 (2.51; 3.38)[b]
Man's lifetime number of sexual partners: ≥5	4.23 (3.33; 5.38)[b]	4.43 (3.46; 5.66)[b]	3.88 (2.85; 5.28)[b]	4.11 (2.99; 5.67)[b]

[a] p<.05.
[b] p<.001.

7. **Relationship between concurrency and number of sexual partners**

To investigate the extent to which reducing a man's number of partners will reduce concurrency, we plotted the mean proportion of partners that are concurrent by number of lifetime partners (Figure 10). As can be seen in the curvilinear shape of the relationship, the greatest increase in the proportion of concurrent partners with each additional partner occurs in men with history of fewer than 12 partners. Once 18–24 year-old men exceed 18 partners, greater than 90% of those partnerships are concurrent. Viewed another way, the odds of partnership concurrency increase with lifetime number of partners (Figure 11) such that partnerships of men with a history of five to six partners have 1.9 times (95% CI: 1.5–2.4) the odds of being concurrent compared to those with one to four partners. This increases to an OR of 9.6 (95% CI: 7.5–12.2) for partnerships of men with a history of more than 12 partners.

There was also significant association between lifetime number of partners and point prevalence of concurrency at interview. Adjusted for age, men who had 3–5 partners were 2.7 times (95% CI: 1.6–4.6) more likely to have two or more ongoing partnerships in the month of the interview, compared to men with less than three partners, increasing to an OR of 8.6 (95% CI: 5.0–14.7) in men with more than five lifetime partners. This association of current concurrency with lifetime number of sexual partners indicates that the long-term sexual experience of an individual does influence the propensity to have concurrent partners at any point in time.

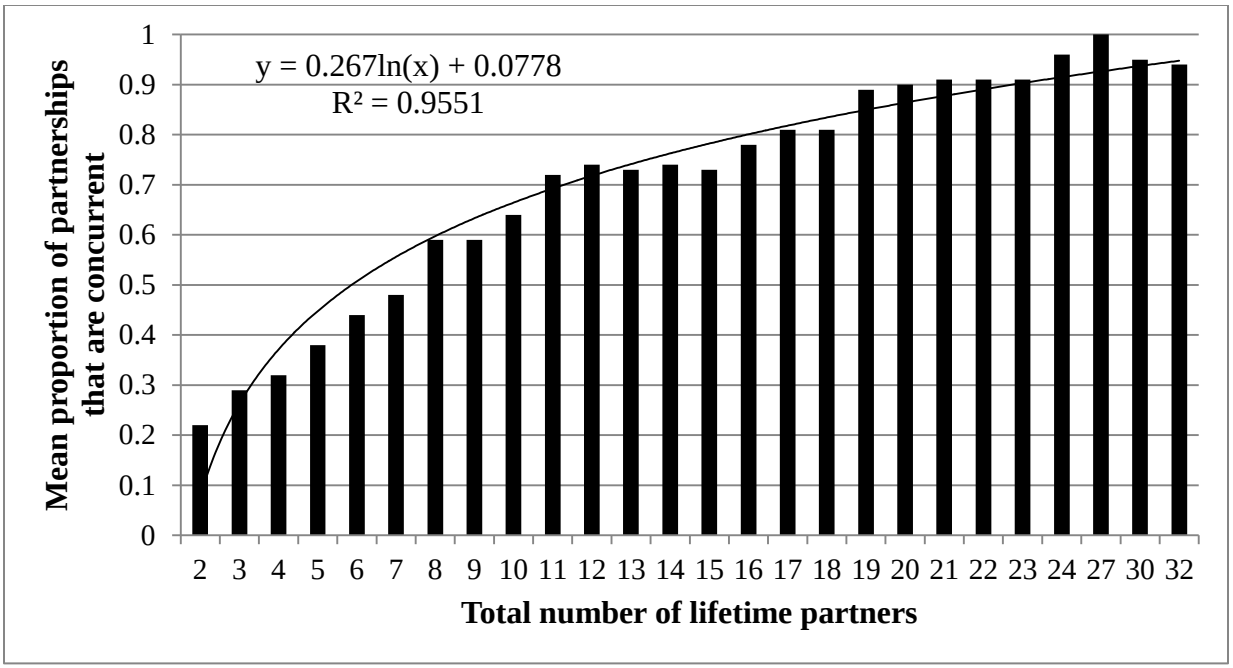

Figure 10. Mean proportion of partnerships that are concurrent by total number of lifetime partners.[a]

[a] Note: The proportion of partnerships that are concurrent was calculated for each study participant as the number of concurrent partners over the total number of partners. This figure presents the study sample stratified by the total number of partners, with mean proportion of concurrent partners calculated for each stratum. For example, among men who reported nine lifetime partners, on average 60% of nine partners were concurrent.

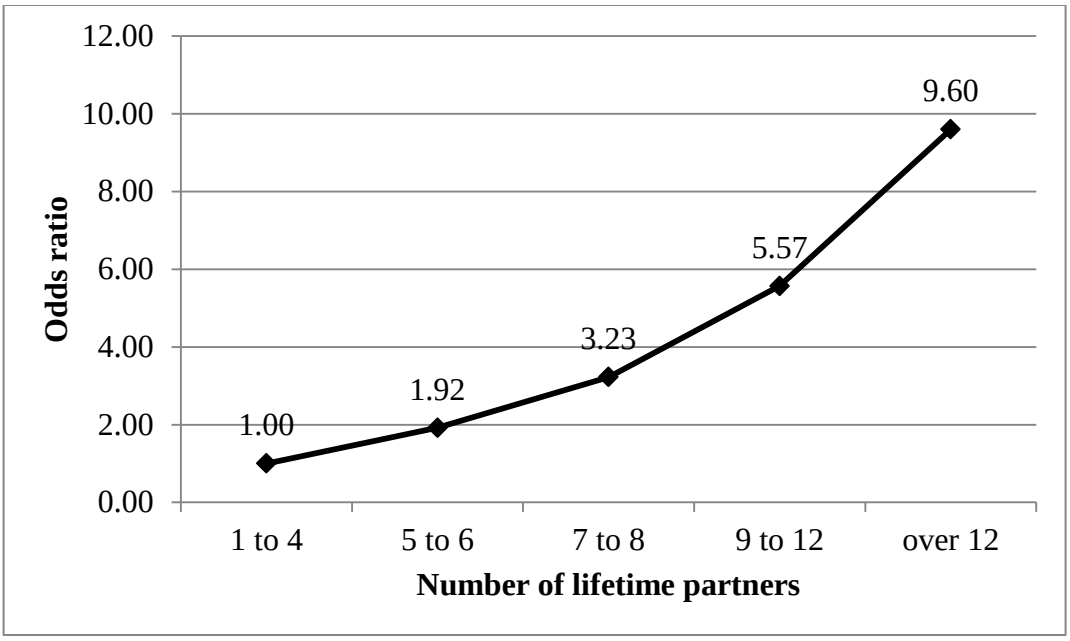

Figure 11. The odds of partnership concurrency as a function of lifetime number of partners, categorized as quintiles.

D. Discussion

We examined the effects of using four different measurement methods on estimating the prevalence of concurrent partnerships. In this study, the UNAIDS-recommended indicator (point prevalence at six months before interview) was consistently the most conservative estimate of concurrency, and point prevalence at the time of the interview was consistently the highest. Several studies have found that concurrency prevalence at the time of the interview was equal to or more accurate compared to the UNAIDS indicator (Glynn et al., 2012; Helleringer et al., 2011). However, it has also been hypothesized to overestimate concurrency, especially in younger men, due to unrealized optimism regarding future sexual encounters with recent partners (Eaton et al., 2012). Our findings of higher prevalence estimates produced by point prevalence at the time of the interview compared to any other time point, support this hypothesis.

Due to our follow-up schedule, the UNAIDS recommendation for six-month recall resulted in significant sample restriction (approximately 50% loss). It was hypothesized that a shorter recall period (e.g., three months) would maintain the same theoretical advantage in assessment of ongoing relationships, while avoiding missing data and selection bias. An empirical study indicated that stable estimates could be calculated at retrospective points between three and seven months with prevalence decreasing before and after this period (Eaton et al., 2012). This was not consistent with our finding of greater variability of estimates and significantly increased estimates at three- versus six-month recall. This difference may relate to selection or reporting biases, if men restricted at six-months were more likely to have concurrent partnerships or if partnerships taking place closer to end of recall were underreported. This highlights the importance of careful consideration in the application of the UNAIDS suggested recall time point in secondary analyses and in future studies designed specifically to address concurrency.

Exclusion and inclusion of one-month overlap provides two opposite estimates, the first being based on the assumption that no two relationships starting and/or ending in the same month are concurrent, while the second assuming that all such relationships are concurrent. The truth likely lies somewhere in between. The treatment of one-month overlap in defining concurrency has consequences in two domains: (1) the accurate classification of concurrent partnerships as "partnerships in which sexual intercourse with one partner occurs between two acts of intercourse with another partner" (UNAIDS Reference Group on Measurement and Modeling, 2010); and (2) assessing the effect of concurrency in the context of HIV and STI transmission (Eaton et al., 2011). In our sample, the impact of redefining partnerships overlapping during only one month as non-concurrent was significant, reducing both the point and cumulative prevalence of concurrency by 3%–9%. This reduction was largely due to redefining short-term

(one month) partnerships as non-concurrent. In general, point prevalence tends to exclude partnerships with short-term overlap, and several studies have found that date-based measurement, such as ours, may additionally underreport short-term partnerships (Glynn et al., 2012; Maughan-Brown and Venkataramani, 2011). While long-term partnerships may play a greater role in HIV transmission dynamics in the specific context of concurrency (Mah and Halperin, 2010), a wider view encompassing an appreciation of acute phase viremia and full consideration of short-term relationships in assessing concurrency seems prudent (Eaton et al., 2011).

A common observation, and one noted here, is that early sexual debut and lifetime number of sexual partners are strongly associated with concurrency (Nelson et al., 2007; Kenyon et al., 2010; Steffenson et al., 2011; Manhart et al., 2002; Sandoy et al., 2010; Adimora et al., 2004). Correlatively, a main thrust of the controversy surrounding concurrent partnerships and reduction of HIV incidence is whether interventions specifically addressing it would achieve results beyond existing efforts toward partner reduction (Lurie et al., 2009; Lurie and Rosenthal, 2010b, 2010a; Mah and Halperin, 2010; Kalichman and Grebler, 2010). That an overall reduction in sexual partners decreases the risk of concurrency is intuitive and supported by our findings (Figures 10 and 11). However, the curvilinear shape of the relationships suggests that for higher-risk men, those with a greater lifetime number of partners, a prevention strategy directly addressing concurrency may be more effective than partner reduction alone. Specifically, once a man has reached 18 partnerships his average number of concurrent partnerships becomes largely insensitive to additional relationships. This suggests that, at least for the highest risk men, counseling directed at the dissolution of current partnerships (concurrency reduction) may have an importance that is independent of future partner reduction. Mathematical modeling has also

suggested that targeting higher-risk men for concurrency reduction would result in the most significant decrease in HIV infections (Voeten et al., 2004).

The factors we found to be associated with concurrency differed by partnership type. Partnerships of longer duration were more likely to be concurrent, which is intuitive, as the probability that an incoming partnership will overlap with a current partnership increases with the partnership duration (Manhart et al., 2002; Nelson et al., 2007). Consistent with Kenyon et al., the belief that a partner has other partners was strongly associated with that partnership being concurrent (Kenyon et al., 2010). This either represents a degree of self-justification or a propensity for "open" relationships in both parties, which could further bridge sexual networks and increase the density of network connectivity (Kenyon et al., 2010; Kretzschmar and Morris, 1996; Xu et al., 2010). Other factors associated with casual partnership concurrency, such as consistent condom use and perception that partner is HIV-positive, have not been explored by other studies as much and, perhaps, indicate that participants perceive concurrent partnerships as higher risk in general.

Considering that the men in our sample were just 18–24 years of age, we found a remarkably high lifetime concurrency prevalence of 77%. As far as we know, no other study assessed lifetime prevalence of concurrency, but comparing to other long-term cumulative prevalence in South Africa (41% based on last 10 partners) and Kenya (26% in last 9.5 years), our estimate remains high (Kenyon et al., 2010; Xu et al., 2010). The point prevalence concurrency estimates observed in this population were also higher than those recently reported throughout sub-Saharan Africa (Kajubi et al., 2011; Morris et al., 2010; Sandoy et al., 2010; Steffenson et al., 2011) or in Kisumu specifically (Xu et al., 2010). As has been discussed, the direct comparison of estimates is problematic; but the overall high HIV risk of this RCT sub-sample likely explains some

of these differences. Of note, the only similar level of concurrency published in the region was observed in Kisumu in mid 1990s, concurrent with the peak in the HIV epidemic there (Ferry et al., 2001; NACC and NASCOP, 2012; Voeten et al., 2004).

This study has a number of important limitations. The men enrolled were self-selected from sexually active men screened for participation in a RCT for HIV prevention. Levels of concurrency, and overall HIV risk, in the general population are likely lower. At baseline, we collected a comprehensive lifetime sexual history from each participant, and the recall period for this history was as long as 10 years. While the accuracy of recall in our study was enhanced by the use of the Timeline Followback approach, the magnitude and direction of any recall bias could lead to an overestimation or underestimation of long-term concurrency. Our use of face-to-face interview may have resulted in increased social desirability bias; however, this risk was limited by using specially trained interviewers with established rapport over multiple interviews. Self-assessed concurrency was not assessed directly and our data did not allow us to measure any network-level risks associated with concurrency (Morris, 2010). Lastly, our evaluation of the relationship between concurrency and the number of partners is limited by the intrinsic correlation between the two measures.

E. Conclusion

Our results show that concurrent sexual partners, as part of both regular and casual partnerships and assessed in varying ways and over varying recall periods, are frequent among young, sexually active men in Kisumu—a generalized HIV epidemic setting with an adult HIV prevalence of 20% (KNBS and ICF Macro, 2010). While point prevalence at the time of the interview produced higher estimates than point prevalence calculated over longer recall periods, it was more consistent across study visits and less likely to be affected by recall bias, missing data,

and sample size fluctuations during follow-up. Further research is needed to explore the effect of the recall period on the timeframe selected for point prevalence calculation, as well as the impact of over- or under-reporting of past, current, and ongoing partners on the magnitude and direction of discrepancies in calculating concurrency (Eaton et al., 2012; Glynn et al., 2012; Helleringer et al., 2011; Maughan-Brown and Venkataramani, 2011). Meanwhile, interventions addressing both individual and partnership indicators of concurrency in this population are warranted, whether directed at reducing concurrency specifically or integrated into broader interventions targeting reduction of multiple sexual partners and other behavioral change interventions.

VI. CONCLUSION AND SIGNIFICANCE

After many years of searching for an effective HIV vaccine and repeated failures in developing effective biomedical prevention strategies, MC was a welcome breakthrough, reinvigorating the hope of ending the HIV pandemic. Proven to provide up to 60% protection against heterosexual HIV acquisition in males by three RCTs in sub-Saharan populations, VMMC was promptly recommended by UNAIDS and WHO as an important additional strategy for HIV prevention. Fourteen countries in eastern and southern Africa, including Kenya, with high HIV prevalence and low levels of MC were set as priority areas for MC scale-up (Bailey et al., 2007; Gray et al., 2007a; Auvert et al., 2005; WHO/UNAIDS, 2007).

Several priority countries took up the implementation of VMMC with enthusiasm and strong political backing. By all measures, Kenya's VMMC program for HIV prevention is the world's most successful (Weiss et al., 2010; WHO, 2011). However, concerns about the effectiveness and the real-life impact of VMMC remained important points of contention for both countries hesitating to begin VMMC scale-up and as operating programs sought continued funding. In this thesis, we investigated two issues pertaining to these questions of real-world effectives including the direct assessment of behavioral risk compensation and quantification of the subjective effect of male circumcision on reproductive health. Additionally, we have conducted an in-depth exploration of one of the most understudied HIV risk behaviors in Kenya: concurrent sexual partnership.

Specifically, our objectives were to: (1) assess the longitudinal change in risk behaviors of men choosing to become circumcised through a general VMMC initiative, (2) determine the prevalence and correlates of penile coital injuries in circumcised and uncircumcised men, and (3) explore the prevalence and correlates of sexual partnership concurrency at the individual and partnership level.

Risk compensation is defined as an increase in risky behavior in response to perceived risk reduction following an intervention (Hogben and Liddon, 2008). Risk compensation is an important possible mechanism that could negatively impact the effectiveness of VMMC programs (Cassell et al., 2006; Kalichman et al., 2007b). If operating, risk compensation could reduce the protective effect of circumcision against HIV and, if of sufficient magnitude, even completely negate the protection (White et al., 2008). The prior evidence of risk compensation following MC has been limited to hypothetical models and behavioral evaluations in the RCT populations (Agot et al., 2007; Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007a; Kong et al., 2012; Mattson et al., 2008). Due to this limitation in real-world assessment, research designed to monitor post-circumcision risk compensation over time, in the context of active promotion of VMMC as an HIV prevention strategy, has been set as a high research priority (Weiss et al., 2010; White et al., 2008).

This is the first study of longitudinal change in HIV-associated risk behaviors in men before and after circumcision in the context of a national population-level VMMC program. Our large prospective study found no evidence of risk compensation in circumcised men. To the contrary, both circumcised and uncircumcised men significantly reduced their HIV risk behaviors over 24 months of follow-up. In light of our results, and in the context of similar findings in varying populations, concerns about risk compensation in the context of VMMC programs for HIV

prevention should not impede the widespread scale-up of the VMMC services (Agot et al., 2007; Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007a; Kong et al., 2012; Mattson et al., 2008; Westercamp et al., 2011). Previously, modeling of the impact of widespread VMMC programs has included sensitivity analyses of the hypothetical effect of increases in risk behaviors after circumcision (Alsallaq et al., 2009; Andersson et al., 2011; Dushoff et al., 2011; Gray et al., 2007b; Hallett et al., 2011; Hallett et al., 2008; Kahn et al., 2006; Nagelkerke et al., 2007; Njeuhmeli et al., 2011; White et al., 2008; Williams et al., 2006; UNAIDS/WHO/SACEMA, 2009). We recommend that future models also include scenarios of men engaging in safer sexual behaviors following the procedure in VMMC impact predictions. The findings from these models are important not only in forecasting the future of the HIV epidemic, but also can inform public opinion, drive national policy debates, and guide funding projections (Njeuhmeli et al., 2011; UNAIDS/WHO/SACEMA, 2009).

Despite our encouraging findings, it remains prudent that educational messages regarding the effectiveness of MC for HIV prevention be balanced with emphasis on continuing or enhancing risk-reduction education. Confirmation of our findings in different populations is needed, and will guide future research to identify the mechanisms behind these observed reductions in HIV risk behavior and help develop strategies to encourage them. Risk compensation in newly circumcised men may be the most logical to develop; however, modeling studies have suggested that it is behavioral change across the population that is the most likely to negatively impact HIV dynamics. Thus, studies evaluating such risk compensation in women, HIV-positive men, and uncircumcised men, will be needed to further our understanding of the more general community-level impact of VMMC. Finally, because community-level response may change as VMMC programs mature, the monitoring of risk compensation should be continued as VMMC initiatives mature.

As a second objective, we evaluated a measure of sexual/reproductive health that has received very little empirical attention, but may have important implications for our understanding of the biological mechanism underpinning the HIV protection afforded circumcised men: the comparative fragility of the preputial mucosa leading to increased mild to moderate injuries during intercourse (Fink, 1986; Cameron et al., 1989; Simonsen et al., 1988; Stone et al., 1986; Szabo and Short, 2000). Such penile coital injuries resulting in epithelial disruption, have been hypothesized to specifically increase the risk of HIV and GUD, as well as have non-specific negative impacts to men's reproductive health. Previous research on the prevalence and correlates of penile coital injuries is limited to the Kenya RCT evaluations. This research concluded that penile coital injuries are more common among uncircumcised men, may be an important non-STI cause of GUD, and increase the risk of *N. gonorrhoeae* (Mehta et al., 2009; Mehta et al., 2010; Mehta et al., 2012a). Using the same measures of coital injury, we observed that declines in cuts, scratches, and abrasions; in soreness; and in bleeding during sex, were evident as early as six months following circumcision. We also identified several factors associated with such injuries. While prevention of coital injuries may be important in that regard alone, the potential motivational force for circumcision may also be of value. In our study we found that men reporting penile coital injuries were more likely to be among the earliest adopters of VMMC and that these men did report a decline in coital injuries following their procedure. Further, our measures of sexual satisfaction suggested that men seeking circumcision services had relatively low levels of pre-procedure sexual satisfaction, and that concurrent penile coital injuries played some part in this (Westercamp et al., 2012). This potentially justifiable role of circumcision in improvement of the sexual experience, through the removal of a potential source of sexual discomfort associated with penile coital injuries, may resonate with a significant portion men targeted for VMMC

(Figueroa et al., 1994; Fleming and Wasserheit, 1999; O'Farrell, 1993; Szabo and Short, 2000; Layer et al., 2012). The role of penile coital injuries in motivation for seeking VMMC services should be explored further.

Very little information on the prevalence of penile coital injuries in different populations is available. Our study confirms findings from the Kenyan RCT that these injuries may be more common than is generally recognized. Future studies should assess the prevalence and correlates of penile coital injuries across different geographical areas, explore potential mechanisms of injury acquisition, identify ways to prevent coital injuries (e.g., MC, lubricants, genital hygiene), and qualify the relationship between penile coital injuries, HIV acquisition, other STIs, and overall reproductive health.

The significance of sexual partner concurrency in explaining the severity of the HIV epidemic in sub-Saharan Africa is a subject of considerable debate (Epstein and Morris, 2011; Lurie et al., 2009; Lurie and Rosenthal, 2010b, 2010a; Epstein, 2010; Morris, 2010; Mah and Halperin, 2010; Kalichman and Grebler, 2010). To conclude this thesis, we set out to evaluate prevalence and correlates of concurrency in Kisumu town using a variety of measures. We also addressed one aspect in the heart of the current debate: the relevance and role of sexual concurrency in HIV prevention as opposed to the classical partner reduction. Our results show that concurrent sexual partners, as part of both regular and casual partnerships, are frequent among young, sexually active men in Kisumu—a generalized HIV epidemic setting with an adult HIV prevalence of 20% (KNBS and ICF Macro, 2010). That an overall reduction in sexual partners decreases the risk of concurrency is intuitive and supported by our findings. However, the curvilinear shape of the observed relationship suggests that for higher-risk men (i.e., those with a greater lifetime number of partners) a prevention strategy directly addressing concurrency may

be more effective than partner reduction alone. Therefore, at least for the highest risk men, counseling directed at the dissolution of current partnerships (concurrency reduction) may have importance in addition to future partner reduction for some men.

As with other sexual behaviors examined in our risk compensation analysis, sexual concurrency did not differ between circumcised and uncircumcised men over time. However, considering how common this practice is in Western Kenya, it may be beneficial to include some information on sexual concurrency in the risk-reduction counseling accompanying the VMMC service provision. Outside of the VMMC provision, further research evaluating the validity of different prevalence measures currently in use is needed to explore the impact of over- or underreporting of past, current, and ongoing partners on the magnitude and direction of discrepancies in calculating concurrency (Eaton et al., 2012; Glynn et al., 2012; Helleringer et al., 2011; Maughan-Brown and Venkataramani, 2011). Prevention studies, possibly targeting different risk groups, would be valuable in identifying the most effective ways to address concurrency at the community level. Regardless, interventions targeting both individual and partnership correlates of concurrency in this population are warranted, either directed at reducing concurrency specifically or integrated into existing partner reduction strategies.

In conclusion, we have addressed one of the prevailing concerns of VMMC initiatives by confirming that newly circumcised men in a general population setting do not increase their HIV risk behavior following the procedure. Further, we suggest that newly circumcised men may be inclined to adopt increasingly protective patterns of behavior possibly improving programmatic impact on the HIV situation. The lack of negative effects of MC on sexual health, as seen with the penile coital injuries and genital ulcers, should alleviate other concerns about providing VMMC services to communities. These findings should justify renewed attention to the structural barriers

that have slowed VMMC program scale-up in many priority countries and should serve as evidence that these concerns should not impede the widespread scale-up of the VMMC services.

APPENDICES

APPENDIX A

SHABS Questionnaire

A. Baseline eligibility

1. How did you hear about study?

1 = Clinic personnel (reception or clinical staff) 2 = Was contacted by study interviewer
3 = Saw the postings / flyers 4 = Was told about study by a friend/colleague
5 = Other, specify _____

2. Are you planning to move from this area in next 2 years? 1 = Yes 2 = No
(if yes – not eligible for the study)

3. At your last birthday, how old were you? _____
(if younger than 18 or older than 35 – not eligible for the study)

B. Circumcision status

4. Are you circumcised? 1 = Yes (go to 7) 2 = No

(verify circumcision by visual inspection at this point; at enrollment: if circumcised – not eligible for the study)

5. If not, how likely are you to become circumcised?

a.	Within 1 month	1 = Definitely 4 = Probably not	2 = Probably 5 = Definitely not	3 = Don't know
b.	Within 6 months	1 = Definitely 4 = Probably not	2 = Probably 5 = Definitely not	3 = Don't know
c.	Within 1 year	1 = Definitely 4 = Probably not	2 = Probably 5 = Definitely not	3 = Don't know
d.	Ever	1 = Definitely 4 = Probably not	2 = Probably 5 = Definitely not	3 = Don't know

(*at enrollment - If definitely at 1 month or at 6 months, direct to the reception to schedule MC and come back to enroll into MC group*).

6. Do you have a circumcision surgery scheduled at this or any other facility? 1 = Yes 2 = No
6a. Specify other facility: _____

If yes, when? __ __/ __ __ / __ __ __ __
dd mm yyyy

7. How far did you travel today to come to this health facility:

_____ hours _____ minutes by bus or matatu _____ kilometers

APPENDIX A (continued)

C. Baseline demographics

1. Date of birth **dd/mm/yyyy**

2. How old were you on your last birthday? _____

3. What is your home district?

1 = Kisumu East	2 = Kisumu West	3 = Siaya	4 = Nyando	5 = Rachuonyo
6 = Bondo	7 = Migori	8 = Suba	9 = Kisii	10 = Gucha
11 = Nyamira	12 = Kuria	13 = Homa Bay	14 = Rarieda	15 = Vihiga
16 = Borabu	17 = Kakamega	18 = Nandi	19 = Kericho	20 = Other
21 = Butere/Mumias	22 = Busia	28 = DK	29 = RE	

4. What is your religion?

1 = Catholic	2 = Anglican	3 = Muslim	4 = Pentecostal	5 = 7th Day Advantist
6 = Other	7 = No religion	28 = DK	29 = RE	

5. What is your ethnic group/tribe?

1 = Luo	2 = Kikuyu	3 = Kisii	4 = Kalenjin	5 = Kamba
6 = Luhya	7 = Meru/Embu	8 = Maasai	9 = Kuria	10 = Coastal
11 = Other				

6. How many years of school have you attained? _____

7. Can you read a newspaper or a letter? 1 = Yes 2 = Some 3 = No 28 = DK 29 = RE

8. Where are you currently staying?

Kisumu Districts divisions: 1 = Kombewa 2 = Maseno 3 = Winam 4 = Kadibo

Nyando District divisions: 5 **=** Lower Nyakach 6 = Miwani 7 = Muhoroni
8 = Nyando (Awasi) 9 = Upper Nyakach 10 = Other: _____

9. How long have you stayed there?

Years ___ ___ Months ___ ___

[If less than one month, enter 00 months. If forever, enter 98 years.]

APPENDIX A (continued)

D. Background characteristics

1. Are you currently employed? **1 = Yes** **2 = No** **28 = DK** **29 = RE**

If Yes, what do you currently do to earn a living

1= Regularly employed
2 = Employed seasonally, on short-term contract, or on a day-to-day basis
3 = Self-employed

If No:

4 = Unemployed and looking for work
5 = A homemaker with no other work outside
6 = A student
7 = Retired or disabled
8 = Other (specify): _____

2. What is your average monthly income over the last 12 months? _____

3. Do you have electricity in your household? 1 = Yes 2 = No

4. How many people stay with you in your household? _____

5. With how many people do you share your bathing room _____

6. Where is the closest to your house source of water? 1 = In house (tap water)
2 = Right outside of house (in your compound)
3 = Less than 10 minutes walk from your house
4 = More than 10 minutes walk from your house

APPENDIX A (continued)

7. With whom do you currently live?

1 = Alone
2 = Wife/live-in female partner
3 = Family
4 = Friend(s)
5 = Other _____
28 = DK
29 = RE

8. What is your current marital status?

1 = Single, without live-in partner →(Go to 11)
2 = Single, with live-in partner
3 = Married, living with wife
4 = Married, not living with wife
28 = DK
29 = RE

9. How many wives/live-in partners do you have?

Wives / partners _____

10. Last night, did you and a wife or live-in partner sleep in the same house?

1 = Yes 2 = No 28 = DK 29 = RE

11. In past 6 months, how many trips of more than one night did you have?

_ _ _

APPENDIX A (continued)

E. Blood Exposures

12. Have you ever donated blood? 1 = Yes 2 = No 28 = DK 29 = RE

12a. If yes, how many times in last 6 months? _____

13. Have you ever received blood in a hospital (a blood transfusion)? 1 = Yes 2 = No 28 = DK 29 = RE

13a. If yes, how many times in last 6 months? _____

14. Have you ever come in contact with blood of another person? 1 = Yes 2 = No 28 = DK 29 = RE

14a. If yes, how many times in last 6 months? _____

14b. Please briefly state what happened (accident, fight, etc.) _____

15. Have you ever been tattooed? 1 = Yes 2 = No 28 = DK 29 = RE

15a. If yes, how many times in last 6 months? _____

16. Have you ever practiced bloodletting (saro) for health or other purposes? 1 = Yes 2 = No 28 = DK 29 = RE

16a. If yes, how many times in last 6 months? _____

17. Have you ever received an injection for any reason? 1 = Yes 2 = No 28 = DK 29 = RE

17a. If yes, how many times in last 6 months? _____

17b. If yes, how many of them were for STD treatment in last 6 months? _____

18. In the last 6 months, have you been pricked by a needle or cut by a knife for any reason? 1 = Yes 2 = No 28 = DK 29 = RE

18a. If yes, how many times? _____

18b. If yes, what were some of the reasons? _____

APPENDIX A (continued)

F. Sexual Practices

19. Have you ever had vaginal sex with a girl/woman? 1 = Yes 2 = No 29 = RE (if no, go to 34)

20. How old were you (in years) when you had sex with a girl/woman for the first time? __ __ years

21. How many different girls/women including your wife/wives have you had sex with during ....

21a. your lifetime? __ __ __

21b. last 12 months? __ __ __

21c. last 6 months? __ __ __

21d. last 30 days? __ __ __

22. Have you had sexual intercourse in the past 6 months? 1 = Yes 2 = No 29 = RE

23. How long since you last had sexual intercourse?

__ __ days
__ __ weeks
__ __ months
__ __ years

24. How many times have you had sexual intercourse including with your wife and any other partner in:

24a. Past 7 days __ __

24b. Past 30 days __ __

APPENDIX A (continued)

25. In the past 6 months, have you ever:

25a. Had sex in a situation in which money or gifts were exchanged? 1 = Yes 2 = No 29 = RE

25b. Had vaginal sex with a woman while she was menstruating? 1 = Yes 2 = No 29 = RE

25c. Had sex with 2 or more partners during the same 30-day period? 1 = Yes 2 = No 29 = RE

26. Have you ever had sex with 2 or more partners during the same 30-day period? 1 = Yes 2 = No 29 = RE

27. The last time you had sex …

27a. Had you been drinking alcohol? 1 = Yes 2 = No 29 = RE

27b. Did you use a condom? 1 = Yes 2 = No 29 = RE

27c. Was it with… 1 = your wife 2 = your regular partner
3 = non-regular partner 4 = sex worker
28 = DK 29 = RE

28. How often have you placed your tongue on or licked the vagina of your sex partner? 1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 28 = DK 29 = RE

29. How often have you stuck your penis in the rectum (anus) of your partner? 1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 28 = DK 29 = RE

30. How often have you had sex with a woman the same day you met her? 1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 28 = DK 29 = RE

31. How often have you had sex after applying any substances (e.g., herbs, creams, lubricants, etc.) on your penis? 1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 28 = DK 29 = RE

31a. If ever, what substances? _____

APPENDIX A (continued)

32. How often have you had sex when your partner has used substances on or in her vagina?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 28 = DK 29 = RE
32a. If ever, what substances?	_____
33. Do you prefer to have sexual intercourse when your partner's vagina is ..... (*read options*)	1 = Dry during intercourse 2 = Wet during intercourse 3 = No preference
If dry, in your experience, what does a woman do to make her vagina dry?	
33a. Wipes vagina with a towel/cloth	
33b. Uses herbs and powders	1 = Yes 2 = No 28 = DK 29 = RE
33c. Uses commercially available products (e.g., antiseptic, soap, etc.)	1 = Yes 2 = No 28 = DK 29 = RE 1 = Yes 2 = No 28 = DK 29 = RE
34. Have you ever had a sexual relationship with a boy or man?	1 = Yes 2 = No 29 = RE No →(Go to 39)
35. If yes, how many different boys/men?	__ __
36. Have you stuck your penis in the rectum (anus) of another man?	1 = Yes 2 = No 29 = RE
37. Have you had a penis stuck in your rectum (anus)?	1 = Yes 2 = No 29 = RE
38. Have you had a man ejaculate in your mouth?	1 = Yes 2 = No 29 = RE

APPENDIX A (continued)

G. Alcohol and drug use

39. Did you have drinks containing alcohol like beer, spirits, chang'aa, busaa, etc. in the last four weeks?	1 = Yes 2 = No 28 = DK 29 = RE No →(Go to 41)
40. How often did you have drinks containing alcohol in the last four weeks? Would you say… ?	1 = At least once a day 2 = At least once a week 3 = Less than once a week
41. During the last 6 months, how often have you had sex after or while you have been drinking?	1 = Never 2 = Sometimes 3 = Often 4 = Always 28 = DK 29 = RE
42. Some people have tried a range of different types of drugs. Which of the following, if any, have you tried?	
42a. Bhang / njaga	1 = Yes 2 = No
42b. Mandrax	1 = Yes 2 = No
42c. Valium	1 = Yes 2 = No
42d. Glue	1 = Yes 2 = No
42e. Miraa	1 = Yes 2 = No
42f. Kuber	1 = Yes 2 = No
42g. Other (specify)	_____
43. Some people have tried injecting drugs using a syringe. Have you ever injected drugs (not for medical reasons)?	1 = Yes 2 = No 28 = DK 29 = RE
44. During the last 6 months, how often have you had sex while or after you have used some of these drugs?	1 = Never 2 = Sometimes 3 = Often 4 = Always 28 = DK 29 = RE

APPENDIX A (continued)

H. Condom Use

45. Have you ever used a condom?	1 = Yes 2 = No 28 = DK 29 = RE No →(Go to 49)
46. Have you ever experienced a problem with using condoms?	1 = Yes 2 = No 28 = DK 29 = RE
If yes, what kind of problem:	
46a. Did not know how to use condom	1 = Yes 2 = No
46b. Condom broke	1 = Yes 2 = No
46c. Condom slipped during the intercourse	1 = Yes 2 = No
46d. Condom was too large	1 = Yes 2 = No
46e. Condom was too small	1 = Yes 2 = No
46f. Other (specify)	_____
47. In the last 6 months, do you think it has been easy or difficult for you to obtain condoms?	1 = Very easy 2 = Somewhat easy 3 = Somewhat difficult 4 = Very difficult 28 = DK 29 = RE
48. Do you currently have a condom with you?	1 = Yes 2 = No 29 = RE

APPENDIX A (continued)

I. Reproductive health history

"Now I would like to ask you some questions about your reproductive health. Some men experience pain during urination, have discharge from the penis, or have sores around their genitals."

49. During the last 6 months, have you experienced:

49a. Painful urination	1 = Yes 2 = No
49b. Frequent urination	1 = Yes 2 = No
49c. Sores around your genitals	1 = Yes 2 = No
49d. Discharge from your penis	1 = Yes 2 = No
49e. Difficulty passing urine (need to wait a long time until urine comes)	1 = Yes 2 = No
49f. Pain during intercourse	1 = Yes 2 = No
49g. Bleeding during intercourse	1 = Yes 2 = No
49h. Lower abdomen pain	1 = Yes 2 = No
49i. Genital warts	1 = Yes 2 = No

50. If yes on any item in 49: Did you have sex while suffering from these symptoms? 1 = Yes 2 = No 28 = DK 29 = RE

51. Has a doctor or other health professional EVER told you that you had a sexually transmitted infection? Yes = 1 No = 2 28 = DK 29 = RE

51a. If yes, do you remember which STI? _____

52. Did you have a sexually transmitted infection in past 6 months? 1 = Yes 2 = No 28 = DK 29 = RE

APPENDIX A (continued)

53. Have you EVER received treatment for a sexually transmitted infection? 1 = Yes 2 = No 28 = DK 29 = RE

53a. If yes, how many times? _____

53b. Were you given an injection for treatment? 1 = Yes 2 = No

53c. Were you treated for a sexually transmitted infection in past 6 months? 1 = Yes 2 = No

J. Sexual function and satisfaction

54. During the last 6 months, has there ever been a period of two weeks or more when you …

54a. Lacked interest in sex? 1 = Yes 2 = No 28 = DK 29 = RE

54b. Were unable to come to a climax (experience an orgasm)? 1 = Yes 2 = No 28 = DK 29 = RE

54c. Came to a climax (had an orgasm) too quickly? 1 = Yes 2 = No 28 = DK 29 = RE

54d. Experienced pain during intercourse? 1 = Yes 2 = No 28 = DK 29 = RE

54e. Did not find sex pleasurable (even if it wasn't painful)? 1 = Yes 2 = No 28 = DK 29 = RE

54f. Had trouble achieving or maintaining erection? 1 = Yes 2 = No 28 = DK 29 = RE

55. In the past 6 months, how often during sex did your penis get sore? 1 = Never 2 = Rarely 2 = Sometimes 3 = Often 4 = Always 28 = DK 29 = RE

56. In the past 6 months, how often during sex did the skin of your penis get scratches, cuts, or abrasions? 1 = Never 2 = Rarely 2 = Sometimes 3 = Often 4 = Always 28 = DK 29 = RE

APPENDIX A (continued)

57. In the past 6 months, how often during or after sex did the skin of your penis bleed?

1 = Never 2 = Rarely 2 = Sometimes 3 = Often 4 = Always 28 = DK 29 = RE

58. Over the past 6 months, how would you generally rate your satisfaction with sexual intercourse?

1 = Very dissatisfied 2 = Dissatisfied
3 = Satisfied 4 = Very satisfied
28 = DK 29 = RE

59. In the past 6 months, do you believe your sexual activity has:

1 = Decreased in frequency →Go to 60
2 = Increased in frequency →Go to 61
3 = Stayed the same →Go to 62
28 = DK →Go to 62
29 = RE →Go to 62

60. What are some of the reasons your sexual activity has decreased in the last 6 months?

60a. Fear of HIV/STIs 1 = Yes 2 = No
60b. Fewer opportunities to have sex 1 = Yes 2 = No
60c. Influences from the media, community, friends, etc. 1 = Yes 2 = No
60d. Personal decision to reduce sexual activity 1 = Yes 2 = No
60e. Other (specify) _____

61. What are some of the reasons your sexual activity has increased in the last 6 months?

61a. Increase in sexual desire 1 = Yes 2 = No
61b. More opportunities to have sex (more partners are available and willing) 1 = Yes 2 = No
61c. Influences from the media, community, friends, etc. 1 = Yes 2 = No
61d. Circumcision 1 = Yes 2 = No
61e. Other (specify) _____

APPENDIX A (continued)

62. What do you think are your chances of getting HIV/AIDS?	1 = No chance at all 2 = Small chance 3 = Moderate chance →Go to 64 4 = Great chance →Go to 64 5 = Don't know →Go to 65
63. Why do you think that you have no chance at all or small chance of getting HIV/AIDS?	When answered, go to 65
63a. Am not having sex	1 = Yes 2 = No
63b. Always use condoms	1 = Yes 2 = No
63c. Have only one partner	1 = Yes 2 = No
63d. Limit the number of partners	1 = Yes 2 = No
63e. Partner is faithful to me	1 = Yes 2 = No
63f. Circumcision	1 = Yes 2 = No
63g. Other (specify)	_____
64. Why do you think that you have a moderate chance or a great chance of getting HIV/AIDS?	
64a. Do not use condoms	1 = Yes 2 = No
64b. Have more than 1 sexual partner	1 = Yes 2 = No
64c. Partner has other partners	1 = Yes 2 = No
64d. Homosexual contacts	1 = Yes 2 = No
64e. Had blood transfusion/injection	1 = Yes 2 = No
64f. I was circumcised	1 = Yes 2 = No
64g. Other (specify)	_____

APPENDIX A (continued)

65. Which activity, in your opinion, puts a person at a higher risk of HIV?

65a. Vaginal or anal intercourse?

1 = Unprotected vaginal intercourse is higher risk
2 = Unprotected anal intercourse is higher risk
3 = Both have same risk of HIV
28 = DK 29 = RE

65b. Dry (when your partner dries her vagina with cloth or substances) or wet sex??

1 = Unprotected wet sex is higher risk
2 = Unprotected dry sex is higher risk
3 = Both have same risk of HIV
28 = DK 29 = RE

66. Do you agree with following statements?

66a. It takes a lot of effort to keep your sexual behavior safe. 1 = Agree 2 = Not sure 3 = Disagree

66b. You feel tired of always having to monitor your sexual behavior. 1 = Agree 2 = Not sure 3 = Disagree

66c. When you are high or drunk, you are more likely to have sex with people other than your regular partner. 1 = Agree 2 = Not sure 3 = Disagree

66d. When you are high or drunk, you are more likely to have sex without a condom. 1 = Agree 2 = Not sure 3 = Disagree

APPENDIX A (continued)

K. Beliefs about sex and sexuality

67. Please tell me whether you agree or disagree with the following statements.

67a. Men can enjoy sex even with partners that they don't love

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67b. A "real man" is ready for sex at any time

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67c. Women have greater control over sexual desires than men

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67d. Sex is an important part of life

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67e. Inability to perform sexually is a source of sadness for partners

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67f. The quality of an erection is what satisfies women

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67g. A real man has sex very frequently

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67h. Women who are not sexually attractive can not be sexually satisfied

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

67i. I am happy with my physical appearance

1 = Strongly agree 2 = Agree 3 = Not sure
4 = Disagree 5 = Strongly disagree 29 = RE

APPENDIX A (continued)

L. Beliefs about circumcision

68. Is it easier to keep your penis clean if you are…..?

1 = Circumcised 2 = Uncircumcised
3 = No difference 28 = DK 29 = RE

69. It is easier to get a disease from a woman if you are …?

1 = Circumcised 2 = Uncircumcised
3 = No difference 28 = DK 29 = RE

70. It is easier to get AIDS if you are …?

1 = Circumcised 2 = Uncircumcised
3 = No difference 28 = DK 29 = RE

71. Men enjoy sex more if they are …?

1 = Circumcised 2 = Uncircumcised
3 = No difference 28 = DK 29 = RE

72. Most women enjoy sex more with men who are…?

1 = Circumcised 2 = Uncircumcised
3 = No difference 28 = DK 29 = RE

73. Men who are ….. are more promiscuous

1 = Circumcised 2 = Uncircumcised
3 = No difference 28 = DK 29 = RE

APPENDIX A (continued)

74. Please state your opinion on circumcision:

74a. Now that circumcision is available, HIV is a less serious threat than it used to be.	1 = Agree	2 = Not sure	3 = Disagree
74b. Now that circumcision is available, condom use during sex is less necessary.	1 = Agree	2 = Not sure	3 = Disagree
74c. Now that circumcision is available, I am less worried about HIV infection.	1 = Agree	2 = Not sure	3 = Disagree
74d. Now that circumcision is available, I am more likely to have more than one sexual partner.	1 = Agree	2 = Not sure	3 = Disagree
74e. Now that circumcision is available, I am more willing to take a chance of getting infected or infecting someone else with HIV.	1 = Agree	2 = Not sure	3 = Disagree
74f. Now that circumcision is available, someone who is HIV positive doesn't need to worry as much about condom use.	1 = Agree	2 = Not sure	3 = Disagree
74g. Now that circumcision is available, you are more likely to have sex without a condom.	1 = Agree	2 = Not sure	3 = Disagree

APPENDIX A (continued)

M. Hygiene

75. How often do you normally wash your penis?	1 = Once a month or less 2 = Several times a month 3 = Weekly 4 = Several times a week 5 = Daily 6 = Don't wash penis
76. The last time you had vaginal intercourse, did you wash your genitals immediately after sex?	1 = Yes 2 = No 28 = DK 29 = RE
What did you use to clean your penis?	
76a. Cloth/rag without water	1 = Yes 2 = No 28 = DK 29 = RE
76b. Water	1 = Yes 2 = No 28 = DK 29 = RE
76c. Soap and water	1 = Yes 2 = No 28 = DK 29 = RE
76d. Herbs	1 = Yes 2 = No 28 = DK 29 = RE
76e. Other (specify)	_____
76f. How long it until you washed your penis after last vaginal intercourse?	_____ hrs _____ min
77. Have you ever put or applied substance(s) on head of your penis for any reason?	1 = Yes 2 = No 28 = DK 29 = RE →Go 78
77a. If yes, why did you apply those substances?	1 = For cleaning / killing germs 2 = Removing bad odor 3 = Contraception 4 = To cure itching 5 = After sex to clean the penis 6 = Before sex for initiation/preparation 7 = To treat ulcers 8 = To protect myself against disease/infection 9 = To protect partner from disease/infection 29 = RE

APPENDIX A (continued)

N. HIV testing and counseling

78. Have you ever been tested for HIV	1 = Yes 2 = No 28 = DK 29 = RE
79. When you were tested for HIV, did you receive information on how to reduce your risk of acquiring or transmitting HIV?	1 = Yes 2 = No 28 = DK 29 = RE
80. How many times have you been tested for HIV?	__ __
81. When was the last time you were tested?	1 = less than one year ago 2 = 1-2 years ago 3 = more than 2 years ago
82. I am going to ask you about the result of your HIV test, but you may refuse to answer if you wish. What was the result of your last HIV tes	1 = Positive 2 = Negative (go to 85) 3 = Did not get the result (go to 85) 29 = RE (go to 85)
83. Do you go to a clinic to get HIV care?	1 = Yes 2 = No 28 = DK 29 = RE
84. Are you on antiretroviral therapy (ART)	1 = Yes 2 = No 28 = DK 29 = RE

APPENDIX A (continued)

O. Circumcision

85. Are you circumcised?

1 = Yes
2 = No → Go to 102

86. Where were you circumcised?

1 = In this clinic
2 = Other (specify)_____

87. How long ago were you circumcised?

__ __ days
__ __ weeks
__ __ months

88. How satisfied are you ....

88a. With the way your circumcision was carried out?

1 = Very satisfied 2 = Somewhat satisfied
3 = No opinion 4 = Somewhat dissatisfied
5 = Very dissatisfied 28 = DK 29 = RE

88b. With the appearance of your penis?

1 = Very satisfied 2 = Somewhat satisfied
3 = No opinion 4 = Somewhat dissatisfied
5 = Very dissatisfied 28 = DK 29 = RE

88c. With your sexual performance?

1 = Very satisfied 2 = Somewhat satisfied
3 = No opinion 4 = Somewhat dissatisfied
5 = Very dissatisfied 28 = DK 29 = RE

APPENDIX A (continued)

89. Have you had an erection since the circumcision?	1 = Yes 2 = No 29 = RE
89a. If yes, do your erections feel normal?	1 = Yes 2 = No 29 = RE
89a.1 If no, why not?	
It hurts	1 = Yes 2 = No 29 = RE
it bleeds	1 = Yes 2 = No 29 = RE
it feels tight/stretched	1 = Yes 2 = No 29 = RE
89b. If yes to 89, compared to before you were circumcised, how hard are your erections	1 = Harder 2 = Less hard 3 = About the same 29 = RE
90. Other than while you were healing, have you ever avoided sex because of being circumcised?	1 = Yes 2 = No 28 = DK 29 = RE
91. Have you had intercourse since the operation?	1 = Yes 2 = No 29 = RE →Go to 97f
92. How soon after surgery did you first have sexual intercourse?	__ __ hours __ __ days __ __ weeks __ __ months
93. Have you used condoms after becoming circumcised?	1 = Yes 2 = No 29 = RE →Go to 95
94. Did you find that it was easier to use condoms after circumcision, compared to when you were uncircumcised?	1 = Easier after circumcision 2 = Easier before circumcision 3 = About the same 4 = Did not use condoms before circumcision 28 = DK 29 = RE

APPENDIX A (continued)

95. Did you find that sex was more enjoyable before circumcision or after circumcision?	1 = More enjoyable before circumcision 2 = More enjoyable after circumcision 3 = No difference 28 = DK 29 = RE
96. Do you think that sex was more enjoyable before your circumcision or after circumcision for your partner(s)?	1 = More enjoyable for partners before MC 2 = More enjoyable for partners after MC 3 = No difference 28 = DK 29 = RE

APPENDIX A (continued)

97. Compared to before you were circumcised:

97a. How sensitive would you say your penis is?
1=Much more 2=Somewhat more
3=About the same 4=Somewhat less
5=Much less 28=DK 29=RE

97b. How easily do you think you reach orgasm during sex?
1=Much more 2=Somewhat more
3=About the same 4=Somewhat less
5=Much less 28=DK 29=RE

97c. How often do you have sex?
1=Much more 2=Somewhat more
3=About the same 4=Somewhat less
5=Much less 28=DK 29=RE

97d. Do you experience more, less, or about the same amount of scratches, tears, or cuts?
1=Much more 2=Somewhat more
3=About the same 4=Somewhat less
5=Much less 6= Did not experience
28=DK 29=RE scratches before

97e. Do you ejaculate earlier than you wanted?
1=Much more 2=Somewhat more
3=About the same 4=Somewhat less
5=Much less 6= Did not experience
28=DK 29=RE early ejaculation before

97f. How protected do you feel against sexual diseases?
1=Much more 2=Somewhat more
3=About the same 4=Somewhat less
5=Much less 28=DK 29=RE

97g. Is your aim during urination better, worse, or about the same?
1=Much better 2=Somewhat better
3=About the same 4=Somewhat worse
5=Much worse 28=DK 29=RE

APPENDIX A (continued)

98. Has circumcision changed your sexual behavior in any way?	1 = Yes 2 = No 28 = DK 29 = RE
99. Since you've been circumcised, how attracted are women to you	1=Much more 2=Somewhat more 3=About the same 4=Somewhat less 5=Much less 28=DK 29=RE
100. Other than your sex partners, is anyone in our family aware that you have been circumcised?	1 = Yes 2 = No 28 = DK 29 = RE
100a. If yes, overall, what is their reaction?	1=Very pleased 2=Somewhat pleased 3=Neutral or expressed no opinion 4=Somewhat displeased 5=Very displeased 28=DK 29=RE
101. Have any of your sex partners been aware that you have been circumcised?	1 = Yes 2 = No 28 = DK 29 = RE
101a. If yes, were they pleased or displeased?	1=Very pleased 2=Somewhat pleased 3=Neutral or expressed no opinion 4=Somewhat displeased 5=Very displeased 28=DK 29=RE

APPENDIX A (continued)

102. What are some of the considerations that would/did encourage you to become circumcised?

102a. Improved hygiene	1 = Yes 2 = No 28 = DK 29 = RE
102b. Protection from STI/HIV	1 = Yes 2 = No 28 = DK 29 = RE
102c. Acceptability by other ethnic groups	1 = Yes 2 = No 28 = DK 29 = RE
102d. Sexual pleasure for self	1 = Yes 2 = No 28 = DK 29 = RE
102e. Sexual pleasure for partners	1 = Yes 2 = No 28 = DK 29 = RE
102f. No cost	1 = Yes 2 = No 28 = DK 29 = RE
102g. It was available in a local health facility	1 = Yes 2 = No 28 = DK 29 = RE
102h. Influence by friends / peers	1 = Yes 2 = No 28 = DK 29 = RE
102i. Other, specify	_____

103. What are some of the considerations that would/did discourage you from becoming circumcised?

103a. Pain during/after the surgery	1 = Yes 2 = No 28 = DK 29 = RE
103b. Potential adverse events and complications	1 = Yes 2 = No 28 = DK 29 = RE
103c. Culture / Tradition / Religion	1 = Yes 2 = No 28 = DK 29 = RE
103d. Cost of procedure, including time off work	1 = Yes 2 = No 28 = DK 29 = RE
103e. Sexual pleasure for self	1 = Yes 2 = No 28 = DK 29 = RE
103f. Sexual pleasure for partners	1 = Yes 2 = No 28 = DK 29 = RE
103g. Nearest facility is far	1 = Yes 2 = No 28 = DK 29 = RE
103h. Long healing period	1 = Yes 2 = No 28 = DK 29 = RE
103i. Other, specify	_____
104. Would you circumcise your son(s)?	1 = Yes 2 = No 28 = DK 29 = RE
104a. If yes, at what age?	_____

APPENDIX B

IRB Approvals

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice

Initial Review (Response To Modifications)

April 29, 2008

Nelli Westercamp, MPH, MBA
Epidemiology and Biostatistics
1603 W. Taylor Street
M/C 923
Chicago, IL 60612
Phone: (312) 413–0887 / Fax: (312) 996–0064

RE: Protocol # 2007–0914
"A Prospective Study of Behavioral Risk Compensation Related to Male Circumcision as an HIV Prevention Method"

Dear Ms. Westercamp:

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on April 17, 2008. You may now begin your research.

Please note the following information about your approved research protocol:

Protocol Approval Period: April 17, 2008 – December 9, 2008
Approved Subject Enrollment #: 7200
Additional Determinations for Research Involving Minors: These determinations have not been made for this study since it has not been approved for enrollment of minors.
Performance Sites: UIC, Kenyatta Nat'l Hospital Ethics & Research Committee (Kenya), Nyanza Reproductive Health Society
Sponsor: Family Health International
PAF#: 2008–01059
Grant/Contract No: 47394

APPENDIX B (continued)

Grant/Contract Title: Male Circumcision Consortium

Research Protocol(s):

a) A Prospective Study of Behavioral Risk Compensation Related to Male Circumcision as an HIV Prevention Method, Version 1, 10/25/2007

Recruitment Material(s):

a) Male Circumcision and Related Studies, Informational Flier, Version 3, 04/07/2008

Informed Consent(s):

a) SHABS, Potential Controls, English, Version 2, 02/06/0208
b) SHABS, Male Participants, English, Version 2, 02/06/2008
c) SHABS, Female Participants, English, Version 2, 02/06/2008

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific category:

(ECR) The Convened (Full) IRB has determined and documented that the research involves no greater than minimal risk and is eligible for Expedited Continuing review of research under review category 9 . "(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, and that categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and where no additional risks have been identified."

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
11/27/2007	Initial Review	Convened	12/11/2007	Modifications Required
03/14/2008	Response To Modifications	Expedited	03/20/2008	Modifications Required
04/16/2008	Response To Modifications	Expedited	04/17/2008	Approved

Please remember to:
→ Use your **research protocol number** (2007–0914) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
"**UIC Investigator Responsibilities, Protection of Human Research Subjects**"

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

APPENDIX B (continued)

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996–1711 or me at (312) 413–8457. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Barbara Maleckar
IRB Coordinator, IRB # 3
Office for the Protection of Research Subjects

Enclosure(s):

1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
2. **Informed Consent Document(s):**
   a) SHABS, Potential Controls, English, Version 2, 02/06/0208
   b) SHABS, Male Participants, English, Version 2, 02/06/2008
   c) SHABS, Female Participants, English, Version 2, 02/06/2008
3. **Recruiting Material(s):**
   a) Male Circumcision and Related Studies, Informational Flier, Version 3, 04/07/2008

cc: Leslie T. Stayner, Epidemiology and Biostatistics, M/C 923
Robert C. Bailey, Epidemiology and Biostatistics, M/C 923
OVCR Administration, M/C 672

APPENDIX B (continued)

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd.
P.O. Box 20723, Nairobi.
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP", Nairobi.
Email: KNHplan@Ken.Healthnet.org

7th January 2008

Ref: KNH-ERC/ 01/ 35

Prof. Ndinya-Achola
Dept. of Med. Microbiology
School of Medicine
University of Nairobi

Dear Prof. Ndinya-Achola

RESEARCH PROPOSAL: "A PROSPECTIVE STUDY OF BEHAVIOURAL RISK COMPE NSATION RELATED TO MALE CIRCUMCISION AS AN HIV PREVENTION METHOD" (P336/11/2007)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and **approved** your above cited research proposal for the period 7th January 2008 – 6th January 2009.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimen must also be obtained from KNH-ERC for each batch.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH-ERC

c.c. Prof. K.M.Bhatt, Chairperson, KNH-ERC
The Deputy Director CS, KNH
The Dean, School of Medicine, UON

CITED LITERATURE

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VITA

NAME: Nelli Westercamp

EDUCATION: PhD, Epidemiology
University of Illinois at Chicago, Chicago, IL, USA (2013)

MPH/MBA, Joint degree
University of Illinois at Chicago, Chicago, IL, USA (2006)

BA, Business Administration
University of Nebraska at Omaha, Omaha, NE, USA (1999)

BA, Business Administration
Academy of Economic Sciences, Rep. of Moldova (1998)

HONORS / ACTIVITIES / AFFILIATIONS

- Recipient of an International Scholarship to attend the XVIII International AIDS Conference, 2010
- Recipient of the Global Health Research Award at the 2nd Annual University of Illinois School of Public Health Research Competition, 2007
- Member of the editors board of AIDS & Behavior Journal, since 2009
- Reviewer for AIDS & Behavior, AIDS, the Journal of International AIDS Society, Journal of Social Aspects of HIV/AIDS (SAHARA), Sexuality and Culture, Health Policy and Planning Journal
- Member of International AIDS Society (IAS), since 2006
- Member of American Public Health Association, since 2005
- Member of Student Epi Corps, University of Illinois at Chicago, 2004–2007
- University of Illinois at Chicago's Public Health Traineeship Award, 2005
- Graduated Summa Cum Laude, University of Nebraska at Omaha, 1999
- Graduated second in class from the Academy of Economic Studies, Republic of Moldova, 1998

PROFESSIONAL EXPERIENCE

Research Project Coordinator 2007–2013

Division of Epidemiology and Biostatistics, School of Public Health
University of Illinois at Chicago, Chicago, IL
Stationed in Kisumu, Kenya

Responsibilities: Served as the principal investigator and project coordinator for a large, multi-site longitudinal study of behavioral risk compensation following male circumcision in western Kenya; ensured that study activities conformed to changing national and local political, health-care, and scientific policy environments; maintained compliance with domestic and international ethical review and approval processes; developed and tested survey instruments in paper and electronic formats (ACASI); hired, trained, and supervised study staff and provided direct oversight of scientific, operational, ethical, and financial aspects of the study; lead the multidisciplinary team of collaborators in data analysis, manuscript preparation, and results dissemination; participated in continuing grant preparation and submission.

Research Assistant/Research Specialist 2004–2007

Division of Epidemiology and Biostatistics, School of Public Health
University of Illinois at Chicago, Chicago, IL

Responsibilities: assisted the principal investigator with an NIH-funded randomized controlled trial of male circumcision to reduce HIV-1 transmission rates among men aged 18–24 in Kisumu, Kenya; conducted preliminary statistical analyses; participated in manuscript, grant and budget preparation; carried out regular expansive literature searches with the maintenance of an exhaustive relevant literature database; coordinated all institutional review board (IRB) submissions for the four international collaborating institutions.

Data Analyst 2006–2006

University of Illinois at Chicago, Chicago, IL

Responsibilities: performed data management, analyses, map generation, and report preparation for the "Needs Assessment: Introduction of Male Circumcision Services for HIV Prevention in Kisumu and Suba Districts, Kenya" project, funded by CHF International, Kenya.

Consultant 2006–2006

University of Illinois at Chicago, Chicago, IL

Responsibilities: assisted in report editing and preparation: "Assessment of Clinical and Traditional Male Circumcision Services in Bungoma District, Kenya: Complications Rates and Operational Needs".

Consultant 2006–2006

Proviso Public Schools, Project on Dating Violence
Cook County Department of Public Health, Oak Park, IL

Responsibilities: performed data management, analyses, and quarterly report preparation for Teens Learning to Choose (TLC) project designed to assess the impact of specially tailored education on prevention of the initiation of teen dating violence and the formation of healthy dating relationships.

Project Coordinator/Chart Abstractor (Rapid Response Volunteer) 2005–2005

Cook County Department of Public Health
Division of Communicable Diseases

Responsibilities: project/volunteer coordination for the detailed health status evaluation and needs assessment of displaced persons following hurricane Katrina housed at local Health Facilities.

Management Methods Analyst 2002–2004

Psychiatric Clinical Research Center
University of Illinois at Chicago, Chicago, IL

Responsibilities: carried out data collection, organization, and analysis from multiple sources throughout the research center; produced scheduled reports on research-related activities and created ad hoc graphical materials used in results dissemination, education, and general publication; managed grant-related financial processes and assured institutional research compliance.

Project Specialist 2001–2002

IT Corporation, Chicago, IL

Responsibilities: assisted in the development of project manuscripts and reports with a focus on graphical and cartological presentation of environmental sampling and analysis.

Export Specialist 1998–2001

Compaq Direct/Inacom, Inc., Omaha, NE

Responsibilities: ensured the legal customs compliance of computer equipment exported to multinational corporate customers.

PEER REVIEWED PUBLICATIONS

Westercamp, N., S. Moses, K. Agot, J. O. Ndinya-Achola, C. Parker, K. O. Amolloh, and R. C. Bailey. 2010. Spatial distribution and cluster analysis of sexual risk behaviors reported by young men in Kisumu, Kenya. *Int J Health Geogr.* 22;9: 24.

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IN PREPARATION

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Risk compensation following male circumcision: Results from longitudinal study of recently circumcised and uncircumcised men in Nyanza Province, Kenya

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Penile coital injuries decline after male circumcision: Results from longitudinal study of recently circumcised and uncircumcised men in Nyanza, Kenya

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Sexual function and satisfaction 24 months after circumcision: Results from longitudinal study of recently circumcised and uncircumcised men in Nyanza Province, Kenya

Westercamp, N., T. Okeyo, K. Agot, W. Jaoko, R. C. Bailey. Attitudes and believes about male circumcision among long-term female partners of recently circumcised men: Results from the risk compensation study in Nyanza Province, Kenya

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Factors associated with the circumcision decision: Baseline results from the risk compensation study in Nyanza Province, Kenya

BOOK CHAPTERS

Eaton, L. A., **N. Westercamp.** "A review of risk compensation in studies of male circumcision, antiretroviral-based HIV prevention, and HIV vaccines" in *The Bio-Tech Revolution in HIV Prevention: New Frontiers in the Fight Against AIDS*, editors: Kalichman S. C. and Eaton L. A. (in press).

SELECTED PRESENTATIONS AND ABSTRACTS

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Behavioral risk compensation 24 months after circumcision: Interim results from a prospective cohort study of circumcised and uncircumcised men in Nyanza Province, Kenya. University of Nairobi Collaborative Meeting, January 23, 2013.

Okeyo, T., **N. Westercamp,** R. C. Bailey, K. Agot, W. Jaoko. What women think about male circumcision: Perceptions of female partners of recently circumcised men in Nyanza Province, Kenya. 19th International AIDS Conference, 22–28 July 2012—Washington, DC.

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Sexual function, satisfaction, and penile trauma 24 months after circumcision among young men in Nyanza Province, Kenya. 19th International AIDS Conference, 22–28 July 2012—Washington, DC. Abstract # WEPE243.

Westercamp, N., K. Agot, W. Jaoko, R. C. Bailey. Risk compensation following male circumcision: A cause for concern? Results from a prospective cohort study of circumcised and uncircumcised men in Nyanza Province, Kenya. 19th International AIDS Conference, 22–28 July 2012—Washington, DC. Abstract # LBPE31.

Okeyo, T., **N. Westercamp,** R. C. Bailey, K. Agot, W. Jaoko. Risk compensation endorsing beliefs among female partners of recently circumcised men in Nyanza Province, Kenya. University of Nairobi Collaborative Meeting, January 25, 2012.

Okeyo, T., **N. Westercamp,** R. C. Bailey, K. Agot. Perceptions on circumcision among female partners of recently circumcised men in Nyanza Province, Kenya. 16th ICASA Conference, 4–8 December 2011—Addis Ababa, Ethiopia. Abstract # WEPE096.

Westercamp, N., K. Agot, R. C. Bailey. Is there behavioral risk compensation 12 months after circumcision: Interim results from a prospective cohort study of circumcised and uncircumcised men in Nyanza Province, Kenya. 16th ICASA Conference, 4–8 December 2011—Addis Ababa, Ethiopia. Abstract # THLB0104.

Westercamp, N., K. Agot, R. C. Bailey. Sexual function and satisfaction improve six months after circumcision among men in Nyanza province, Kenya. 6th IAS Conference on HIV pathogenesis, treatment, and prevention, 17–20 July 2011—Rome, Italy Abstract # TUPE384.

Westercamp, N., K. Agot, R. C. Bailey. A prospective study of risk compensation following male circumcision as an HIV prevention method in Nyanza Province, Kenya: Interim results. 6th IAS Conference on HIV pathogenesis, treatment, and prevention, 17–20 July 2011—Rome, Italy. Abstract # WEPDC0102.

Westercamp, N., C. L. Mattson, S. Moses, K. Agot, J. O. Ndinya-Achola, R. C. Bailey. Prevalence and correlates of concurrent partnerships in young, sexually active Kenyan men. XVIII International AIDS Conference held in Vienna, Austria, July 18–24, 2010. Abstract # TUPE0760.

Westercamp, N., K. Agot, J. O. Ndinya-Achola, R. C. Bailey. Factors associated with the circumcision decision: Baseline results from the risk compensation study in Nyanza Province, Kenya. XVIII International AIDS Conference held in Vienna, Austria, July 18–24, 2010. Abstract # MOPE0332.

Westercamp, N., R. C. Bailey, S. Moses, K. Agot, I. Maclean, J. O. Ndinya-Achola, K. Kamolloh. The use of Geographic Information System (GIS) to investigate the spatial distribution of STIs and behavioral characteristics in young Kenyan men. XVI International AIDS Conference held in Toronto, Canada, August 13–18, 2006.

Westercamp, N., R. C. Bailey. A Review of Acceptability of Male Circumcision as a Prevention Strategy for HIV/AIDS in Sub-Saharan Africa. Presented at the XVI International AIDS Conference held in Toronto, Canada, August 13–18, 2006.

Mattson, C. L., **N. Westercamp,** R. C. Bailey, S. Moses, K. Agot, J. O. Ndinya-Achola. Risk factors for sexually transmitted infections among young men in Kisumu, Kenya. Presented at Epidemiology without Borders, a joint meeting between The Society for Epidemiologic Research (SER) and The Canadian Society for Epidemiology and Biostatistics (CSEB) in Toronto, Canada on June 29, 2005. American Journal of Epidemiology 2005; 161 (Supp): S1–S152.