Scaling-up Male Circumcision (MC) for HIV Prevention in Western Kenya: Risk Compensation and Infant MC

BY

MARISA R. YOUNG
BA, University of Washington, 2002

THESIS

Submitted as partial fulfillment of the requirements
for the degree of Doctor of Philosophy in Public Health Sciences
in the Graduate College of the
University of Illinois at Chicago, 2015

Chicago, Illinois

Defense Committee:

Robert C. Bailey, PhD, MPH, Chair and Advisor
Donald Hedeker, PhD
Supriya Mehta, PhD, MHS
Sherry Nordstrom, MD
Nadine Peacock, PhD, MPH

For Obi, gi hera

ACKNOWLEDGMENTS

I am indebted to a great many people who helped nurture this dissertation and the research projects it relies on. Thanks to the Kenyan Ministry of Health and hospital administration, maternity ward staff, and maternal child health staff at the Nyanza Provincial General Hospital, Kisumu District Hospital, Kombewa District Hospital, Siaya District Hospital, and Lumumba Health Centre for your partnership and support.

I am grateful for the dedication and assistance provided by all the Nyanza Reproductive Health Society family, especially the Mtoto Msafi study team—Betha Ochomo, Jacinta Badia, Jude Kitur, Pauline Abuor, Anabel Dollah, Millicent Oundo, and study coinvestigators Dr. Kawango Agot, Dr. Tracy E. Irwin, Dr. Sherry K. Nordstrom, Dr. Elijah Odoyo-June, Dr. Dedan O. Ongong'a and the late Dr. J. O. Ndinya-Achola.

To participants of the research studies that formed the basis of this dissertation, I thank you for your time and honesty. None of this would be possible without you.

Thanks to the funders of the Mtoto Msafi study, the Bill & Melinda Gates Foundation, who provided financial support through a grant to FHI360 (grant #47394).

I could not have asked for a more expert, thoughtful, and helpful dissertation committee. Thank you, Drs. Robert Bailey, Don Hedeker, Supiya Mehta, Sherry Nordstrom, and Nadine Peacock. I owe a special word of thanks to Supriya Mehta, who made numerous substantial improvements to my development as an epidemiologist and to the risk compensation portion of this dissertation. Your wit is razor sharp and you give your views honestly. Your feedback always makes me smarter.

More than any single individual, Professor Robert Bailey has guided and developed my educational and professional life. I can never thank you enough for your mentorship, patience and

good humor. You gave me the opportunity of a lifetime and, indeed, you changed my life. From steering me through writing my first manuscript to serving as chief dowry negotiator, I am a better social scientist and a better person because of you.

Finally, I wish to thank my family, especially my parents, Janet, Dan, and Camille, my siblings Emery, Indira, Alanna, and Darren, and my family in Kenya, Christine, Sarah, Patricia, Ben, and Tony. And, most of all, my husband Walter Obiero Ochieng for your love and the gift of laughter.

MRY

CONTRIBUTION OF AUTHORS

Chapter III contains previously published material. Several individuals contributed to the content of the chapter, as described in this paragraph. Robert C. Bailey and Marisa R. Young conceived and designed the study. Marisa R. Young conducted data analysis. Marisa R. Young wrote the first draft of the manuscript. Marisa R. Young, Robert C. Bailey, Elijah Odoyo-June, Sherry K. Nordstrom, Tracy E. Irwin, and Kawango Agot made substantive revisions to the manuscript.

TABLE OF CONTENTS

CHAPTER			PAGE
I. BACKGROUND			1
	A.	Male Circumcision for HIV Prevention	1
	B.	Endorsement and Scale-Up	2
	C.	Biological Basis for Protective Effect of Male Circumcision	2
		1. Penile trauma and coital injuries	3
		2. Susceptibility of foreskin tissue to HIV	3
		3. Lack of circumcision and sexually transmitted infections	4
		4. Subpreputial environment	5
	D.	Infant Male Circumcision	5
		1. Rationale for conducting infant male circumcision research	5
		2. Acceptability of infant male circumcision in East and southern Africa	6
		3. Decision-making in infant male circumcision: The role of the father	7
	E.	Setting	8
II. A SIX-YEAR LONGITUDINAL ANALYSIS OF RISK COMPENSATION FOLLOWING MALE CIRCUMCISION IN KISUMU, KENYA			9
	A.	Abstract	9
		1. Background	9
		2. Methods	9
		3. Results	9
		4. Conclusions	10
	B.	Background	10
	C.	Methods	13
		1. Data source	13
		2. Dependent and independent variables	14
		3. Generation of weights for marginal structural modeling	14
		4. Statistical methods	15
		a. Missing data	15
		b. Marginal structural model	16
	D.	Results	17
	E.	Discussion	26
	F.	Conclusion	29

TABLE OF CONTENTS (continued)

CHAPTER PAGE

III. FACTORS ASSOCIATED WITH UPTAKE OF INFANT MALE CIRCUMCISION FOR HIV PREVENTION IN WESTERN KENYA 30
A. Abstract 30
1. Background 30
2. Patients and methods 30
3. Findings 30
4. Conclusion 31
B. Background 31
C. Methods 33
1. Study design 33
2. Statistical analysis 35
a. Dependent variables 35
b. Independent variables 35
c. Bivariate analyses 36
d. Analysis for outcome 1 (preference for infant male circumcision) 36
e. Analysis for outcome 2 (observed uptake of infant male circumcision) 37
D. Results 38
1. Sample 38
2. Characteristics of mothers and fathers enrolled 39
3. Analysis 1: Actor preference for infant male circumcision 40
a. Bivariate Analysis 40
b. Multivariate modeling 46
4. Analysis 2: Acceptance of infant male circumcision 47
a. Bivariate analysis 47
b. Multivariate analysis 47
5. Decision-making in infant male circumcision 52
E. Discussion 53

IV. SAFETY OF OVER TWELVE HUNDRED INFANT MALE CIRCUMCISIONS USING THE MOGEN CLAMP IN KENYA 57
A. Abstract 57
1. Background 57
2. Methods 57
3. Results 57
4. Conclusion 58
B. Background 58
C. Methods 59
D. Results 61
E. Discussion 66

V. CONCLUSION 69

TABLE OF CONTENTS (continued)

CHAPTER	PAGE
APPENDICES	75
APPENDIX A	76
APPENDIX B	77
APPENDIX C	80
CITED LITERATURE	89
VITA	101

LIST OF TABLES

TABLE		PAGE
I.	SELECTED BASELINE AND 30-MONTH VISIT CHARACTERISTICS AND SEXUALLY TRANSMITTED INFECTIONS BY TREATMENT ASSIGNMENT (AT BASELINE) AND OBSERVED MALE CIRCUMCISION STATUS (AT 30 MONTHS OF FOLLOW-UP)	18
II.	RESULTS OF LOGISTIC REGRESSION MODELS TO GENERATE WEIGHTS FOR TREATMENT AND CENSORING	22
III.	ODDS RATIO ESTIMATES AND P-VALUES FOR TIME, CIRCUMCISION STATUS, AND INTERACTING VARIABLES FROM MARGINAL STRUCTURAL MODELS FOR FOUR SEXUAL RISK-TAKING VARIABLES	25
IV.	CONSTRUCTION OF DYAD EDUCATION VARIABLE	36
V.	CHARACTERISTICS OF MOTHERS, FATHERS, AND COUPLES IN SAMPLE	42
VI.	BIVARIATE ANALYSIS OF FACTORS ASSOCIATED WITH ACTOR PREFERENCE FOR IMC	44
VII.	CHARACTERISTICS OF MEN AND WOMEN WHO ACCEPTED CIRCUMCISION FOR THEIR INFANTS (CASES AND THOSE WHO DECLINED INFANT CIRCUMCISION [CONTROLS])	48
VIII.	MULTIVARIATE LOGISTIC REGRESSION MODEL RESULTS OF FACTORS PREDICTING ACCEPTANCE OF IMC IN NON-MUSLIM, NON-NOMIYA MOTHERS (A) AND FATHERS (B)	50
IX.	CHARACTERISTICS OF RESEARCH AND NON-RESEARCH IMC PROCEDURES	63
X.	TYPE AND FREQUENCY OF ADVERSE EVENTS AND OTHER EVENTS	64
XI.	ADVERSE EVENT RATE AND RISK FACTORS FOR ADVERSE EVENTS IN RESEARCH AND NON-RESEARCH CIRCUMCISIONS	65

LIST OF FIGURES

FIGURE		PAGE
1.	Nyanza Province, Kenya.	8
2.	Example of time-dependent confounding where exposure is male circumcision status, outcome is no condom use at last sex, and confounder/mediator is male circumcision endorsement.	13
3.	Prevalence of self-reported sexual risk behaviors for circumcised (darker dashed line) and uncircumcised (lighter solid line) men over time.	20
4.	Enrollment flow chart.	39
5.	Distribution of marginal structural model weights at each follow-up visit.	76

LIST OF ABBREVIATIONS

AE	Adverse Event
aOR	Adjusted Odds Ratio
CHW	Community Health Worker
CI	Confidence Interval
CT	*Chlamydia trachomatis*
GEE	Generalized Estimating Equation
GUD	Genital Ulcer Disease
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HSV	Herpes Simplex Virus
ICC	Intraclass Correlation Coefficient
IMC	Infant Male Circumcision
IPCW	Inverse Probability of Censor Weight
IPTW	Inverse Probability of Treatment Weight
IQR	Interquartile Range
IRR	Incidence Rate Ratio
MC	Male Circumcision
MOH	Ministry of Health
MSM	Marginal Structural Model
ND	No Difference
NG	*Neisseria gonorrhoeae*
NS	Not Sure

LIST OF ABBREVIATIONS (continued)

OR	Odds Ratio
PICC	Pairwise Intraclass Correlation Coefficient
RCT	Randomized Controlled Trial
STI	Sexually Transmitted Infection
TV	*Trichomonas vaginalis*
UNAIDS	Joint United Nations Programme on HIV/AIDS
USD	United States Dollars
UTI	Urinary Tract Infection
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

SUMMARY

Male circumcision (MC) is one of the few HIV prevention strategies with proven efficacy and it does not rely on sustained adherence. Modeling studies indicate MC would be more cost-effective than treatment as prevention and anti-retroviral therapy scale-up in hyperendemic settings. Scale-up of voluntary medical male circumcision (VMMC) in Kenya began in 2008 with an initial goal of circumcising 426,000 HIV-negative men aged 15–49 years in Nyanza Province by 2013. This first phase of MC scale-up is termed the "catch-up" phase, because it targets men most at risk of acquiring HIV in the short-term. As of December 2011, Nyanza Province had achieved more than 220,000 circumcisions (and Kenya achieved 273,000 of the 860,000 country-wide target) and is on track to complete the catch-up phase before any other priority country. The relative maturity of the Kenyan program provides an opportunity, unique in sub-Saharan Africa, to study pending operations research issues surrounding MC scale-up and the transition to infant male circumcision (IMC). Findings from the Kenyan context could be of use to other priority countries as they expand VMMC service delivery.

Male circumcision programs will be undermined if men increase risky sexual behavior following the procedure (termed "risk compensation"). In our analysis of the Kisumu randomized controlled trial (RCT) data and post-trial follow-up through 72 months, we found no condom use at last sex increased modestly over time for both circumcised and uncircumcised men (odds ratio [OR] for 6-month increase in time 1.06). Compared to uncircumcised men, circumcised men had increased odds of no condom use at last sex (OR=1.17, p=.006). There was no evidence of risk compensation in other sexual behavioral outcome variables.

Infant male circumcision has several advantages over adolescent and adult circumcision including: faster healing, reduced risk of adverse events, technically easier procedure, and reduced cost. Modeling suggests IMC will be cost-saving for HIV prevention in high-to-moderate HIV prevalence regions. We examined parental decision-making and differences in characteristics of parents accepting and declining IMC services in Nyanza Province, Kenya. Our results highlight the importance of fathers in the IMC decision-making process. Fathers, as well as mothers, should be targeted for optimal scale-up of IMC services. Circumcision programs should offer services for males of all ages, since MC at some age is highly acceptable to both men and women.

A potential concern in scale-up of IMC for HIV prevention in East and southern Africa is rates of adverse events (AEs). Little data exist about the safety of IMC in East and southern Africa, where IMC is not commonly practiced. We analyzed data from 1,239 IMC procedures conducted in the context of research and routine clinical practice. We found IMC services provided in Kenyan government hospitals in the context of routine IMC programming have AE rates comparable to those in developed countries. The optimal time for IMC is within the first month of life.

I. BACKGROUND

A. Male Circumcision for HIV Prevention

In a short 1986 correspondence to the *New England Journal of Medicine*, A. J. Fink proposed lack of MC may increase a man's risk of acquiring HIV during heterosexual sex.[6] As early as 1988, lack of MC was described as a risk factor for HIV infection in a case/control study of men attending a sexually transmitted infections (STI) clinic in Nairobi, Kenya[7]. One year later in the same setting, results from a prospective cohort study showed uncircumcised men had an eight-fold greater risk of HIV acquisition in comparison to circumcised men (adjusted OR 8.2; 95%CI 3.0, 23.0). A decade later in the year 2000, the observational evidence suggesting MC was protective against HIV acquisition in men was compelling. In a systematic review and meta-analysis of the effect of MC on HIV acquisition in men in sub-Saharan Africa,[4] 20 of the 27 studies included in the analysis found a decreased risk of HIV in circumcised men. Among the 15 studies that controlled for confounding variables, the pooled adjusted relative risk of HIV in circumcised men compared to uncircumcised men was 0.42 (95%CI 0.34, 0.54). Lack of MC as a risk factor for HIV helps to explain some of the disproportionate burden of disease, in particular the very high incidence and prevalence of HIV/AIDS in East and southern Africa,[8] where MC is less frequently practiced than in West Africa. Despite the strong epidemiologic and ecologic evidence, MC was not endorsed and funded as a prevention intervention until the publication of three RCTs, all showing a statistically significant protective effect of MC on HIV acquisition in sub-Saharan African men.[1–3]

The three RCTs enrolled more than 10,000 men and results were published in 2005 and 2007. All three trials randomized HIV-negative, uncircumcised men to immediate or delayed circumcision. Early stopping criteria were met in all three trials. In meta-analysis, the pooled

incidence rate ratio (IRR) of HIV acquisition after 24 months of follow-up for circumcised men versus uncircumcised men was 0.41 (95%CI 0.30, 0.56) with no evidence of heterogeneity across the three studies.[9] This IRR corresponds to a 59% protective effect of MC on HIV acquisition and is extremely close to the summary relative risk of 0.42 reported from observational studies.[4]

B. Endorsement and Scale-Up

Following the results of the three African trials, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended MC be offered as one component of a comprehensive HIV-prevention package in areas with low prevalence of MC, high HIV burden, and where the disease is primarily transmitted through heterosexual sex.[5] Scale-up of MC services began in 13 priority countries (Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe) between 2008 and 2010.[10] Modeling estimates reaching 80% coverage of MC in the 13 countries by 2015 would entail circumcising approximately 20 million men at a cost of USD$2 billion in order to avert 3.4 million new infections through 2025 for a savings of USD$16.5 billion.[11] Although estimates of the costs and impact of circumcision vary, several different studies—using different assumptions and methods— have found that MC could have a large impact on the HIV epidemic in sub-Saharan Africa.[12–15]

C. Biological Basis for Protective Effect of Male Circumcision

Although there is still controversy about the mechanisms by which MC protects against HIV acquisition and debate about the relative contribution of these mechanisms, substantial data exist to support a biological basis for the relationship between MC and HIV. The four main mechanisms

include: increased susceptibility to penile trauma in uncircumcised men, enhanced susceptibility of foreskin tissue (especially the inner mucosal surface) to HIV infection, increased risk of genital ulcer disease (GUD) in uncircumcised men, and effects of the subpreputial environment on HIV acquisition. Each of these four areas are considered briefly below.

1. **Penile trauma and coital injuries**

Susceptibility of uncircumcised men to penile trauma and abrasion is frequently reported anecdotally.[16–18] Even microscopic disruptions of the mucosa could act as a portal of entry for HIV. A cross-sectional study of men in Mbale, Uganda found high overall rates of penile coital injuries (15% reported sores, 33% scratches/abrasions, 8% bleeding) but no differences in self-reported penile coital injuries between circumcised and uncircumcised men.[19] In the Kenya RCT, Mehta et al. found statistically significant reduced risk of all three penile coital injury outcomes in circumcised versus uncircumcised men in multivariable generalized estimating equations (GEE) analysis[20]: penile soreness during sex aOR 0.71 (95%CI: 0.64, 0.80), penile bleeding after sex aOR 0.62 (95%CI: 0.51, 0.75), abrasions/scratches/cuts to penis during sex aOR 0.52 (95%CI: 0.46, 0.59).

2. **Susceptibility of foreskin tissue to HIV**

Another plausible biological explanation for the observed effect of reduced HIV risk with circumcision is that foreskin tissue itself might be more susceptible to uptake of the virus. This theory is supported by data from the Rakai group who found increased risk of HIV in men with larger foreskins (>75th percentile) compared to those with the lowest quartile of foreskin surface area.[21] The validity of these findings are called into question, however, by difficulty in standardizing amount of skin removed and measurement of skin removed and by the observation that men in the

middle two quartiles of foreskin surface area had the same HIV risk as those in the lowest quartile. The two proposed mechanisms by which presence of foreskin tissue may confer increased risk of becoming infected with HIV are weak keratinization of the inner mucosal surface of the foreskin and higher density of HIV target cells in foreskin tissue. Keratin may provide a kind of natural barrier to entry of the virus, and a thin keratin layer on the inner mucosal surface of the foreskin compared to the outer foreskin and, by extension, to the skin of the circumcised penis, was early proposed as a mechanism by which lack of circumcision could increase HIV risk.[18] Although some studies have found the inner foreskin surface to have a thinner keratin layer relative to the outer foreskin surface,[22, 23] the evidence is equivocal with other studies finding no difference or a thicker layer of keratin in the inner surface relative to the outer surface.[24–26] There is strong evidence that the inner surface of the foreskin is rich in HIV target cells (including Langerhans cells and CD4+ T-cells),[26, 27] though this finding is not universal.[24]

3. **Lack of circumcision and sexually transmitted infections**

Uncircumcised men are at increased risk of GUD, high-risk human papilloma virus (HPV) and *Mycoplasma genitalium.*[28–32] Results across the three RCTs were not consistent with respect to the effect of MC on Herpes Simplex Virus 2 (HSV-2) incidence, with the Ugandan[30] and South African[33] trial finding evidence for decreased risk of HSV-2 with MC and the Kenyan trial finding no effect of MC on HSV-2 risk.[34] Male circumcision was not found to be protective against incidence of syphilis, gonorrhea, or Trichomonas.[30, 35] Nevertheless, concurrent STIs have been clearly shown to increase risk of HIV acquisition and transmission[36–39] and therefore it is plausible that some of the protective effect of MC on HIV acquisition is mediated through decreased risk of GUD, HPV, mycoplasma, and possibly HSV-2.

4. **Subpreputial environment**

Finally, characteristics of the subpreputial environment are thought to influence HIV risk. A study that sequenced the entire microbiome of the penis in 12 men before and after circumcision found a decrease in anaerobic bacteria following MC.[40] Anaerobic bacteria, including species associated with bacterial vaginosis in females, are pro-inflammatory, and may facilitate HIV acquisition.[41] In addition, penile wetness and lower level of hygiene may be more common in uncircumcised men[42, 43] and could lead to increased inflammation and thus increased density of HIV target cells, making HIV acquisition more likely.

D. Infant Male Circumcision

1. Rationale for conducting infant male circumcision research

Given the compelling epidemiologic and biologic evidence for the protective effect of MC on HIV transmission, WHO/UNAIDS urges MC be offered as one component of a comprehensive HIV-prevention package. These organizations further recommend countries consider neonatal circumcision as a long-term HIV-prevention strategy.[5] The Kenyan government's national strategy for scale-up of VMMC outlines a plan to transition from adolescent and adult MC to predominantly IMC.[44] Compared to adolescent and adult MC, the circumcision of an infant is associated with fewer adverse events, less technically challenging, less time-consuming, less expensive, easier to care for postoperatively, and likely to reduce chances of risk compensation.[45–49] Benefits to boys circumcised in infancy include reduction in urinary tract infections (UTIs) in early life and avoidance of phimosis, paraphimosis, and other conditions affecting the foreskin.[16, 50] The same health benefits afforded to circumcised men later in life accrue to those circumcised in infancy. These include reduction in ulcerative STIs, reduction in oncogenetic HPV prevalence and incidence,

and penile cancer. Benefits to female sexual partners of circumcised men include reduced risk of bacterial vaginosis, *Trichomonas vaginalis* (TV), HPV infection, and cervical cancer.[51–53] Despite the many advantages of circumcising infants, potential drawbacks include the lack of familiarity with IMC in the 14 MC target countries of East and southern Africa and the lengthy interval between the surgery and impact on the HIV epidemic. However, a recent analysis has shown that IMC would be cost-saving for HIV prevention in Rwanda, a country with an adult HIV prevalence of 3%.[48] The Rwandan IMC model was robust and suggests IMC could be cost-saving under a wide variety of conditions, including those that prevail in many African countries. These findings support those of White et al., who modeled the cost-effectiveness of MC at different ages assuming a high HIV-prevalence population in sub-Saharan Africa. The authors found neonatal circumcision would be cost-saving, but only after 30 years.[14] Large-scale IMC would represent a transition from managing the HIV epidemic as an emergency toward focusing on sustainable, long-term solutions to this major public-health problem.

2. **Acceptability of infant male circumcision in East and southern Africa**

Despite the advantages of IMC, research on the acceptability and feasibility of MC implementation has focused on adolescent and adult males.[29, 54, 55] Most studies in East and southern Africa find a larger proportion of men and women prefer adolescent circumcision to infant circumcision, with the exception of Botswana where 55%–63% of adults preferred circumcision to be performed on infants or young children,[56] and 81% of postpartum mothers of male infants say the best time to circumcise is within the first year of life.[57] However, these results rely on hypothetical acceptability among parents who were not actually offered IMC services. Plank et al. conducted a study of acceptability and safety of neonatal MC using the Mogen clamp and Plastibell methods at

two facilities in southeastern Botswana.[58] Results from an interim safety analysis showed high rates of acceptability with 100 out of 158 mothers (63%) approached accepting IMC for their son. By contrast, a study in Lusaka, Zambia found that although 97% of the 1,000 mothers recruited through the postnatal ward said they would definitely or probably have their newborn baby circumcised, only 11% (n=110) returned to the health facility to access circumcision services.[59]

In regions where acceptability studies have been conducted, those who favor infant over adolescent or adult circumcision cite hygiene benefits, reduced pain, fast healing, the ability to maintain a controlled environment, and having the boy habituated to his circumcision status before he becomes an adult[54, 56, 60–64] and, more recently, for medical reasons—e.g., reduced risk of sexually transmitted diseases, UTIs, and phimosis.[57, 59, 65] The reasons given for opposing infant circumcision include the fragility of babies, traditional beliefs (e.g., that a mother should not see her son's circumcised penis), fear of bleeding, and allowing the boy to consent to the procedure himself.[54, 56, 60–64, 66]

3. **Decision-making in infant male circumcision: The role of the father**

Despite growing recognition of the importance of fathers in health decisions,[76] few data on the role of fathers in pediatric health decisions exist.[77, 78] Research on child health decisions often focuses on mothers. For example, the National Survey of Early Childhood Health sampled 2,068 children in the United States and interviewed the parent identified as being most responsible for the child's medical care.[79] Eighty-seven percent of the respondents were mothers and only 11% were fathers. Because IMC is a health decision about male genitalia, the father may often be perceived by parents as the more important decision-maker within the couple,[66, 80, 81] though some

studies have found a greater proportion of parents make the decision together.[70, 72] Decision-making between parents about IMC is therefore an important area of study.

E. Setting

Data for all three components were or will be collected in Nyanza Province, Kenya (see Figure 1). The dominant ethnic group in Nyanza is the Luo, a Nilotic people who do not traditionally practice MC. Kisumu, the capital of Nyanza Province, is the third largest city in Kenya and the site of one of the RCTs of MC for HIV prevention. Since 2008, adolescent and adult MC services have been scaled up in the area and prevalence of MC in adults has increased from approximately 25% to 50%.[82] The 2008–2009 Demographic and Health Survey estimated HIV prevalence in Nyanza Province was 16% and 11% in 15–49-year-old women and men, respectively.[57]

Figure 1. Nyanza Province, Kenya.

II. A SIX-YEAR LONGITUDINAL ANALYSIS OF RISK COMPENSATION FOLLOWING MALE CIRCUMCISION IN KISUMU, KENYA

A. Abstract

1. Background

Male circumcision is approximately 60% effective against heterosexual HIV transmission among men. Male circumcision is being scaled-up across East and southern Africa. If men engage in riskier sex after becoming circumcised (termed "risk compensation"), the protective effect of MC could be diminished.

2. Methods

From 2002 to 2005, 2,784 HIV-negative men were randomized to immediate or delayed circumcision. After a median of 24 months of follow-up, uncircumcised men were offered the surgery and follow-up continued to 72-months. Generalized estimating equations models with incorporation inverse probability of treatment and censor weights were used to estimate the association between circumcision status and four time-varying measures of sexual risk-taking behavior: no condom use at last sex, sex the same day as meeting someone in the previous six months, >two sexual partners in the previous six months, and exchange of sex for gifts or money in the previous six months.

3. Results

No condom use at last sex increased modestly over time for both circumcised and uncircumcised men (OR for 6-month increase in time 1.06). Compared to uncircumcised men, circumcised men had increased odds of no condom use at last sex (OR=1.17, p=.006). There was no evidence of risk compensation in the other sexual behavioral outcome variables.

4. **Conclusions**

Both circumcised and uncircumcised men were less likely to use condoms over time. Further studies on risk compensation following MC may not be warranted.

B. Background

Three RCTs conducted in sub-Saharan Africa, enrolling more than 10,000 men, demonstrated MC protects a man from heterosexually acquired HIV by approximately 60%.[1–3] All three trials randomized HIV-negative, uncircumcised men to immediate or delayed circumcision and early stopping criteria were met in all three studies. In meta-analysis, the pooled IRR of HIV acquisition after 24 months of follow-up for circumcised men versus uncircumcised men was 0.41 (95%CI 0.30, 0.56) with very little heterogeneity across the three studies.[9]

Following the results of the trials, the WHO and UNAIDS recommended MC be offered as one component of a comprehensive HIV-prevention package in areas with low prevalence of MC, high HIV burden, and where the disease is primarily transmitted through heterosexual sex.[5] Scale-up of MC services began in 13 priority countries (Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe) between 2008 and 2010.[10] One modeling study estimates reaching 80% coverage of MC in the 13 countries by 2015 would entail circumcising approximately 20 million men at a cost of USD$2 billion in order to avert 3.4 million new infections through 2025 for a savings of USD$16.5 billion.[11] Although estimates of the costs and impact of circumcision vary, several different studies—using different assumptions and methods— have found that MC could have a large impact on the HIV epidemic in sub-Saharan Africa[12–15] and would be more cost-effective than treatment as prevention and antiretroviral therapy scale-up in hyperendemic settings.[83] One caveat of these results involves

whether men who undergo circumcision subsequently engage in riskier sexual behaviors (termed "risk compensation").

Risk compensation involves, "increases in risky behaviour sparked by decreases in perceived risk."[84] In the context of MC, presence of risk compensation implies men who become circumcised increase risky sexual behaviors (e.g., reduce condom use, increase number of sexual partners) in response to having lowered their perceived risk of HIV through circumcision. Since MC is not 100% protective against HIV, risk compensation could mitigate or even negate the benefits of MC in the population.[14, 85]

All three of the RCTs examined risk compensation. In the South African trial, mean number of sexual contacts was higher in circumcised men versus uncircumcised men—5.9 contacts versus 5.0 ($p<.0001$) at 12 months and 7.5 versus 6.4 ($p=.002$) at 21 months, respectively.[1] In the Ugandan trial[2] at the 6-month follow-up visit, circumcised men were more likely than uncircumcised men to have inconsistent condom use (37% versus 31%, $p=.0004$) but were less likely to report no condom use (45% versus 52%, $p<.0001$) and less likely to report alcohol use with sexual intercourse (49% versus 55%, $p=.001$), which was maintained at the 12 and 24 month visits. In a subsequent study examining three years of post-trial follow-up (after randomization had been halted), there were no differences between circumcised and uncircumcised men in several measures of sexual risk-taking, although both groups significantly decreased condom use.[86] In the Kenyan trial, risky behaviors declined in both circumcised and uncircumcised men across the study.[3] However, by the time randomization was halted, uncircumcised men had increased condom use and decreased amount of unprotected intercourse even more than circumcised men had.[3] Finally, a prospective cohort study nested within the Kenyan RCT enrolled three-quarters of the trial participants and compared circumcised and uncircumcised men using an index variable created from 18 sexual risk behaviors

and laboratory-diagnosed STI variables.[87] This analysis found no difference between circumcised and uncircumcised men (and no significant change over time in either group from baseline) at 6-months and 12-months of follow-up.

Examining follow-up data from these RCTs after randomization is halted has a potential methodological limitation: time-dependent confounding. Robins et al. define time-dependent confounding as occurring when "there exists a time-dependent covariate that is a risk factor for, or predictor of, the event of interest and also predicts subsequent exposure."[88] An analytic issue arises from this situation because such variables are both confounders of the association of interest (in this case, the effect of MC on sexual risk behaviors) and mediators in the causal pathway. One theoretical example of time-dependent confounding is illustrated in Figure 2. The extent to which a man endorses MC is plausibly associated with his current circumcision status and predicts his future decisions about condom use. Controlling for MC endorsement could alter the estimated association between circumcision status and condom use (i.e., MC endorsement could be a confounder of the relationship of interest). Further, prior circumcision status is likely to predict future MC endorsement. Therefore, it is plausible that endorsement of MC is both a confounder and mediator of the association between MC status and condom use.

An appropriate method for controlling for confounding while not over-adjusting for mediating variables is through the use of marginal structural models (MSMs).[89] In the MSM approach, separate models are constructed where (1) the exposure of interest (i.e., MC) is used as an outcome, and (2) loss to follow-up is used as an outcome. The predicted probabilities of outcome from these models are then used to estimate a weight for each man at each study visit. Assuming no bias and no unmeasured confounders, these weights control for confounding, while preserving the causal association between circumcision status and sexual risk behaviors.[88]

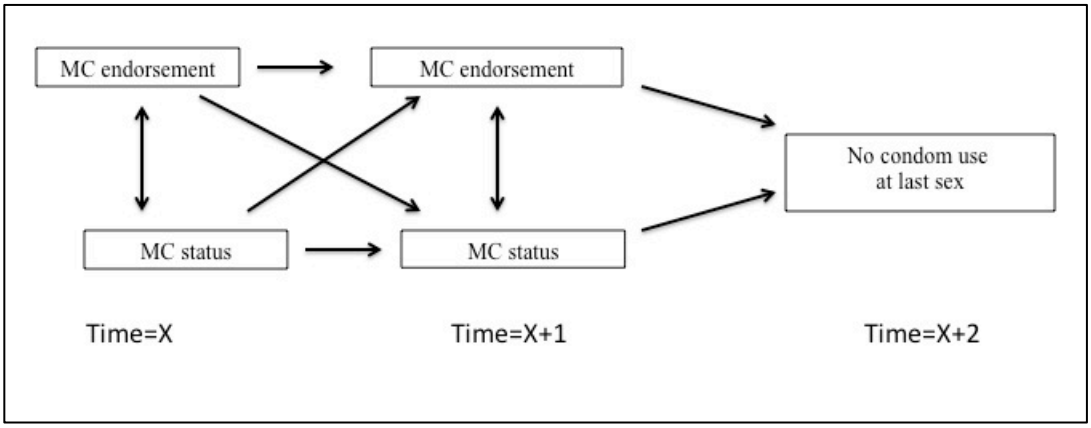

Figure 2. Example of time-dependent confounding where exposure is MC status, outcome is no condom use at last sex, and confounder/mediator is MC endorsement.

Previous analyses of risk compensation after MC have been limited to relatively short follow-up of not more than two years[87, 90] or do not control for potential time-varying confounding.[86] It is possible that circumcised men could become habituated to their circumcision status or fatigued by targeted safe-sex messaging, and that increased sexual risk-taking could ensue several years after the circumcision surgery. The current analysis adds to the literature by using robust statistical methods to examine risk compensation through 72 months of follow-up in the Kenyan trial and post-trial follow-up data.

C. Methods

1. Data source

Data from this analysis come from the RCT of MC for HIV prevention in Kisumu, Kenya.[3, 20, 32, 34, 91] In the trial, 2,784 HIV-negative men aged 18 to 24 were randomized 1:1 to circumcision (intervention) or to delayed circumcision (control) between 2002 and 2005. Stopping criteria were met at the third interim analysis in December 2006 and the trial was halted when

median follow-up time was 24 months. Circumcision was offered to the control group and men were invited to re-consent for extended follow-up. Of 1,740 men still enrolled and eligible, 1,545 (89%) provided additional consent. As during the trial, this cohort was interviewed about their sexual behaviors and tested for STIs every six months through 72 months. For this analysis, we censored HIV+ men at the seroconversion visit. Extended follow-up was completed in September 2010.

2. **Dependent and independent variables**

Four binary self-reported time-varying measures of sexual risk behavior were chosen a priori on the basis of their being behavioral risk factors for HIV infection;[92–94] each outcome was modeled separately. Outcomes are: (1) no condom use at last sex, and the following risk behaviors in the previous six months: (2) having sex with someone the same day as meeting them; (3) having two or more sex partners; (4) exchanging sex for money or gifts (transactional sex). These outcomes are not considered independent and are likely to be correlated.

The main exposure variable of interest is the time-varying covariate MC (MC) status. Circumcision status was assessed by a visual exam at each follow-up. To assess whether differences in sexual risk behaviors differed by MC status over time, we assessed an MC by time interaction term in the final model. To account for a potential curvilinear relationship between risk behaviors and time, we also assessed a time*time interaction term in the final model.

3. **Generation of weights for marginal structural modeling**

Predictors used in weight generation for the MSM were chosen a priori and include time-varying and baseline factors that are conceptually likely to be associated with the decision to become circumcised and/or confounders of the association between MC and sexual risk-taking behaviors. The goal was to include sufficient number of variables to control adequately for confounding without adding too many, which could lead to non-positivity bias.[95] Predictor variables

were in the following domains: demographic characteristics, STIs (laboratory or self-reported GUD, HSV-2 serostatus, laboratory-confirmed *Chlamydia trachomatis* [CT], *Neisseria gonorrhoeae* [NG], TV, coital injuries (self-reported scratches, cuts, abrasions, or bleeding of the skin of the penis after sex), sexual dysfunction (any premature ejaculation, lack of orgasm, lack of interest in sex, lack of pleasure with sex, pain with sex, or erectile dysfunction for at least two weeks) and endorsement of circumcision. Endorsement of MC was measured as a scale variable constructed from five variables that ask the respondent about the relationship between MC status and: susceptibility to STIs, susceptibility to AIDS, ease of penile cleanliness, sexual pleasure for men, and sexual pleasure for women. Response categories are: "circumcised men," "uncircumcised men," "no difference," and "not sure." One point is added to the endorsement score for each question the participant answers favorably toward the circumcised state. The scale ranges from zero to five with higher values indicating greater endorsement of MC.

4. **Statistical methods**

a. **Missing data**

We had relatively low levels of missing data. Only four variables had >1% missing values; self-reported urethral discharge (1.2% missing), lab detected infection with NG, CT, or TV (4.2% missing), transactional sex (12.5% missing), and any sexual dysfunction (12.7% missing). Since transactional sex was one of our four outcome variables, we explored missingness further by comparing individuals who were missing on this variable to those were not missing. We used a complete case analysis, but compared this to an analysis where missing data were imputed using the last observation carried forward (or, if unavailable, next observation carried backward) method.[96]

b. **Marginal structural model**

We first evaluated whether the MSM was necessary, by checking whether several key time-varying covariates met the criteria for confounders and mediators of the relationship between MC status and a sexual behavior outcome variable. In particular, we assessed (1) whether the time-varying covariates were longitudinally associated with circumcision status, (2) whether circumcision status was predictive of the covariates, and (3) whether the covariates were associated with sexual behavioral outcome variables, independent of circumcision status. These associations were assessed using Cox regression models with time to MC as the outcome (a) and GEE models with the time-varying covariate as the outcome (b), or the sexual risk behavior as the outcome (c).

Next, we used marginal structural logistic regression models for repeated binary measures with robust standard errors to model the odds of the four different measures of sexual risk-taking behavior.

The final weights used in the MSMs are the product of stabilized inverse probability of treatment weights (IPTW) and stabilized inverse probability of censor weights (IPCW). Stabilized weights (where a numerator and denominator are estimated) are preferred to non-stabilized weights (where one is used as the numerator), because they are more efficient and are more likely to have "actual coverages rates that are closer to 95%."[89] The denominator of the IPTWs is estimated using a Cox proportional hazards model where the outcome is time to circumcision. Due to software constraints, the Cox model is approximated using pooled logistic regression with the inclusion of smoothed time covariates.[97] The numerator of the IPTW is estimated similarly, but uses only baseline measurements of covariates. These models are then used to derive predicted probabilities that a man had his observed circumcision status at each visit, given his other baseline covariates

(numerator) or baseline and time-dependent covariates (denominator). The IPCWs are estimated similarly, except that the outcome is time to censorship. The purpose of the IPCWs is to adjust for selection bias due to loss to follow-up.[88] The final weight is the product of the IPTW and the IPCW.

The GEE regression models incorporating the MSM weights were estimated using the Proc Genmod command with a "weight" statement in SAS version 9.2 (SAS Institute, Inc., Cary, North Carolina). The working correlation structure was first-order autoregressive, and chosen on the basis of the observed correlation in the outcome variable over time and minimizing the Quasi-Akaike Information Criterion. Since stabilized weights were used, baseline covariates were included in the final model.[95] To assess the impact of outliers, we truncated weights at the 1st and 99th percentiles and reran the MSM models.[95]

D. **Results**

Selected characteristics of participants by assignment group at baseline and by observed circumcision status at the 30-month visit are shown in **Error! Reference source not found.** I. As previously reported, participants in the circumcision and control arms were comparable at baseline on sociodemographic variables, STI prevalence, and other characteristics. By 30-months of follow-up, however, after circumcision was offered to the control group and men were invited to participate in extended follow-up, there were some differences between circumcised and uncircumcised men. These differences could be due to circumcision itself, to selection bias (e.g., in an individual's decision to undergo the cut), or could be the result of chance.

TABLE I

SELECTED BASELINE AND 30-MONTH VISIT CHARACTERISTICS AND SEXUALLY TRANSMITTED INFECTIONS BY TREATMENT ASSIGNMENT (AT BASELINE) AND OBSERVED MALE CIRCUMCISION STATUS (AT 30 MONTHS OF FOLLOW-UP)

	Baseline			30-month visit		
Characteristic[a]	Circumcision Group, N=1388 n (%)	Control group, N=1390 n (%)	χ^2 p-value	Circumcised men, N=854 n(%)	Uncircum-cised men, N=469 n(%)	χ^2 p-value
Age (years) at baseline			0.819			0.591
18–20	710 (51.2)	705 (50.7)		453 (53.0)	256 (54.6)	
21–24	678 (48.8)	685 (49.3)		401 (47.0)	213 (45.4)	
Highest level of education completed			0.450			0.195
None, primary 1–8	467 (33.7)	478 (34.4)		291 (34.1)	183 (39.0)	
Some secondary	257 (18.5)	232 (16.7)		173 (20.3)	90 (19.2)	
Secondary or higher	664 (47.8)	680 (48.9)		390 (45.7)	196 (42.8)	
Marital status			0.700			0.115
Not married/living with a female sex partner	1294 (93.5)	1288 (93.1)		554 (65.0)	324 (69.2)	
Married or living with a female sex partner	90 (6.5)	95 (6.9)		299 (35.0)	144 (30.8)	
Location of residence			0.865			0.548
Kisumu	679 (49.0)	683 (49.3)		483 (56.6)	273 (58.3)	
Outside Kisumu	708 (51.0)	703 (50.7)		370 (43.4)	195 (41.7)	
Endorsement of circumcision score, median (IQR)[b]	3 (2, 4)	3 (2, 4)	0.437	5 (3, 5)	3 (2, 5)	<0.001
Self-reported scratches, cuts, abrasions, or bleeding of skin of penis after sex in the past 6 months			0.648			<0.001
No	685 (49.5)	696 (50.3)		746 (87.6)	358 (76.5)	
Yes	700 (50.5)	687 (49.7)		106 (12.4)	110 (23.5)	
Painless or painful genital ulcer in past 6 months or currently (by report), or ulcer on exam			0.33			0.011
No	1328 (95.7)	1340 (96.4)		839 (99.2)	454 (97.4)	
Yes	60 (4.3)	50 (3.6)		7 (0.8)	12 (2.6)	
HSV-2 Status			0.089			0.409
Seronegative	1002 (72.2)	1043 (75.0)		544 (63.7)	288 (61.4)	
Seropositive	386 (27.8)	347 (25.0)		310 (36.3)	181 (38.6)	

SELECTED BASELINE AND 30-MONTH VISIT CHARACTERISTICS AND SEXUALLY TRANSMITTED INFECTIONS BY TREATMENT ASSIGNMENT (AT BASELINE) AND OBSERVED MALE CIRCUMCISION STATUS (AT 30 MONTHS OF FOLLOW-UP)

	Baseline			30-month visit		
Non-ulcerative sexually transmitted infection						
NG	32 (2.3)	25 (1.8)	0.346	21 (2.7)	9 (2.1)	0.520
CT	69 (5.0)	53 (3.8)	0.136	25 (3.2)	16 (3.7)	0.637
TV	23 (1.7)	27 (1.9)	0.573	3 (0.4)	2 (0.5)	0.835
Infection with NG, CT, and/or TV	111 (8.0)	92 (6.6)	0.163	45 (5.7)	24 (5.5)	0.890
Any sexual dysfunction (premature ejaculation, no orgasm, lacked interest in sex, no pleasure with sex, pain with sex, erectile dysfunction) for at least 2 weeks in previous 6 months			0.100			0.740
No	669 (56.6)	712 (59.9)		682 (89.4)	363 (88.8)	
Yes	514 (43.4)	477 (40.1)		81 (10.6)	46 (11.2)	

[a] Sample sizes vary slightly by characteristic due to a few missing responses
[b] p-value reported is for Wilcoxon-Mann-Whitney test

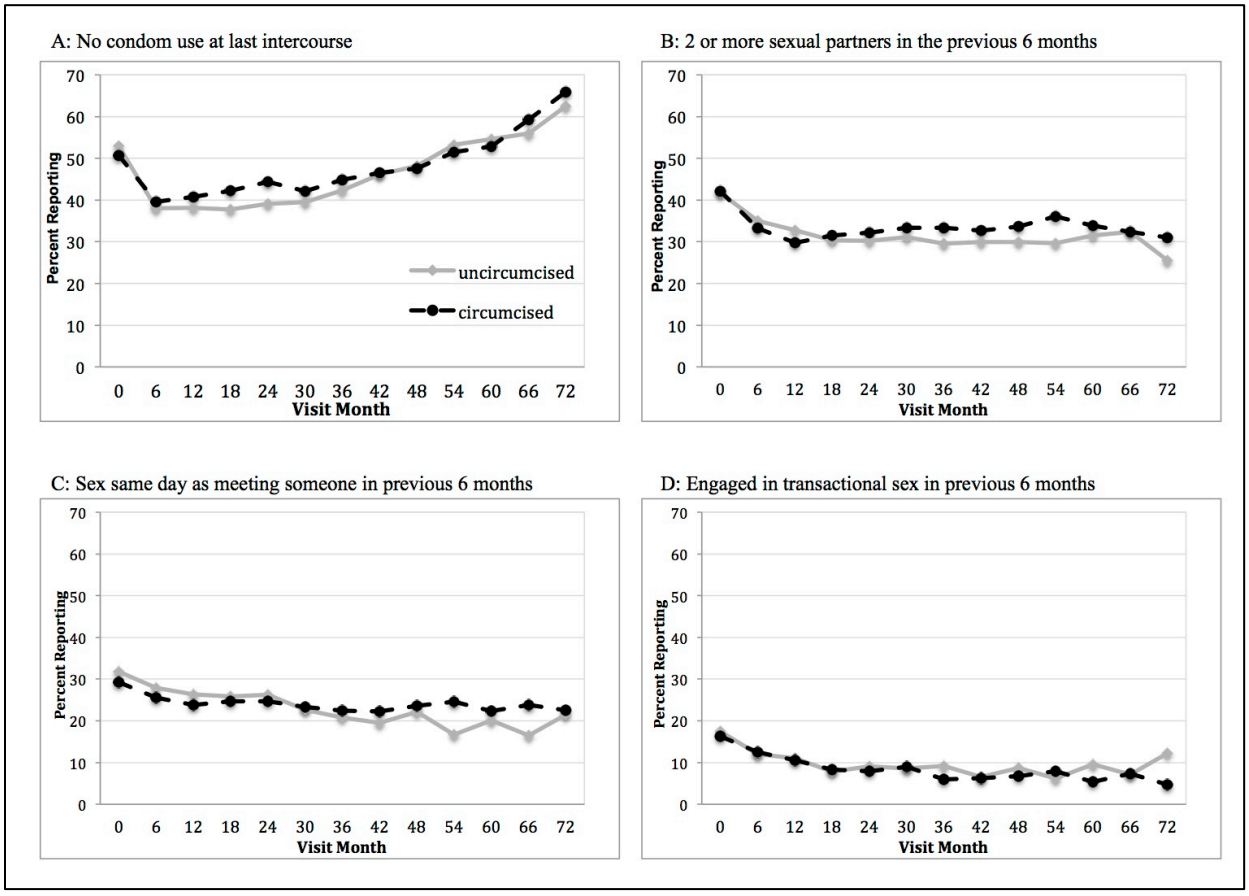

Figure 3. Prevalence of self-reported sexual risk behaviors for circumcised (darker dashed line) and uncircumcised (lighter solid line) men over time. Circumcision status is by assignment at baseline (visit month = 0) and by direct observation thereafter.

Prevalence of outcome variables by circumcision status at each follow-up visit are shown in panels A–D of Figure 3. No condom use at last sex declined from approximately 50% in circumcised and uncircumcised men at baseline to roughly 40% in both groups at six months then gradually increased to 63% among circumcised men and 66% among uncircumcised men at 72 months. Over time, there were modest and equivalent declines among both circumcised and uncircumcised men in two or more sex partners in the previous six months, sex the same day as meeting someone in the previous six months and transactional sex.

Criteria for use of MSMs were met; penile coital injuries and circumcision endorsement met the criteria for confounders and mediators of the relationship between MC status and no condom use at last sex.

By the 30-month visit, 29% of men originally allocated to the control arm were circumcised and by the end of follow-up (72 months), half of men in the control arm had opted for circumcision (n=395). Factors associated with choosing circumcision were modeled for the purpose of estimating the MSM weights. In pooled logistic regression, the following were associated with opting for circumcision (Table II): age 21–24 years (versus 18–20 years) at baseline, having greater than a primary-level education, being married or cohabiting with a female partner at baseline, and having higher endorsement of MC at follow-up. Men residing in Kisumu at baseline and those reporting coital injuries at follow-up were less likely to undergo circumcision.

TABLE II

RESULTS OF LOGISTIC REGRESSION MODELS TO GENERATE WEIGHTS FOR TREATMENT AND CENSORING

Characteristic	Treatment, OR (95% CI)	Censoring, OR (95% CI)
Baseline covariates		
Age 21–24 years (versus 18–20 years)	1.23 (1.07, 1.42)	1.00 (0.90, 1.10)
Highest completed educational attainment		
None, primary 1–8	ref	ref
Some secondary	1.52 (1.25, 1.85)	0.94 (0.81, 1.08)
Secondary or higher	1.45 (1.22, 1.73)	1.01 (0.89, 1.14)
Married or cohabiting (versus not married and not cohabiting)	1.48 (1.12, 1.96)	1.09 (0.88, 1.36)
Resides in Kisumu District (versus other district)	0.70 (0.51, 0.97)	0.69 (0.53, 0.88)
Income source		
None	ref	ref
Self-employed	0.86 (0.67, 1.11)	0.88 (0.74, 1.04)
Salaried	0.89 (0.70, 1.14)	0.86 (0.72, 1.01)
Endorsement of circumcision	0.98 (0.94, 1.03)	1.05 (1.02, 1.09)
HSV-2 seropositive	0.86 (0.69, 1.08)	1.05 (0.88, 1.26)
Self-reported or clinically detected GUD	0.90 (0.57, 1.40)	0.91 (0.70, 1.19)
Urogenital infection with NG, CT, or TV	0.99 (0.76, 1.30)	0.96 (0.79, 1.15)
Self-reported scratches, cuts, abrasions, bleeding of skin of penis after sexual intercourse, occurring in the past 6 months	0.94 (0.82, 1.08)	0.99 (0.89, 1.10)
Time-varying covariates		
Circumcised	-	0.94 (0.84, 1.05)
Married or cohabiting (versus not married and not cohabiting)	0.94 (0.80, 1.09)	0.79 (0.70, 0.90)
Resides in Kisumu District (versus other district)	1.33 (0.96, 1.84)	1.02 (0.79, 1.30)
Income source		
None	ref	ref
Self-employed	0.92 (0.78, 1.10)	0.78 (0.69, 0.89)
Salaried	1.18 (0.95, 1.46)	0.84 (0.72, 0.97)
Endorsement of circumcision	1.41 (1.35, 1.48)	0.92 (0.89, 0.95)

RESULTS OF LOGISTIC REGRESSION MODELS TO GENERATE WEIGHTS FOR TREATMENT AND CENSORING

Characteristic	Treatment, OR (95% CI)	Censoring, OR (95% CI)
HSV-2 seropositive	1.17 (0.97, 1.43)	1.08 (0.91, 1.28)
Self-reported or clinically detected GUD	0.48 (0.22, 1.05)	1.50 (1.03, 2.17)
Urogenital infection with NG, CT, or TV	1.09 (0.80, 1.49)	1.17 (0.94, 1.45)
Self-reported scratches, cuts, abrasions, bleeding of skin of penis after sexual intercourse, occurring in the past 6 months	0.52 (0.43, 0.63)	1.18 (1.04, 1.34)

Note. Models presented are for the denominators of the stabilized weights: pooled logistic regression models for circumcision and for censoring.

Of the 1,545 men who consented to long-term follow-up, the retention rates at 36, 48, 60, and 72 months were 84%, 72%, 68%, and 52%, respectively. From pooled logistic regression models used to derive the IPCW, residing in Kisumu at baseline, being married or cohabiting with a female partner at follow-up, being employed (versus unemployed), and having higher endorsement of circumcision at follow-up were associated with reduced odds of loss to follow-up (censorship) (Table III). Men who had high endorsement of circumcision at baseline, those with GUD, and men reporting penile coital injuries had higher odds of censorship.

The mean MSM weight was 1.00 (SD=.34; median 1.00; range 0.04, 19.92). The mean of weights should be close to one and have a small range.[95] Although our range was large, just 11 weights were >5. Figure 5, Appendix A shows the distribution of weights at each follow-up visit.

No condom use at last sex increased modestly over time for both circumcised and uncircumcised men (OR for 6-month increase in time 1.06). Compared to uncircumcised men, circumcised men had increased odds of no condom use at last sex (OR=1.17) that was statistically significant (Table III). There is no evidence of a difference between circumcised and uncircumcised men in >2 sexual partners in the previous six months or transactional sex. Nonsignificant (p>.10) MC*time interaction terms were removed from final models. The lack of statistical significance of the MC*time interaction term in three of the four models suggests that the sexual behavioral trajectory of circumcised and uncircumcised men did not differ over time for these outcomes. Although circumcised men had initially lower odds of sex the same day as meeting someone, over time, uncircumcised men modestly decreased this risk behavior, whereas circumcised men neither increased nor decreased.

TABLE III

ODDS RATIO ESTIMATES AND P-VALUES FOR TIME, CIRCUMCISION STATUS, AND INTERACTING VARIABLES FROM MARGINAL STRUCTURAL MODELS FOR FOUR SEXUAL RISK-TAKING VARIABLES

	OR (95% CI) p-value			
Variable[1]	A	B	C	D
	No condom use at last sexual intercourse	>2 sexual partners (previous 6 months)	Sex same day as meeting someone (previous 6 months)	Exchanged gifts/money for sex (previous 6 months)
Circumcised	1.17 (1.05, 1.31) p=.006	0.99 (0.87, 1.11) p=.820	0.81 (0.69, 0.97) p=.006	0.90 (0.73, 1.11) p=.318
Time[2] (6-month increase)	1.06 (1.04, 1.07) p<.001	1.00 (0.98, 1.02) p=.705	0.94 (0.91, 0.97) p<.001	0.95 (0.92, 0.99) p<.006
MC*time[3]	—	—	1.06 (1.02, 1.10) p=.006	—

[1]All four models are weighted by product of IPTW*IPCW and include the variables listed plus the following baseline characteristics: age, education, married/cohabitating, residing in Kisumu, income source, endorsement of MC, HSV-2 serostatus, GUD, infection with NG, CT, or TV.
[2]Baseline visits were excluded; time=0 refers to the 6-month visit
[3]For parsimony, nonsignificant MC*time interaction terms (p>.10) were removed from final models.

The transactional sex variable had a concerning amount of missing data (12.7%) and men who were missing on this variable were older, better educated, more likely to have sexual debut at 15 or older, and be a salaried employee. Men missing on the variable were less likely to be married/cohabitating; live in Kisumu; endorse circumcision; be HSV-2 seropositive; have NG, CT, or TV; and to report penile coital injuries. Missingness increased over time. Despite this, modeling results for all four outcomes were not materially different when compared to models where a simple deterministic imputation method (last observation carried forward / next observation carried back) was used for missing data. Inclusion of time*time interaction terms did not change other model estimates, so they were removed. Truncating the weights at the 1st and 99th percentile (0.38 and 2.12, respectively) did not materially affect modeling results.

E. **Discussion**

Risk compensation following MC involves increasing sexual risk to offset the perceived protective benefit of the procedure. We examined four sexual risk behaviors in the Kisumu RCT and post-trial follow-up data to determine whether circumcised men increase risky sexual behaviors over a six-year period. Over time, both circumcised and uncircumcised men used condoms less. Circumcised men were moderately more risky in this behavioral outcome; they had 0.17 higher odds of no condom use at last sex. There is no evidence of risk compensation in the other three sexual behavioral outcomes. Uncircumcised men reduced levels of sex on the same day as meeting someone and circumcised men did not change in this behavior over time; therefore, there is no evidence risk compensation occurred in this outcome.

Modeling studies estimate very high levels of risk compensation would be necessary to completely offset the benefits of MC: reduced condom use by 90%,[12] increase mean number of

sexual contacts per year from 1 to approximately 1.5,[85] 200% increase in rate of partnership formation,[98] 43% of circumcised men and their female partners move from "non-core" to "core" group (core group has 3–5 times higher number of sexual contacts per year).[99] Our results support earlier investigations of risk compensation,[1–3, 86, 87, 90] indicating that such dramatic levels of behavioral change are unlikely to occur. Moreover, empirical evidence suggests high levels of risk compensation would be necessary to mitigate the strong biological effect of MC. In the South African trial[1] and Kenyan trial and post-trial follow-up data (Mehta, 2013), controlling for differences in sexual behaviors between circumcision and control groups did not attenuate protective effect of MC on HIV incidence.

No condom use at last sex increased in circumcised and uncircumcised men, even as other sexual risk behaviors declined. The men in our trial were young (18–24 years) and mostly unmarried at baseline. It is likely condom use declined as more men entered into stable partnerships. Indeed, in unweighted multivariable GEE analysis, married/cohabitating men had 4.61 (95%CI 4.01, 5.31) higher odds of no condom use at last sex relative to unmarried and not cohabitating men (data not shown).

Several of the factors associated with choosing circumcision from the MSM weight models were surprising. Men who were older at baseline (21–24 versus 18–20 years old) were more likely to choose circumcision, as were men who were married or cohabitating at baseline. Previous acceptability research from the study area indicates barriers to MC uptake include older age and the post-surgical abstinence period, the latter especially among married men.[60, 100] That men who had coital injuries were less likely to choose circumcision was also unexpected, given that several studies suggest avoidance of such penile injuries is a commonly cited circumcision facilitator in East and southern Africa.[60, 62, 64, 101]

There were substantial differences between men choosing circumcision and those declining and men who were lost to follow-up and those who remained in the study. Although Kong et al. did not find differences between the baseline characteristics of men choosing circumcision and those remaining uncircumcised in Uganda,[86] some of the differences we detected between these groups were in time-varying covariates. This underscores an advantage of the MSM approach, which accounts for baseline and time-varying differences between exposed and unexposed and between censored and uncensored.

The MSM assumption of no unmeasured confounding is not empirically testable. It is possible there was residual confounding in our models. Alternatively, the inclusion of too many covariates in the models used to estimate the treatment and censor weights could introduce non-positivity bias.[95] We attempted to balance desire for control of confounding and parsimony by choosing variables a priori that were conceptually likely to confound the association between circumcision status and sexual risk behaviors.

Men in this study were interviewed, received risk-reduction counseling, HIV/STI testing, and condoms every six months. These efforts do not simulate conditions that would likely be found in routine health settings and may have altered sexual behaviors, or men's reporting of them.

We experienced significant loss to follow-up over the lengthy period of this study. We addressed this limitation by using inverse probability of censor weights to adjust for differences between censored and uncensored men on measured variables. It is possible, however, there were unmeasured variables that contributed to censorship, which we could not adjust for in our IPCW models.

Despite these limitations, previous studies of risk compensation following MC included measurements only up to two years after MC[1, 2, 87, 90, 102] or did not account for potential time-varying

differences between men choosing to undergo circumcision and those remaining uncircumcised.[86] We used robust analytic methods to assess risk compensation for four measures of sexual behavior over a six-year period in Kisumu, Kenya.

F. **Conclusion**

In extended follow-up, both circumcised and uncircumcised men reduced condom use. Circumcised men had 0.17 higher odds of no condom use at last sex, compared to uncircumcised men. There was no evidence for risk compensation in other sexual risk-taking behaviors. Given the consistency across numerous studies and over a six-year observation period, additional research on risk compensation following MC may not be warranted.

III. FACTORS ASSOCIATED WITH UPTAKE OF INFANT MALE CIRCUMCISION FOR HIV PREVENTION IN WESTERN KENYA[1]

A. Abstract

1. Background

Three RCTs demonstrated MC decreases female-to-male HIV incidence by approximately 60%. Male circumcision research in sub-Saharan Africa has focused on adolescents and adults. Modeling suggests IMC will be cost-saving for HIV prevention in high- to moderate-HIV prevalence regions. This study examined parental decision-making and differences in characteristics of parents accepting and declining IMC services in Nyanza Province, Kenya.

2. Patients and methods

This case-control study was conducted in 2010 at five government health facilities in western Kenya. Cases were mothers and fathers accepting circumcision for their son. Controls were parents who declined IMC services. A questionnaire comprising 41 questions was administered.

3. Findings

A total of 627 mothers and 492 of their male partners enrolled. In multivariable logistic regression modeling, factors associated with accepting IMC among mothers were: father circumcised, both partners Luo (versus father uncircumcised, both partners Luo OR=5.47, p<.001) and agreeing with the father about the IMC decision (OR=5.00, p<.001). Among fathers, factors associated with accepting IMC were: being circumcised and Luo (versus uncircumcised and Luo OR=3.96, p=<.001) and having higher endorsement of MC (OR=3.79, p<.001). Fathers were the

[1] Parts of this chapter have been previously published in Young, M. R., Odoyo-June, E., Nordstrom, S. K., Irwin, T. E., Ongong'a, D. O., Ochomo, B., . . . Bailey, R. C. (2012). Factors associated with uptake of infant male circumcision for HIV prevention in Western Kenya. *Pediatrics*, *130*(1), e175–182. Please see Appendix B for permission to use the previously published material.

primary decision makers in most instances (66%). Few parents (3%) reported they would prefer a future son to remain uncircumcised.

4. **Conclusion**

Fathers are important in the IMC decision-making process. Fathers, as well as mothers, should be targeted for optimal scale-up of IMC services. Circumcision programs should offer services for males of all ages, since MC at some age is highly acceptable to both men and women.

B. Background

Three RCTs and numerous observational studies have demonstrated that MC significantly decreases risk of HIV acquisition in men.[1–4, 103] The WHO guidelines recommend MC services be provided as a component of a comprehensive HIV prevention package.[5] Given the limited armamentarium of proven HIV-prevention techniques, MC could play an important role in the containment of the epidemic in high-prevalence areas where the disease is primarily transmitted heterosexually and where circumcision rates are low, as is the case in many regions of sub-Saharan Africa.

To date, research on the acceptability and provision of circumcision services in sub-Saharan Africa, as well as rollout of services, have focused on adolescent and adult males.[29, 54, 55] Compared to adolescent and adult MC, the circumcision of an infant is safer, less technically challenging, faster, less expensive, easier to care for postoperatively, and likely to reduce chances of risk compensation.[45–49]. Benefits to boys circumcised in infancy include reduction in UTI in early life and avoidance of phimosis.[16, 50] The same health benefits afforded to circumcised men later in life accrue to those circumcised in infancy. These include reduction in: ulcerative STIs, oncogenic HPV

incidence, and penile cancer.[52, 104–106] Benefits to female sexual partners of circumcised men include reduced risk of bacterial vaginosis, trichomoniasis, HPV infection, and cervical cancer.[51, 53, 106] Despite the many advantages of circumcising infants, potential drawbacks include the inability of the infant to consent to the procedure himself and the lengthy interval between the intervention and impact on the HIV epidemic, even if a recent analysis has shown that infant circumcision is cost-saving for HIV prevention under conditions that prevail in many African countries.[48]

While IMC is practiced in Ghana and other parts of West Africa, it is little known in East and southern Africa.[107] Studies from areas in East and southern Africa where MC (at any age) is not traditionally practiced report levels of acceptability for MC of around 75% under the conditions that MC is protective against HIV acquisition, and that it is offered safely and affordably.[54] Most research has found a greater proportion of men and women prefer adolescent circumcision to infant circumcision with the exception of Botswana, where one study showed 55%–63% of adults preferred circumcision to be performed on infants or young children, and another study showed 81% of postpartum mothers of male infants felt the best time to circumcise was within the first year of life.[56, 57] In regions where acceptability studies have been conducted, those who favor infant over adolescent or adult circumcision cite reduced pain, fast healing, the ability to maintain a controlled environment, and having the boy habituated to his circumcision status before he becomes an adult.[54, 56, 60–64] The reasons given for opposing infant circumcision include the fragility of babies, traditional beliefs (e.g., that a mother should not see her son's circumcised penis), fear of bleeding, and allowing the boy to consent to the procedure himself.[54, 56, 60–64]

This study assesses parental decision-making, barriers and facilitators to IMC uptake, and differences between parents who accept and decline IMC services in Nyanza Province, Kenya. The dominant ethnic group in Nyanza is the Luo, a Nilotic people who do not traditionally practice MC.

Since 2008, MC services have been scaled-up in the area and prevalence of MC in adults has increased from approximately 25% to 50%.[82] This study provides insight into why parents actually choose or decline IMC for a son when the service is offered.

C. Methods

1. Study design

This case-control study was conducted between March and October 2010 at five government health facilities in three Districts in western Kenya. Cases were mothers and fathers, aged 18 years or older, accepting circumcision for their son at a participating health facility. Controls were mothers and fathers who had been offered IMC for an eligible son and declined the service. All participants provided written informed consent.

Mothers delivering on the maternity ward or present at the maternal child health clinic (for antenatal care, vaccinations, well baby visits) were given group health talks on the benefits and risks of IMC. At the three urban health facilities (a district hospital, a provincial hospital, and a health center), talks and IMC services were offered Monday through Friday. At the two smaller, peri-urban facilities (both district hospitals) talks and IMC services were offered twice per week. Information provided in the group talks included: that MC protects a man from heterosexual HIV acquisition by approximately 60%; that UTIs are less common in circumcised infants; and that complications associated with the procedure are rare but could include pain, bleeding, and infection. Women were approached individually after the group talks. Because of movement of women through the health facilities, neither the number of women at the group health talks nor the number of women approached individually were recorded. Mothers who had a male child less than two months of age and who declined IMC were referred to a research assistant, enrolled as controls, and interviewed in

a private location. Women who accepted circumcision for their son were referred to the IMC procedure room. All women who presented for IMC services and provided written consent for the medical procedure were offered participation in the study as a case. Trained nurses and clinical officers (similar to physician assistants) provided circumcision services in an IMC room on the maternity ward at each study facility. The study interview took place on the same day as the circumcision.

By design, we aimed to enroll 300 case mothers and 300 control mothers. Sample-size calculation was performed for comparisons of demographic information and circumcision beliefs and attitudes between those accepting circumcision and those declining. Estimated proportions for sample-size determination were based on previously published research on MC acceptability in Nyanza Province.[108] In order to achieve equity in number of cases and controls, case enrollment was reviewed weekly and additional controls enrolled as needed. After a woman consented to participate, she was asked if the father of the boy could be contacted for a separate interview. If she agreed, study personnel recorded contact information for the father and attempted to trace and interview him. Research assistants fluent in English, Kiswahili, and DhoLuo conducted face-to-face interviews (separately for mothers and fathers) lasting approximately 30 minutes using a questionnaire consisting of 41 closed-ended questions (types of questions included yes/no and multiple response items—see Appendix C) several of which also allowed the interviewer to choose "other" and write a unique response. Data were entered into Microsoft Access 2007 (Microsoft Corporation, Seattle, Washington) and imported into SAS software version 9.2 for Windows (SAS Institute Inc, Cary, North Carolina) for analysis. The Kenyatta National Hospital Ethics and Research Committee and the University of Illinois at Chicago Institutional Review Board provided ethical approval for this study.

2. **Statistical analysis**

a. **Dependent variables**

We explored two outcome variables. The first is individual-stated preference for circumcision of one's son, which may be different for the mother and father within a couple. This variable was measured as: for IMC, against IMC, and not sure. The second outcome is actual acceptance of IMC (i.e., case/control status), which is the same for both parents within a dyad.

b. **Independent variables**

Independent variables include demographic factors, circumcision status of the father, IMC decision-making variables (e.g., primary IMC decision-maker), and endorsement of circumcision. To measure general endorsement of MC, we created a scale from six variables that assess beliefs and attitudes about MC. These questions ask the respondent about the relationship between circumcision status and susceptibility to diseases/AIDS, hygiene, sexual pleasure for men and their partners, and cosmetic appearance of the penis. Response categories are: "circumcised men," "uncircumcised men," "no difference," and "not sure." One point is added to the endorsement score for each question the participant answers favorably toward the circumcised state and the item is scored as zero if the person responded favorably toward the uncircumcised state, if they felt there was no difference or if they were unsure. The scale therefore ranges from zero to six with higher values indicating greater endorsement of MC.

To explore the relationship between ethnicity and circumcision status (which are highly correlated) on preference for IMC, we created a composite variable of ethnicity and father's circumcision status with the following five categories: (1) Luo/Luo partnerships where the father is uncircumcised (referent category), (2) Luo/Luo partnerships where the father is circumcised, (3) ethnically discordant partnerships, and (4) non-Luo/non-Luo partnerships. In the final category we

did not distinguish between circumcised and uncircumcised men, since all these men come from circumcising communities and nearly all (57/59 couples, 97%) are circumcised.

Dyad education (categories included: low, medium, and high) was constructed from mother and father's educational attainment as illustrated in Table IV.

TABLE IV

CONSTRUCTION OF DYAD EDUCATION VARIABLE

		Father's educational attainment		
		None	Primary/secondary	>Secondary
Mother's Educational Attainment	None	low	low	med
	Primary/secondary	low	med	high
	>Secondary	med	high	high

c. **Bivariate analyses**

Differences between mothers whose partner was interviewed for the study and those whose partner was not interviewed, differences between those for and those against IMC for their son, and differences between cases and controls were computed using ORs, Pearson's χ^2 test for independence or, for continuous variables, the Wilcoxon two-sample Z test.

d. **Analysis for outcome 1 (preference for infant male circumcision)**

Since mothers and fathers cannot be considered independent, conventional regression models that include both mothers and fathers may underestimate standard errors and lead to inappropriate inference. To assess within-dyad interdependence, we used the Pearson-type pairwise intraclass correlation coefficient (PICC), which is similar to the intraclass correlation

coefficient (ICC) but appropriate for binary data.[109, 110] We used random intercept multivariate regression models with a logit link function to identify predictors of preference for IMC and potential confounders. Data were structured using the actor partner interdependence model (APIM) framework.[111,112] In this framework, each individual is represented on one line of data. Variables include the person's own characteristics (i.e., "actor" variables—such as the person's age), the individual's partner's data (e.g., partner's age) and variables that are the same for both actor and partner (e.g., marital status). We considered all three types of effects—actor (level 1), partner (level 1) and dyad (level 2)—on an individual's preference for IMC.

Demographic variables and other explanatory variables significant at $p<.10$ in bivariate analysis were examined in exploratory logistic models. Variables with considerable correlation (Pearson's $r >.60$) were not entered into the same model. Model selection proceeded using a manual stepwise methodology. Statistically significant variables at $p<.10$ were entered and nonstatistically significant variables were eliminated one variable at a time in an iterative process. Likelihood ratio statistics and model parameters were compared after each addition or elimination. Models in which the estimated variance of the random effect was zero were considered invalid and parameter estimates ignored. We excluded dyads where one partner was unsure about IMC preference (n=10 dyads). Dyads where both partners were Muslim (n=26 dyads) or Nomiya (n=8 dyads) were considered non-informational and excluded from analyses relating to preference for IMC.

e. **Analysis for outcome 2 (observed uptake of infant male circumcision)**

Multivariate logistic regression models were used to identify predictors of actual uptake of IMC and potential confounders. Since mothers and fathers are not independent and since the outcome variable is the same for both partners (i.e., there is no within-dyad variability), we built separate models for mothers and fathers. Model-building proceeded using the manual stepwise

procedure described above. Muslim and Nomiya participants (n=54 mothers and 40 fathers), who traditionally practice IMC, were considered non-informational and were therefore excluded from models.

D. Results

1. Sample

We approached 629 eligible women for participation in this study (see Figure 4); of these we enrolled 312 mothers who declined IMC services, 315 mothers who accepted IMC services, and two mothers (<1%) declined participation. Of the 312 control mothers, 28 (9%) did not give consent to contact the father of the baby, 32 fathers (10%) could not be traced or were not available to be interviewed, and 252 fathers (81%) were enrolled. Of the 315 case mothers, 32 mothers (10%) did not provide consent to contact the father, 43 fathers (14%) could not be traced or were not available, and 240 fathers (76%) were enrolled. No fathers refused participation outright. A total of 1,120 individuals (627 mothers, 492 fathers, 492 dyads) are included in the analyses.

In comparison to mothers whose partners were not enrolled in the study (n=135), mothers whose partners did enroll (n=492) were younger (p=.050) and more likely to live with their spouse/partner (p<.001), to have consulted the father about the IMC decision (p<.001), and to report circumcised men experience greater sexual pleasure (p=.021). Other maternal variables are similar between those whose partners were interviewed and those whose partners were not interviewed.

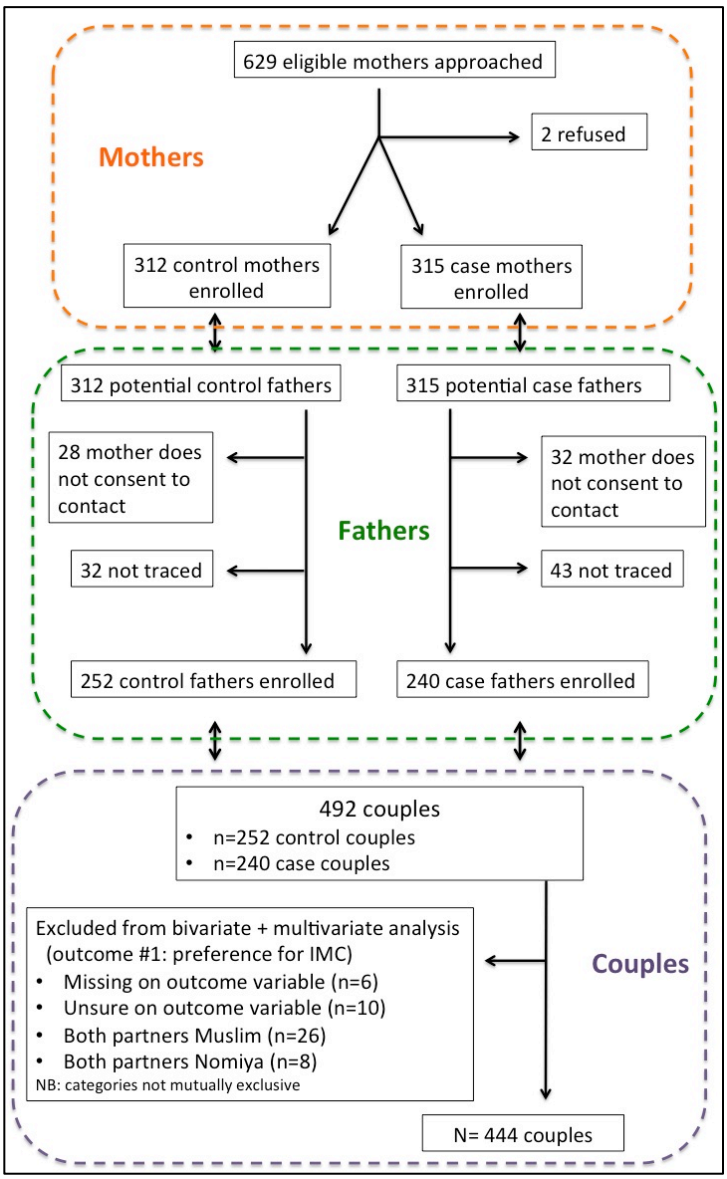

Figure 4. Enrollment flow chart.

2. Characteristics of mothers and fathers enrolled

The median age of mothers was 25 years (Interquartile range [IQR] 21–30) and the median age of fathers was 32 years (IQR 28–37). Most participants (79% of women and 83% of men) were of Luo ethnicity and the remaining were from 18 different ethnic groups. Close to half of

fathers were circumcised (45% by mother's report and 43% by father's self-report). Ninety percent of parents (570 women, 439 men) were Christians; 6% (40 women, 31 men) were Muslim; 2% (14 women and nine men) were Nomiya (a Kenyan Christian sect traditionally practicing IMC on the eighth day of life); and few participants (<1% of mothers and 2% of fathers) reported not belonging to any religion. Mothers had lower educational attainment, employment, and earnings than fathers. Most women (73%) were unemployed and 68% reported having earned no income in the previous month. Among fathers, 23% reported being unemployed and 13% earned no income in the previous month. At the dyad level, half (49%) of couples were those where both the mother and father were for the procedure. A third (35%) of couples comprised parents who were both against the procedure and in the remaining 15%, one partner was for and the other against. In three-quarters (73%) of couples, both parents were Luo. Most couples lived together (81%) and had two Christian members (88%). Other characteristics of individuals and dyads are listed in Table V.

3. Analysis 1: Actor preference for infant male circumcision

We first explored characteristics associated with actor preference for IMC using the actor-partner interdependence model framework. For this analysis, we excluded dyads with either partner missing on this outcome variable (n=6 dyads) and those where one partner was unsure about IMC preference (n=10 dyads). Dyads where both partners were Muslim (n=26 dyads) or both Nomiya (n=8 dyads) were considered non-informational and excluded from analyses relating to preference for IMC. A total of 444 couples were included in bivariate and multivariate analyses (two couples met more than one exclusion).

a. Bivariate Analysis

Having a partner who preferred IMC was associated with 27 times increased odds (OR 27.3 95%CI: 19.0, 39.0) of the actor being for the procedure. As expected, preference for

IMC is very closely related to uptake; among actors who were for IMC, 81/487 (16.6%) were controls and, strikingly, just 8 of 401 (2.0%) actors against IMC were cases (OR for being a case in those for IMC versus those against 246.2 95%CI: 117.5, 515.8).

Using a significance level of $p<.05$, several actor, partner, and dyad-level factors were associated with preference for IMC. Actor-level factors associated with preference for IMC in bivariate analysis include none/postsecondary actor educational attainment (versus primary/secondary finishers), some actor income (versus none), and high-actor endorsement of MC. High/low partner educational attainment was the only partner-level factor associated with actor preference for IMC. Finally, dyad-level factors associated with preferring circumcision for one's son include more than six years age difference between dyad members, ethnically discordant couples (i.e., one partner Luo and the other non-Luo) versus Luo/Luo couples, circumcised father, high/low dyad education, both dyad members earning some income, and partners not residing together (see Table VI).

TABLE V

CHARACTERISTICS OF MOTHERS, FATHERS, AND COUPLES IN SAMPLE

Characteristic	Mother n=627	Father n=492	Couples n=492
Preference for IMC			
For	295 (48)	278 (57)	
Against	247 (40)	210 (43)	
Not sure	79 (13)	0 (0)	
Both for			237 (49)
Both against			168 (35)
Mother for, father against			34 (7)
Father for, mother against			37 (8)
Mother not sure			10 (2)
Accepted/Declined IMC			
Case			240 (49)
Control			252 (51)
Age			
Median (IQR)	25 (21, 30)	32 (28, 37)	
Difference, median (IQR)			6 (4, 10)
Ethnicity			
Luo	493 (79)	409 (83)	
Non-Luo	134 (21)	83 (17)	
Ethnically concordant, Luo			360 (73)
Ethnically concordant, non-Luo			59 (12)
Ethnically discordant			73 (15)
Circumcision status of father/self			
Circumcised	279 (45)	210 (43)	
Uncircumcised, not sure	348 (56)	282 (57)	
Circumcised (father and mother report)			181 (37)
Circumcised (father report; mother not sure)			9 (2)
Circumcised (father report; mother reports uncircumcised)			20 (4)
Uncircumcised (father and mother report)			223 (45)
Uncircumcised (father report; mother not sure)			22 (4)
Uncircumcised (father report; mother reports circumcised)			37 (8)
Education			
None	59 (9)	20 (4)	
Primary/Secondary	519 (83)	406 (83)	
Postsecondary	49 (8)	66 (13)	
Low			62 (13)
Med			356 (72)
High			74 (15)

CHARACTERISTICS OF MOTHERS, FATHERS, AND COUPLES IN SAMPLE

Characteristic	Mother n=627	Father n=492	Couples n=492
Employment			
Employed	169 (27)	380 (77)	
Unemployed	458 (73)	112 (23)	
Both partners employed			126 (26)
Both partners unemployed			101 (21)
Dad employed, mom not			254 (52)
Mom employed, dad not			11 (2)
Income			
None	426 (68)	64 (13)	
Some	198 (32)	423 (87)	
Both earn some			147 (30)
Both earn none			56 (12)
Dad earns some, mom none			274 (56)
Dad earns none, mom some			8 (2)
Marital status			
Parents live together			400 (81)
Parents do not live together			40 (8)
Discordant answers			52 (11)
Religion			
Catholic	207 (33)	174 (36)	
Protestant	363 (58)	265 (54)	
Muslim	40 (6)	31 (6)	
Nomiya	14 (2)	9 (2)	
None	3 (0)	11 (2)	
Both Christian			431 (88)
Both Muslim			26 (5)
Both Nomiya			8 (2)
Different religions			25 (5)
Endorsement of circumcision scale			
median (IQR)	5 (4, 6)	5 (4, 6)	
0–4	283 (45)	230 (47)	
5–6	341 (55)	258 (53)	

Note. Numbers in table are n (%), unless otherwise specified.

TABLE VI

BIVARIATE ANALYSIS OF FACTORS ASSOCIATED WITH ACTOR PREFERENCE FOR IMC

Characteristic	Actor for IMC n=487 n(%)	Actor against IMC n=401 n(%)	OR (95%CI)
	Actor-level factors		
Sex			
Mother	242 (49.7)	202 (50.4)	.97 (.75, 1.27)
Father	245 (50.3)	199 (49.6)	ref
Age			
Actor age [years], median (IQR)	28 (24, 34)	30 (24, 34)	Wilcoxon p=.314
Ethnicity			
Luo	409 (83.9)	329 (82.0)	1.15 (.81, 1.63)
Non-Luo	78 (16.0)	72 (18.0)	ref
Education			
None	32 (6.6)	18 (4.5)	1.60 (.88, 2.91)
Primary/Secondary	390 (80.1)	352 (87.8)	ref
Postsecondary	65 (13.4)	31 (7.7)	1.89 (1.20, 2.97)
Employment			
Employed	264 (54.2)	212 (52.9)	1.06 (.81, 1.38)
Unemployed	223 (45.8)	189 (47.1)	ref
Income			
Some	311 (64.0)	223 (55.8)	1.41 (1.08, 1.85)
None	175 (36.0)	177 (44.3)	ref
Religion			
Catholic	177 (36.3)	145 (36.3)	n/a
Protestant	290 (59.6)	249 (62.4)	
Muslim	10 (2.1)	0 (0)	
Nomiya	4 (.82)	0 (0)	
None	6 (1.2)	5 (1.3)	
Endorsement of circumcision scale			
High (5–6)	337 (69.6)	130 (32.6)	4.74 (3.57, 6.31)
Med/Low (0–4)	147 (30.4)	269 (67.4)	ref
	Partner-level factors		
Partner preference			
For IMC	416 (85.4)	71 (17.7)	27.2 (19.0, 39.0)
Against IMC	71 (14.6)	330 (82.3)	ref
Partner ethnicity			
Luo	415 (85.2)	323 (80.6)	1.39 (.98, 1.78)
Non-Luo	72 (14.8)	78 (19.5)	ref
Partner education			
None	36 (7.4)	14 (3.5)	2.40 (1.27, 4.52)
Primary/Secondary	384 (78.9)	358 (89.3)	ref
Postsecondary	67 (13.8)	29 (7.2)	2.15 (1.36, 3.41)
Partner employment			
Employed	259 (53.2)	217 (54.1)	.96 (.74, 1.26)
Unemployed	228 (46.8)	184 (45.9)	ref

BIVARIATE ANALYSIS OF FACTORS ASSOCIATED WITH ACTOR PREFERENCE FOR IMC

Characteristic	Actor for IMC n=487 n(%)	Actor against IMC n=401 n(%)	OR (95%CI)
Partner income			
Some	304 (62.7)	230 (57.4)	1.25 (.95, 1.64)
None	181 (37.3)	171 (42.6)	ref
	Dyad-level factors		
Case/Control			
Case	406 (83.4)	8 (2.0)	246.2 (117.5, 515.8)
Control	81 (16.63)	393 (98.0)	ref
Age (continuous)			
Couple age difference [years], median (IQR)	7 (4, 11)	5 (3, 8)	Wilcoxon p=.001
Baby age [days], median (IQR)	5 (2, 28)	5 (2, 22)	Wilcoxon p=.543
Age (categorical)			
Age difference >6 years	244 (50.1)	148 (36.9)	1.72 (1.31, 2.25)
Age difference <=6 years	243 (49.9)	253 (63.1)	ref
Ethnicity			
Ethnically concordant, Luo	368 (75.6)	304 (75.8)	ref
Ethnically concordant, non-Luo	31 (6.37)	53 (13.2)	.48 (.30, .77)
Ethnically discordant	88 (18.1)	44 (11.0)	1.65 (1.12, 2.45)
Circumcision status of father			
Circumcised	242 (46.7)	108 (26.9)	2.68 (2.02, 3.56)
Uncircumcised	245 (50.3)	293 (73.1)	ref
Composite variable: ethnicity/circumcision status			
Both Luo, father circumcised	150 (30.8)	30 (7.5)	6.28 (4.09, 9.67)
Both Luo, father uncircumcised	218 (44.8)	274 (68.3)	ref
Ethnically discordant, father circumcised	62 (12.7)	26 (6.5)	3.00 (1.83, 4.90)
Ethnically discordant, father uncircumcised	26 (5.3)	18 (4.5)	1.82 (.97, 3.40)
Both non-Luo	31 (6.4)	53 (13.2)	.74 (.46, 1.19)
Education			
Low	64 (13.1)	28 (7.0)	2.27 (1.42, 3.63)
Med	328 (67.4)	326 (81.3)	ref
High	95 (19.5)	47 (11.7)	2.01 (1.37, 2.94)
Employment			
Both partners employed	128 (26.3)	108 (26.9)	.95 (.69, 1.29)
Both partners unemployed	92 (18.9)	80 (20.0)	.92 (.65, 1.30)
One employed, one not	267 (54.8)	213 (53.1)	ref
Income			
Both earn some	169 (34.9)	107 (26.8)	1.36 (1.01, 1.83)
Both earn none	39 (8.1)	55 (13.8)	.61 (.39, .95)
Some/none	276 (57.0)	238 (59.5)	ref
Parents live together	397 (81.5)	357 (89.0)	ref
Parents do not live together	90 (18.5)	44 (11.0)	1.84 (1.25, 2.71)

Examination of the ethnicity/circumcision composite variable highlights the complicated relationship between these variables and IMC preference. Luo/Luo ethnically concordant couples where the man was uncircumcised were used as the referent group. Being in a Luo/Luo dyad where the father *is* circumcised was associated with six times higher odds of preferring IMC in comparison to the referent group (OR 6.28 95%CI: 4.09, 9.67). Membership in an ethnically discordant dyad, whether or not the father was circumcised, was also associated with higher odds of preference for IMC versus the referent category. Finally, concordant non-Luo dyad members were less likely to prefer IMC than the referent group though this finding was not significant (OR 0.74 95%CI: 0.46, 1.19).

b. **Multivariate modeling**

To assess the appropriateness of a multilevel modeling, we first computed the PICC to determine the degree of within-dyad interdependence in preference for IMC. The PICC value was 0.68 (95%CI 0.61, 0.75) indicating substantial within-dyad interdependence and suggesting a multilevel modeling approach is warranted.[111]

Many of the multivariate models of interest could not be fit with the available data and model parameter estimates were unstable. For example, being in a dyad with a circumcised father conferred 70.7, 18.9, and 6.7 times higher odds of preferring IMC in three different models, each controlling for only one additional parameter (data not shown). Many model estimates were imprecise (e.g., odds of endorsing IMC were 174 times higher [95%CI: 29, 1,030] with Luo/Luo circumcised father dyad versus Luo/Luo uncircumcised father dyad). Construction of a valid multivariable mixed model was not statistically possible with these data.

4. **Analysis 2: Acceptance of infant male circumcision**

a. **Bivariate analysis**

Multivariable modeling using IMC preference as the outcome variable was not possible. We therefore explored actual acceptance of IMC for one's son (i.e., case/control status) as an outcome. We examined mothers and fathers separately, since dyad members are not independent and there was no within-dyad variability in the outcome.

In bivariate analysis of mothers, cases and controls were similar in terms of ethnic origin and current employment status (see Table VII). Women who adopted circumcision for their infant (cases) were more likely to know the circumcision status of the father and report the father was circumcised compared to women who declined circumcision for their son (controls). Case mothers were more likely to have no formal education or to have finished postsecondary education, to be Muslim or Nomiya and to report some earnings in the previous month. Case mothers were less likely to be living with their husband/partner and more likely to have high endorsement of MC in questions that ascertain knowledge, beliefs, and attitudes about MC.

Among fathers, cases and controls were similar in terms ethnic origin, current marital status, and any income earned in the past month. Fathers who sons were circumcised were more likely to be circumcised themselves, to have completed no education or post-secondary education, and to be Muslim or Nomiya and have high endorsement of MC. Fathers whose sons were not circumcised were more likely to be employed.

b. **Multivariate analysis**

Separate multivariate logistic regression models for mothers and fathers were built to predict uptake of IMC in non-Muslim, non-Nomiya participants (Table VIII). Among the 573 women and 452 men, ten (1%) were excluded due to missing data.

TABLE VII

CHARACTERISTICS OF MEN AND WOMEN WHO ACCEPTED CIRCUMCISION FOR THEIR INFANTS (CASES AND THOSE WHO DECLINED INFANT CIRCUMCISION (CONTROLS)

	Mothers (*N*=627)						Fathers (*N*=492)					
	Case		Control				Case		Control			
Characteristic	N	%	N	%	OR	p	N	%	N	%	OR	p
Ethnic origin												
Other	76	24	58	19	1.39	0.09	42	18	41	16	1.09	0.716
Luo	239	76	254	81	ref		198	83	211	84	ref	
Circumcision status of the father/self												
Circumcised	196	62	83	27	4.54	<.001	142	59	68	27	3.92	<.001
Uncircumcised/NS	119	38	229	73	ref		98	41	184	73	ref	
Highest level of school completed												
None	41	13	18	6	2.75	0.001	14	6	6	2	2.73	0.037
Primary/Secondary	235	75	284	91	ref		187	78	219	87	ref	
Postsecondary	39	12	10	3	4.75	<.001	39	16	27	11	1.69	0.050
Currently employed												
Yes	87	28	82	26	1.07	0.71	176	73	204	81	0.65	0.044
No	228	72	230	74	ref		64	27	48	19	ref	
Current marital status												
Does not live with spouse/partner	89	28	62	20	1.59	0.01	28	12	29	12	1.02	0.956
Lives with spouse/partner	226	72	250	80	ref		212	88	223	88		
Religion												
Muslim/Nomiya	50	16	4	1	14.5	<.001	37	15	3	1	15.01	<.001
Christian/No Religion	265	84	308	99	ref		203	85	247	99	ref	
Earning in past month												
Some	116	37	82	26	1.64	0.004	206	87	217	87	1.01	0.969
None	197	63	229	74	ref		31	13	33	13	ref	
Endorsement of Circumcision Scale												
Higher endorsement (5–6)	230	73	111	36	4.91	<.001	169	71	89	35	4.52	<.001
Lower endorsement (0–4)	84	27	199	64	ref		68	29	162	65	ref	
Agreed with partner about the IMC decision												<.001
Did not consult partner about IMC	41	13	38	12	0.813	0.40	3	1	2	1	1.18	0.857
Did not agree/NS	4	1	70	23	0.043	<.001	4	2	68	27	0.04	<.001
Agreed	268	86	202	65	ref		230	97	181	72	ref	

CHARACTERISTICS OF MEN AND WOMEN WHO ACCEPTED CIRCUMCISION FOR THEIR INFANTS (CASES AND THOSE WHO DECLINED INFANT CIRCUMCISION (CONTROLS)

	Mothers (*N*=627)						Fathers (*N*=492)					
	Case		Control				Case		Control			
Characteristic	N	%	N	%	OR	p	N	%	N	%	OR	p
Primary decision maker*					40.2	<.001					8.76	0.033
Mother	120	38	79	25			41	17	64	26		
Father	161	51	218	70			181	76	173	70		
Both parents	30	10	4	1			14	6	6	2		
Other	4	1	11	4			3	1	5	2		
All reasons for primary decision maker choosing IMC (categories not mutually exclusive)						n/a						n/a
Protection against HIV	191	78	n/a				194	81	n/a			
Protection against STI	247	61					156	65				
Penile hygiene	175	56					163	68				
Religious reason	33	10					23	10				
Other	65	21					46	19				
All reasons for primary decision maker declining IMC (categories not mutually exclusive)						n/a						n/a
Pain	n/a		181	58			n/a		161	64		
Risk			141	45					124	49		
Did not want in infancy			110	35					111	44		
Partner did not want			65	21					38	15		
Against culture			45	14					62	25		
Other/Not sure			28	9					26	10		
If you have another baby boy, you will want him to. . .*					432	<.001					328	<.001
Be circumcised birth–8wk	309	98	50	16			232	97	41	16		
Be circumcised 9wk to 8yr	4	1	79	25			3	1	55	22		
Be circumcised 9yr to 17yr	0	0	70	22			2	1	45	18		
Be circumcised 18+ yr	0	0	91	29			1	0	89	35		
Remain uncircumcised	1	0	10	3			0	0	18	7		
Not sure	1	0	12	4			0	0	4	2		

Note. ND=No difference; NS=Not sure; IMC=infant MC; STI=Sexually Transmitted Infection.*Chi-square value given instead of OR.

TABLE VIII

MULTIVARIATE LOGISTIC REGRESSION MODEL RESULTS OF FACTORS PREDICTING ACCEPTANCE OF IMC IN NON-MUSLIM, NON-NOMIYA MOTHERS (A) AND FATHERS (B)

A. Non-Muslim, non-Nomiya mothers (N=566)

Variable	Unadjusted odds of accepting IMC	Adjusted odds of accepting IMC[a]	95% CI	p
Couple's ethnicity / MC status of father				
Father circumcised, both partners Luo	7.91	5.47	3.08, 9.69	<.001
Ethnically discordant partnership	3.05	1.92	1.00, 3.67	0.050
Both partners non-Luo	1.16	0.56	0.29, 1.09	0.089
Mother not sure about ethnicity / MC status of father	0.43	0.56	0.22, 1.45	0.233
Father uncircumcised, both partners Luo	ref	ref	—	—
Highest level of school completed				
None	2.94	3.86	1.82, 8.22	0.001
Postsecondary	5.13	4.83	1.97, 11.83	0.001
Primary/Secondary	ref	ref	—	—
Current marital status				
Does not live with spouse/partner	1.69	2.98	1.77, 5.04	<.001
Lives with spouse/partner	ref	ref	—	—
Endorsement of MC scale				
Higher (score 5–6)	4.89	4.38	2.84, 6.76	<.001
Lower (score 0–4)	ref	ref	—	—
Parental agreement				
Parents agreed	3.06	5.00	2.90, 8.60	<.001
Did not agree/NS/Did not consult father	ref	ref	—	—

MULTIVARIATE LOGISTIC REGRESSION MODEL RESULTS OF FACTORS PREDICTING ACCEPTANCE OF IMC IN NON-MUSLIM, NON-NOMIYA MOTHERS (A) AND FATHERS (B)

B. Non-Muslim, non-Nomiya fathers (N=449)

Variable	Unadjusted odds of accepting IMC	Adjusted odds of accepting IMC*	95% CI	p
Father's ethnicity / MC status				
Luo, circumcised	6.14	3.96	2.33, 6.73	<.001
Non-Luo	0.98	0.52	0.27, 0.98	0.043
Luo, uncircumcised	ref	ref	—	—
Endorsement of Circumcision Scale				
Higher endorsement (5–6)	4.22	3.79	2.42, 5.93	<.001
Lower endorsement (0–4)	ref	ref	—	—

Note. MC=Male Circumcision; ND=No Difference; NS=Not Sure.
[a]Adjusted for other variables listed

In the final model selected for mothers, the following characteristics were all associated with acceptance of IMC: not residing with the husband/partner, agreeing with the husband/partner about the IMC decision, higher endorsement of MC and having either no education or having finished postsecondary education (versus primary and secondary school finishers). The relationship between acceptance of IMC and ethnicity and circumcision status of the father is complex. Using couples where both partners are Luo and the father is *un*circumcised as the reference group, women who were in partnerships where both members were Luo and the father *is* circumcised had more than five times higher odds of accepting IMC (OR=5.47; 95%CI 3.08, 6.69). Using the same reference group, women in ethnically discordant partnerships had twice the odds of accepting IMC (OR=1.92; 95%CI 1.00, 3.67) and women in partnerships where both partners were non-Luo had lower odds of accepting IMC (OR=0.56 95%CI: 0.29, 1.09), though the latter was not statistically significant (p=.089). The variable that explained the most variance in accepting IMC among mothers in multivariate analysis was the couple ethnicity/circumcision composite variable (Wald χ^2 48.5), followed by endorsement of MC (Wald χ^2 44.5).

In the multivariate logistic regression model for fathers (Table VIII), the following variables were associated with accepting IMC: high endorsement of circumcision (OR=3.79; 95% CI 2.42, 5.93), and being circumcised and Luo (versus uncircumcised and Luo; OR=3.96; 95% CI 2.33, 6.73). After adjusting for MC endorsement, non-Luo fathers were less likely to accept IMC for their son in comparison to uncircumcised Luo fathers (OR=0.52 95%CI: 0.27, 0.98).

5. **Decision-making in infant male circumcision**

The father was the primary IMC decision-maker in the majority of instances according to interviews with mothers and fathers (60% and 72%, respectively). Mothers who had

their sons circumcised were less likely to report the father was the primary decision-maker in comparison to mothers who declined IMC services (51% versus 70%).

When asked all the reasons why the primary decision-maker chose IMC, 315 mothers gave 20 unique, unprompted reasons; the four most frequent reasons were protection against HIV (78%), protection against STI (61%), penile hygiene (56%), and religious reasons (10%). Fathers reported similar reasons (see Table VII), though a greater proportion of fathers than mothers reported hygiene was a reason for choosing IMC (68% versus 56%).

Controls were asked the reasons that the primary decision-maker had declined IMC and 312 mothers gave 19 unique responses. The most frequently cited reasons among mothers were pain (58%), risk (45%), desire to defer circumcision to an older age (35%), the partner being against the circumcision (21%), and going against cultural tradition (14%). The variable was scored as "risk" if the mother cited bleeding, infection, swelling, injury, damage to the penis, lidocaine toxicity, or death as the reason for declining IMC. Responses from fathers were similar (Table VII), though fathers were more likely than mothers to cite going against cultural tradition as a reason for not circumcising.

Nearly all cases (98% of mothers and 97% of fathers) said that they would prefer to have a future son circumcised in infancy. Although only 16% of control parents preferred a future son to be circumcised during early infancy, 76% of mothers and fathers declining infant circumcision reported a preference for a future son to be circumcised at a later age.

E. **Discussion**

To our knowledge, this is the first study of factors associated with uptake and decision-making surrounding IMC in sub-Saharan Africa among parents who are actually offered the service.

Comparison of parents who accept and those who decline IMC and their reasons for doing so were achieved through our case-control study design. Adjusting for confounders, we found that circumcised Luo fathers had an increased likelihood of accepting IMC. Although the primary stated motivation for having a son circumcised may be health- or hygiene-related, social acceptability of IMC among circumcised fathers appears to play a large role in the acceptability and uptake of IMC, consistent with findings from the United States[71] In Nyanza Province, where this study was conducted, approximately 235,000 adolescent and adult circumcisions have been achieved in the last three years with a goal of an additional 200,000 to be performed by the end of 2013.[113] As adult MC becomes more prevalent, demand for IMC is likely to increase. Future programming should design messages specifically for adult men who become circumcised to educate them about the availability and benefits of IMC.

Agreement between the mother and father about the IMC decision was clearly important in the decision-making process. Where disagreement about IMC existed, fathers were more likely than mothers to oppose IMC, indicating that IMC might be more acceptable among mothers. This finding is consistent with our previous studies of adult MC and those of others from sub-Saharan Africa[54, 56, 60–64] and suggests that fathers have more decision-making power over IMC than do mothers. However, it is notable that when parents disagreed about IMC, the decision not to circumcise tended to predominate, regardless of whether the mother or father was the one to decline. For example, when the father was against the procedure and the mother for it, only two out of 41 infants (5%) were circumcised. Similarly, when the mother was against the procedure but the father for it, only one out of 23 infants (5%) were circumcised.

Our results indicate cases and controls agree that protection against diseases and improved penile hygiene are main reasons to choose IMC. However, all mothers received a health talk that

included information about the benefits and risks of IMC before enrolling in the study, which likely influenced responses. Remarkably, while controls declined circumcision for their infant, nearly all (92%) expressed the desire for their son's circumcision at some age.

Pain and perceived health risks to the infant, including bleeding, swelling, infection, and penile damage are the major barriers reported by those declining IMC services. Even among those accepting IMC, 25% report pain as the primary reason not to circumcise a baby boy. Educational campaigns and counseling about pre- and postoperative pain control and the low risk of complications will be needed in IMC programs.

Limitations of our study include the potential bias associated with convenience sampling and the inability to record the number of mothers screened for participation. Additionally, since eligibility for the study required that the parent had made a decision about IMC, those parents who were undecided were unlikely to be screened and asked to participate again after they had made an initial decision. Such parents might have been different from those enrolled into the study. Our results might not be generalizable to non-circumcising communities in Kenya, or to the general population in Nyanza Province, since recruitment took place from government facilities and particularly from maternity wards. The majority of women (56%) in Nyanza Province do not deliver in a heath care facility.[114] However, since 81% of women in Nyanza receive antenatal care from a provider in the government sector and 93% of infants receive the Bacillus Calmette-Guérin vaccine,[114] promoting IMC at government facilities among perinatal women may be a feasible approach to scale-up of services. Finally, the lack of variation in preference for IMC limited our ability to use multivariate modeling techniques to identify predictors of actor preference for IMC among mothers and fathers simultaneously, while controlling for confounding variables.

Our results are useful for identifying measures that will likely reduce barriers and increase access to IMC services. As MC programs are scaled up in sub-Saharan African countries, transitioning from adolescent and adult circumcision services to infant circumcision will be prudent for sustained, cost-efficient HIV prevention.

IV. SAFETY OF OVER TWELVE HUNDRED INFANT MALE CIRCUMCISIONS USING THE MOGEN CLAMP IN KENYA

A. Abstract

1. Background

Several sub-Saharan African countries plan to scale-up IMC for cost-efficient HIV prevention. Little data exist about the safety of IMC in East and southern Africa. We calculated AE rate and risks for AEs associated with introduction of IMC services at five government health facilities in western Kenya.

2. Methods

The AE data were analyzed for IMC procedures performed between September 2009 and November 2011. Healthy infants aged ≤2 months and weighing ≥2.5 kg were eligible for IMC. Following parental consent, trained clinicians provided IMC services free of charge under local anesthesia using the Mogen clamp. Odds ratios and 95%CIs were used to explore AE risk factors.

3. Results

A total of 1,239 IMC procedures were performed. Median age of infants was 4 days (IQR=1, 16). The overall AE rate among infants reviewed postoperatively was 2.7% (18/678; 95%CI: 1.4, 3.9). There was one severe AE involving excision of a small piece of the lateral aspect of the glans penis. Other AEs were mild or moderate and were treated conservatively. Babies one month of age or older were more likely to have an AE (OR 3.20; 95%CI: 1.23, 8.36). The AE rate did not differ by nurse versus clinical officer or number of previous procedures performed.

4. **Conclusion**

The IMC services provided in Kenyan government hospitals in the context of routine IMC programming have AE rates comparable to those in developed countries. The optimal time for IMC is within the first month of life.

B. Background

Male circumcision has been practiced for cultural and religious reasons for more than 4,000 years.[16] Although MC has been associated (often spuriously) with various behaviors and health outcomes over the centuries, recent epidemiological and biological evidence demonstrates MC confers several health benefits. These include reduced risk of heterosexual HIV acquisition in men by 50%–60%, reduced risk of GUD and ulcerative STIs, and reduction in oncogenic HPV incidence and penile cancer.[1–4, 103] Benefits to female sexual partners of circumcised men include reduced risk of bacterial vaginosis, TV, and cervical cancer.[28, 51, 53, 106] In addition, boys circumcised in infancy have reduced risk of UTIs in the first year of life and avoid pathologies of the foreskin, including phimosis, paraphimosis, and balanitis that may be medical indications for MC.[16, 50]

Global prevalence of MC varies widely, ranging from greater than 80% in the Middle East, North Africa, and West Africa to less than 20% in Europe, most of Asia, and Latin America.[115] In East and southern Africa, ethnicity is a major determinant of circumcision practices. Among circumcising communities in this region, MC is typically performed during adolescence.[115] In Kenya, an estimated 86% of men aged 15–49 are circumcised, the vast majority during adolescence.[114] Infant circumcision is little-known and infrequently practiced in Kenya and throughout East and southern Africa.[115]

Following the results of three RCTs demonstrating the protective effect of MC against HIV acquisition, the WHO and UNAIDS recommended scale-up of MC services in areas with low prevalence of MC, high HIV burden, and where the disease is primarily transmitted through heterosexual sex.[5] Roll-out of adolescent and adult MC services is now underway in 14 countries in East and southern Africa.[113] To date, the focus of research and program implementation has been primarily on adult MC.[29, 54, 55] In comparison to adolescent and adult MC, the circumcision of an infant is less expensive, safer, easier to perform, and likely to reduce the chance of risk compensation.[45, 46, 49] Two recent cost-effectiveness analyses have found IMC is cost-saving for HIV prevention under a wide variety of conditions, including those that prevail in many African nations.[14, 48] As MC is scaled-up, governments are likely to shift efforts toward IMC for long-term, sustainable HIV prevention along with other benefits. If IMC programs are to be effectively rolled-out, providing safe surgical services will be of paramount importance. This paper reports rate, type and severity of AE measured as part of provision of IMC services in Nyanza Province, Kenya where IMC is not traditionally practiced.

C. **Methods**

We partnered with the Kenyan Ministry of Health to introduce IMC services in five government health facilities in three districts in Nyanza Province, western Kenya. The data for this analysis come from two sources: (1) a case/control study[116] examining factors associated with parental acceptance of IMC services where infants were actively followed-up postoperatively (research infants), and (2) routine monitoring of IMC services where postoperative follow-up was passive (non-research infants). In the research study, "case" parents were those who accepted IMC for a son and "control" parents had declined IMC services for an eligible son. We used safety data

from babies who were circumcised. Information on demographic characteristics of parents and parental satisfaction with IMC was recorded for research infants but not for non-research infants. The following information was collected as part of routine monitoring of IMC services for all infants: date and location of procedure, name of parent/guardian, weight of baby, date of birth of baby, IMC provider and cadre, date of follow-up (if any), and type and severity of any intra-operative or postoperative AE. The IMC services were available to term male neonates and infants, aged ≤2 months, weighing ≥2.5 kg, generally healthy (e.g., absence of fever and jaundice), and without an anomaly of the genitals. All mothers (and fathers, if present) were counseled on the benefits and risks of IMC and provided written informed consent for the procedure prior to surgery.

The IMC services were provided on a voluntary basis to all infants free of charge by a trained nurse or clinical officer (similar to a physician's assistant) using the Mogen clamp method. A dorsal penile nerve block of 0.15 mg per kg of 2% lidocaine, diluted with an equal amount of water for injection, was administered for intra-operative analgesia. Parents were given verbal and written instructions on postoperative wound care in their language of choice (English, Kiswahili, or DhoLuo), a 50 ml bottle of petroleum jelly to apply to the wound, a 50 ml bottle of acetaminophen (paracetamol) for postoperative analgesia, and one disposable diaper. All parents were asked to return to the health facility with the infant three to four days following IMC to assess progress of wound healing. Research participants were given a transport stipend (approximately USD$1.50) upon return to the health facility for the postoperative review and were actively followed-up if they did not return. Active follow-up included calls to the parents, attempted tracing, and home visits to review the wound postoperatively. Non-research infants were not given a stipend and were not called or traced if they failed to return for review. We used a standardized data collection form for documenting AEs that was adapted from our earlier trial of adult MC for HIV prevention in Kisumu[3]

and was completed by an IMC-trained clinician. All parents were given the telephone number for an IMC hotline, staffed by an IMC-trained clinician, and instructed to call with any questions or concerns.

This analysis is largely descriptive in nature. We report medians, IQRs, and proportions, as appropriate. Differences in AE rates by provider type, provider experience level, and age of baby were computed using ORs. Data were entered into Microsoft Access 2007 (Microsoft Corporation, Seattle, Washington) and imported into Stata/IC 12.1 for Mac (StataCorp, College Station, Texas) for analysis. The University of Illinois at Chicago Institutional Review Board and the Kenyatta National Hospital Ethics and Research Committee provided ethical approval for the research study. Data on infant safety in non-research participants was collected according to Government of Kenya monitoring and evaluation guidelines for routine IMC services.

D. **Results**

Between September 1, 2009 and November 29, 2011, 1,261 babies were registered for IMC at the five facilities where the procedure was offered. Of these, 22 infants (2%) were excluded from surgery due to contraindications discovered after entry into the surgical register: eleven with penile anomaly (nine hypospadias, one epispadias, one micropenis), five with dense foreskin adhesions, two with fever, two with impetigo, one with severe phimosis, and one reason was not recorded. All but the last of these were referred to a pediatric surgeon who was a coinvestigator in the study or to a nurse at the health facility where the IMC took place.

Fifty-one providers performed 1,239 IMC procedures (74% of procedures were provided by 10 clinicians). Three hundred and eight infants (25%) were research infants and the remaining 931 infants were non-research infants. The median age of babies circumcised was four days (IQR 1–16).

Among research infants, 294 of 308 infants (95%) were reviewed postoperatively. The postoperative review rate among non-research infants was 41% (384/931). Other characteristics of research and non-research infants are listed in Table IX.

Most postoperative reviews (96%) occurred within one week of surgery. The remaining 4% occurred up to 45 days following IMC. Seven research infants had an IMC-related AE (AE rate 2.4%, 95%CI: 0.6, 4.1). One research infant had two AEs, for a total of eight AEs in this group. Among non-research infants returning for review, the AE rate was 2.9% (11/384, 95%CI: 1.2, 4.5). Therefore, there were a total of 19 AEs detected in 18 unique infants out of 678 infants reviewed postoperatively (Total AE rate 2.7%, 95%CI: 1.4, 3.9). Out of the total 1,239 infants circumcised, the AE rate was 1.5% (95%CI: 0.8, 2.1). We had one severe AE involving excision of a small piece of the dorsolateral aspect of the glans penis. Other events were classified as mild or moderate and treated conservatively (see Table X). These included: intra-operative or postoperative bleeding arrested with pressure (n=7) or sutures (n=3), postoperative abrasion (n=3), and wound infection (n=5).

The AEs were more common in older babies; 7/205 babies aged one month or older (3.4%) experienced an AE, in comparison to 11/1,007 babies (1.1%) less than one month of age (OR=3.20, p=.02). There was no difference in AE rate by type of provider or experience level of provider (Table XI).

Nearly all (282/294, 96%) parents of research infants reported being “very satisfied” with IMC services received. All parents of research infants returning for review who were asked said they would choose circumcision for their son, if they could do it again. We did not ask non-research parents about satisfaction or the decision to circumcise again.

TABLE IX

CHARACTERISTICS OF RESEARCH AND NON-RESEARCH IMC PROCEDURES

	Research Infants (active follow-up) n=308		Non-research Infants (passive follow-up) n=931	
	n	%	n	%
Postoperative follow up				
Yes	294	95.5	384	41.3
No	14	4.5	547	58.8
Age, days [median (IQR)]	7 (1, 26)		4 (1, 10)	
Provider type				
Nurse	233	75.7	590	63.4
Clinical Officer	75	24.4	326	35.0
Missing	0	0.0	15	1.6
Experience level of provider				
<10 procedures	73	23.7	221	23.7
10+ procedures	234	76.0	674	72.4
Missing	1	0.3	36	3.9
Satisfaction with IMC at postoperative visit				
Very satisfied	282	95.9	N/A	
Somewhat satisfied	11	3.7	N/A	
Somewhat dissatisfied	1	0.3	N/A	
Very dissatisfied	0	0.0	N/A	
Would circumcise son again[a]				
Yes	293	99.7	N/A	
No	0	0.0	N/A	
Missing	1	0.3	N/A	

Note. IQR; N/A, Not applicable.
[a]Question wording: "If you were to do it again, would you circumcise your baby?"

TABLE X

TYPE AND FREQUENCY OF ADVERSE EVENTS AND OTHER EVENTS

	Research Infants n=308	Non-research Infants n=931
	n (%)	n (%)
IMC-related AEs		
Severe AE		
Damage to the glans	0 (0.0)	1 (0.1)
Mild/Moderate AE		
Intra-operative bleeding—suture required	1 (0.3)	2 (0.2)
Intra-operative bleeding—resolved with pressure	2 (0.6)	2 (0.2)
Post-operative bleeding—resolved with pressure	1 (0.3)	2 (0.2)
Infection	2 (0.6)	3 (0.3)
Meatal abrasion	2 (0.6)	1 (0.1)
Sub-total:	8 (2.6)	11 (1.2)
Other Events		
Too little foreskin removed	3 (1.0)	6 (0.6)
Impetigo/rash not involving genitals	1 (0.3)	2 (0.2)
Postoperative fever without other symptoms, not IMC related	0 (0.0)	2 (0.2)
Subtotal:	4 (1.3)	10 (1.1)

Note. AE, adverse event; IMC, infant male circumcision.

TABLE XI

ADVERSE EVENT RATE AND RISK FACTORS FOR ADVERSE EVENTS
IN RESEARCH AND NON-RESEARCH CIRCUMCISIONS

	Research Infants (active follow-up) n=308					Non-research Infants (passive follow-up) n=931					Combined N=1,239				
AE rate (reviewed post-op)	7/294 (2.4%; 95%CI: 0.6, 4.1)					11/384 (2.9%; 95%CI: 1.2, 4.5)					18/678 (2.7%; 95%CI: 1.4, 3.9)				
AE rate (all procedures)	7/308 (2.3%; 95%CI: 0.6, 3.9)					11/931 (1.2%; 95%CI: 0.5, 1.9)					18/1239 (1.5%; 95%CI: 0.8, 2.1)				
	AEs	IMCs	%	OR	p	AEs	IMCs	%	OR	p	AEs	IMCs	%	OR	p
Provider type				0.80	0.79				0.97	0.96				0.97	0.96
Nurse	5	233	2.1			7	590	1.2			12	823	1.5		
Clinical Officer	2	75	2.7			4	326	1.2			6	401	1.5		
Experience level				2.46	0.25				1.15	0.84				1.56	0.38
<10 procedures	3	73	4.1			3	221	1.4			6	294	2.0		
10+ procedures	4	234	1.7			8	674	1.2			12	908	1.3		
Baby's age				2.72	0.20				3.27	0.06				3.20	0.02
Age 30+ days	3	68	4.4			4	137	2.9			7	205	3.4		
Age <30 days	4	240	1.7			7	767	0.9			11	1,007	1.1		

E. **Discussion**

There are few published reports on safety of IMC in developing country settings.[115] The available data show AE rates associated with IMC vary widely by setting, type of provider, method used, and classification of what constitutes an AE. A recent review found that the median AE rate following neonatal and IMC was 1.5% (range 0%–16%) among 16 prospective studies from 12 countries.[45] The median rate of serious AE was 0% (range 0%–2%). The review did not include any studies in which the Mogen clamp method was used. We are aware of only one other study reporting AE rates from East Africa, where IMC is rarely performed.[117] In that Tanzanian study, 368 infants were circumcised using the Plastibell device with an overall AE rate of 2.8% and no serious AEs. Our observed AE rate of 2.4% among research infants and 2.9% among non-research infants is consistent with the lower range of AEs reported from studies conducted in the developing world.[117–121] Lack of consistency in ascertainment and definition of AEs contributes to the wide range of published AE rates. For example, we elected not to include cases of too little foreskin removed (n=9) in our AE calculations because this is not a medical adverse event, per se. Others have chosen to include this type of event, because re-breaking of adhesions and corrective surgery may be necessary in the future. If we included these cases in our count of AEs, the overall AE rate among those returning for postoperative review would be 4.0% (27/678; 95%CI: 2.5, 5.5).

The wide variation in AE rates reported in the literature may be due to differences in experience and training of provider, traditional versus medical IMC, device used, location of procedure, and age of infant. In this study, IMC was provided in a healthcare setting by trained medical providers (nurses or clinical officers) using sterile equipment on neonates and young infants (≤2 months of age); factors that likely contributed to our low observed AE rate. We found no difference in AE rates by provider type, a finding that supports the inclusion of trained nurses as

IMC providers. Infants one month of age or older had more than three times the odds of experiencing an AE and this result was statistically significant (p=.02) despite the relatively small number of events, which suggests that the optimal time for IMC is in the first month of life. That IMC is safer at younger ages is consistent with the few published reports on this topic[122,123] and reinforces the WHO recommendation that IMC be performed within the first two months of life.[124]

Early AEs following neonatal or infant circumcision are generally minor and treatable. These include bleeding resolved with conservative management or suturing, minor infection resolved with antibiotic therapy, pain that can be managed with analgesic therapy, problems with incomplete separation or retention of Plastibell or other disposable device used in circumcision, and parental dissatisfaction with appearance.[125,126] The AEs we observed in this study are consistent with these early minor events. More rarely, severe or life threatening AEs following IMC have been reported. These complications can be early or late and include complete denudation of penile shaft skin, formation of skin bridges between the shaft and glans, damage to the penis including partial or complete amputation or necrosis, damage to the urethra, buried or trapped penis, and meatal stenosis.[126–129] We did not actively follow infants after the initial review, usually occurring within one week of the procedure. Therefore, we cannot exclude the possibility of serious late AEs. However, we did not receive telephone calls or follow-up visits from parents with concerns about late complications and we offered treatment of AEs free of charge.

This analysis has several limitations. We did not record information about the number or type of phone calls between study staff and parents who had questions or concerns about IMC. Our follow-up period was relatively short and the routine monitoring data did not collect several variables of interest potentially associated with AE risk (e.g., hygiene practices). Nevertheless, this

study provides valuable data on AE rate and type in an area where IMC is little-practiced and relatively few published reports on this topic exist.

The rate at which non-research parents brought their infant back for the three-to-four day postoperative review was low at 41%. However, the AE rate among non-research infants was comparable to that among research infants (2.9% versus 2.4%), and the latter group had a 95% follow-up rate. Review rates for IMC may be low in the absence of financial reimbursement for transport costs and active follow-up.

Our study shows IMC services can be provided safely by nurses and clinical officers and with high parental satisfaction in a developing country setting where infant circumcision is little-known and rarely practiced. These results are consistent with the two-month cut-off period recommended by the WHO, and suggest that the optimal time for IMC is the first month of life. Targeted efforts should be made to encourage parents to bring their children for IMC within the first month of life. Our findings are informative for policy makers who seek to scale-up IMC services for long-term, sustainable HIV prevention and for circumcision's other health benefits.

V. CONCLUSION

Male circumcision is one of the few HIV prevention strategies with proven efficacy and it does not rely on sustained adherence. Modeling studies indicate MC would be more cost-effective than treatment as prevention and antiretroviral therapy scale-up in hyperendemic settings.[83] Scale-up of VMMC in Kenya began in 2008 with an initial goal of circumcising 426,000 15–49 year old HIV-negative men in Nyanza Province by 2013.[130] This first phase of MC scale-up is termed the "catch-up" phase, because it targets men most at risk of acquiring HIV in the short-term. As of December 2011, Nyanza Province had achieved more than 220,000 circumcisions (and Kenya achieved 273,000 of the 860,000 country-wide target) and is on track to complete the catch-up phase before any other priority country.[113,131] The relative maturity of the Kenyan program provides an opportunity, unique in sub-Saharan Africa, to study pending operations research issues surrounding MC scale-up and the transition to IMC. Findings from the Kenyan context could be of use to other priority countries as they expand VMMC service delivery.

The impact of MC interventions will be undermined if men engage in significant levels of risk compensation. However, the evidence supporting risk compensation is limited. Two small qualitative studies explored men's behavioral changes after MC and found a minority of men may engage in riskier practices.[132,133] Several cross-sectional studies indicate there exists the potential for risk compensation because of incorrect knowledge about MC (e.g., belief that MC is fully protective against HIV),[134] belief that circumcised men do not need to worry about using a condom,[135] or because some respondents report an intention to engage in riskier behavior, since they perceive the availability of MC lowers their risk of infection.[136] A small randomized trial of a risk-reduction counseling intervention following VMMC in South Africa recruited men at circumcision and re-

interviewed them three months later. The authors found that control group men (n=75) increased unprotected vaginal intercourse from a mean of 3.5 occasions (sd 5.7) in the previous month at baseline to a mean of 6.6 occasions (sd 11.5) at follow-up, whereas the intervention group decreased reported unprotected vaginal intercourse from a mean of 4.8 occasions (sd 8.9) to 1.9 (sd 4.0) over the same period.[137] However, it is unclear whether the control group session, which comprised a one-hour informational talk "that included a brief segment on HIV-prevention education information" is comparable to the counseling given to men routinely undergoing VMMC.

Evidence from cohort studies and the three African RCTs, which were larger and involved longer follow-up periods, have consistently failed to detect risk compensation. This evidence includes a prospective cohort study occurring before the RCT results were published,[90] the three MC for HIV-prevention RCTs,[1–3] a nested cohort study within the Kenyan RCT,[87] a three-year extended follow-up study after randomization was halted in the Ugandan RCT,[86] a two-year prospective cohort study in Kenya,[102] and the current analysis. Our own assessment used robust statistical methods to analyze the potential for risk compensation over a six-year follow-up period. We found that both circumcised and uncircumcised men decreased condom use over time and that circumcised men had 0.17 higher odds of no condom use at last sex, adjusting for confounders including marital status. There was no evidence of risk compensation in the other three sexual behavioral variables (sex the same day as meeting someone in the previous six months, >2 sexual partners in the previous six months, and transactional sex in the previous six months). Viewed in the context of the available literature, our results indicate further examination of risk compensation may not be warranted. Results from our study and others indicate condom use declines over time after MC. Novel ways of encouraging men to use condoms consistently—regardless of their circumcision status— are urgently needed.

One of the many advantages of IMC over adult MC is that risk compensation is less likely to occur, since boys grow up habituated to their circumcision status. For this and other reasons, the WHO/UNAIDS recommend IMC for long-term, cost-efficient HIV prevention.[5] The Kenyan government's national strategy for scale-up of VMMC outlines a plan to transition from adolescent and adult MC to predominantly IMC.[44] As discussed above, the relative maturity of the Kenyan VMMC program makes the country uniquely situated to conduct MC operations research. Timely development of a safe and effective strategy for IMC scale-up will be needed in Kenya before any other priority country.

Our study of IMC in Kenya found IMC can be delivered safely in routine clinical settings and identified important barriers to uptake and reasons for accepting or declining IMC. The consent of the father was crucial to parents choosing IMC, as was agreement between the parents about the IMC decision. Only 13% of mothers did not consult the father before making the IMC decision. Pain, risk, and desire to defer IMC until an older age were the most commonly reported barriers to circumcision. Protection from HIV and better penile hygiene were the most commonly reported facilitators. Based on these results and the observed high rate of home-based maternal delivery in Kenya, there is need to reach women and their male partners before delivery, as well as parents who deliver at home, to achieve high rates of IMC uptake. Research is needed to explore novel approaches for involving the fathers in IMC decision-making as early as possible and providing safe and convenient IMC services to babies who are born at home.

The current context of delivery of perinatal care in Kenya provides several opportunities for integrating IMC education and circumcision services into existing care structures and for identifying novel approaches for IMC scale-up. These opportunities include:

1. Educational talks at health facilities. Nearly all expectant mothers (94%) in Nyanza Province receive some antenatal care from a skilled provider.[138] At government health facilities mothers accessing perinatal services are routinely given informational group talks about a variety of health topics (e.g., breastfeeding, safe delivery, immunization). Nurses at the maternal child health clinic could be trained to give informational talks to perinatal women about IMC. Health facilities routinely record the frequency and content of health talks and report this information to the District Health Records and Information Officer each month. Therefore, IMC talks could be integrated into this existing infrastructure and tracked using available systems.
2. Community-based counseling. Kenya has implemented a community strategy wherein each health facility has at least one community unit, which comprises approximately 50 community health workers (CHWs). Each CHW is responsible for between 20 and 100 homes. The role of the CHW is to visit each home at least once per month and serve as a link between the community and the health facility. The CHWs record several health indicators for each home under their stewardship. Indicators include: the number of pregnant women, the number of recent deliveries, and the vaccine coverage of any children in the home, among others. The CHW reports information on these indicators at a monthly Community Unit meeting attended by health facility staff. Under this system, every household is covered by one CHW. The CHWs could be trained to counsel pregnant and postnatal mothers and their male partners at home about IMC, and referral for IMC could be an additional indicator reported by CHWs. As is the case under existing adult VMMC service delivery, CHWs could be compensated for their time in counseling and

referring clients. Indeed, the Kenyan government encourages this arrangement, since CHWs are otherwise an unpaid cadre of health workers.

3. Community-delivered IMC services. Retired and unemployed health workers living in rural communities have recently been targeted by the Kenyan MOH to be used by health facilities to augment their community programs, including skilled home-based deliveries.[139] The Kenyan MOH targets this group of health providers because of their high level of training, underutilization, and close connection to the community. These "domiciliary midwives" have medical training, nursing or clinical officer licensing, and reside in the community. This cadre of workers could be trained to provide IMC services (including counseling) and could refer mothers to health facilities for IMC or, if the mother is unable to reach the health facility before her child turns two months old (the cutoff for IMC surgery), the domiciliary midwife could offer circumcision in the home.

With relative ease, IMC programmers could capitalize on existing health infrastructure targeting perinatal women. This could include integrating IMC education into facility-based perinatal health talks and training community health workers to provide information about IMC and referral to the health facility for the procedure. These measures would address two major barriers to IMC uptake identified by our study: providing prenatal IMC counseling would give parents more time to discuss and agree about IMC, and providing IMC information in the community would directly involve fathers in IMC decision-making. These efforts alone, however, may not be enough to ensure high uptake of the procedure. Just 44% of mothers in Nyanza deliver in a health facility[138] and the most commonly cited reason for delivering outside a facility is distance to the facility and lack of transport (46% of women delivering outside a health facility cited this as a reason for not

delivering in a clinical setting). Difficulties relating to distance and transport would also likely be a barrier to accessing IMC services. Therefore, training domiciliary midwives as community-based IMC providers would be an innovative way of directly involving fathers and ensuring parents could access surgical services before the two-month cutoff period.

Male circumcision is an important tool in the limited armamentarium of HIV-prevention interventions for sub-Saharan Africa. Results from the analyses presented in this dissertation indicate concerns about risk compensation following MC are not supported by available evidence and IMC is a promising avenue for future programs. More research will be needed to explore the most efficacious and cost-effective ways of delivering safe IMC services.

APPENDICES

APPENDIX A

DISTRIBUTION OF MARGINAL STRUCTURAL MODEL WEIGHTS AT EACH FOLLOW-UP VISIT

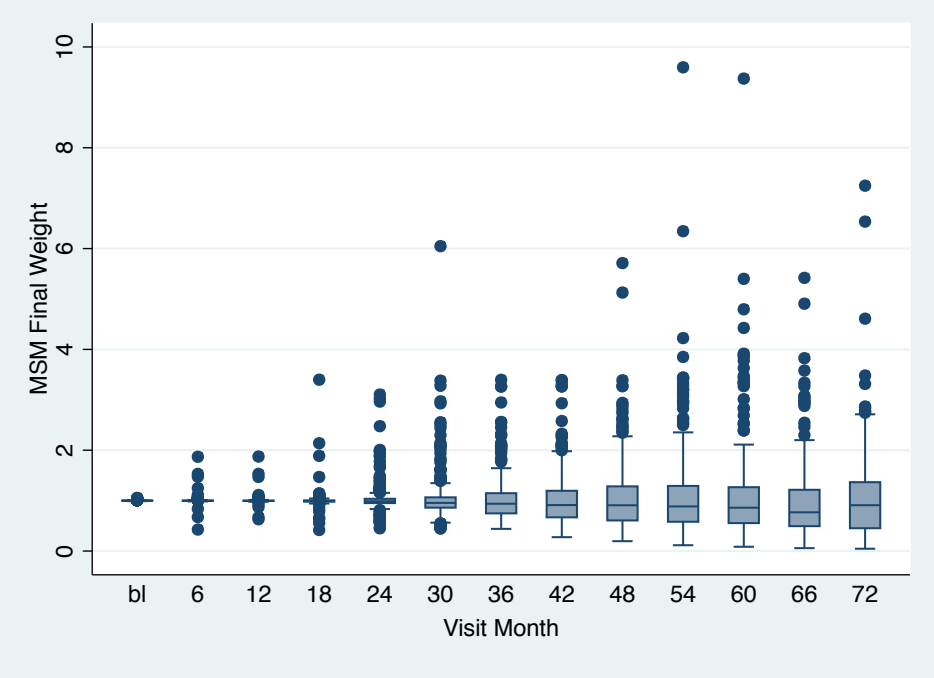

Figure 5. Distribution of marginal structural model weights at each follow-up visit. n=1 weight equal to 19.2 at visit month 66 omitted to reduce the scale of the plot y-axis.

APPENDIX B

PERMISSION TO USE PREVIOUSLY PUBLISHED MATERIAL

AMERICAN ACADEMY OF PEDIATRICS LICENSE TERMS AND CONDITIONS

Mar 04, 2015

This is a License Agreement between Marisa R Young ("You") and American Academy of Pediatrics ("American Academy of Pediatrics") provided by Copyright Clearance Center ("CCC"). The license consists of your order details, the terms and conditions provided by American Academy of Pediatrics, and the payment terms and conditions.

All payments must be made in full to CCC. For payment instructions, please see information listed at the bottom of this form.

License Number	3581910006775
License date	Mar 04, 2015
Licensed content publisher	American Academy of Pediatrics
Licensed content publication	Pediatrics
Licensed content title	Factors Associated With Uptake of Infant Male Circumcision for HIV Prevention in Western Kenya
Licensed content author	Marisa R. Young, Elijah Odoyo-June, Sherry K. Nordstrom, Tracy E. Irwin, Dedan O. Ongong'a, Betha Ochomo, Kawango Agot, Robert C. Bailey
Licensed content date	Jul 1, 2012
Volume number	130
Issue number	1
Start page	e175
End page	e182
Type of Use	Dissertation/Thesis
Requestor type	Individual
Format	Print, Online, and Electronic
Portion	Full article
Order reference number	None
Billing Type	Invoice
Billing Address	Marisa R Young 1603 W Taylor St MC 923 Dept Epidemiology & Biostatistics CHICAGO, IL 60612 United States Attn: Marisa R Young
Total	0.00 USD
Terms and Conditions	

APPENDIX B (continued)

AAP TERMS ANDCONDITIONS

The American Academy of Pediatrics grants permission to use the content cited above for the purpose stated. This letter shall serve as a receipt for payment of the permissions fee(s) and as an approval agreement.

1. The following credit line must appear:
   Reproduced with permission from Journal <Journal>, Vol. <Vol>, Page(s) <Pages>, Copyright © <Year> by the AAP
2. The requester guarantees to reprint the materials exactly as originally published. Obvious typographical errors maybe corrected. No deletions, alterations, or other changes may be made to the information or statistical data without the written consent of the American Academy of Pediatrics.
3. Rights granted herein are not exclusive and the American Academy of Pediatrics reserves the right to grant the same permission to others. Permission is granted for only the reproduction media specified.
4. Original artwork or copies of articles cannot be supplied, but PDF files may be downloaded from www.aappublications.org . Quantities of reprints and eprints can be obtained by contacting Jorie Rayfield, Reprint Sales Manager, The Walchli Tauber Group, Inc., 2225 Old Emmorton Road, Suite 201, Bel Air, MD 21046. 443.512.8899 x 112 office, 443.512.8909 fax, Jorie.rayfield@wt-group.com.
5. This permission is granted on a one-time, annual basis only. Reproduction of this material is confined to the purpose and/or media for which permission is hereby given. Future use of this material is subject to the conditions stated herein. *Gratis permissions are not issued for use in materials available for commercial sale, even for educational use.*
6. If the permission fee for the requested use of our material is waived in this instance, please be aware future requests for AAP materials are subject to fees.
7. Reservation of Rights: Publisher reserves all rights not specifically granted in the combination of (i) the license details provided by you and accepted in the course of this licensing transaction, (ii) these terms and conditions and (iii) CCC's Billing and Payment terms and conditions.
8. License Contingent Upon Payment. Provided that you have disclosed complete and accurate details of your proposed use, no license is effective unless and until full payment is received from you(either by publisher or by CCC) as provided in the CCC's Billing and Payment terms and conditions. If full payment is not received on a timely basis, then any license preliminarily granted shall be deemed automatically revoked and shall be void as if never granted. Further, in the event that you breach terms and conditions or any of CCC's Billing and Payment terms and conditions, the license is automatically revoked and shall be void as if never granted.
9. Warranties: Publisher makes no representations or warranties of any kind, express or implied, including but not limited to, accuracy, timeliness or completeness of the information contained in the licensed materials, or merchantability, title or fitness of a use for a particular purpose.
10. Indemnity: You hereby indemnify and agree to hold harmless publisher and CCC, and their respective officers, directors, employees and agents, from and against any and all claims arising out of your use of the licensed material other than specifically authorized pursuant to this license.
11. No Transfer of License: This license is personal to you and may not be sublicensed, assigned or transferred by you to any other person without publisher's written permission.
12. No Amendment Except in Writing: This license may not be amended except in writing signed by both requestor and publisher.
13. This permission, if permission has been granted for use of figures/tables/images, does not cover any third party copyrighted work which may appear in the material requested and does not apply to materials credited to publications other than American Academy of Pediatrics (AAP) journals. For materials credited to non-AAP journal publications, you will need to obtain permission from the publication referenced in the material legend or credit

APPENDIX B (continued)

line before proceeding with usage of the materials. You agree to hold harmless and indemnify the AAP against any claims arising from your use of any content in your work that is credited to non-AAP sources.

14. This permission does not apply to and is not valid for photographs depicting identifiable individuals, including images where individuals' eyes have been blacked out or images depicting victims of abuse.
15. If the requester is translating the material, the following translation disclaimer must be included:
    The materials reused with permission from the American Academy of Pediatrics ("AAP") appeared originally in English, published by the AAP. The AAP assumes no responsibility for any inaccuracy or error in the contents of these materials, including any inaccuracy or error arising from the translation from English.
16. **Other Terms and Conditions:**

v1.3

Questions? customercare@copyright.com or +1-855-239-3415 (toll free in the US) or +1-978-646-2777.

Gratis licenses (referencing $0 in the Total field) are free. Please retain this printable license for your reference. No payment is required.

APPENDIX C

INFANT MALE CIRCUMCISION QUESTIONNAIRE

MSAFI	Questionnaire—Female participant
Date (dd/mm/yy): ____/____/____	**Participant Number: _____** **Site ID:_____**

Part 1: Demographic Information
[Read: I am going to start by asking you some questions about yourself]

1. What is your date of birth? *[dd/mm/yy]* _____/_____/_____

2. How old are you now? _____ years old

3. What is your son's date of birth? *[dd/mm/yy]* _____/_____/_____

4. What is your Ethnic origin? *[check one]*
   ☐ 0 = Luo
   ☐ 1 = Other (specify): _____

5. What is the Ethnic origin of the father of the baby? *[check one]*
   ☐ 0 = Luo
   ☐ 1 = Other (specify): _____
   ☐ 2 = Not sure

6. What is the circumcision status of the father of the baby? *[check one]*
   ☐ 1 = Circumcised
   ☐ 2 = Uncircumcised
   ☐ 3 = Not sure

   a. If **CIRCUMCISED**, when in his life was the father of the baby circumcised? *[check one]*
      ☐ 1 = Birth to 8 weeks
      ☐ 2 = 9 weeks to 10 years old
      ☐ 3 = 11 to 17 years old
      ☐ 4 = 18 or older
      ☐ 5 = Not sure

APPENDIX C (continued)

7. What district do you currently live in? *[check one]*
   - ☐ 1 = Kisumu East
   - ☐ 2 = Kisumu West
   - ☐ 3 = Siaya
   - ☐ 4 = Other (specify): _____

8. What is the highest level of school you completed? *[check one]*
   - ☐ 1 = No level completed
   - ☐ 2 = Primary
   - ☐ 3 = Secondary
   - ☐ 4 = Postsecondary

9. Are you currently employed? *[check one]*
   - ☐ 1 = Yes
   - ☐ 0 = No

10. What is your occupation? *[check one]*
    - ☐ 0 = Unemployed
    - ☐ 1 = Hawker/Small Business
    - ☐ 2 = Farmer
    - ☐ 3 = Professional/Managerial
    - ☐ 4 = Student
    - ☐ 5 = Other (specify):_____

11. What is your current marital status? *[check one]*
    - ☐ 1 = Not married, without a regular live-in partner
    - ☐ 2 = Not married, with a regular live-in partner
    - ☐ 3 = Married, not living with husband
    - ☐ 4 = Married, living with husband
    - ☐ 5 = Other (please specify): _____

12. What is your religion? *[check one]*
    - ☐ 1 = Anglican
    - ☐ 2 = Catholic
    - ☐ 3 = Muslim
    - ☐ 4 = Pentecostal
    - ☐ 5 = Nomiya
    - ☐ 6 = 7th Day Adventist
    - ☐ 7 = Africa Independent Churches
    - ☐ 8 = Other (please specify):_____
    - ☐ 9 = None
    - ☐ 10 = Not sure

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

APPENDIX C (continued)

14. Where have you received information about infant circumcision? *[check all that apply]*
    - ☐ 1 = From MSAFI team member
    - ☐ 2 = Health care worker
    - ☐ 3 = Family member(s)
    - ☐ 4 = Friend(s)
    - ☐ 5 = Poster or brochure at this hospital/clinic
    - ☐ 6 = Other (specify): _____
    - ☐ 7 = Not sure

Part 2: Decision Making

[Read: Now I am going to ask you some questions about how the decision about your son's circumcision was made]

15. Was your son circumcised at this facility? *[check one]*
    - ☐ 1 = Yes my son has been circumcised at this facility or will be circumcised at this facility today [*Go to Question 16*]
    - ☐ 0 = No, my son has not been circumcised at this facility and I do not intend to have him circumcised at this facility [***Skip to Question 17***]

16. *[Ask mothers in the circumcising group only]* Who was the primary person who made the decision to circumcise your son? *[DO NOT read list of answers –**check only one**]*
    - ☐ 1 = Mother of infant
    - ☐ 2 = Father of infant
    - ☐ 3 = Family member (specify relationship to infant): _____ ☐ 4 = Community leader (specify): _____
    - ☐ 5 = Religious leader (specify): _____
    - ☐ 6 = Other (specify): _____
    - ☐ 7 = Not sure

    a. According to the primary decision-maker, what were the reasons for choosing circumcision? *[DO NOT read list of answers—**check all that apply**]*
        - ☐ 1 = Protection against STI
        - ☐ 2 = Protection against HIV
        - ☐ 3 = Penile hygiene
        - ☐ 4 = Going against cultural tradition
        - ☐ 5 = Improved sexual pleasure of circumcised men
        - ☐ 6 = Diminished sexual pleasure of circumcised men
        - ☐ 7 = Improved sexual pleasure of the sex partners of circumcised men
        - ☐ 8 = Diminished sexual pleasure of the sex partners of circumcised men
        - ☐ 9 = Improved ethnic mixing
        - ☐ 10 = Religious reason
        - ☐ 11 = Not sure
        - ☐ 12 = Other (specify): _____

APPENDIX C (continued)

b. According to the primary decision-maker, what was the single most important reason for choosing to circumcise the infant? *[DO NOT read list of answers—**check only one**]*
   - ☐ 1 = Protection against STI
   - ☐ 2 = Protection against HIV
   - ☐ 3 = Penile hygiene
   - ☐ 4 = Going against cultural tradition
   - ☐ 5 = Improved sexual pleasure of circumcised men
   - ☐ 6 = Diminished sexual pleasure of circumcised men
   - ☐ 7 = Improved sexual pleasure of the sex partners of circumcised men
   - ☐ 8 = Diminished sexual pleasure of the sex partners of circumcised men
   - ☐ 9 = Improved ethnic mixing
   - ☐ 10 = Religious reason
   - ☐ 11 = Not sure
   - ☐ 12 = Other (specify): _____

c. To the best of your knowledge, have you participated in this study in the past as a parent who did not want circumcision for their son? *[check one]*
   - ☐ 1 = Yes
   - ☐ 0 = No

   i. If YES, why did you change your mind about circumcision? *[DO NOT read list of answers—**check all that apply**]*
      - ☐ 1 = Protection against STI
      - ☐ 2 = Protection against HIV
      - ☐ 3 = Penile hygiene
      - ☐ 4 = Going against cultural tradition
      - ☐ 5 = Improved sexual pleasure of circumcised men
      - ☐ 6 = Diminished sexual pleasure of circumcised men
      - ☐ 7 = Improved sexual pleasure of the sex partners of circumcised men
      - ☐ 8 = Diminished sexual pleasure of the sex partners of circumcised men
      - ☐ 9 = Improved ethnic mixing
      - ☐ 10 = Religious reason
      - ☐ 11 = I did not change my mind, someone else wanted the circumcision
      - ☐ 12 = Not sure
      - ☐ 13 = Other (specify): _____

17. *[Ask mothers in the non-circumcising group only]* Who was the primary person who made the decision not to circumcise your son? *[DO NOT read list of answers—**check only one**]*
   - ☐ 1 = Mother of infant
   - ☐ 2 = Father of infant
   - ☐ 3 = Family member (specify relationship to infant): _____
   - ☐ 4 = Community leader (specify): _____
   - ☐ 5 = Religious leader (specify): _____
   - ☐ 6 = Other (specify): _____
   - ☐ 7 = Not sure

APPENDIX C (continued)

a. According to the primary decision-maker, what were reasons for not circumcising your baby? *[DO NOT read list of answers—**check all that apply**]*

- ☐ 1 = Pain associated with the procedure
- ☐ 2 = Risk associated with the procedure
- ☐ 3 = The father did not want the procedure
- ☐ 4 = Going against cultural tradition
- ☐ 5 = Improved sexual pleasure of circumcised men
- ☐ 6 = Diminished sexual pleasure of circumcised men
- ☐ 7 = Improved sexual pleasure of the sex partners of circumcised men
- ☐ 8 = Diminished sexual pleasure of the sex partners of circumcised men
- ☐ 9 = Insufficient time
- ☐ 10 = Did not want to circumcise in infancy
- ☐ 11 = Wanted to have the circumcision done elsewhere
- ☐ 12 = Not sure
- ☐ 13 = Other (specify): _____

b. According to the primary decision-maker, what was the single most important reason for not circumcising your baby? *[DO NOT read list of answers—**check only one**]*

- ☐ 1 = Pain associated with the procedure
- ☐ 2 = Risk associated with the procedure
- ☐ 3 = The father did not want the procedure
- ☐ 4 = Going against cultural tradition
- ☐ 5 = Improved sexual pleasure of circumcised men
- ☐ 6 = Diminished sexual pleasure of circumcised men
- ☐ 7 = Improved sexual pleasure of the sex partners of circumcised men
- ☐ 8 = Diminished sexual pleasure of the sex partners of circumcised men
- ☐ 9 = Insufficient time
- ☐ 10 = Did not want to circumcise in infancy
- ☐ 11 = Wanted to have the circumcision done elsewhere
- ☐ 12 = Not sure
- ☐ 13 = Other (specify): _____

18. Who else was consulted in the decision about your son's circumcision? *[DO NOT read list of answers— **check all that apply**]*

- ☐ 1 = Mother of infant
- ☐ 2 = Father of infant
- ☐ 3 = Family member (specify relationship to infant): _____
- ☐ 4 = Community leader (specify): _____
- ☐ 5 = Religious leader (specify): _____
- ☐ 6 = Other (specify): _____
- ☐ 7 = No one else was consulted in the decision

APPENDIX C (continued)

19. Did you consult the father of your son in deciding to circumcise? *[check one]*
    - ☐ 1 = Yes *[Go to Question 19a]*
    - ☐ 0 = No ***[Skip to Question 20]***

    a. Was he for or against the baby being circumcised? *[check one]*
        - ☐ 1 = For
        - ☐ 2 = Against

    b. Did you agree with his opinion? *[check one]*
        - ☐ 1 = Yes
        - ☐ 0 = No
        - ☐ 2 = Not sure

20. In your opinion, who is the primary person who should decide about circumcision for a baby? *[DO NOT read list of answers—**check only one**]*
    - ☐ 1 = Mother of infant
    - ☐ 2 = Father of infant
    - ☐ 3 = Family member (specify relationship to infant): _____
    - ☐ 4 = Community leader (specify): _____
    - ☐ 5 = Religious leader (specify): _____
    - ☐ 6 = Doctor
    - ☐ 7 = Other (specify): _____
    - ☐ 8 = Not sure

21. In your opinion, what is the primary reason to circumcise a baby boy? *[DO NOT read list of answers—**check only one**]*
    - ☐ 1 = Protection against STI
    - ☐ 2 = Protection against HIV
    - ☐ 3 = Penile hygiene
    - ☐ 4 = Going against cultural tradition
    - ☐ 5 = Improved sexual pleasure of circumcised men
    - ☐ 6 = Diminished sexual pleasure of circumcised men
    - ☐ 7 = Improved sexual pleasure of the sex partners of circumcised men
    - ☐ 8 = Diminished sexual pleasure of the sex partners of circumcised men
    - ☐ 9 = Improved ethnic mixing
    - ☐ 10 = There is no reason to circumcise a baby boy
    - ☐ 11 = Not sure
    - ☐ 12 = Other (specify): _____

APPENDIX C (continued)

22. In your opinion, what is the primary reason not to circumcise a baby boy? *[DO NOT read list of answers—**check only one**]*
    - ☐ 1 = Pain associated with the procedure
    - ☐ 2 = Risk associated with the procedure
    - ☐ 3 = Going against cultural tradition
    - ☐ 4 = Improved sexual pleasure of circumcised men
    - ☐ 5 = Diminished sexual pleasure of circumcised men
    - ☐ 6 = Improved sexual pleasure of the sex partners of circumcised men
    - ☐ 7 = Diminished sexual pleasure of the sex partners of circumcised men
    - ☐ 8 = It is better to wait until the boy is older
    - ☐ 9 = There is no reason not to circumcise a baby boy
    - ☐ 10 = Not sure
    - ☐ 11 = Other (specify): _____

23. What is the best age for male circumcision? *[check one]*
    - ☐ 1 = Birth to one years old
    - ☐ 2 = 2 to 10 years old
    - ☐ 3 = 11 to 17 years old
    - ☐ 4 = 18 years or older

24. Who should be allowed to perform infant circumcision? *[check all that apply]*
    - ☐ 1 = Nurse
    - ☐ 2 = Medical Officer
    - ☐ 3 = Clinical Officer
    - ☐ 4 = Religious leader
    - ☐ 5 = Traditional circumciser
    - ☐ 6 = Other (specify): _____
    - ☐ 7 = Not sure

25. Who is the best person to perform infant circumcision? *[check one]*
    - ☐ 1 = Nurse
    - ☐ 2 = Medical Officer
    - ☐ 3 = Clinical Officer
    - ☐ 4 = Religious leader
    - ☐ 5 = Traditional circumciser
    - ☐ 6 = Other (specify): _____
    - ☐ 7 = Not sure

26. Where should infant circumcisions be offered? *[check all that apply]*
    - ☐ 1 = Hospital
    - ☐ 2 = Clinic
    - ☐ 3 = Dispensary
    - ☐ 4 = In the village or home
    - ☐ 5 = Other (specify): _____

APPENDIX C (continued)

27. Where is the best place to perform infant circumcision? *[check one]*
    - ☐ 1 = Hospital
    - ☐ 2 = Clinic
    - ☐ 3 = Dispensary
    - ☐ 4 = In the village or home
    - ☐ 5 = Other (specify): _____

Part 3: Beliefs about Circumcision

[Read: Now I am going to ask you some questions about your beliefs about male circumcision]

28. Is it easier to keep a penis clean if a man is . . . . ? *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

29. Is it easier for a man to get a disease from a woman if the man is. . . . ? *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

30. Is it easier for a man to get AIDS if he is. . . . ? *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

31. Do men enjoy sex more if they are. . . . ? *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

32. Do most women enjoy sex more with men who are. . . . ? *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

33. Are men more promiscuous if they are. . . . *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

APPENDIX C (continued)

34. Does a penis look better if it is . . . . ? *[check one]*
    - ☐ 1 = Circumcised
    - ☐ 2 = Uncircumcised
    - ☐ 3 = No difference
    - ☐ 4 = Not sure

35. If you have another baby boy, will you want him to be . . . . ? *[check one]*
    - ☐ 1 = Circumcised as an infant (up to eight weeks old)
    - ☐ 2 = Circumcised as a young boy (9 weeks to 8 years old)
    - ☐ 3 = Circumcised as an older boy (9 years to 17 years old)
    - ☐ 4 = Circumcised as a man (18 years or older)
    - ☐ 5 = Remain uncircumcised
    - ☐ 6 = Not sure

36. In the past month, how many shillings have you earned from all sources? *[check one]*
    - ☐ 1 = None
    - ☐ 2 = < 2,000
    - ☐ 3 = 2,000–4,999
    - ☐ 4 = 5,000–9,999
    - ☐ 5 = 10,000–25,000
    - ☐ 6 = > 25,000

[For those in the circumcising group only]

37. If you have the following contact information, please give your:

    a. Phone number: _____

    b. Email: _____

    c. Name of workplace: _____

38. Please give contact information for a close friend or family member who can contact you:

    a. Name and popular name(s): _____

    b. Personal telephone contact number: _____

    c. Name of workplace: _____

CITED LITERATURE

1. Auvert, B., Taljaard, D., Lagarde, E., Sobngwi-Tambekou, J., Sitta, R., & Puren, A. (2005). Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: The ANRS 1265 Trial. *PLoS Medicine*, *2*(11), e298.

2. Gray, R. H., Kigozi, G., Serwadda, D., Makumbi, F., Watya, S., Nalugoda, F., . . . Wawer, M. J. (2007). Male circumcision for HIV prevention in men in Rakai, Uganda: A randomised trial. *Lancet*, *369*(9562), 657–666.

3. Bailey, R. C., Moses, S., Parker, C. B,, Agot, K., Maclean, I., Krieger, J. N., . . . Ndinya-Achola, J. O. (2007). Male circumcision for HIV prevention in young men in Kisumu, Kenya: A randomised controlled trial. *Lancet*, *369*(9562), 643–656.

4. Weiss, H. A., Quigley, M. A., & Hayes, R. J. (2000). Male circumcision and risk of HIV infection in sub-Saharan Africa: A systematic review and meta-analysis. *AIDS*, *14*(15), 2361–2370.

5. WHO/UNAIDS. (2007, March). *Technical consultation on male circumcision and HIV prevention:Research implications for policy and programming.* Montreaux: UNAIDS.

6. Fink, A. J. (1986). A possible explanation for heterosexual male infection with AIDS. *New England Journal of Medicine*, *315*(18), 1167.

7. Simonsen, J. N., Cameron, D. W., Gakinya, M. N., Ndinya-Achola, J. O., D'Costa, L. J., Karasira, P., . . . Plummer, F. A. (1988). Human immunodeficiency virus infection among men with sexually transmitted diseases. Experience from a center in Africa. *New England Journal of Medicine*, *319*(5), 274–278.

8. Global Report. (2010). *UNAIDS report on the global AIDS epidemic.* Retrieved from http://www.unaids.org/globalreport/Global_report.htm

9. Siegfried, N., Muller, M., Deeks, J. J., & Volmink, J. (2009). Male circumcision for prevention of heterosexual acquisition of HIV in men. *Cochrane Database Systematic Reviews*, (*2*), CD003362.

10. Dickson, K. E., Tran, N. T., Samuelson, J. L., Njeuhmeli, E., Cherutich, P., Dick, B., . . . Hankins, C. A. (2011). Voluntary medical male circumcision: A framework analysis of policy and program implementation in eastern and southern Africa. *PLoS Medicine*, *8*(11), e1001133.

11. Njeuhmeli, E., Forsythe, S., Reed, J., Opuni, M., Bollinger, L., Heard, N., . . . Hankins, C. (2011). Voluntary medical male circumcision: Modeling the impact and cost of expanding male circumcision for HIV prevention in eastern and southern Africa. *PLoS Medicine*, *8*(11), e1001132.

12. Hallett, T. B., Singh, K., Smith, J. A., White, R. G., Abu-Raddad, L. J., & Garnett, G. P. (2008). Understanding the impact of male circumcision interventions on the spread of HIV in southern Africa. *PLoS One*, *3*(5), e2212.

13. Nagelkerke, N. J., Moses, S., de Vlas, S. J., & Bailey, R. C. (2007). Modelling the public health impact of male circumcision for HIV prevention in high prevalence areas in Africa. *BMC Infectious Diseases*, *7*, 16.

14. White, R. G., Glynn, J. R., Orroth, K. K., Freeman, E. E., Bakker, R., Weiss, H. A., . . . Hayes, R. J. (2008). Male circumcision for HIV prevention in sub-Saharan Africa: Who, what and when? *AIDS*, *22*(14), 1841–1850.

15. Williams, B. G., Lloyd-Smith, J. O., Gouws, E., Hankins, C., Getz, W. M., Hargrove, J., . . . Auvert, B. (2006). The potential impact of male circumcision on HIV in sub-Saharan Africa. *PLoS Medicine*, *3*(7), e262.

16. Alanis, M. C., & Lucidi, R. S. (2004). Neonatal circumcision: A review of the world's oldest and most controversial operation. *Obstetrics and Gynecolgical Survey*, *59*(5), 379–395.

17. Schoen, E. J. (2007). Should newborns be circumcised? Yes. *Canadian Family Physician*, *53*(12), 2096–2098, 2100–2092.

18. Szabo, R., & Short, R. V. (2000). How does male circumcision protect against HIV infection? *BMJ*, *320*(7249), 1592–1594.

19. Bailey, R. C., Neema, S., & Othieno, R.. (1999). Sexual behaviors and other HIV risk factors in circumcised and uncircumcised men in Uganda. *Journal of Acquired Immune Deficiency Syndromes*, *22*(3), 294–301.

20. Mehta, S. D., Krieger, J. N., Agot, K., Moses, S., Ndinya-Achola, J. O., Parker, C., & Bailey, R. C. (2010). Circumcision and reduced risk of self-reported penile coital injuries: Results from a randomized controlled trial in Kisumu, Kenya. *Journal of Urolology*, *184*(1), 203–209.

21. Kigozi, G., Wawer, M., Ssettuba, A., Kagaayi, J., Nalugoda, F., Watya, S., . . . Gray, R. H. (2009). Foreskin surface area and HIV acquisition in Rakai, Uganda (size matters). *AIDS*, *23*(16), 2209–2213.

22. McCoombe, S. G. (2006). Short RV. Potential HIV-1 target cells in the human penis. *AIDS*, *20*(11), 1491–1495.

23. Patterson, B. K., Landay, A., Siegel, J. N., Flener, Z., Pessis, D., Chaviano, A., & Bailey, R. C. (2002). Susceptibility to human immunodeficiency virus-1 infection of human foreskin and cervical tissue grown in explant culture. *American Journal of Pathology*, *161*(3), 867–873.

24. Qin, Q., Zheng, X. Y., Wang, Y. Y., Shen, H. F., Sun, F., & Ding, W. (2009). Langerhans' cell density and degree of keratinization in foreskins of Chinese preschool boys and adults. *International Urology and Nephrology*, *41*(4), 747–753.

25. Dinh, M. H., McRaven, M. D., Kelley, Z., Penugonda, S., & Hope, T. J. (2010). Keratinization of the adult male foreskin and implications for male circumcision. *AIDS*, *24*(6), 899–906.

26. Hirbod, T., Bailey, R. C., Agot, K., Moses, S., Ndinya-Achola, J., Murugu, R., . . . Broliden, K. (2010). Abundant expression of HIV target cells and C-type lectin receptors in the foreskin tissue of young Kenyan men. *American Journal of Pathology*, *176*(6), 2798–2805.

27. Ganor, Y., & Bomsel, M. (2010). HIV-1 Transmission in the Male Genital Tract. *American Journal of Reproductive Immunology*, 65(3), 284-91.

28. Wawer, M. J., Tobian, A. A., Kigozi, G., Kong, X., Gravitt, P. E., Serwadda, D., . . . Gray, R. H. (2011). Effect of circumcision of HIV-negative men on transmission of human papillomavirus to HIV-negative women: A randomised trial in Rakai, Uganda. *Lancet*, *377*(9761), 209–218.

29. Weiss, H. A., Dickson, K. E., Agot, K., & Hankins, C. A. (2010). Male circumcision for HIV prevention: Current research and programmatic issues. *AIDS*, *24* Suppl 4, S61–69.

30. Tobian, A. A., Serwadda, D., Quinn, T. C., Kigozi, G., Gravitt, P. E., Laeyendecker, O., . . . Gray, R. H. (2009). Male circumcision for the prevention of HSV-2 and HPV infections and syphilis. *New England Journal of Medicine*, *360*(13), 1298–1309.

31. Backes, D. M., Bleeker, M. C., Meijer, C. J., Hudgens, M. G., Agot, K., Bailey, R. C., . . . Smith, J. S. (2012). Male circumcision is associated with a lower prevalence of human papilloma virus-associated penile lesions among Kenyan men. *International Journal of Cancer.*, *130*(8), 1888–1897.

32. Mehta, S. D., Gaydos, C., Maclean, I., Odoyo-June, E., Moses, S., Agunda, L., . . . Bailey, R. C. (2012). The effect of medical male circumcision on urogenital Mycoplasma genitalium among men in Kisumu, Kenya. *Sexually Transmitted Diseases*, *39*(4), 276–280.

33. Sobngwi-Tambekou, J., Taljaard, D., Lissouba, P., Zarca, K., Puren, A., Lagarde, E., & Auvert, B. (2009). Effect of HSV-2 serostatus on acquisition of HIV by young men: Results of a longitudinal study in Orange Farm, South Africa. *Journal of Infectious Diseases*, *199*(7), 958–964.

34. Mehta, S. D., Green, S. J., Maclean, I., Hu, H., Bailey, R. C., Gillevet, P. M., & Spear, G. T. (2012). Microbial diversity of genital ulcer disease in men enrolled in a randomized trial of male circumcision in Kisumu, Kenya. *PLoS One*, *7*(7), e38991.

35. Mehta, S. D., Moses, S., Agot, K., Parker, C., Ndinya-Achola, J. O., Maclean, I., & Bailey, R. C. (2009). Adult male circumcision does not reduce the risk of incident Neisseria gonorrhoeae, Chlamydia trachomatis, or Trichomonas vaginalis infection: Results from a randomized, controlled trial in Kenya. *Journal of Infectious Diseases*, *200*(3), 370–378.

36. Fleming, D. T., & Wasserheit, J. N. (1999). From epidemiological synergy to public health policy and practice: The contribution of other sexually transmitted diseases to sexual transmission of HIV infection. *Sexually Transmitted Infections*, *75*(1), 3–17.

37. Johnson, L. F., & Lewis, D. A. (2008). The effect of genital tract infections on HIV-1 shedding in the genital tract: A systematic review and meta-analysis. *Sexually Transmitted Diseases*, *35*(11), 946–959.

38. Smith, J. S., Moses, S., Hudgens, M. G., Parker, C. B., Agot, K., Maclean, I., . . . Bailey, R. C. (2010). Increased risk of HIV acquisition among Kenyan men with human papillomavirus infection. *Journal of Infectious Diseases*, *201*(11), 1677–1685.

39. Gray, R. H., Serwadda, D., Tobian, A. A., Chen, M. Z., Makumbi, F., Suntoke, T., . . . Wawer, M. J. (2009). Effects of genital ulcer disease and herpes simplex virus type 2 on the efficacy of male circumcision for HIV prevention: Analyses from the Rakai trials. *PLoS Medicine*, *6*(11), e1000187.

40. Price, L. B., Liu, C. M., Johnson, K. E., Aziz, M., Lau, M. K., Bowers, J., . . . Gray, R. H. (2010). The effects of circumcision on the penis microbiome. *PLoS One*., *5*(1), e8422.

41. Atashili, J., Poole, C., Ndumbe, P. M., Adimora, A.A., & Smith, J. S. (2008). Bacterial vaginosis and HIV acquisition: A meta-analysis of published studies. *AIDS*, *22*(12), 1493–1501.

42. O'Farrell, N., Morison, L., Moodley, P., Pillay, K., Vanmali, T., Quigley, M., . . . Sturm, A. W. (2006). Association between HIV and subpreputial penile wetness in uncircumcised men in South Africa. *Journal of Acquired Immune Deficiency Syndrome*, *43*(1), 69–77.

43. O'Farrell, N., Chung, C. K., & Weiss, H. A. (2008). Foreskin length in uncircumcised men is associated with subpreputial wetness. *International Journal of STD and AIDS*., *19*(12), 821–823.

44. Ministry of Public Health and Sanitation, Republic of Kenya. (2009). *Kenya national strategy for voluntary medical male circumcision*. Retrieved from http://nascop.or.ke/library/VMMC/VMMC%20Strategy.pdf.

45. Weiss, H. A., Larke, N., Halperin, D., & Schenker, I. (2010). Complications of circumcision in male neonates, infants and children: A systematic review. *BMC Urology*, *10*, 2.

46. Wiswell, T. E., & Geschke, D. W. (1989). Risks from circumcision during the first month of life compared with those for uncircumcised boys. *Pediatrics*, *83*(6), 1011–1015.

47. Bailey, R. C., Egesah, O., & Rosenberg, S. (2008). Male circumcision for HIV prevention: A prospective study of complications in clinical and traditional settings in Bungoma, Kenya. *Bulletin of the World Health Organization*, *86*(9), 669–677.

48. Binagwaho, A., Pegurri, E., Muita, J., & Bertozzi, S. (2010). Male circumcision at different ages in Rwanda: A cost-effectiveness study. *PLoS Medicine*, *7*(1), e1000211.

49. Johnson, K. E., & Quinn, T. C. (2008). Update on male circumcision: Prevention success and challenges ahead. *Current Infectious Disease Reports*, *10*(3), 243–251.

50. Wiswell, T. E., & Hachey, W. E. (1993). Urinary tract infections and the uncircumcised state: An update. *Clinical Pediatrics*, *32*(3), 130–134.

51. Gray, R. H., Kigozi, G., Serwadda, D., Makumbi, F., Nalugoda, F., Watya, S., . . . Wawer, M. J. (2009). The effects of male circumcision on female partners' genital tract symptoms and vaginal infections in a randomized trial in Rakai, Uganda. *American Journal of Obstetrics and Gynecology*, *200*(1), 42.e41–47.

52. Auvert, B., Sobngwi-Tambekou, J., Cutler, E., Nieuwoudt, M., Lissouba, P., Puren, A., & Taljaard, D. (2009). Effect of male circumcision on the prevalence of high-risk human papillomavirus in young men: Results of a randomized controlled trial conducted in Orange Farm, South Africa. *Journal of Infectious Diseases*, *199*(1), 14–19.

53. Castellsague, X., Bosch, F. X., Munoz, N., Meijer, C. J., Shah, K. V., de Sanjose, S., . . . Franceschi, S. (2002). Male circumcision, penile human papillomavirus infection, and cervical cancer in female partners. *New England Journal of Medicine*, *346*(15), 1105–1112.

54. Westercamp, N., & Bailey, R. C. (2007). Acceptability of male circumcision for prevention of HIV/AIDS in sub-Saharan Africa: A review. *AIDS and Behavior*, *11*(3), 341–355.

55. de Bruyn, G., Martinson, N. A., & Gray, G. E. (2010). Male circumcision for HIV prevention: Developments from sub-Saharan Africa. *Expert Review of Anti-Infective Therapy*, *8*(1), 23–31.

56. Kebaabetswe, P., Lockman, S., Mogwe, S., Mandevu, R., Thior, I., Essex, M., & Shapiro, R. (2003). Male circumcision: An acceptable strategy for HIV prevention in Botswana. *Sexually Transmitted Infections*, *79*(3), 214–219.

57. Plank, R. M., Makhema, J., Kebaabetswe, P., Hussein, F., Lesetedi, C., Halperin, D., . . . Lockman, S. (2010). Acceptability of infant male circumcision as part of HIV prevention and male reproductive health efforts in Gaborone, Botswana, and surrounding areas. *AIDS and Behavior*, *14*(5), 1198–1202.

58. Plank, R. M., Ndubuka, N., Mwakomba, J., Makama, J. G., Mmalane, M., Hussein, F., . . . Lockman, S. (2011, February–March). *Neonatal Male Circumcision in Gabarone, Botswana and Surrounding Areas: Uptake and Outcomes*. Poster session presented at the meeting of *Conference on Retroviruses and Opprotunistic Infections*, Boston, USA.

59. Waters, E., Li, M., Mugisa, B., Bowa, K., Linyama, D., Stringer, E., & Stringer, J. (2013). Acceptability and uptake of neonatal male circumcision in Lusaka, Zambia. *AIDS and Behavior*, 17(6), 2114-22.

60. Bailey, R. C., Muga, R., Poulussen, R., & Abicht, H. (2002). The acceptability of male circumcision to reduce HIV infections in Nyanza Province, Kenya. *AIDS Care*, *14*(1), 27–40.

61. Lagarde, E., Dirk, T., Puren, A., Reathe, R. T., & Bertran, A. (2003). Acceptability of male circumcision as a tool for preventing HIV infection in a highly infected community in South Africa. *AIDS*, *17*(1), 89–95.

62. Ngalande, R. C., Levy, J., Kapondo, C. P., & Bailey, R. C. (2006). Acceptability of male circumcision for prevention of HIV infection in Malawi. *AIDS and Behavior*, *10*(4), 377–385.

63. Scott, B. E., Weiss, H. A., & Viljoen, J. I. (2005). The acceptability of male circumcision as an HIV intervention among a rural Zulu population, Kwazulu-Natal, South Africa. *AIDS Care*, *17*(3), 304–313.

64. Lukobo, M. D., & Bailey, R. C. (2007). Acceptability of male circumcision for prevention of HIV infection in Zambia. *AIDS Care*, *19*(4), 471–477.

65. Mugwanya, K. K., Whalen, C., Celum, C., Nakku-Joloba, E., Katabira, E., & Baeten, J. M. (2011). Circumcision of male children for reduction of future risk for HIV: Acceptability among HIV serodiscordant couples in Kampala, Uganda. *PLoS One*, *6*(7), e22254.

66. Mavhu, W., Hatzold, K., Laver, S. M., Sherman, J., Tengende, B. R., Mangenah, C., . . . Cowan, F. (2012). Acceptability of early infant male circumcision as an HIV prevention intervention in Zimbabwe: A qualitative perspective. *PLoS One*, *7*(2), e32475.

67. Reyna, V. F. (2008). Theories of medical decision-making and health: An evidence-based approach. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, *28*(6), 829–833.

68. Ajzen, I. (2011). The theory of planned behaviour: Reactions and reflections. *Psychology and Health*, *26*(9), 1113–1127.

69. Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes*, *50*, 179–211.

70. Walton, R. E., Ostbye, T., & Campbell, M. K. (1997). Neonatal male circumcision after delisting in Ontario. Survey of new parents. *Canadian Family Physician*, *43*, 1241–1247.

71. Binner, S. L., Mastrobattista, J. M., Day, M. C., Swaim, L. S., & Monga, M. (2002). Effect of parental education on decision-making about neonatal circumcision. *Southern Medical Journal*, *95*(4), 457–461.

72. Adler, R., Ottaway, M. S., & Gould, S. (2001). Circumcision: We have heard from the experts; now let's hear from the parents. *Pediatrics*, *107*(2), E20.

73. Gabrysch, S., Cousens, S., Cox, J., & Campbell, O. M. (2011). The influence of distance and level of care on delivery place in rural Zambia: A study of linked national data in a geographic information system. *PLoS Medicine*, *8*(1), e1000394.

74. Parkhurst, J. O., & Ssengooba, F. (2009). Assessing access barriers to maternal health care: Measuring bypassing to identify health centre needs in rural Uganda. *Health Policy and Planning*, *24*(5), 377–384.

75. van Eijk, A. M., Bles, H. M., Odhiambo, F., Ayisi, J. G., Blokland, I. E., Rosen, D. H.,. . . Lindblade, K. A. (2006). Use of antenatal services and delivery care among women in rural western Kenya: A community based survey. *Reproductive Health*, *3*, 2.

76. Coleman, W. L., & Garfield, C. (2004). Fathers and pediatricians: Enhancing men's roles in the care and development of their children. *Pediatrics*, *113*(5), 1406–1411.

77. Moore, T., & Kotelchuck, M. (2004). Predictors of urban fathers' involvement in their child's health care. *Pediatrics*, *113*(3 Pt 1), 574–580.

78. Garfield, C. F., & Isacco, A. (2006). Fathers and the well-child visit. *Pediatrics*, *117*(4), e637–645.

79. Blumberg, S. J., Halfon, N., & Olson, L. M. (2004). The national survey of early childhood health. *Pediatrics*, *113*(6 Suppl), 1899–1906.

80. Isacco, A., & Garfield, C. (2010). Child healthcare decision-making: Examining "conjointness" in parental identities among residential and non-residentital fathers. *Fathering*, *8*(1), 109–130.

81. Myers, R. A., Omorodion, F. I., Isenalumhe, A. E., & Akenzua, G. I. (1985). Circumcision: Its nature and practice among some ethnic groups in southern Nigeria. *Social Science and Medicine*, *21*(5), 581–588.

82. Westercamp, M., Agot, K., & Bailey, R. C. (2011, July). *Risk factors for HIV infection in a general population sample of circumcised and uncircumcised men: Kisumu, Kenya* [MOLBPE047]. Paper presented at the Sixth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Rome, Italy. Abstract retrieved from pag.ias2011.org/PosterExhibition.aspx

83. Barnighausen, T., Bloom, D. E., & Humair, S. (2012). Economics of antiretroviral treatment vs. circumcision for HIV prevention. *Proceedings of the National Academy of Sciences of the United States of America*, 109(52), 21271–21276.

84. Cassell, M. M., Halperin, D. T., Shelton, J. D., & Stanton, D. (2006). Risk compensation: The Achilles' heel of innovations in HIV prevention? *BMJ*, *332*(7541), 605–607.

85. Gray, R. H., Li, X., Kigozi, G., Serwadda, D., Nalugoda, F., Watya, S., . . . Wawer, M. (2007). The impact of male circumcision on HIV incidence and cost per infection prevented: A stochastic simulation model from Rakai, Uganda. *AIDS*, *21*(7), 845–850.

86. Kong, X., Kigozi, G., Nalugoda, F., Musoke, R., Kagaayi, J., Latkin, C., . . . Gray, R. (2012). Assessment of changes in risk behaviors during 3 years of posttrial follow-up of male circumcision trial participants uncircumcised at trial closure in Rakai, Uganda. *American Journal of Epidemiology*, 176(10), 875-85.

87. Mattson, C. L., Campbell, R. T., Bailey, R. C., Agot, K., Ndinya-Achola, J. O., & Moses, S. (2008). Risk compensation is not associated with male circumcision in Kisumu, Kenya: A multi-faceted assessment of men enrolled in a randomized controlled trial. *PLoS One*, *3*(6), e2443.

88. Robins, J. M., Hernan, M. A., & Brumback, B. (2000). Marginal structural models and causal inference in epidemiology. *Epidemiology*, *11*(5), 550–560.

89. Hernan, M. A., Brumback, B., & Robins, J. M. (2000). Marginal structural models to estimate the causal effect of zidovudine on the survival of HIV-positive men. *Epidemiology*, *11*(5), 561–570.

90. Agot, K. E., Kiarie, J. N., Nguyen, H. Q., Odhiambo, J. O., Onyango, T. M., & Weiss, N. S. (2007). Male circumcision in Siaya and Bondo Districts, Kenya: Prospective cohort study to assess behavioral disinhibition following circumcision. *Journal of Acquired Immune Deficiency Syndromes*, *44*(1), 66–70.

91. Mehta, S. D., Moses, S., Parker, C. B., Agot, K., Maclean, I., & Bailey, R. C. (2012). Circumcision status and incident HSV-2 infection, genital ulcer disease, and HIV infection. *AIDS*, 26(9), 1141-9.

92. Ahmed, S., Lutalo, T., Wawer, M., Serwadda, D., Sewankambo, N. K., Nalugoda, F., . . . Gray, R. H. (2001). HIV incidence and sexually transmitted disease prevalence associated with condom use: A population study in Rakai, Uganda. *AIDS*, *15*(16), 2171–2179.

93. Chen, L., Jha, P., Stirling, B., Sgaier, S. K., Daid, T., Kaul, R., & Nagelkerke, N. (2007). Sexual risk factors for HIV infection in early and advanced HIV epidemics in sub-Saharan Africa: Systematic overview of 68 epidemiological studies. *PLoS One*, *2*(10), e1001.

94. Mermin, J., Musinguzi, J., Opio, A., Kirungi, W., Ekwaru, J. P., Hladik, W., . . . Bunnell, R. (2008). Risk factors for recent HIV infection in Uganda. *JAMA The Journal of the American Medical Association*, *300*(5), 540–549.

95. Cole, S. R., & Hernan, M. A. (2008). Constructing inverse probability weights for marginal structural models. *American Journal of Epidemiology*, *168*(6), 656–664.

96. Engels, J. M., & Diehr, P. (2003). Imputation of missing longitudinal data: A comparison of methods. *Journal of Clinical Epidemiology*, *56*(10), 968–976.

97. D'Agostino, R. B., Lee, M. L., Belanger, A. J., Cupples, L. A., Anderson, K., & Kannel, W. B. (1990). Relation of pooled logistic regression to time dependent Cox regression analysis: The Framingham Heart Study. *Statistics and Medicine*, *9*(12), 1501–1515.

98. Alsallaq, R. A., Cash, B., Weiss, H. A., Longini, I. M., Jr., Omer, S. B., Wawer, M. J., . . . Abu-Raddad, L. J. (2009). Quantitative assessment of the role of male circumcision in HIV epidemiology at the population level. *Epidemics*, *1*(3), 139–152.

99. Londish, G. J., & Murray, J. M. (2008). Significant reduction in HIV prevalence according to male circumcision intervention in sub-Saharan Africa. *International Journal of Epidemiology*, *37*(6), 1246–1253.

100. Herman-Roloff, A., Otieno, N., Agot, K., Ndinya-Achola, J., & Bailey, R. C. (2011). Acceptability of medical male circumcision among uncircumcised men in Kenya one year after the launch of the national male circumcision program. *PLoS One*, *6*(5), e19814.

101. Rain-Taljaard, R. C., Lagarde, E., Taljaard, D. J., Campbell, C., MacPhail, C., Williams, B., & Auvert, B. (2003). Potential for an intervention based on male circumcision in a South African town with high levels of HIV infection. *AIDS Care*, *15*(3), 315–327.

102. Westercamp, N., Agot, K., Jaoko, W., & Bailey, R. C. (2012, July). *Risk compensation following male circumcision: A cause for concern? Results from a prospective cohort study of circumcised and uncircumcised men in Nyanza Province, Kenya.* Poster exhibition presented at the XIX International AIDS Conference. Washington, DC, USA. Abstract retrieved from pag.aids2012.org /PosterExhibition.aspx

103. Bailey, R. C., Plummer, F. A., & Moses, S. (2001). Male circumcision and HIV prevention: Current knowledge and future research directions. *Lancet Infectious Diseases*, *1*(4), 223–231.

104. Minhas, S., Manseck, A., Watya, S., & Hegarty, P. K. (2010). Penile cancer—Prevention and premalignant conditions. *Urology*, *76*(2 Suppl 1), S24–35.

105. Weiss, H. A., Thomas, S. L., Munabi, S. K., & Hayes, R. J. (2006). Male circumcision and risk of syphilis, chancroid, and genital herpes: A systematic review and meta-analysis. *Sexually Transmitted Infections*, *82*(2), 101–109; discussion 110.

106. Tobian, A. A., & Gray, R. H. (2011). Male foreskin and oncogenic human papillomavirus infection in men and their female partners. *Future Microbiology*, *6*(7), 739–745.

107. *Male circumcision: Global trends and determinants of prevalence, safety and acceptability.* (2007). Retrieved from: http://www.malecircumcision.org/ Geneva, Switzerland: World Health Organization, Joint United Nations Programme on HIV/AIDS.

108. Mattson, C. L., Bailey, R. C., Muga, R., Poulussen, R., & Onyango, T. (2005). Acceptability of male circumcision and predictors of circumcision preference among men and women in Nyanza Province, Kenya. *AIDS Care*, *17*(2), 182–194.

109. Zou, G., & Donner, A. (2004). Confidence interval estimation of the intraclass correlation coefficient for binary outcome data. *Biometrics*, *60*(3), 807–811.

110. McMahon, J. M., Pouget, E. R., & Tortu, S. (2006). A guide for multilevel modeling of dyadic data with binary outcomes using SAS PROC NLMIXED. *Computational Statistics and Data Analysis*, *50*(12), 3663–3680.

111. Kenny, D. A., Kashy, D. A., & Cook, W. L. (2006). *Dyadic Data Analysis*. New York, NY: Guilford Press.

112. Kenny, D. A., & Cook, W. (1999). Partner effects in relationship research: Conceptual issues, analytic difficulties, and illustrations. *Personal Relationships*, *6*(4), 433–448.

113. Mwandi, Z., Murphy, A., Reed, J., Chesang, K., Njeuhmeli, E., Agot, K., . . . Bock, N. (2011). Voluntary medical male circumcision: Translating research into the rapid expansion of services in Kenya, 2008–2011. *PLoS Medicine*, *8*(11), e1001130.

114. Kenya National Bureau of Statistics (KNBS) IM. (2010). *Kenya Demographic and Health Survey 2008–09.* Calverton, MD: ICF Macro.

115. Weiss, H., Larke, N., Halperin, D., & Schenker, I. (2010). *Neonatal and child male circumcision: A global review.*Geneva, Swizerland: WHO/UNAIDS. Retrieved from http://www.who.int/hiv/pub/malecircumcision/neonatal_mc/en/index.html

116. Young, M. R., Odoyo-June, E., Nordstrom, S. K., Irwin, T. E., Ongong'a, D. O., Ochomo, B., . . . Bailey, R. C. (2012). Factors associated with uptake of infant male circumcision for HIV prevention in Western Kenya. *Pediatrics*, 130(1), e175-82.

117. Manji, K. P. (2000). Circumcision of the young infant in a developing country using the Plastibell. *Annals of Tropical Paediatrics*, *20*(2), 101–104.

118. al-Samarrai, A. Y., Mofti, A. B., Crankson, S. J., Jawad, A., Haque, K., & al-Meshari A. (1988). A review of a Plastibell device in neonatal circumcision in 2,000 instances. *Surgery, Gynecology and Obstetrics*, *167*(4), 341–343.

119. Amir, M., Raja, M. H., & Niaz, W. A. (2000). Neonatal circumcision with Gomco clamp—A hospital-based retrospective study of 1,000 cases. *Journal of the Pakistan Medical Association*, *50*(7), 224–227.

120. Banieghbal, B. (2009). Optimal time for neonatal circumcision: An observation-based study. *Journal of Pediatric Urology*, *5*(5), 359–362.

121. Ben Chaim, J., Livne, P. M., Binyamini, J., Hardak, B., Ben-Meir, D., & Mor, Y. (2005). Complications of circumcision in Israel: A one-year multicenter survey. *Israel Medical Association Journal*, *7*(6), 368–370.

122. Horowitz, M., & Gershbein, A. B. (2001). Gomco circumcision: When is it safe? *Journal of Pediatric Surgery*, *36*(7), 1047–1049.

123. Moosa, F. A., Khan, F. W., & Rao, M. H. (2010). Comparison of complications of circumcision by 'Plastibell device technique' in male neonates and infants. *Journal of the Pakistan Medical Association*, *60*(8), 664–667.

124. *Manual for early infant male circumcision under local anaesthesia*. (2010). Geneva, Switzerland: WHO/Jhpiego. Retrieved from http://www.who.int/hiv/pub/malecircumcision/manual_infant/en/index.html

125. Palit, V., Menebhi, D. K., Taylor, I., Young, M., Elmasry, Y., & Shah, T. (2007). A unique service in UK delivering Plastibell circumcision: Review of 9-year results. *Pediatric Surgery International*, *23*(1), 45–48.

126. Krill, A. J., Palmer, L. S., & Palmer, J. S. (2011). Complications of circumcision. *Scientific World Journal*, *11*, 2458–2468.

127. Sherman, J., Borer, J. G., Horowitz, M., & Glassberg, K. I. (1996). Circumcision: Successful glanular reconstruction and survival following traumatic amputation. *Journal of Urology*, *156*(2 Pt 2), 842–844.

128. Pieretti, R. V., Goldstein, A. M., & Pieretti-Vanmarcke, R. (2010). Late complications of newborn circumcision: A common and avoidable problem. *Pediatric Surgery International*, *26*(5), 515–518.

129. Patel, H. I., Moriarty, K. P., Brisson, P. A., & Feins, N. R. (2001). Genitourinary injuries in the newborn. *Journal of Pediatric Surgery*, *36*(1), 235–239.

130. *Kenya National Strategy for Voluntary Medical Male Circumcision.* (2009). Kenyan Ministry of Public Health and Sanitation.

131. Cherutich, P., Ochieng, A., Kimanga, D., Mwandi, Z., Mwalili, S., Chesang, K., . . . Bock, N. (2012). Progress in voluntary medical male circumcision service provision —Kenya, 2008–2011 *Morbidity and Mortality Weekly Report*. *61*(47), 957–961 Retrieved from http://www.cdc.gov/mmwr/pdf/wk/mm6147.pdf

132. Grund, J. M., & Hennink, M. M. (2011). A qualitative study of sexual behavior change and risk compensation following adult male circumcision in urban Swaziland. *AIDS Care*, 24(2), 245–251.

133. Riess, T. H., Achieng, M. M., Otieno, S., Ndinya-Achola, J. O., & Bailey, R. C. (2010). "When I was circumcised I was taught certain things": Risk compensation and protective sexual behavior among circumcised men in Kisumu, Kenya. *PLoS One*, *5*(8), e12366.

134. Andersson, N., & Cockcroft, A. (2011). Male circumcision, attitudes to HIV prevention and HIV status: A cross-sectional study in Botswana, Namibia, and Swaziland. *AIDS Care*, 24(3-4), 301–309.

135. Gust, D. A., Kretsinger, K., Pals, S. L., Gaul, Z. J., Hefflefinger, J. D., Begley, E. B., . . . Kilmarx, P. H. (2011). Male circumcision as an HIV prevention intervention in the U.S.: Influence of health care providers and potential for risk compensation. *Preventive Medicine*, *52*(3–4), 270–273.

136. Westercamp, M., Agot, K. E., Ndinya-Achola, J., & Bailey, R. C. (2011). Circumcision preference among women and uncircumcised men prior to scale-up of male circumcision for HIV prevention in Kisumu, Kenya. *AIDS Care*, *24*(2), 157–166.

137. Peltzer, K., Simbayi, L., Banyini, M., & Kekana, Q. (2011). HIV risk reduction intervention among medically circumcised young men in South Africa: A randomized controlled trial. *International Journal of Behavioral Medicine*, *19*(3), 336–141.

138. *Kenya Demographic and Health Survey 2008–09.* (2010). Calverton, MD: ICF Macro. Retrieved from http://www.measuredhs.com/pubs/pdf/FR229/FR229.pdf

139. Mwangi, A., & Warren, C. (2008).*Taking critical services to the home: Scaling-up home-based maternal and postnatal care, including family planning, through community midwifery in Kenya: USAID, Population Council*. Retrieved from http://maternalhealthtaskforce.org/discover/library/cat_view/48-population-council?start=20

VITA

NAME: MARISA R. YOUNG

EDUCATION:

2007-2015 The University of Illinois at Chicago, Chicago, Illinois
PhD, Epidemiology, School of Public Health
MD

2000-2002 University of Washington, Seattle, WA
BA, Latin American Studies

PROFESSIONAL EXPERIENCE:

Research Assistant 2009–2013
School of Public Health, University of Illinois at Chicago

Principal Investigator and field-based study coordinator for a case/control research study titled Mtoto Msafi ("clean child" in Swahili). My role involved conceiving study design, developing the research protocol, drafting survey instruments, hiring and managing five study staff, analyzing data, and publishing findings. This case/control study recruited more than 1,000 parents of infant males in Nyanza Province, Kenya. The study examined safety and acceptability of infant circumcision and factors associated with acceptance of the procedure as an HIV prevention intervention.
Advisor: Robert C. Bailey, PhD MPH.

Technician, Pulmonary Diagnostic Unit 2006–2007
Presbyterian Hospital, Columbia University
Full-time technician in the Pulmonary Diagnostic Unit of Presbyterian Hospital. Responsible for administering pulmonary function examinations to adult inpatients and outpatients.

Research Assistant 2005–2006
Mailman School of Public Health, Columbia University
Part-time research assistant for a birth cohort study examining risk factors for incident asthma in children of Puerto Rican descent living in the Bronx. Responsibilities included interviewing mothers during home visits, collecting dust samples, processing and analyzing dust and serum samples in the laboratory.

TEACHING/MENTORING ROLES:
Teaching Assistant, Epidemiology 403: Principals of Epidemiology
Fall Semester, 2011

VITA (continued)

RECENT PUBLICATIONS:

1. **Young, M. R.**, Odoyo-June, E., Nordstrom, S. K., Irwin, T. E., Ongong'a, D. O., Ochomo, B., . . . Bailey, R. C. (2012). Factors associated with uptake of infant male circumcision for HIV prevention in western Kenya. *Pediatrics*, *130*(1), e175–82

2. **Young, M. R.**, Bailey, R. C., Odoyo-June, E., Irwin, T. E., Obiero, W., Ongong'a, D. O., . . . Nordstrom, S. K. (2012). Safety of over twelve hundred infant male circumcisions using the Mogen clamp in Kenya. *PLoS One*, *7*(10), e47395.

3. Obiero, W, **Young, M. R.**, & Bailey, R. C. (2013). The PrePex Device Is Unlikely to Achieve Cost-Savings Compared to the Forceps-Guided Method in Male Circumcision Programs in Sub-Saharan Africa. *PLoS One*, *8*(1), e53380.

POSTER PRESENTATIONS:

1. **Young, M. R.**, Nordstrom, S. N., Odipo, T., Adera, F., Jaoko, W., & Bailey, R. C. 2014, July). Knowledge and attitudes towards early infant male circumcision in a representative sample of parents of male infants in Rachuonyo District, Kenya. [Poster A-641-0259-09128]. Poster session presented at the meeting of 20th International AIDS Conference (AIDS 2014), Melbourne, Australia.

2. **Young, M. R.**, Bailey, R. C., Odoyo-June, E., Irwin, T., Agot, K., Ongong'a, D., & Nordstrom, S. (2011, December). Infant male circumcision services for HIV prevention in Nyanza Province, Kenya: Factors associated with uptake by mothers. [Poster THLBPE019]. Poster session presented at the meeting of the 16th International Conference on HIV/AIDS and Sexually Transmitted Infections in Africa (ICASA), Addis Ababa, Ethiopia.

3. **Young, M. R.**, Bailey, R. C., Odoyo-June, E., Irwin, T., Ongong'a, D. O., Ochomo, B., . . . Nordstrom, S. K. (2012, July). Infant male circumcision for HIV prevention in Nyanza Province, Kenya: Safety and outcomes. [Poster WEPE253]. Poster session presented at the meeting of the XIX International AIDS Conference (IAS), Washington, DC, USA.

ORAL PRESENTATIONS:

1. Obiero, W., **Young, M. R.**, & Bailey, R. C. (2013, January). *Will the PrePex achieve cost-savings compared to the forceps-guided method in male circumcision programs in sub-Saharan Africa?* Presented at the University of Nairobi Collaborative Meeting, Nairobi, Kenya.

2. **Young, M. R.**, Bailey, R. C., Odoyo-June, E., Irwin, T., Ongong'a, D. O., Badia, J. A., . . . Nordstrom, S. K. (2012, October). *Safety of infant male circumcision for HIV prevention in Nyanza Province, Kenya*. Presented at the meeting of the XX FIGO World Conference of Gynecology and Obstetrics, Rome, Italy.

VITA (continued)

3. Bailey, R. C., **Young, M. R.**, Nordstrom, S., & Ongong'a, D. O. (2011, January). *Infant male circumcision in Nyanza Province: Uptake and outcomes*. Presented at the University of Nairobi Collaborative Meeting, Nairobi, Kenya.

4. **Young, M. R.**, Ongong'a, D. O., & Bailey, R. C. (2010, October). *Infant male circumcision in Nyanza Province: Preliminary results from the Mtoto Msafi study*. Presented at the Male Circumcision Consortium Dissemination Workshop, Kisumu, Kenya.

5. **Young, M. R.**, Bailey, R. C., & Odoyo-June, E. (2010, March). *Keeping our watoto wasafi: A pilot programme introducing infant male circumcision services in three districts in Nyanza Province*. Presented at the KEMRI/CDC Kisumu Research Lecture Series, Kisumu, Kenya.

6. **Young, M. R.**, Irwin, T., Nordstrom, S., & Bailey, R. C. (2009, October). *Preventing HIV acquisition with male circumcision: A pilot program training medical providers to perform infant male circumcision in Kisumu, Kenya* [Abstract O1035].
Presented at the XIX FIGO World Conference of Gynecology and Obstetrics, Cape Town, South Africa.

AWARDS:

1. Recipient—2013 William Haenszel Award for Excellence in Research. Presented a summary of my research at a one-hour School of Public Health seminar and was awarded a $500 prize.

2. Winner—best PhD student poster, best global health poster. Annual School of Public Health research day and poster competition 2011 for poster entitled, "Parental decision-making and factors associated with accepting or declining infant male circumcision services in Kisumu, Kenya."