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Voluntary medical male circumcision for prevention of heterosexual transmission of HIV and risk compensation in adult males in Soweto: what do indicators and incidence rate show?

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VOLUNTARY MEDICAL MALE CIRCUMCISION FOR PREVENTION OF HETEROSEXUAL TRANSMISSION OF HIV AND RISK COMPENSATION IN ADULT MALES IN SOWETO: WHAT DO INDICATORS AND INCIDENCE RATE SHOW?

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A research report submitted to the School of Public Health, faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of master of science in epidemiology and biostatistics

Johannesburg, December 2015

DECLARATION

I declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science in Epidemiology and Biostatistics at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University. My role in this primary data collection study was, design of the protocol, study implementation and data analysis. Supervision was provided by Professors Neil Martinson and Benn Sartorius. Data collection and other study procedures were done by Nelisiwe Hlatshwayo, Petros Tlou, Archie Khuba, Sibusiso Sibiya, Alton Mboneli and Lucky Mathebula.

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(Signature of candidate)

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ABSTRACT

Objective: Biomedical prevention of HIV transmission, resulting from medical male circumcision, was confirmed in clinical trials and then rolled out in voluntary medical male circumcision programmes in sub-Saharan Africa. Data assessing its effectiveness, under programmatic conditions, are not available. Concerns about possible risk compensation in males after circumcision have been raised. Thus, the objectives of the study were to determine, the effectiveness of medical male circumcision in prevention of heterosexual (female to male) transmission of HIV and differences in presence or absence of risk compensation behaviour in males before and after medical male circumcision.

Methods: A prospective cohort of 233 seronegative adult males aged 18-40 years seeking medical male circumcision at a public hospital were followed for a median period of 363 (IQR 302–397) days after which HIV serostatus rate and risky sexual behaviour were re-ascertained. HIV risk factors before and after medical male circumcision were compared by calculating odds ratio (OR) with the 95% confidence interval and p-value using McNemar's test given paired participants' data. Logistic regression was used to determine predictors of risky sexual behaviour.

Results: HIV incidence rate post medical male circumcision was found to be 2.64 (95% CI 0.54–4.75) per 100 person years. There was evidence of risk compensation in the post circumcision period in that, participants were three times (OR 2.70 95% CI 1.34–5.69, p=0.003) more likely to have sexual intercourse after than before medical male circumcision. This was mainly due to 7.3% of the participants having either their sexual debut after medical male circumcision or not having sexual intercourse in six months before medical male circumcision but after. Conversely they were found to be 3.5 times (OR=3.50 95% CI 1.88–7.14, p=<0.0001) more likely to perceive themselves to be at risk of HIV and 58% (OR=0.42 95% CI 0.16–1.01, p=0.05) less likely to use alcohol with sex after than before medical male circumcision.

Conclusion: These findings suggest that HIV incidence in males post medical male circumcision remains high but in a programme setting, but appears to reduce risky sexual behaviour. Some aspects of risk compensation after medical male circumcision still need to be addressed, as shown by increased sexual encounters..

Remember:

Dolly Millicent Summerton-Mukudu

And

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LIST OF FIGURES **Page**

Figure 1: Screening, enrolment and follow-up of study participants **15**

Figure 2: Comparison of the difference in proportion of HIV-risk factors before and after MMC, to determine risk compensation **32**

Figure 3: Sub-analysis of participants who had sexual debut after MMC **32**

LIST OF TABLES **Page**

Table 1: Study schema, showing timing and procedures of study visits **15**

Table 2: Comparison of HIV risk factors between participants retained in the study and lost to follow-up**.** **16**

Table 3: Baseline demographic characteristics of study participants **17**

Table 4: Distribution of biological risk factors before MMC **18**

Table 5: Distribution of behavioural and sexual risk factors before MMC **19**

Table 6: Univariate analysis of demographic risk factors before MMC **21**

Table 7: Univariate analysis of biological risk factors associated with proxy HIV risk before MMC **22**

Table 8: Univariate analysis of sexual risk factors associated with proxy HIV risk before MMC **22**

Table 9: Univariate analysis of behavioural risk factors associated with proxy HIV risk before MMC **23**

Table 10: Multi-variate analysis of risk factors associated with proxy HIV risk before MMC **24**

Table 11: Distribution of biological risk factors after MMC **24**

Table 12: Distribution of behavioural and sexual risk factors after MMC **26**

Table 13: Univariate analysis of demographic risk factors associated with proxy HIV risk after MMC **28**

Table 14: Univariate analysis of sexual risk factors associated with proxy HIV risk after MMC **29**

Table 15: Univariate analysis of behavioural risk factors associated with proxy HIV risk after MMC **29**

Table 17: Risk compensation: comparison of proportions risk factors before and after circumcision **31**

Table 18: Sub-analysis for participants who had sexual contact after MMC, but not before MMC **33**

Table 19: Comparison of HIV incidence rate in cohort with other studies **35**

CONTENTS **Page**

Title and Title page **i**

Declaration **ii**

Abstract **iii**

Dedication **iv**

Acknowledgements **v**

List of figures **vi**

List of tables **vii**

CHAPTER ONE - INTRODUCTION **1**

1.1 General introduction **1**

1.2 General objectives **2**

1.2.1 Specific objectives **2**

1.3 Literature review **3**

CHAPTER TWO – METHODS **6**

2.1 Study setting **6**

2.2 Type of research **5**

2.3 Study design **6**

2.4 Target population **6**

2.5 Study population **6**

2.5.1 Inclusion criteria **6**

2.5.2 Exclusion criteria **7**

2.6 Study sample **7**

2.6.1 Selection of sample **7**

2.6.2 Determination of sample size **7**

2.7 Data sources **7**

2.8 Variables **9**

2.8.1 Reliability and validity of data sources **9**

2.9 Bias and limitations **10**

2.10 Statistical processing **10**

2.10.1 Double entry for data **10**

2.10.2 Outcomes **11**

2.10.3 Determinants **11**

2.10.4 Effect measures **12**

2.10.5 Statistical analysis **13**
2.11 The intervention **13**
2.12 Ethical considerations **13**
CHAPTER THREE - RESULTS **14**
3.1 Introduction **13**
3.2 Comparison of participants retained to those lost to follow up **16**
3.3 Demographic characteristics **17**
3.4 Before MMC **17**
3.4.1 Distribution of risk factors **17**
3.4.2 Univariate analysis risk factors **20**
3.4.3 Multivariate analysis **23**
3.5 After MMC **25**
3.5.1 Distribution of risk factors **25**
3.5.2 Univariate analysis of risk factors **28**
3.5.3 Multivariate analysis **29**
3.6 Comparison of risk factors before and after MMC **30**
3.7 Comparison for sexual contact after, but not before MMC **32**
CHAPTER FOUR- DISCUSSION **34**
4.1 Summary of principal findings **34**
4.2 Proxy HIV Risk **34**
4.3 HIV Incidence rates **35**
4.4 Comparison of findings with published studies **35**
4.5 Risk compensation **36**
4.6 Predictors of HIV risk behaviour **37**
4.7 Study limitations **38**
CHAPTER FIVE – CONCLUSION **40**
CHAPTER SIX - RECOMMENDATIONS **41**
References **42**
Appendix A **Study inclusion and exclusion criteria** **48**
Appendix B **Data collection tools** **49**
Appendix C **Ethics clearance certificate** **58**
Appendix D **Translation certificate** **59**
Appendix E **Definitions of risk indicators** **60**

CHAPTER ONE

1. INTRODUCTION

1.1 General Introduction

In 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended that medical male circumcision (MMC) be offered in countries with a hyper-endemic or generalised HIV epidemic and low MMC[1]. This was based on compelling evidence from three randomised clinical trials done in Kisumu, Kenya[2], Rakai District, Uganda[3], and Orange Farm, South Africa[4], which showed that MMC reduces the risk of heterosexually acquired HIV infection in men by approximately 60%. These findings supported those of earlier ecological studies that showed a geographical correlation between HIV and MMC [5]. They were also further supported by a systemic review of the three clinical trials[6]. As a result, a number of countries in Eastern and Southern Africa have scaled-up MMC programmes aiming to reach an MMC prevalence of 80% among males aged 15 to 49 years by 2015. In South Africa more than 1.3 million (30% of the targeted 4.3 million by 2016) MMCs were done from 2009 to 2013[7].

The protective effect of MMC for HIV infection in a controlled trial setting is clear[6]. However, little is known about the HIV incidence rate among males in a programmatic setting, post MMC. In responding to the concerns raised about the Orange Farm clinical trial, the authors of the trial mentioned that:

> The magnitude of the effect in a trial of this nature cannot, in any case predict precisely what to expect in the actual intervention for four reasons. Firstly, the trial was conducted in a specific population (young men of the age range 18–24 years); it was not representative of the whole population. Secondly, the participants received intense counselling periodically throughout the follow-up period. Thirdly, they were informed that the result of the trial was unpredictable. Finally, the duration of the follow-up period was short. This is why operational research should be conducted to test if MMC, in association with existing and validated prevention methods, can be used in community intervention[8].

This study is the first to determine if MMC is effective in the prevention of heterosexual (female to male) transmission of HIV in a programme setting, without involving participants from the efficacy studies. Unlike in the clinical trial done in South Africa, which covered only the 18–24-year-olds, this study also included the 25–40-olds, as the HIV incidence rate is higher in this age group[9], therefore, results can be more generalizable.

A concern raised about MMC as a public health intervention for prevention of HIV transmission, was the issue of potential increases in sexual risk behaviour as a result of risk compensation[10]. This is the modification of risk behaviour as a result of changes in the perceived risk of HIV infection[11]. With respect to HIV and MMC, this would manifest itself in circumcised males knowing that they are less likely to contract HIV than before MMC and increase their risk behaviour, thereby increasing the risk of contracting HIV. Studies that were aimed at addressing this, after the three MMC clinical trials, have not been conclusive[12,13,14]. Ours is the first study, to determine the presence or absence of – HIV-risk behaviour compensation among circumcised males in a programme setting.

1.2 General Objective

To determine effectiveness of MMC in the prevention of heterosexual HIV transmission in a programmatic setting among males aged 18-40 years by comparing the difference in HIV serostatus and risk behaviour before and after MMC in a cohort of circumcised males in Soweto.

1.2.1 Specific Objectives

1. To report the distribution of demographic, biological, behavioural and sexual risk factors of - HIV seronegative males seeking MMC.
2. To determine the distribution of biological, behavioural and sexual risk factors of males, after MMC.
3. To determine HIV incidence rate in circumcised males, in a routine programmatic setting after MMC.
4. To determine predictors of HIV risky behaviour in males, before MMC.
5. To determine predictors of HIV risky behaviour in males, after MMC.

6. To determine the presence or absence of risk compensation in males, as a result of MMC.

1.3 Literature Review

Risk factors for heterosexual HIV transmission in males (female to male) are broadly classified in to biological and behavioural factors[15]. Biological risk factors include Sexually Transmitted Infections (STIs), vaginal and anal sexual intercourse as well as MMC status. Behavioural risk factors include condom use, concurrent sexual partners, use of alcohol with sexual intercourse and age of sexual debut.

The STIs increase HIV transmission by increasing both infectiousness and susceptibility to HIV[16,17,18]. However, MMC has been found to be protective of certain STIs[19]. The fact that MMC confers protective effect for both HIV and STIs makes it an important public health intervention.

Results of three randomised control trials of MMC have shown a significant reduction in risk of HIV transmission attributable to MMC. An efficacy of 61% for age group 18–24 years was reported in Orange Farm[4], South Africa, and 53% in Kisumu, Kenya[2], while 48% for age group 15–49 was found in Rakai, Uganda[3]. All these trials were stopped before the predetermined study termination because of overwhelming evidence in support of MMC for prevention of HIV transmission. Participants in all three trials received extensive counselling in HIV prevention, not only at entry, but also at all subsequent visits. Based on these findings, the WHO and UNAIDS have recommended that MMC be recognised as an additional important intervention to reduce the risk of heterosexually acquired HIV among men[1].

Behavioural HIV risk factors such as use of alcohol with sexual intercourse, have been found to increase the HIV transmission[20,21,22,23]. This effect also increases the risk STIs and condom non-use[24,25]. Thus, positive behaviour change as a result of MMC would positively impact HIV prevention. Other behavioural risk factors include early sexual debut which has been found to increase risk of HIV transmission[26,27]. As a result delaying age of sexual debut would help reduce HIV transmission.

A number of concerns have been raised as to the effectiveness of medical MMC in the prevention of HIV transmission in consideration of several factors. For example, a qualitative study done in Kisumu Kenya among men and women, including some men who participated in the MMC trial, found that protective behaviour change can result from men being circumcised[14]. Thus, counselling within or related to MMC programmes appear to be influential in promoting protective behaviour change among participants[14]. The effect on HIV transmission, seen in the clinical trials, may have been as a result of the numerous counselling that participants received, which is not part of the MMC procedures in the programme setting.

Other concerns relate to the possibility of risk compensation. This was raised with respect to MMC, in that circumcised males may start perceiving themselves as being at reduced risk of HIV acquisition, and would increase risky behaviour. This would undermine the MMC protective effect[10]. This is even more important considering that in the Kisumu Kenya clinical trial, unprotected sexual intercourse reduced by 63% and condom use increased by 19% in the circumcised group compared to 95% and 25%, respectively, in the uncircumcised group[14]. In the clinical trial done in Orange Farm, South Africa, sexual behaviour measures, specifically mean number of sexual contacts, were significantly higher in the circumcised compared to the uncircumcised group[28]. However, in the Rakai, Uganda clinical trial no difference was found in risky behaviour measures between the two groups of males[28]. Actually, modelling studies on HIV intervention, such as antiretroviral therapy, have shown that even minimal increase in risky HIV behaviour can offset the beneficial effects, by way of risk compensation[29].

In the Nelson Mandela Human Sciences Research Council (HSRC) study Report of 2002 on HIV/AIDS[30], the prevalence of HIV among males in the age group 25–40 years in South Africa, was found to be the highest of all age groups at 12–22% depending on the province. This gender and age group were also found to be at higher risk of acquiring HIV as measured by behavioural factors such as frequency of sexual intercourse and condom use at last sexual act[31]. Analyses of the three South African national HIV surveys of 2002[9] (HSRC report above), 2005 and 2008, estimating HIV incidence rates using mathematical models, revealed that HIV incidence rates among men aged 25–49 was much higher than in the 15–24-age-group[32,33]. According to

HSRC Report of 2012 the yearly incidence rates among men were found to be the highest in those above age 25 years at 1.29(95% CI 0.91-1.67) per100 person years, compared to those less than 25 years which is 0.55 (95% CI 0.45-0.65)[9].

We thus, aimed to determine the effectiveness of MMC in the prevention of heterosexual transmission of HIV, as evidence that informed its roll-out was based on clinical trials. There are also significant differences between clinical trials inclusion criteria and burden of HIV in terms of age, in that while the clinical trials concentrated on the 18–24-year-age group, HIV incidence rate is higher and in need of immediate attention in the 25–40-year-age group. We also aimed to determine the presence or absence of adoption of risky HIV-transmission behaviour after MMC. The presence of risk compensation would not only reduce the impact of MMC on prevention of HIV as projected from the trial findings, but also, in some cases, reverse gains made in HIV prevention.

CHAPTER TWO

2. METHODS

2.1 Setting

This study was conducted in Soweto, where 2 million people live in an area of 61 km². This formerly apartheid resettlement area is situated on the outskirts of Johannesburg, Gauteng. Khula Ndoda Medical Male Circumcision Clinic (KNMMC) is located on the 2nd Floor of the new outpatient department of Chris Hani-Baragwanath Academic Hospital. This is the biggest hospital in South Africa, and is very accessible to patients in and around Soweto. KNMMC is a public clinic that provides free MMC services to males living in and around Soweto. This clinic was selected for the study because it was one of only two high volume MMC clinics in Soweto. Although this clinic is based at a tertiary hospital, all MMC clients seek service directly at the site.

KNMMC was established in October 2010, with the specific purpose of contributing to the MMC of 80% of the male population in and around Soweto. More than 35 000 males aged between 10 and 86 years have been circumcised at this site since its establishment. As part of the MMC process the site also provides HIV counselling and testing, which is offered prior to MMC for all males seeking MMC[34].

2.2 Type of research

This was a quantitative primary data collection research.

2.3 Study design

This was a prospective cohort study.

2.4 Target population

Adult males aged 18-40 years seeking MMC

2.5 Study population

A random sample of HIV non-reactive adult males aged 18-40 seeking MMC at KNMMC clinic in Soweto.

2.5.1 Inclusion criteria were:

1. Non-reactive HIV-test result on day of MMC.
2. Age 18–40 years.

3. Living in and around Soweto (trip taxi fare less than R30).
4. Client expected to stay in current community for the following 12 months.
5. Willing to repeat HIV test 12 months post MMC.

2.5.2 Exclusion criteria were:

1. HIV-test result indeterminate on day of MMC.
2. Currently on highly active antiretroviral treatment for HIV.
3. Not able to provide consent for study participation
4.

2.6 Study sample

233 males randomly selected from HIV non-reactive adult males aged 18-40 seeking MMC at KNMMC from November 2012 to July 2014

2.6.1 Selection of sample

At entry, every third MMC client, who met the study inclusion criteria (**Appendix A**), was randomly selected from those seeking MMC at KNMMC during duration of the study. This was done by programme counsellors who do HIV counselling and testing for all males seeking MMC. As per study inclusion criteria, participants' HIV status on routine HIV testing was non-reactive immediately prior to enrolment to the study. Selected participants were then required to sign consent for participation in the study before any study procedures were initiated.

2.6.2 Determination of sample size

A target sample size of 904 was set to determine a 50% difference in one year HIV sero-incidence and a power of 80%, between before and after MMC in adult males. Of these, 452 were in the 18–24-years age group and the other 452 in the 25–40-years age group, assuming a 15% non-informative loss to follow-up. However, as a result of funding constraints and logistical challenges, the study only enrolled 496 participants of which 233 completed the study exit visit by the time of analysis.

2.7 Data Sources

Study participants were selected by programme HIV counsellors who had been given a list of inclusion criteria. After identifying those participants who met inclusion criteria, they referred those who had tested HIV seronegative to the study coordinator, who obtained their consent for participation. This process was followed before any study procedures were initiated by study interviewers.

After consent procedures, study interviewers administered a structured questionnaire (**Appendix B**), which focused on participants HIV-risk behaviour in the 6–12 months before MMC. This questionnaire was also administered focusing on the 6-12 period after MMC. Thus, the information covering the 6-12 months before MMC was classified as the before MMC (entry) visit and the one covering the 6-12 period after MMC was classified as after MMC (follow-up) visit, as shown in **table 1**.

HIV testing at both time points (entry and follow-up) was done in line with current clinic guidelines using the HIV antibody-based skin prick rapid test. Specimens were collected from the fingertip using a lancet and transferred to the HIV-testing kits using a MiniCollect capillary tube (Greineir Bio-One, Kremsmunster, Austria). The serial test algorithm procedure was used; if the first test was negative, the result was reported as such. However, if the first test was indeterminate or positive, a second confirmatory rapid test was done. In case of a contradictory result between the first and second test, a third test was done as a tie breaker. The first test kit used was First Response HIV 1-2.0 card test (Premier Medical Corporation Ltd, Daman, India), the second one was Abon HIV1/2/0 (Abon Biopharm, Ltd, Hangzhou, China), and the tie breaker used Unigold HIV (Trinity Biotech Plc, Wicklow, Ireland).

Questionnaire responses were then handed over to the data capturers, who entered these into the study database using RedCap[35].

Table 1: Study Schema, showing timing and procedures of study visits

Study Procedure **Visit**	**Informed Consent**	**Questionnaire**	HIV Test
Entry Visit *(On the day of MMC)*	**X**	**X**	**X***
Follow-up Visit		**X**	**X**

Participants were scheduled to have a follow-up visit 6-12 months post MMC. However, study interviewers maintained telephonic contact with these participants, at

* All HIV non-reactive as per inclusion criteria.

least once a month. At the follow-up visit they were requested to come back to KNMMC where study interviewers administered the questionnaire. This focused on HIV risky behaviour in the 6–12 months between day of MMC and the follow-up visit. HIV counselling and testing was repeated at this visit by the programme counsellors. Responses and results were handed over to data capturers, who entered data into the study database.

2.8 Variables

In the questionnaire, high-risk sexual behaviour was divided into biological, sexual and behavioural risk factors. The division into biological and behavioural risk is in line with the Centre for Disease and Control (CDC) HIV-prevention indicators[36]. However, because of the long list of behavioural indicators which could make data entry and processing procedures prone to errors, this was sub-categorised into sexual and behavioural risk. Sexual risk related to behaviour during sexual intercourse, while general behaviour risk related to seeking sexual intercourse.

Biological risk factors included information on blood transfusions, intravenous drug use (IVDU), sexual intercourse, vaginal sexual intercourse and sexually transmitted infections. Sexual risk factors included behaviour during sexual intercourse, such as condom use, alcohol use and transactional sex. Behavioural risk factors were all other factors related to seeking sexual intercourse, such as number of sexual partners, concurrent sexual partners, transactional sex, knowledge of sexual partners' HIV status, perception of HIV risk, relationship of sexual partner and age at sexual debut.

The questionnaires were designed in English and translated into *isiZulu* and *Sesotho* by a professional agency that provided a translation certificate (**Appendix D**). These were pre-tested in the pilot study in October 2012, ensuring that consent forms were standardised.

2.8.1 Reliability and validity of data sources

A structured interviewer-administered questionnaire was used to capture socio-demographic characteristics and information on high-risk sexual behaviour at entry and follow-up visits. Study interviewers, who were qualified HIV counsellors, and

trained on questionnaire administration in a workshop by the principal investigator, completed these questionnaires. Competency of the interviewers was tested in a pilot study in October 2012.

After the interview, the questionnaire and responses were handed over to data capturers. Data quality was checked by having two data capturers go through the questionnaire before entry. We also made use of the RedCap double entry feature which allows two data capturers to enter the same questionnaire into the database. Where differences occurred, it was possible to detect probable errors on the system which were corrected in consultation with study interviewers and/or by referring to the questionnaire.

2.9 Bias and limitations

Bias was likely in the study on measuring HIV risk behaviour. The use of a structured questionnaire of which the responses were dependent on participants providing historical information introduced recall bias in to the study. The participants could have either over or under reported the exposure.

Measurement of HIV serostatus had limitation in that it was done using an antibody based test kit, which cannot detect HIV infection in the absence of seroconversion.

2.10 Statistical processing

2.10.1 Double entry of data:

Study data were collected and managed using REDCap electronic data capture tools hosted at Perinatal HIV Research Unit (PHRU)[20]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. This tool provides 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources'.

2.10.2 Outcomes:

Outcome of interest was the HIV serostatus at the post-MMC visit. HIV incidence rate was calculated according to the number of seroconversions between before MMC and after-MMC visit, with the denominator as all person time in follow-up from time of MMC to follow-up HIV test. However, since HIV infection was a rare occurrence during the study for meaningful analysis, a proxy HIV result variable was created by combining two factors that classified a participant as being at high risk of HIV acquisition[36]. These factors are:

1. Concurrent sexual partners
2. Condom non-use during sexual intercourse (unprotected sexual intercourse).

Concurrent sexual partners and condom use during sexual intercourse were categorised as Yes (1) and No (0) responses. Proxy HIV risk was derived by numerical addition of these responses which could be 0, 1 or 2. Thus, this proxy risk was categorised as risky (2) and non-risky (0 or 1). The choice of these two factors is based on the fact that concurrent sexual partnerships are main drivers behind high prevalence of HIV in sub-Saharan Africa among males. Furthermore, condom use is an effective mode of HIV prevention[17,37,38].

The scientific justification of this outcome is that high rates of HIV among males in east and southern Africa (which bear 50% of the HIV global burden, yet they only have 3%[24] of world population) is likely attributable to three factors, low prevalence of MMC, high rate of concurrent long term partnerships and low rate of condom use[38,39]. MMC alone does not account for this discrepancy, because HIV rates in these regions are still higher than in India and Europe that have similar lower MMC prevalence. Neither does the absolute number of lifetime sexual partners because these were found to be lower in these regions compared to those in Asia. However, the presence of concurrent sexual partner relationships was found to be significantly longer in these regions than in Asia[38,40].

2.10.3 Determinants:

Determinants (independent variables) considered were socio-demographic and HIV risk factors **(see Appendix E for definitions)**. Socio-demographic factors were age, marital status, education and employment collected on the day of MMC. HIV risk factors were injecting drug use, blood transfusions, sexually transmitted diseases, anal

or vaginal penetrative sexual intercourse, condom use and other HIV-prevention practices, nature of sexual relationships, use of drugs or alcohol with sex, number of sexual partners, transactional sex, and knowledge of sexual partners' HIV status and source of this knowledge (categorised as reliable and unreliable). These were collected on days of MMC and at the post-MMC visit. A descriptive summary of these was based on frequencies and proportions.

2.10.4 Effect measures:

We report the HIV incidence rate in a cohort of adult males' post-MMC and its 95% confidence interval. Determination of presence or absence of risk compensation post-MMC was done by comparing HIV-risk factors before and after MMC using McNemar's test and the Student's t-test, for categorical and continuous variables, respectively. Logistic regression was used to determine factors associated with HIV risky behaviour before and after MMC.

The choice of effect measure depended on specific objectives.

i. To report the distribution of demographic, biological, behavioural and sexual risk factors of HIV-seronegative males, who seek MMC, we created frequency tables according to risk factors that were being measured before MMC.

ii. To determine the distribution of biological, behavioural and sexual risk factors of males, we created frequency tables according to risk factors that were being measured after MMC.

iii. To determine the HIV incidence rate in circumcised males in a programme setting after MMC, we calculated the incidence of all HIV seroconversions among participants from MMC through follow-up after MMC.

iv. To determine predictors of HIV risky behaviour in males, before MMC, we first used univariate analysis in logistic regression with the significant level set at 20% (p-values ≤ 0.20), and then multivariate analysis at 5% (p-value ≤ 0.05) for all factors.

v. To determine predictors of HIV risky behaviour in males, after MMC, we first used univariate analysis in logistic regression with significant level set at 20% (p-values ≤ 0.20), and then multivariate analysis at 5% (p-value ≤ 0.05) for all factors.

vi. To determine if there is evidence of risk compensation in males, aged 18–40 years, as a result of MMC, we calculated odds ratios (OR), 95% confidence

interval and p-value using the McNemar's test as participants' data were paired as measured by respective categorical variables measured before and after MMC. The continuous characteristics were compared using the t-test.

Chi-square/Fischer's exact tests were used to compare participants who were retained in the study to the ones lost to follow-up as well as those who refused consent or were ineligible for study participation.

2.10.5 Statistical analysis:

Analysis was performed using STATA 11C (Statacorp, Texas 77845, USA). Logistic regression was used for both univariate and multivariate analyses to identify factors associated with a risk of HIV acquisition in uncircumcised and circumcised males that is before and after MMC, respectively.

2.11 The intervention

The intervention tested was surgical MMC, which was done according to WHO guidelines on surgical MMC procedures[34]. The MMC is the removal of the skin fold that covers the head of the penis, which is referred to as the foreskin; the procedure is performed under local anaesthesia by a healthcare professional in a clinic or hospital setting.

2.12 Ethical Considerations

The protocol for this study was reviewed and approved by the University of Witwatersrand Human Research Ethics Committee on 29th June 2012, certificate number M120634 (**Appendix C**). Approval for the study was provided by Chris Hani-Baragwanath Hospital Research Committee. Strict confidentiality procedures were maintained throughout study and written informed consent was signed by all participants before any study procedures were initiated. All study files were stored in a lockable unit and only study personnel had access. The database also has data security features to which only authorised study personnel had access.

CHAPTER THREE

3. RESULTS

3.1 Introduction

Risk factors for HIV acquisition in the study are classified as:

1. Demographic factors
2. Biological factors
3. Sexual factors
4. Behavioural factors

This classification was selected according to questionnaire design, easier data processing, and justifiable by standards set by some HIV research institutions[36,41]. Demographic factors were age, education level, marital status, race and employment. Biological factors were inherent factors increasing risk for HIV infection: intravenous drug use, blood transfusion, STIs, and anal and vaginal sexual intercourse. Sexual risk factors were those related to behaviours during sexual intercourse, which were condom use at sexual debut, condom use with current partner, transactional sex, use of recreational drugs during sexual intercourse, and use of alcohol during sexual intercourse. Behavioural factors included general behaviour relating to seeking sexual intercourse, which were age at sexual debut, number of sexual partners, perception of HIV risk, relationship of sexual partner, knowledge of HIV status of sexual partner, and knowledge of sexual partner having other sexual partners.

Analysis of explanatory covariates is broadly divided into factors before MMC and those after MMC. Distribution of these covariates (univariate analysis) are first presented and then multivariate analysis, with before and after MMC separately, using logistic regression.

Figure 1 shows the study schema. Of the 875 screened, potentially eligible participants, 306 were excluded because they lived in communities on the outskirts of Soweto. Although, they had given physical addresses in Soweto on registration which was only discovered on determination of the transport refund. A further 64 refused consent, mainly citing the sensitive and sexual nature of the questions in the questionnaire. Thus, 496 (56.7% of eligible participants) were enrolled for study at

the time of MMC. However, only 233 of these had completed exit visit post MMC at time of data analysis.

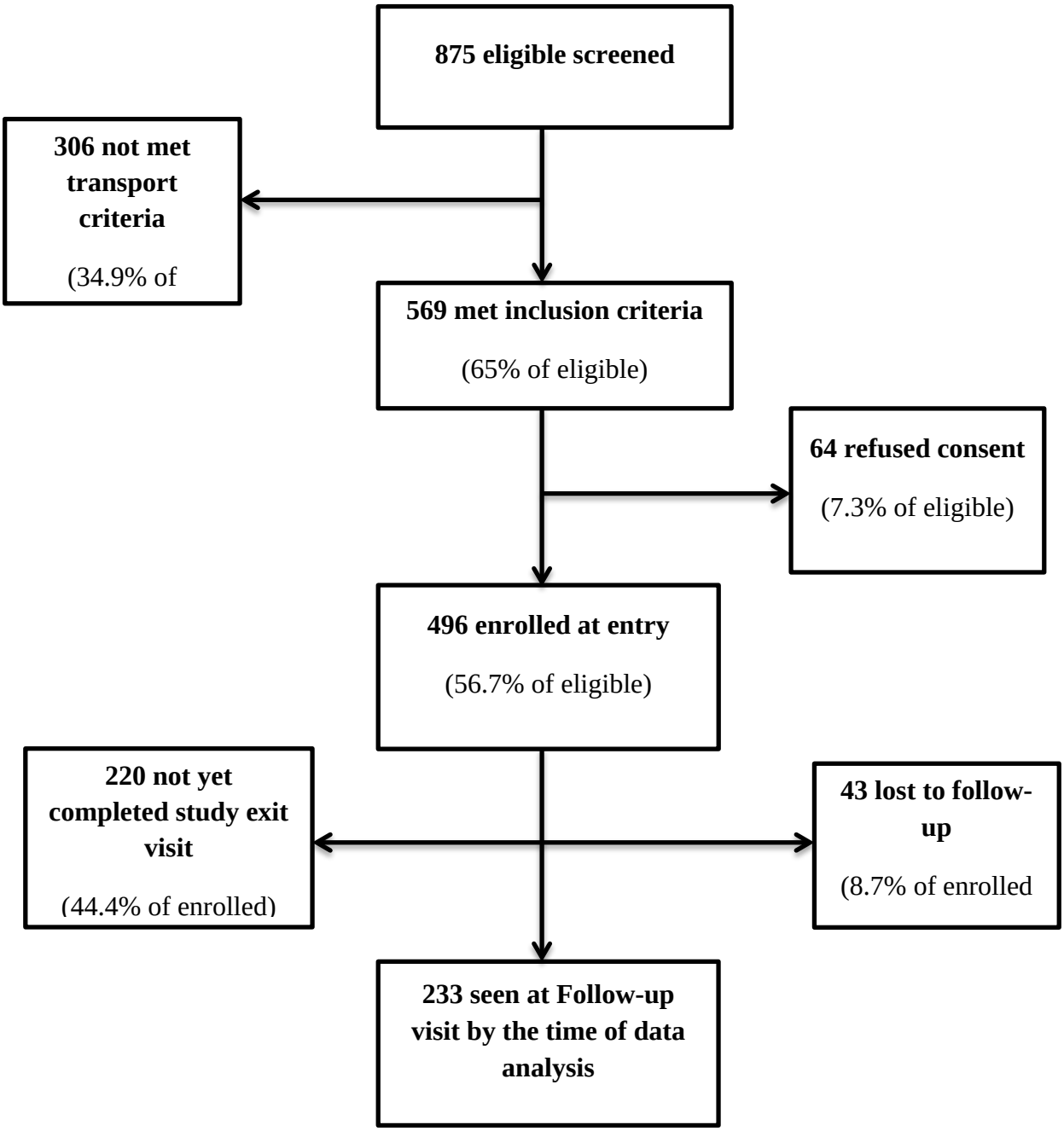


Figure 1: Screening, enrolment and follow-up of study participants

3.2 Comparison of participants retained to those lost to follow-up

Participants lost to follow-up did not differ from those retained in the study at time of post-MMC visit regarding race, age, age at sexual debut, history of STIs, history of anal intercourse, condom use, transactional sex, use of drugs with sexual intercourse, risky sexual relationships, knowledge of sexual partners HIV status, and concurrent sexual partners (all p-values >0.05) (**Table 2**). However, those who completed follow-up were more likely to have used intravenous drugs (3.2% vs. 0%, p=0.03) and more likely to use alcohol with sexual intercourse (10% vs. 0.2%, p=0.05).

Table 2: Comparison of HIV risk factors between participants retained in the study and lost to follow-up.

Risk Factor	Proportion/Mean: Retained (N = 233)	Proportion/Mean: Lost to Follow-up (N = 43)	Chi^2/Fischer's or t-test p-value
Race: African (%)	100	93	0.51
Age (mean years*)*	25.5	25.6	0.55
Age at Sexual Debut (mean years*)*	16.6	16.8	0.50
Intravenous drug use (%)	0	3.2	**0.03**
STIs (%)	1.7	14.3	**0.00**
Concurrent sexual partners (%)	4.0	4.1	1.00
Vaginal Sexual Intercourse (%)	94.8	96.9	0.70
Condom Use (%)	57.8	62.1	0.10
Transactional Sexual Intercourse (%)	1.0	1.4	1.00
Use of alcohol with sexual intercourse (%)	0.2	10	**0.05**
Use of drugs with sexual intercourse (%)	0	0.2	1.00
Sexual Partners with other partners (%)	21	16	0.22
Knowledge of Partner's status (%)	60	49	0.12
Risky Sexual Relationships (%)	72	78%	0.51
Proxy HIV Risk[†] *(*%)	13.3	12	0.86

[†] This variable was created by a combination of factors that could classify the participant as being at high risk of HIV acquisition, which are (1) concurrent sexual partners (2) condom non-use (unprotected sexual intercourse)

3.3 Demographic Characteristics

Table 3: demographic characteristics of participants who completed the post-MMC visit are shown as analysis was based on paired data for before and after MMC. Mean age was 25.6 years, about half were between 18 and 24 years and the other half between 25 and 40 years old. Most of them were single (77%), and only a third of them were in full-time employment.

Table 3: Baseline demographic characteristics of the study participants

Risk Factor		Number (N)	%
Race			
	Black African	233	100
Age			
	Mean = 25.6 Years		
Age Category			
	18 – 24 Years	113	48.5
	25 – 40 Years	120	51.5
Education Level			
	Primary	6	2.6
	Secondary	10	4.3
	High	151	64.8
	Tertiary	66	28.3
Marital Status			
	Single	179	76.8
	Not married, not living together	21	9.0
	Not Married, living together	16	6.9
	Married, living together	14	6.0
	Married, not living with wife	2	0.9
	Other	1	0.4
Employment Status			
	Unemployed, not looking	7	3.0
	Unemployed, looking	51	22.0
	Informal work	14	6.0
	Employed, full time	90	38.6
	Employed, part time	14	6.0
	Student primary to high school	15	6.4
	Student tertiary	42	18.0

3.4 Before MMC

3.4.1 Distribution of risk factors

Tables 4–6: risk factors of participants before MMC are shown. Time covered, is 6–12 months before MMC. **Table 4** shows distribution of biological factors before MMC. Nearly 14% of participants did not have sexual intercourse in the 6–12 months before MMC, with 1.7% of them having a self-reported STI. Prevalence of anal sex with female sexual partners was almost 4%. All participants were HIV-negative as per study inclusion criteria. No participant had received a blood transfusion pre-MMC.

Table 4: Distribution of biological risk factors before MMC

Risk Factor		Number (N)	%
Intravenous Drug Use			
	No	231	99.1
	Yes	2	0.9
Blood Transfusion			
	No	233	100
STIs			
	No	429	98.3
	Yes	4	1.7
Anal Sexual Intercourse			
	Yes	9	3.9
	No	224	96.1
Vaginal Sexual intercourse			
	No	32	13.7
	Yes	201	86.3

Table 5: the distribution of behavioural and sexual factors before MMC is shown, with age of sexual debut at almost 17 years. Most subjects (65%) felt at risk of acquiring HIV, with 4.7% not being sure, meaning that only 31% felt they were not at risk of HIV. The prevalence of concurrent sexual partners was almost a third of the cohort. According to proxy HIV risk, almost 15% of all subjects were classified as being at risk of HIV acquisition before MMC. More than 60% of primary sexual partners' HIV status was known to the participants compared to 30% of non-primary partners.

Condom use before MMC with a primary and non-primary sexual partner was 60% and 77%, respectively. More (1.6%) sexual encounters among participants, before MMC, were of a transactional nature where they received money or gifts from their female partners, as opposed to men paying for sex (1%). Slightly more sexual encounters with the non-primary partner (18%) involved use of alcohol compared to those with primary partner (12%), though this difference was not statistically significant (p=0.13).

Table 5: Distribution of behavioural and sexual risk factors before MMC

Risk Factor		Number (N)	%
Age at Sexual Debut			
	Mean = 16.7 Years		
Relationship of sexual partner			
Primary partner			
	Married	13	6.7
	Living together	16	8.3
	Main Partner	135	69.6
	Friend	6	3.1
	Someone known for a while	12	6.2
	One night encounter	3	1.5
	Someone I just met	9	4.6
Non-Primary partner			
	Main Partner	20	21.5
	Friend	10	10.8
	Someone known for a while	35	37.6
	One night encounter	8	8.6
	Someone I just met	20	21.5
Number of Sexual Partners			
	Zero	49	21.0
	One	114	48.9
	Two	51	21.9
	Three	15	6.5
	≥ Four	4	1.7
Concurrent Sexual Partners			
	No	163	70
	Yes	70	30
Perception of HIV Risk			
	No	71	30.5
	Yes	151	64.8
	Not Know	11	4.7
Proxy HIV Risk[*]			
	No	202	86.7
	Yes	31	13.3
Sexual partners with other partners			
Primary partner			
	No	153	78.9
	Yes	41	21.1
Non-Primary partner			
	No	28	40
	Yes	42	60
Knowledge of Partners' HIV Status			
Primary partner			
	No	76	39.2
	Yes	118	60.8
Non-Primary partner			
	No	49	70
	Yes	21	30

[*] This variable was created by a combination of factors that could classify the participant as being at high risk of HIV acquisition, which are (1) concurrent sexual partners (2) condom non-use (unprotected sexual intercourse)

Table 5: Distribution of behavioural and sexual risk factors before MMC (Continued)

Risk Factor		Number (N)	%
How HIV status is known			
Primary partner			
	Unreliable	98	49.5
	Reliable	96	50.5
Non-Primary partner			
	Unreliable	58	82.9
	Reliable	12	17.1
Condom Use during Sexual Intercourse			
Primary partner			
	No	82	42.5
	Yes	111	57.5
Non-Primary partner			
	No	16	22.9
	Yes	54	77.1
Paid for Sexual Intercourse			
Primary partner			
	Yes	2	1.0
	No	191	99.0
Non-Primary partner			
	No	69	98.6
	Yes	1	1.4
Got paid for Sexual Intercourse			
Primary partner			
	No	190	98.5
	Yes	3	1.6
Non-Primary partner			
	No	70	98.6
Use of Alcohol with Sexual Intercourse by participants			
Primary partner			
	No	171	88.1
	Yes	23	11.9
Non-Primary partner			
	No	57	81.4
	Yes	13	18.6
Use of Alcohol with Sexual Intercourse female partners			
Primary partner			
	No	178	91.8
	Yes	16	8.3
Non-Primary partner			
	No	61	87.1
	Yes	9	12.9

3.4.2 Univariate analysis

Tables 6–9: univariate analysis of risk factors before MMC associated with an increased risk of HIV acquisition (proxy HIV risk) is shown. Significance level of association on univariate analysis with proxy HIV for inclusion in multivariate analysis was set at 20% (p-value ≤0.20). Factors that had been included in the creation of the proxy HIV outcome variable were excluded due to confounding. These are:

1. Concurrent sexual partners
2. Condoms non-use during sexual intercourse (unprotected sexual intercourse)

The following factors were found to be statistically significant:

1. Age category (18–24 years)
2. Education
3. Knowledge of the primary sexual partners' HIV status
4. Basis for the knowledge of HIV status for the primary partner
5. Age at sexual intercourse debut

Use of intravenous drugs by both males and females was excluded due to inadequate sample size as evidenced by the high standard error and a wide confidence interval. However, STIs was included on the basis of clinical significance even if it was not statistically significant[42,43,44,18,45]. Variables education, marital status and employment have been recoded and education categories were combined into less than tertiary and tertiary. Less than tertiary represents primary, secondary and high school. Marital status was recoded into four categories and employment into three.

Table 6: in univariate analysis, the association with proxy HIV risk among demographic risk factors shows that only age category and education level were statistically significant.

Table 6: Univariate analysis of demographic risk factors associated with proxy HIV transmission risk before MMC

		Logistic Regression			
Risk Factor	**Number (N=233)**	**% at Risk**	**OR**	**95% CI**	**p-value**
Age Category					
18 – 24 Years	113	29.0	-		
25 – 40 Years	120	71.0	2.60	1.14 – 5.91	**0.023**
Education					0.921
Less than Tertiary	167	61.3	-		
Tertiary	66	38.7	1.73	0.79 –3.80	**0.182**
Marital Status					
Single	179	80.7	-		
Not married ,not cohabiting	21	6.4	0.65	0.14 – 2.96	0.582
Not married, cohabiting	16	9.7	1.42	0.38 – 5.35	0.603
Married	17	3.2	0.39	0.045– 3.03	0.371
Employment					
Employed	58	25.8	-		
Unemployed	118	54.8	1.05	0.43– 2.60	0.911
School	57	19.4	0.74	0.24 – 2.27	0.593

Table 7: shows that in univariate analysis of the association with proxy HIV risk among biological risk factors, none were found to be statistically significant, as indicated by the 95% confidence interval being wide and all p-values more than 0.05.

Table 7: Univariate analysis of biological risk factors associated with proxy HIV transmission risk before MMC

		Logistic Regression				
		Number (N=233)	**% at Risk**	**OR**	**95% CI**	**p-value**
STIs						
	No	229	96.8	-		
	Yes	4	3.2	2.21	0.22 – 22.0	0.502
Anal sex						
	No	224	96.7	-		
	Yes	9	3.3	2.30	0.23 – 22.7	0.482

Table 8: shows that in univariate analysis of the association with proxy HIV risk among sexual risk factors, none were found to be statistically significant, as indicated by the 95% confidence interval being wide and all p-values more than 0.05.

Table 8: Univariate analysis of sexual risk factors associated with proxy HIV transmission Risk before MMC

		Logistic Regression				
		Number (N=233)	**% at Risk**	**OR**	**95% CI**	**p-value**
Use of Alcohol with Sexual Intercourse by participants						
Primary partner						
	No	171	87.1	1	-	-
	Yes	23	12.9	1.12	0.35 – 3.56	0.846
Use of Alcohol with Sexual Intercourse female partners						
Primary partner						
	No	178	90.3	1	-	-
	Yes	16	9.7	1.24	0.33 – 4.62	0.757

Table 9: shows that in univariate analysis of the association with proxy HIV risk among behavioural risk factors, only knowledge of primary partners HIV status, basis of knowing this status and age at sexual debut were found to be statistically significant.

Table 9: Univariate analysis of behavioural risk factors associated with proxy HIV risk before MMC

	Logistic Regression				
	Number	**% at Risk**	**OR**	**95% CI**	**p-value**
Condom at sex debut					
No	108	54.8	-		
Yes	113	45.2	0.76	0.35 – 1.62	0.473
Reason for MMC					
Prevention (HIV/STI)	158	77.4	-		
Others	75	24.6	0.57	0.24 – 1.40	0.223
Sexual partners with other partners					
Primary partner					
No	153	74.2	1	-	-
Yes	41	25.8	1.37	0.56 – 3.34	0.496
Knowledge of Partners' HIV Status					
Primary partner					
No	76	51.6	1	-	-
Yes	118	48.4	0.55	0.25 – 1.18	**0.126**
How HIV status is known					
Primary partner					
Unreliable	98	61.3	1	-	-
Reliable	96	38.7	0.60	0.27 – 1.30	**0.189**
Risk Factor	**Low Risk**	**High Risk**	**OR**	**95% CI**	**p-value**
Age at Sexual debut (mean = 16.7)					
Mean (SD)	16.8 (2.3)	16.1 (2.02	0.86	0.73 – 1.05	**0.135**

3.4.3 Multivariate analysis

In multivariate analysis, as shown in **Table 10** using logistic regression, predictors of high-risk HIV sexual behaviour before MMC were found to be

1. Age category,
2. Age category at sexual debut,
3. Knowledge of primary sexual partners HIV status, and
4. Basis for knowledge of HIV status.

Participants in the 25–40-year-age category were found to be more than three times likely to have high-risk sexual behaviour than those in the 18–24-year group. Regarding age of sexual debut, it was found that participants, who had sexual debut at 16 years or older, were 66% less likely to have high sexual risk behaviour compared to those younger than 16 years old. Participants, who knew about their female sexual partners' HIV status, were found to be 90% less likely to

have high-risk sexual behaviour. Those who gave a reliable source of this knowledge were almost five times more likely to have high sexual risk behaviour.

Table 10: Multivariate analysis of risk factors associated with proxy HIV transmission risk before MMC

	Logistic Regression				
	Number (N=233)	**% at Risk**	**OR**	**95% CI**	**p-value**
Age Category					
18 – 24 Years	113	29.0	1	-	-
25 – 40 Years	120	71.0	3.16	1.27–7.90	**0.014**
Age Category at Sexual Debut					
< 16 Years	145	77.4	1		
≥ 16 Years	88	22.6	0.34	0.13 – 0.89	**0.028**
Knowledge of Partners' HIV Status					
Primary partner					
No	76	51.6	1		
Yes	118	48.4	0.10	0.02 – 0.51	**0.005**
How HIV status is known					
Primary partner					
Unreliable	75	41.9	1		
Reliable	119	58.1	4.7	2.68 – 6.72	**0.052**
Education					
Less than Tertiary	167	61.3	1		
Tertiary	66	38.7	0.9	0.61 – 3.54	0.381

3.5 After MMC

3.5.1 Distribution of risk factors

Tables 11–12: Risk factors posts MMC are shown.

Table 11: The distribution of biological risk factors after MMC is shown. There were 6 participants who tested HIV reactive during follow-up, HIV incidence rate of 2.64 per 100 person years (95% CI 0.54 - 4.7). Mean age of the participants who tested HIV reactive on the exit visit was 28.3 years (SD 3.8) and mean CD4 count was 491 (SD 339).

Table 11: Distribution of biological risk factors after MMC

Risk Factor		Number (N=233)	%
HIV Status			
	Reactive	6	2.6
	Non-reactive	227	97.4
Intravenous Drug Use			
	No	233	100
Blood Transfusion			
	No	233	100
STIs			
	No	229	98.3
	Yes	4	1.7
Vaginal Sexual Intercourse			
	No	15	6.0
	Yes	218	94.0

Table 12: the proportion of males with a perception of HIV risk post MMC increased to 81% from 65%. The proportion of concurrent sexual partners post MMC remained unchanged at 30% as shown in the Table. According to proxy HIV risk, almost 17% of all subjects were classified as being at risk of HIV acquisition after MMC, similar to before MMC. This also shows that more than 65% of primary sexual partners' HIV status was known to the participants compared to 23% of non-primary partners. These are marginal changes when compared to pre-MMC.

There was minimal change in condom use during sexual intercourse after MMC with both primary and non-primary sexual partners showing a proportion of 52% and 67%, respectively. As seen in the Table, there were also minor changes after MMC in transactional sex. However, after MMC there was a reduction in the proportion of alcohol use during sexual intercourse for both primary and non-primary sexual partners.

Table 12: Distribution of behavioural and sexual risk factors after MMC

Risk Factor		Number (N=233)	%
Relationship of sexual partner			
Primary			
	Married	17	7.8
	Living together	25	11.5
	Main Partner	150	68.8
	Friend	4	1.8
	Someone known for a while	12	5.5
	One night encounter	5	2.3
	Someone I just met	5	2.3
Non-primary			
	Married	1	0.9
	Main Partner	27	23.3
	Friend	7	6.0
	Someone known for a while	45	38.8
	One night encounter	25	21.5
	Someone I just met	11	9.5
Number of Sexual Partners			
	Zero	29	12.4
	One	133	57.2
	Two	41	17.6
	Three	15	6.4
	Four	15	6.4
Multiple Sexual Partners			
	Yes	71	30.5
	No	162	69.5
Perception of HIV Risk			
	No	38	16.4
	Yes	187	81.0
	Do Not Know	8	2.6
Proxy HIV Risk[*]			
	No	194	83.3
	Yes	39	16.7
Primary Partner with other partners			
Primary			
	No	173	79.3
	Yes	45	20.7
Non-primary			
	No	36	50.7
	Yes	35	49.3
Knowledge of Partner's HIV Status			
Primary			
	No	78	35.5
	Yes	140	64.5
Non-primary			
	No	55	77.5
	Yes	16	22.5

[*] This variable was created by a combination of factors that could classify the participant as being at high risk of HIV acquisition, which are (1) Multiple sexual partners (2) Unprotected sexual intercourse

Table 12: Distribution of behavioural and sexual risk factors after MMC (Continued)

How HIV status is known			
Primary partner			
	Unreliable	125	57.3
	Reliable	93	42.7
Non-Primary partner			
	Unreliable	65	91.6
	Reliable	6	8.4
Condom Use during Sexual Intercourse			
Primary			
	No	105	47.7
	Yes	113	52.3
Non-primary			
	No	23	32.4
	Yes	48	67.6
Paid for Sexual Intercourse			
Primary			
	No	214	98.2
	Yes	4	1.8
Non-primary			
	No	68	95.8
	Yes	3	4.2
Got paid for Sexual Intercourse			
Primary			
	No	214	98.2
	Yes	4	1.8
Non-primary			
	No	67	95.7
	Yes	3	4.3
Use of Alcohol with Sexual Intercourse by participants			
Primary			
	No	204	93.6
	Yes	14	6.4
Non-primary			
	No	58	81.7
	Yes	12	18.3
Use of Alcohol with Sexual Intercourse by the partners			
Primary			
	No	213	97.7
	Yes	5	2.3
Non-primary			
	No	64	90.1
	Yes	7	9.9

3.5.2 Univariate analysis

Tables 13–15: predictors of proxy HIV risk after MMC on univariate analysis are shown.

The following were statistically significant on univariate analysis:

1. Marital status,
2. Reason for seeking MMC,
3. Use of alcohol with sex by the participants, and
4. Age of sexual intercourse debut (<16 years).

In this analysis both covariates used in the creation of the outcome proxy HIV risk (multiple sexual partners and unprotected sexual intercourse) were excluded.

Table 13: shows that in univariate analysis of the association with proxy HIV risk among the demographic risk factors after MMC, only marital status was statistically significant.

Table 13: Univariate analysis of demographic risk factors associated with proxy HIV risk after MMC

	Logistic Regression				
Risk Factor	**Number (N=233)**	**% at Risk**	**OR**	**95% CI**	**p-value**
Age Category					
18 – 24 Years	113	46.2	-		
25 – 40 Years	120	53.8	1.12	0.56 – 2.23	0.748
Education					
<Tertiary	151	71.8			
Tertiary	66	28.2	1.00	0.46 – 2.13	0.985
Marital Status					
Single	179	71.8	-		
Not married ,not together	21	10.2	1.27	0.39 – 4.05	0.688
Not married, living together	16	2.6	0.36	0.05– 2.83	0.331
Married, living together	3	15.4	2.94	1.00 – 8.60	**0.049**
Employment					
Employed	58	28.2	-		
Unemployed	118	51.3	0.87	0.39 – 1.97	0.741
School	57	20.5	0.70	0.26–1.89	0.478
	Low Risk	**High Risk**	**OR**	**95% CI**	**p-value**
Age					
Mean (SD)	25.5(5.5)	26.3(5.3)	1.03	0.96 – 1.09	0.436

Table 14: shows that in univariate analysis of the association with proxy HIV risk after MMC among the sexual risk factors, only age category at sexual debut was found to be statistically significant.

Table 14: Univariate analysis of sexual risk factors associated with proxy HIV risk after MMC

	Logistic Regression				
	Number (N=233)	**% at Risk**	**OR**	**95% CI**	**p-value**
Use of Alcohol with Sexual Intercourse by participants					
Primary partner					
No	204	94.9	1	-	-
Yes	14	5.1	0.75	0.16 – 3.50	0.709
Age Category at Sexual Debut					
< 16 Years	145	82.1			
≥ 16 Years	88	17.9	0.31	0.13 – 0.73	**0.007**

Table 15: shows that in univariate analysis of the association with proxy HIV risk after MMC among the behavioural risk factors, only the reason for MMC was found to be statistically significant.

Table 15: Univariate analysis of behavioural risk factors associated with proxy HIV risk after MMC

	Logistic Regression				
	Number	**% at Risk**	**OR**	**95% CI**	**p-value**
Reason for MMC					
Prevention (HIV/STI)	158	76.9	-		
Others	75	23.1	0.58	0.26 – 1.30	**0.172**
Sexual partners with other partners					
Primary partner					
No	172	82.1	1	-	-
Yes	45	17.9	0.81	0.33 – 1.97	0.631
Knowledge of Partners' HIV Status					
Primary partner					
No	77	34.2	1	-	-
Yes	140	65.8	1.07	0.51 – 2.24	0.857
How HIV status is known					
Primary partner					
Unreliable	125	48.7	1	-	-
Reliable	93	51.3	1.53	0.76 – 3.06	0.232

3.5.3 Multivariate analysis

In multivariate analysis of predictors of risky sexual behaviour after MMC, only age of sexual debut was found to be statistically significant. As depicted in **Table 16**, of

those older or equal to 16 years, 69% of them were less likely to have risky sexual behaviour than those younger than 16 years.

Table 16: Multivariate analysis of factors associated with proxy HIV risk after MMC

	Logistic Regression				
	Number	**% at Risk**	**OR**	**95% CI**	**p-value**
Reason for MMC					
Prevention (HIV/STI)	158	76.9	-		
Others	75	23.1	0.49	0.22 – 1.14	0.098
Marital Status					
Single	179	76.8			
Stable sexual relationship	54	23.2	1.56	0.70 – 3.50	0.280
Use of Alcohol with Sexual Intercourse by participants					
Primary partner					
No	204	94.9			
Yes	14	5.1	1.88	0.74 – 4.82	0.186
Age Category at Sexual Debut					
< 16 Years	145	82.1			
≥ 16 Years	88	17.9	0.31	0.13 – 0.75	**0.009**

3.6 Comparison of risk factors before and after MMC

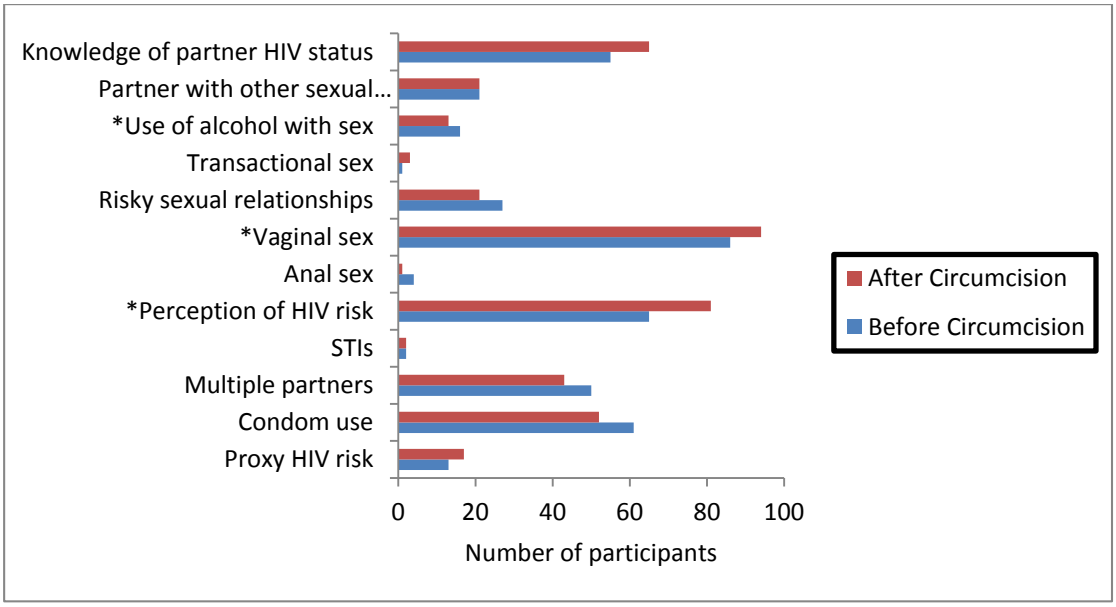
Table 17: a comparison of risk factors before and after MMC is shown. Chi-square using McNemar's test revealed that proportions of subjects with a risk factor before and after MMC did not differ significantly except for the following:

1. After MMC, participants were more than two and a half times likely (OR=2.6, 95% CI 1.34 – 5.69) to have vaginal sexual intercourse than before.
2. After MMC, participants were three and a half times (OR=3.5, 95% CI 1.88 – 7.14) more likely to perceive themselves at risk of HIV acquisition than before MMC.
3. After MMC, participants were 58% less likely (OR = 0.42, 95% CI 0.16 – 1.01) to use alcohol with sexual intercourse than before MMC.
4. After MMC, participants were 77% less likely (OR = 0.23, 95% CI 0.04 – 0.84) to have sexual intercourse with a partner who used alcohol after than before MMC.

Table 17: Risk compensation: comparison of proportions of risk factors before and after MMC

Risk factor	% Before MMC (N=233)	% After MMC (N=233)	*OR*	OR 95% CI	McNemar's / Exact (*p-value*)
STIs	1.72	1.81	1	0.19 – 5.37	1.00
Proxy Risk of HIV	13.3	16.7	1.40	0.76– 2.62	0.312
Anal Sexual Intercourse	3.86	1.29	0.33	0.06 – 1.34	0.15
Vaginal Sexual Intercourse	**86.3**	**94.0**	**2.6**	**1.34 – 5.69**	**0.003**
Multiple Sexual Partners	30.0	30.5	1.03	0.64 – 1.64	1.00
Perception of HIV Risk	**69.5**	**83.7**	**3.5**	**1.88– 7.14**	**<0.001**
Risky Sexual Relationships	78.5	73.0	1.54	0.90 – 2.70	0.12
Transactional sex by participants (Primary)	1.04	1.83	3	0.24 – 157	0.63
Use of Alcohol with sex (Males) (Primary)	**11.9**	**6.4**	**0.42**	**0.16 – 1.01**	**0.048**
Use of Alcohol with sex (Males) (Non-primary)	18.6	18.3	0.774	0.38 – 5.60	1.4
Use of Alcohol with sex (Females) (Primary)	**8.25**	**2.30**	**0.23**	**0.04 –0.84**	**0.021**
Use of Alcohol with sex (Females) (Non-primary)	12.8	12.5	1	0.83 – 5.37	1.00
Condom use during Sexual Intercourse (Primary)	57.5	52.3	0.59	0.34 – 1.01	0.06
Condom use during Sexual Intercourse (Non-primary)	77.1	67.6	0.43	0.07 – 1.88	0.34
Sexual Partner with other partners (Primary)	21.1	20.7	0.96	0.53 – 1.73	0.63
Sexual Partner with other partners (Non-primary)	60.0	49.3	0.56	0.15 – 1.85	0.42
Knowledge of partner's status (Primary)	60.8	64.5	1.48	1.87 – 2.56	0.16
Knowledge of partner's status (Non-primary)	30.0	22.5	1.25	0.27 – 6.30	1.00

Figure 2: provides a graphic representation of change in high risk sexual behaviour from before to after MMC, which shows statistically significant differences in risky sexual behaviour. Two of the three factors showed an enhancement of positive behaviour change, these were a reduction in alcohol use with sex and an increased perception of participants that they were at risk of HIV. The other factor showing an increase in overall sexual intercourse was that of 7.3% participants who either had sexual debut after MMC or had no sexual intercourse before MMC, but only afterwards. This resulted in a 53% reduction in number of participants who did not have sexual intercourse after MMC compared to before. This group of participants was further analysed by comparing risk factors with the rest of the participants post MMC, as outlined in **Figure 3** and **Table 18**.



* Statistically significant change from before to after MMC

Figure 2: Comparison of the difference in proportion of HIV-risk factors before and after MMC, to determine risk compensation

3.7 Comparison of risk factors for sexual contact after MMC, but not before MMC

Given that after MMC, participants were more than two and a half times likely to have sexual intercourse than before, mainly because of the participants who had their sexual debut after MMC and those that did not have intercourse before but after MMC, we compared this group with the other participants. As shown in **Figure 3 and Table 18,** the only differences noted were in the age category, proxy HIV risk and the use of condoms.

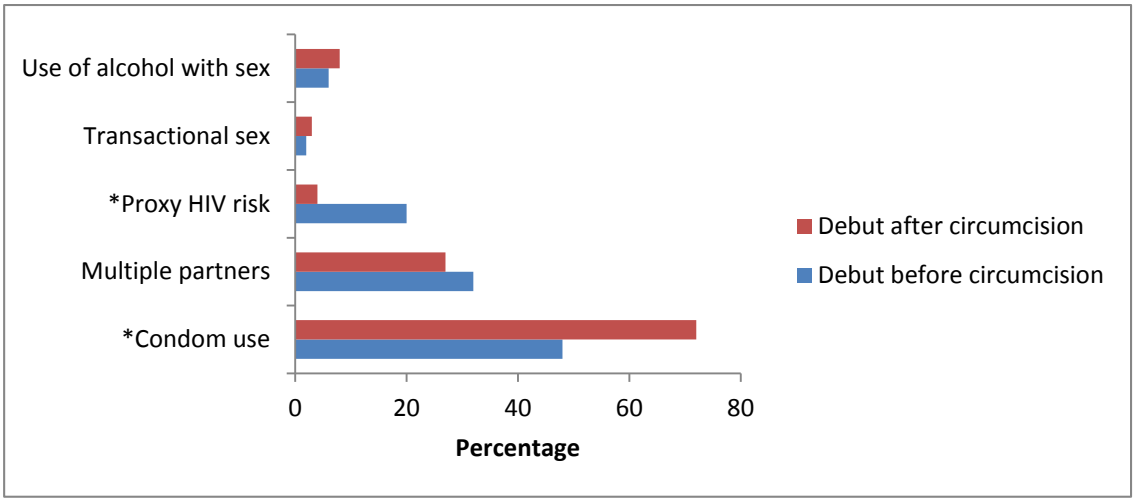


Figure 3: Sub-analysis of participants who had sexual debut after MMC

Table 18: a sub-analysis of 39 participants, who did not have sexual intercourse before MMC, but reported this in the post-MMC period, is shown. These contributed to increased proportion of vaginal sexual intercourse post MMC. As can be seen in the Table, they were more likely to be in the 18–24-year-old category, to use condoms during sexual intercourse, and less likely to acquire HIV as measured by proxy HIV.

Table 18: Characteristics of participants who had sex post MMC but not before MMC

Risk Factor	Number (N=39)	%	OR	95% CI	p-value
Age Category					
18 – 24 Years	37	75.5			
25 – 40 Years	2	24.5	0.29	0.10 – 0.49	**<0.001**
Condom use with primary partner					
No	11	28.2			
Yes	28	71.8	2.76	1.23 – 6.50	**0.007**
Multiple Sexual Partners					
No	36	73.5			
Yes	3	26.5	0.78	0.35 – 1.66	0.500
*Proxy HIV Risk**					
No	37	95.9			
Yes	2	4.1	0.17	0.02 – 0.70	**0.008**
Transactional sex primary partner (participants)					
No	38	97.4			
Yes	1	2.6	1.54	0.03 – 19.7	0.708
Transactional sex primary partner (female partners)					
No	12	92.3			
Yes	1	7.7	1.54	0.03 – 19.7	0.712
Use of Alcohol with Sexual Intercourse by participants					
Primary partner					
No	36	92.3			
Yes	3	7.7	1.27	0.22 – 5.15	0.721
Sexual partners with other partners					
Primary partner					
No	29	74.4			
Yes	10	25.6	1.41	0.56 – 3.32	0.404

CHAPTER FOUR

4. DICUSSION

4.1 Summary of principal findings

Indicators of HIV-transmission and -incidence rates provide evidence that roll-out of mass MMC in a service delivery setting has limitations in preventing heterosexual transmission of HIV in adult males in this study. Furthermore, it provides evidence that there are aspects of HIV risky behaviour that remain unchanged. However, in this study we also found that there were some aspects of risky HIV behaviour that are enhanced after MMC, possibly suggesting the presence of risk compensation[14,46].. Thus, a discussion of risk compensation should be broken down into its respective constituents so as to be meaningful.

4.2 Proxy HIV risk

Primary outcome used in the study at the follow-up visit was a proxy HIV risk, which was a combination of two variables. These were concurrent sexual partners and unprotected sexual intercourse (condom non-use). Besides the low proportion of MMC, these two risk factors are the main drivers for the high HIV proportion among males in eastern and southern Africa. Consistent condom use has been found to be as high as 80% effective in prevention of HIV infection[47]. Though this was necessitated by the small number of HIV seroconversions at the follow-up visit, our findings support the use of proxy HIV risk. This is because more than 70% of participants' non-primary sexual partners could be described as being in a long-term concurrent sexual relationship before and after MMC. Since there is a sense of commitment and trust in a long-term relationship, they are less likely to use a condom[48,49]. Another supportive finding in this study was that sexual intercourse with a non-primary sexual partner was more likely to involve use of alcohol, a known risk factor for HIV acquisition[21]. Since MMC was the intervention being tested, it was logical that we used the remaining two determinants of increased HIV rates in east and southern Africa as a proxy HIV risk. These are concurrent multiple sexual partners and lack of condom use (unprotected sexual intercourse).

4.3 HIV incidence rates

The calculated HIV incidence rate of 2.64 (95% CI 0.54–4.75) per 100 person years is similar to findings of the intervention arm of the clinical trial done in Kenya. However, it is higher than in intervention arms of two other clinical trials[2,3,4]. Nevertheless, this HIV incidence rate is much lower than most non-intervention incidence rates among different groups of interest in South Africa[50]. Thus, the HIV-incidence rate in this cohort of circumcised males shows that MMC is an effective intervention in HIV prevention compared to no intervention as depicted in **Table 19**[51].

Table 19: Comparison of HIV incidence rates in cohort with in other studies

Study	Type of Study	Place	Incidence rate (per 100 person-years) 95% CI
Gray H et al. (2003–2006)	Intervention Circumcised males	Rakai District Uganda	0.66 (0.28 – 0.84)
	Uncircumcised males		1.33 (0.78–2.40)
Auvert B et al. (2002–2004)	Intervention Circumcised males	Orange Farm South Africa	0.85 (0.55 – 1.32)
	Uncircumcised males		3.70 (1.72 – 7.8)
Bailey C et al. (2002–2005)	Intervention Circumcised males	Kisumu District Kenya	2.10 (1.20 – 3.02)
	Uncircumcised males		4.20 (3.0 – 5.40)
HSRC (2007–2011)	Prospective	South Africa	1.60 (0.60– 2.70)
Mukudu et al (2012-2014)	Circumcised males Prospective cohort	Soweto South Africa	2.64(0.54–4.75)
Barnighausen T et al. (2003–2005)	Prospective	KZN South Africa	5.10 (3.80 – 7.90)

4. 4 Comparison of findings with other published studies

Study findings on the proportion of condom use and concurrent sexual partners before MMC of 58% and 30% are supported by those in the general population, which were found to be 36–68% and 18–38%, respectively[9]. However, the perception of HIV risk was found to be much higher than in the general population (27% vs. 65%). We believe that this could be because of information given to subjects during MMC and HIV counselling, which is routine procedure in all MMC programmes, as these were done before questionnaire administration. This is supported by the fact that after MMC the perception of HIV risk dramatically increased to 81%.

4.5 Risk Compensation

In this study we found that there are aspects of HIV-risk behaviour that may suggest absence of risk compensation among circumcised adult males post MMC. These factors were proportion of condom use and concurrent sexual partners as they remained statistically unchanged before and after MMC. This is more important since these two constitute the main drivers of a high proportion of HIV among males in eastern and southern Africa. This evidence supports what was found in the clinical trial setting in Uganda[12] and also in more recent studies done in a programme setting, which found absence of risk compensation behaviour after MMC [46].

The study also found evidence for risk compensation which enhances positive behaviour change. Participants were 58% (OR 0.42 95% CI 0.16–1.01, p=0.048) less likely to use alcohol with sex after than before MMC. This is important, because alcohol use with sexual intercourse is strongly associated with many factors that increase the risk of HIV transmission,[21,22] such as unprotected sex[20], sexually transmitted diseases[24], impairment of cognitive function leading to negative impact on sexual choices, not using condoms,[25] and higher rates of condom failure[52]. This could be explained by the fact that undergoing MMC made participants more aware of the risk of HIV acquisition as a result of the counselling session. Possibly they could have realised that they put themselves at risk of HIV transmission, particularly when they use alcohol with sexual intercourse.

This behaviour change could also be explained by an increased perception of HIV risk. Participants were found to perceive themselves 3.5 times (OR 3.5 95% CI 1.88–7.14, p=<0.001) more likely at risk of contracting HIV after than before MMC. This finding supports what was found in a similar study[20]. One possible explanation for, is that since MMC provision includes providing accurate HIV information, the participants became more aware of their risk after MMC. Thus, they were able to adapt certain aspects of sexual-related behaviour. This benefit of MMC is in exclusion of the actual biological preventive benefit conferred by MMC. Thus, MMC is not only a biomedical intervention, but also a behavioural intervention in heterosexual HIV-transmission prevention. This dual effect is the recommended intervention to achieve a significant reduction in HIV transmission[9].

However, the participants were found to be 2.6 (OR 2.7 95% CI 1.34–5.69, p=0.003) times more likely to have sexual intercourse after than before MMC. This finding indicates the presence of risk compensation post- MMC, leading to adoption of HIV risk behaviour. This was mainly because of 19 participants who had their sexual debut after MMC and 30 participants who did not have sexual intercourse before, but after MMC. They were mainly from younger age group (18–24 years) which is also in keeping with more recent study findings which show that post-MMC younger males tend to increase sexual encounters[46]. Despite this difference, analysis of these 39 participants showed that their age of sexual debut was higher (16.7 vs. 22.2 years), thus, the risk of HIV transmission was lower than in those whose age of sexual debut was lower[53,54]. They were also found to be 2.7 times (OR 2.7 95% CI 1.23–6.50, p=0.007) more likely to use condoms and 73% (OR 0.17 95% CI 0.02–0.70, p=0.008) less likely to be at risk of HIV acquisition as measured by the variable proxy HIV risk. This means that although there was an increase in overall number of sexual intercourse, these encounters were at a lesser risk of HIV transmission than those by participants who had sexual debut before MMC.

4.6 Predictors of HIV risk behaviour

Predictors of risky sexual practices before MMC as measured by proxy HIV risk was age category, age category at sexual debut, knowledge of primary sexual partners' HIV status, and what basis for this knowledge was. According to age category, participants in the 25–40-year-age group were more than three times (OR 3.16 95% CI 1.27–7.90 p=0.014) likely to be at risk of HIV acquisition than those in the 18–24-year-age group. This finding is in line with age-specific HIV-incidence rates among males in South Africa[9]. Importance of this predictor is that HIV-prevention strategies, including MMC and HIV testing, can be more emphasised in this age group to have an immediate impact. This also gives support to the need to provide services required for HIV prevention even to younger males.

In terms of age of sexual debut, it was found that participants who had their sexual debut at 16 years or older, were 66% (OR = 0.34, 95% CI 0.13–0.89, p=0.028) less likely to have high sexual risk compared to those younger than 16 years. This is in line with previous findings, which show that age of sexual debut is an important determinant of HIV infection[26,53] Thus, delaying sexual debut remains an important

HIV-prevention intervention. This also means that important HIV-prevention strategies, such as MMC and HIV testing should be encouraged even in younger males before they attain puberty.

We also found that participants who knew HIV status of their female sexual partners were 90% (OR = 0.10 95% CI 0.02–0.52, p=0.005) less likely to have high risk sexual behaviour. This is consistent with the finding of many studies, where HIV counselling and testing is shown to be an important HIV-prevention strategy. Those who gave a reliable source of this knowledge, i.e. who had seen the HIV-test results of the partner, were almost five times (OR = 4.7 95% CI 2.68–6.72, p=0.052) more likely to have had a high sexual risk behaviour. This is explained by the fact that when people know the HIV-negative status of a sexual partner, they are more likely not to use condoms.

4.8 Study limitations

There are several limitations in our study. The primary limitation in interpreting our data, is that only half of patients who had enrolled in the study had completed the post-MMC visit by the time of data analysis, hence, posing a threat to external validity. Thus, the HIV-incidence rates calculated in the study may not reflect true incidence rate, which is the reason why interpretation was based on the proxy HIV risk. However, those lost to follow-up were not significantly different to those retained in the study in terms of baseline demographic and HIV-risk factors.

Presence or absence of HIV infection was determined based on a skin-prick antibody test, which takes about 3 months for seroconversion. This was not an accurate measure, as on entry there was no way of confirming the HIV result for those infected, but not yet seroconverted. Thus, it was possible that a participant could have been infected on entry, but only tested serostatus reactive on the follow-up visit. Besides, HIV infection could not be used as a primary outcome; instead a proxy HIV risk was used by combining two variables. This combination is not exhaustive of all possible contributors of HIV risk in the general population, but was limited by data obtained in the study.

The other limitation was that all risk-factor measures were dependent on participants self-reporting behaviour. Thus, it was possible that there was under- or over-reporting of factors, and that there was recall bias in the study.

Generalisability of study findings is restricted by several factors brought about by selection bias. These include that we excluded participants whose HIV serostatus was reactive at entry, those who lived outside Soweto, were below 18 or above 40 years old, and all those who were not black South Africans.

Statistical methods used in the analysis, specifically logistic regression, could be another limitation. “Large sample sizes are required for logistic regression to provide sufficient numbers in both categories of the response variable. The more explanatory variables, the larger the sample size required. With small sample sizes, the Hosmer–Lemeshow test has low power and is unlikely to detect subtle deviations from the logistic model. Hosmer and Lemeshow recommend sample sizes greater than 400”[55].

CHAPTER FIVE

5. CONCLUSION

HIV incidence rate in circumcised males aged 18–40 years in Soweto, was found to be 2.64 (95% CI 0.54 – 4.75) per 100 person years. This study also found that while the most important factors constituting risk compensation in clients who undergo MMC in a programme setting remain unchanged, others are enhanced or others even reduced. Condom use, concurrent sexual partners, transactional sex and knowledge of sexual partners' HIV status all remained unchanged from pre to post MMC. Use of alcohol with sex for both the males and their female sexual partners reduced. The perception of HIV risk and sexual encounters by males post MMC, especially in the 18–24-year-age group, increased from the pre- to post-MMC period. Predictors of HIV-transmission risk in pre-MMC period were found to be age category, age category at sexual debut, knowledge of sexual partners' HIV status, and how this knowledge was acquired. However, in the post-MMC period, only age category at sexual debut was a predictor. Despite limitations of the study, we believe that these important findings underscore the effectiveness of MMC in a programme setting as a biomedical and behaviour change intervention for the prevention of HIV transmission. However, risk-reduction counselling for MMC needs to emphasise that this is only partially protective of HIV transmission.

CHAPTER SIX

6. RECOMMENDATIONS

On the basis of findings of the study, the following recommendations can be made:

1. Risk-reduction counselling sessions before MMC should emphasise that MMC is only partially protective, thus, increasing number of sexual encounters post MMC would increase risk of HIV transmission. This will apply mainly to younger males in the 18–24-year-age group and those who had their sexual debut before 16 years old.
2. HIV-counselling and -testing protocols should be designed in a way that helps to identify possible risk factors for HIV transmission in an individual. Then according to the identified risk factors, risk reduction should be tailored.
3. Studies on risk-compensation behaviour in HIV-prevention strategies should involve a breakdown into different constituents of this behaviour, which would make interpretation of results meaningful.

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APPENDIX A

STUDY INCLUSION AND EXCLUSION CRITERIA

MEDICAL MALE MMC, SOWETO – 2012

INCLUSION/EXCLUSION CRITERIA

1. HIV negative on the day of MMC ☐
2. Age range 18 to 40 years of age. ☐
3. Lives in or around Soweto, taxi fare all round R30 ☐
4. Likely to continue living as in 3 for the coming 12 months ☐
5. Willing to repeat HIV test at 6 months and 12 months ☐
6. Has signed written consent form ☐

APPENDIX B

DATA COLLECTION TOOLS

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

A1. The respondent is in the room with no others present except for the interviewer.	**1=Yes 0=No**	
A2. I have read the individual information sheet, statement of confidentiality and informed consent form	**1=Yes 0=No**	
A3. If the participant agreed to participate, did he sign the consent form?	**1=Yes 0=No**	
A4. Has the participant retained a copy of the information sheet?	**1=Yes 0=No**	
A5. Is the HIV status of the participant non-reactive? (Please attach results)	**1=Yes 0=No**	**If No, please discontinue**
A6. If the participant is sexually active, does he exclusively have sex with males?	**1=Yes 0=No**	**If Yes, Please discontinue (explain fully)**

SECTION 1: DEMOGRAPHICS

1.1	**Race of the respondent** [DO NOT READ OUT LOUD]	**1= Black 2= Coloured** 3**= White 4= Indian** **5 = Other (specify)**	
1.2	**PRESENT age of the respondent today**		**Years**
1.3	**What is your marital status? (Marital status referring to legal, traditional or common-law)** [DO NOT READ OUT LOUD] [ONE RESPONSE ONLY]	**1 = Single** **2 = Not married or living together but in a steady sexual relationship lasting more than 3 months** **3 = Not married, but living with sexual partner/boyfriend/girlfriend** **4 = Married, living with husband/wife** **5 = Married, NOT living with husband/wife** **6 = Divorced/Widowed** **7 = Other (specify)**	
1.4	**What is your present employment status?** [DO NOT READ OUT LOUD] [ONE RESPONSE ONLY]	**1 = Unemployed, not looking for work** **2 = Unemployed, looking for work** **3 = Informal work (such as making things for sale, selling things or providing a service)** **4 = Employed full-time [40 or more hours a week]** **5 = Employed part-time [less than 40 hours a week]** **6 = Full-time student / pupil / learner at SCHOOL** **7 = Full-time student at COLLEGE / TECHNIKON / UNIVERSITY** **8 = Pensioner** **9 = Living on disability or other grant** **10 = Other (specify)**	

Medical Male MMC: Entry Initial: Date: / /

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview_____/_____/_____

0 0 0 1

1.5	**What is the HIGHEST grade of education you have completed?** [DO NOT READ OUT LOUD] [ONE RESPONSE ONLY]	**0 = No schooling** **1 = grade 1** **2 = grade 2** **3 = grade 3** **4 = grade 4** **5 = grade 5** **6 = grade 6** **7 = grade 7 (Standard 5)** **8 = grade 8** **9 = grade 9** **10 = grade 10** **11 = grade 11 (Standard 9)** **12 = grade 12 (Standard 10 / Matric / Diploma, certificate after Matric)** **13 = one to three years of university** **14 = Bachelor's degree from a University** **15 = Post graduate degree (e.g. Honours, Masters)** **16 =Doctoral degree (PhD)** **17 = Other (specify)**	
1.6	**What is your main reason for wanting to be circumcised?** [SPONTANEOUS MENTION] [MORE THAN ONE RESPONSE POSSIBLE]	**1 = Prevention against HIV** **2 = Prevention against other STIs** **3 = Personal hygiene** **4 = To improve my sexual performance** **5 = Religious reasons** **6 = Traditional reasons** **7 = Because my partner asked me to** **8 = Because my parents/guardian asked me to** **9 = Because my friends are circumcised** **10 = Other (specify)**	

SECTION 2: BIOLOGICAL RISK FACTORS

Interviewer read out loud: I am now going to ask you some questions on other ways apart from sex that can transmit or increase the chances of transmission of HIV.

2.0	**Which of the following has happened to you?** READ OUT ALL		
2.1	**Have you ever had an injection for anything other than medical problem, such as intravenous drugs use?**	**0 = No** **1 = Yes**	
2.2	**Have you ever received a blood transfusion?**	**0 = No** **1 = Yes**	
2.3	**Have you ever had an ulcer on the genital area?**	**0 = No** **1 = Yes**	
2.4	**Have you ever had swellings in the groin area?**	**0 = No** **1 = Yes**	
2.5	**Have you had a discharge from the urethra?**	**0 = No** **1 = Yes**	
2.6	**Have you ever had pain on passing urine?**	**0 = No** **1 = Yes**	
2.7	**Have you ever had a sexually transmitted disease?**	**0 = No** **1 = Yes**	

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

SECTION 3: SEXUAL BEHAVIORAL RISK FACTORS

Now I am going to ask you some questions about sex. The answers you give are very important for helping to know whether a circumcised person is subjected to similar risks as the uncircumcised. We know that some people have had sexual intercourse and some have sexual intercourse with more than one person. Your answers are confidential and will not be known by anyone else.

3.0	**Have you ever had anal sex with another male?**	**1 = Yes** **0 = No**	
3.1. ☞	**Have you ever had sex with any one? (that is to say when the penis was in the vagina)**	**1 = Yes** **2 = No ➡ SKIP TO QUESTION Q3.15** **3 = Do not know ➡ SKIP TO SECTION Q3.15**	
3.2	**How old were you when you first had sex with any one (that is to say when the penis was in vagina/anus)?** WRITE AGE IN YEARS. NOTE: If respondent is unsure, they can estimate approximate age**.** **(THIS SHOULD BE CHECKED AGAINST AGE IN Q1.2)**	_____ **Age in years**	
3.3	**Did you use a condom the first time you had sex?**	**1 = Yes** **0 = No**	
3.4 ☞	**Have you had sex with anyone within the Past 6 months? (that is to say when the penis was in vagina/anus)**	**1 = Yes** **0 = No ➡SKIP TO Q3.15**	
3.5	**I would like to ask you a few questions about the person that you most recently had sex with. We do not need to know who she is, so let's just use her initials: instruction: need to repeat definition to ensure sex took place** **[***only ask if had vaginal or anal sex***]**		
3.5.1	**Let's identify the last person you had sex with by calling this person X1…**	**X1**	
3.5.2	**When was the first time that you had sex with this person?** PROVIDE AN ESTIMATE [dd/mm/yyyy]	D D M M Y Y Y Y	
3.5.3	**How would you describe your relationship with this person?** [READ OUT]	**1 = Married** **2 = Living together** **3 = Main partner** **4 = A friend** **5 = Someone I've known for a while** **6 = Someone I just met** **7 = One night encounter** **8 = Other [Specify]** _____	
3.5.4	**In the past 6 months, have you provided sex to this person/partner in exchange for money or gifts?**	**1 = Yes** **0 = No**	
3.5.5	**In the past 6 months, have you provided money or gifts to this person/partner in exchange for sex?**	**1 = Yes** **0 = No**	
3.5.6	**How often do you usually have sex with this person?** [READ OUT; ONE RESPONSE ONLY]	**1 = Just this once** **2 = Once in while** **3 = 2-3 times per month** **4 = 2-3 times per week or more often**	

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

3.5.7	**When was the <u>most recent/last time</u> that you had sex with this person?** [dd/mm/yyyy] (MUST BE IN PAST 6 MONTHS)	D D M M Y Y Y Y	
3.5.8	**Sometimes people like to drink before they have sex. Did you have too much to drink when you had sex with this person the last time?**	**1 = Yes 0 = No**	
3.5.9	**Did this person/X1 have too much to drink when she/he had sex with you the last time?**	**1 = Yes 0 = No**	
3.5.10	**Sometimes people like to take drugs before they have sex. Did you take drugs when you had sex with this person the last time?**	**1 = Yes 0 = No**	
3.5.11	**Did this person/X1 take drugs when she/he had sex with you the last time?**	**1 = Yes 0 = No**	
3.5.12	**During the last time you had sex with this person, what did you do to prevent infection from HIV?** [MULTIPLE RESPONSES POSSIBLE] [DO NOT READ OUT]	**0 = Nothing 1 = Used condoms 2 = I am faithful and trust this partner not to cheat (have sex with others) 3 = My partner and I know our HIV status 4 = Stopped before ejaculation (withdrawal) 5 = Had thigh sex 6 = Had anal sex 7 = Had oral sex 8 = Used contraceptives (pill, IUD/loop, injection, etc.) 9 = Use the natural method / safe period 10 = Other (specify) _____**	
3.5.13	**Did you use a condom the last time you had sex with this person?**	**1 = Yes 0 = No**	
3.5.14	**Do you expect to have sex with this person again?**	**1 = Yes 0 = No**	
3.5.15	**Do you think this person currently has other sex partners?**	**1 = Yes 0 = No**	
3.5.16 ☞	**I don't want you to tell me what it is, but do you know this person's HIV status?**	**1 = Yes 0 = No ➡SKIP TO 3.6**	
3.5.17	**How do you know this person's status?** [DO NOT READ OUT]	**0 = Do not know status 1 = They look sick 2 = They look well 3 = The person told me 4 = Someone else told me 5 = I saw their HIV results 6 = Other (specify)**	

Medical Male MMC: Entry Initial: Date: _____/_____/_____

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

[INTERVIEWER: BEFORE ASKING ABOUT ANY ADDITIONAL SEXUAL PARTNERS, READ THE FOLLOWING]

Some people have more than one partner during the year. We are also interested in other sexual relationships you might have had in the past six months, regardless of the nature, timing or duration of the relationships. As mentioned, there are no right or wrong answers. Please do not feel shy or embarrassed about talking to us; you will never be judged and all your answers will be private.

3.6	**How many DIFFERENT PEOPLE have you had sex with in THE PAST 6 MONTHS INCLUDING X1?** WRITE NUMBER BUT DON'T RESTRICT.	***Write in Number:***	
3.7	**Do you think that during the PAST 6 MONTHS you had more sex partners, sex partners or about the same number of sex partners than you had a year ago?**	**1 = More sex partners** **2 = About the same number** **3 = Less sex partners** **4 = Don't remember**	
3.8	**During the PAST 6 MONTHS, did you have sex with more than one person within the same month?**	**1 = Yes** **0 = No**	
3.9	**How many DIFFERENT PEOPLE have you had sex with in THE PAST MONTH?** WRITE NUMBER BUT DON'T RESTRICT. (CANNOT BE HIGHER THAN 3.6)	***Write in Number:***	
3.10	**How many sexual partners do you CURRENTLY have?** WRITE NUMBER BUT DON'T RESTRICT.	***Write in Number:***	

Filtre A Y= Yes N= No	
1. Check q 3.6 Respondent has had 2 or more sexual partners in the past 6 months [__] If Y go to next block of this filter → If N go to Q 3.15	2. IF you end up in this block – Place a X in the [___] And ask the respondent to talk about another sex partner they had sex with in the past 6 months. and go to Q 3.11.1 at the start of the grid

Medical Male MMC: Entry Initial: Date: / /

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

[IF NECESSARY, SHOW VISUAL AID CALENDAR TO ASSIST RESPONDENTS]

Interviewer read out loud: You mentioned that you have had more than one sex partner in the past 6 months. We have already spoken about x1. Now let's talk about another sex partner.

	3.11 Other Sex Partner	3.12 Other Sex Partner	3.13 Other Sex Partner	3.14 Other Sex Partner
Let's identify this sexual partner as…	3.11.1 **X2**	3.12.1 **X3**	3.13.1 **X4**	3.14.1 **X5**
When was the first time that you had sex with this person? PROVIDE AN ESTIMATE	3.11.2 M M Y Y	3.12.2 M M Y Y	3.13.2 M M Y Y	3.14.2 M M Y Y
How would you describe your relationship with this person? [READ OUT] **1 = Married 2 = Living together 3 = Main partner 4 = A friend 5 = Someone I've known for a while 6 = Someone I just met 7 = One night encounter 8 = Other [Specify]** _____	3.11.3 **X2**	3.12.3 **X3**	3.13.3 **X4**	3.14.3 **X5**
In the past year, have you provided sex to this person in exchange for money or gifts? **1 = Yes 0 = No**	3.11.4 **X2**	3.12.4 **X3**	3.13.4 **X4**	3.14.4 **X5**
In the past year, have you provided money or gifts to this person in exchange for sex? **1 = Yes 0 = No**	3.11.5 **X2**	3.12.5 **X3**	3.13.5 **X4**	3.14.5 **X5**
How often do you usually have sex with him/her? [ONE RESPONSE ONLY] **1 = Just this once 2 = Once in while 3 = 2-3 times per month 4 = 2-3 times per week or more often**	3.11.6 **X2**	3.12.6 **X3**	3.13.6 **X4**	3.14.6 **X5**
When was the most recent/last time that you had sex with this person?	3.11.7 M M Y Y	3.12.7 M M Y Y	3.13.7 M M Y Y	3.14.7 M M Y Y

Medical Male MMC: Entry Initial: Date: / /

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

Sometimes people like to drink before they have sex. Did you have too much to drink when you had sex with this person the last time? 1 = Yes 0 = No	**3.11.8**	**X2**	**3.12.8**	**X3**	**3.13.8**	**X4**	**3.14.8**	**X5**
Did this person (that we are talking about now) have too much to drink when she had sex with you the last time? 1 = Yes 0 = No	**3.11.9**	**X2**	**3.12.9**	**X3**	**3.13.9**	**X4**	**3.14.9**	**X5**
Sometimes people take drugs before they have sex. Did you take drugs when you had sex with this person the last time? 1 = Yes 0 = No	**3.11.10**	**X2**	**3.12.10**	**X3**	**3.13.10**	**X4**	**3.14.10**	**X5**
Did this person (that we are talking about now) take drugs when she had sex with you the last time? 1 = Yes 0 = No	**3.11.11**	**X2**	**3.12.11**	**X3**	**3.13.11**	**X4**	**3.14.11**	**X5**
During the last time you had sex with this person, what did you do to prevent infection from HIV? MULTIPLE RESPONSES POSSIBLE] **0 = Nothing 1 = Used condoms 2 = Was faithful 3 = My partner and I know our HIV status 4 = Withdrawal 5 = Thigh sex 6 = Anal sex 7 = Oral sex 8 = contraceptives (pill, IUD/loop, injection, etc.) 9 = Use the natural method / safe period 10 = Other [Specify]**	**3.11.12**	**X2**	**3.12.12**	**X3**	**3.13.12**	**X4**	**3.14.12**	**X5**

Medical Male MMC: Entry Initial: Date: / /

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

Did you use a condom the last time you had sex with this person? 1 = Yes 2 = No	**3.11.13**	**X2**	**3.12.13**	**X3**	**3.13.13**	**X4**	**3.14.13**	**X5**
Do you expect to have sex with this person again? 1 = Yes 0 = No	**3.11.14**	**X2**	**3.12.14**	**X3**	**3.13.14**	**X4**	**3.14.14**	**X5**
Do you think this person currently has other sex partners? 1 = Yes 0 = No	**3.11.15**	**X2**	**3.12.15**	**X3**	**3.13.15**	**X4**	**3.14.15**	**X5**
I don't want you to tell me what it is, but do you know this person's HIV status? 1 = Yes 0 = No	**3.11.16**	**X2**	**3.12.16**	**X3**	**3.13.16**	**X4**	**3.14.16**	**X5**
How do you know this person's status? [DO NOT READ OUT] **0 = Do not know status 1 = They look sick 2 = They look well 3 = The person told me 4 = Someone else told me 5 = Other [specify]**	**3.11.17**	**→GO TO FILTER B**	**3.12.17**	**→GO TO FILTER C**	**3.13.17**	**→GO TO FILTER D**	**3.14.17**	**NOW GO TO Q.3.15**

Filtre B Y= Yes N= No	
2. Check q 3.6 Respondent has had 3 or more sexual partners in the past 6 months [__] If Y go to next block of this filter → If N go to Q 3.15	2. IF you end up in this block – Place a X in the [___] And ask the respondent to talk about another sex partner they had sex with in the past 6 months and go to Q 3.12.1 at the start of the grid

Medical Male MMC: Entry Initial: Date: _____/_____/_____

MEDICAL MALE MMC, SOWETO – 2012

ENGLISH VERSION

QUESTIONNAIRE NUMBER ENTRTY VISIT Date of Interview _____/_____/_____

0 0 0 1

Filtre C Y= Yes N= No	
3. Check q 3.6 Respondent has had 4 or more sexual partners in the past 6 months [__] If Y go to next block of this filter → If N go to Q 3.15	2. IF you end up in this block – Place a X in the [___] And ask the respondent to talk about another sex partner they had sex with in the past 6 months and go to Q 3.13.1 at the start of the grid

Filtre D Y= Yes N= No	
4. Check q 3.6 Respondent has had 5 or more sexual partners in the last 6 months [__] If Y go to next block of this filter → If N go to Q 3.15	2. IF you end up in this block – Place a X in the [___] And ask the respondent to talk about another sex partner they had sex with in the past 6 months and go to Q 3.14.1 at the start of the grid

	Instruction: Check question Q.3.4. If participant answered YES to Q. 3.4, DO NOT ask Q. 3.15 without answering the above questions.

3.15	**Does the participant think that he is personally at risk of HIV?**	**1 = No** **2 = Yes** **3 = Do not know**	

APPENDIX C

ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Hillary Mukudu

CLEARANCE CERTIFICATE	**M120634**
PROJECT	Male Circumcision for the Prevention of Hetrosexual Transmission of HIV in Adult Male in Soweto, What So Do Indicators and Incidence Rates Show?
INVESTIGATORS	Dr Hillary Mukudu.
DEPARTMENT	School of Public Health
DATE CONSIDERED	29/06/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 15/08/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Benn Sartorius

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX D

Translation Certificate

This is to certify that the translation of the document entitled:

Consent Form & Information Sheet

PERINATAL HIV RESEARCH UNIT (PHRU)
Male MMC, Soweto, 2012
STUDY INFORMATION
Version 1.0 August 2012

From English into Zulu and Sesotho has been completed to the best of the ability of our translators and is true to the meaning and wording of the original English text. The translation was carried out by the following translators:

English to Zulu by Zanele Mtshweni
English to Sesotho by Thabiso Ntsielo

APPENDIX E

Definition of risk indicators

1. **Age at sexual debut:** (categorised to <16 and ≥16 years) It is the age in years of the participant at the time they first had penetrative sexual intercourse, when the penis was in the anus or vagina.
2. **Intravenous drug use:** Use of recreational or substance dependent drugs that are introduced to the body using needles and syringes.
3. **Sexually Transmitted Infections (STIs): A**ny infection transmitted sexually as diagnosed by a health professional other than HIV.
4. **Anal sexual intercourse:** type of penetrative sexual intercourse in which the participants' penis was inserted in the anus.
5. **Vaginal sexual intercourse:** type of penetrative sexual intercourse in which the participants' penis was inserted in the vagina.
6. **Condom use:** This was where the participant used a condom during sexual intercourse.
7. **Transactional sex:** This is the use of valuable things such as money or gifts in order to get the partner to have sexual intercourse. It was divided to **got paid for sex,** where the participant was given this inducement and **Paid for sex** where the participant gave this inducement to a sexual partner.
8. **Use of alcohol with sex:** This is where the participant or the female sexual had taken alcohol before sexual intercourse.
9. **Use of drugs with sex:** This is where the participant or the female sexual had taken recreational or substance dependent drugs before sexual intercourse.
10. **Sexual partner with other partners:** This whether the participant knew that his sexual partner had other sexual partner(s).
11. **Knowledge of partner's status:** This is whether the participant knew the HIV status of his sexual partner.
12. **How status is known:** This was how the participant got to know the HIV of his female sexual partner. This was divided to **Reliable**, where he saw the HIV test results or **Unreliable** for all the other ways.
13. **Risky relationship:** This is whether the participant was in a sexual relationship in which the risk of HIV transmission was high, such as transactional sex and sexual partner with other sexual partners.
14. **Number of sexual partners:** This was the number of sexual partners had sexual intercourse in the period of the study under consideration.
15. **Multiple sexual partners:** Whether the participant had more than one concurrent sexual partners at the time of the study in consideration
16. **Perception of HIV risk:** Whether the participant felt that he was likely to get HIV at the time of the interview.
17. **Primary sexual partner:** The first person the participant had sexual intercourse with in the period under consideration.
18. **Non-primary sexual partner:** The second, third, fourth etc., person the participant had sexual intercourse with in the period of the study under consideration.