

**Evaluation of the Acceptability and Safety of the PrePex
Device**

For

Adult Male Circumcision in South Africa:

A Pilot Study in Three Clinical Sites

April 2016

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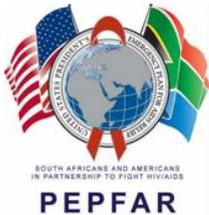


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List of Acronyms

AE	Adverse Event
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
CA	Clinical Associate
CHAPS	Centre for HIV / AIDS Prevention Studies
CIPRA	Comprehensive International Program of Research on AIDS
CRF	Case Report Forms
DOH	Department of Health
FGD	Focus Group Discussion
FDA	Food and Drug Administration
HCT	HIV Counselling and Testing
HIV	Human Immunodeficiency Virus
HPP	Health Policy Project
ID	Identification Document
MC	Male Circumcision
NGO	Non-Governmental Organisation
NSP	National Strategic Plan
SAE	Severe Adverse Event
SMS	Short Message Service
STI	Sexually Transmitted Infections
USAID	United States Agency for International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organisation

Investigators, Institutional Affiliations, Roles and Responsibilities

Organisation and Responsibility	Investigator Name and title	Role
<u>South African Department of Health:</u> Overall leadership and supervision of the field study with support from the following organisations:	Dayanund Loykissoonlal	Co-Principal Investigator: Providing policy guidance and direction of study in line with the priorities and policies of South Africa.
<u>Anova Health Institute:</u> Overall leadership and supervision of the field study with support from CHAPS	Prof James McIntyre	Principal Investigator: Responsible for oversight of all aspects of study planning and implementation including protocol development, procedures, results, and publications distribution.
<u>The Centre for HIV / AIDS Prevention Studies (CHAPS):</u> Joint protocol development, research training facilitation, coordination of study implementation study mentoring, statistical data analysis, reporting.	Dr. Dirk Taljaard	Co-Principal Investigator
	Dr. Dino Rech	Investigator
	Ms Genevieve N Dean Ms Sasha Frade Ms Alexandra Spyrelis	Research Coordinators
<u>USAID:</u> Joint protocol development, research and programme implementation input	Mr Emmanuel Njeuhmeli	Co-Investigator
	Dr Delivette Castor	Co-Investigator
<u>HPP:</u> Protocol development, research training facilitation, coordination of study, cost analysis, and reporting of the costing component only.	Dr Katharine Kripke	Costing Component Supervisor

Executive Summary

Introduction Throughout Sub-Saharan Africa, national governments and NGOs are scaling up programmes to provide VMMC. Some of the barriers that they face include creating demand for VMMC, financing the health facilities necessary to provide VMMC and hiring the trained human resources necessary to perform the procedure. In South Africa, the human resource challenge is perceived to be one of the limiting factors to meeting the government's goal of 2.5 million circumcisions. Medical circumcision devices have the potential to accelerate delivery of male circumcision by making the procedure quicker, easier, more replicable, safer, and potentially more cost-effective. In addition to these factors that are likely to facilitate expansion of adult male circumcision programmes for HIV prevention and address some of the common capacity issues in countries with a high HIV burden, devices may be more acceptable to clients than a surgical approach in some circumstances. One device for adult male circumcision is PrePex (Circ MedTech Limited., Horizon Chambers Road Town Tortola POB 4622, British Virgin Islands).

Methodology This study was conducted in compliance with the protocol, as well as the applicable local regulations and guidelines. We recruited 803 men, aged 18 to 49 years. Study recruitment was TIME₀ (day of device application) and 56 days follow-up per participant. The study assessed provider training, providers' acceptance of the PrePex, ease of use, and providers' perceptions; client acceptability and safety; as well as costs of PrePex.

Findings and Discussion Most of the providers felt that the time of the training was inadequate, and did not feel confident in their skills, after the training had been completed but prior to the commencement of the study. Providers were in consensus that all medical healthcare professionals with knowledge on circumcision are capable of performing the procedure as long as they are properly trained. It was expressed that persons who place and remove the PrePex device should have prior knowledge on circumcision to be able to perform the procedure. There was a general concern amongst providers about the lack of control associated with allowing clients to go home for seven days with the device attached. An additional concern was that dealing with a large number of clients on one day could cause difficulties in keeping track of clients who need the device to be removed especially men who do not return after seven days.

For providers, a key benefit of using the PrePex device for VMMC was the assurance of a needle and stitch-free procedure as well as the lack of blood loss. Providers were overall very impressed with the cosmetic result and the speed at which the PrePex circumcision could be done.

Providers suggested that PrePex be offered in conjunction with surgical circumcision. Providing clients with the option to choose from two methods of circumcision (surgical circumcision or PrePex circumcision) can positively deal with the large amounts of men that come in to clinics to be circumcised.

Most participants experienced no pain after device placement. However, they began to experience pain after the first two days. Further the pain was much more severe at night than during the day. Numerous men complained of additional pain during urination. Men found that the pain subsided substantially after the PrePex device was removed. Numerous men found the pain experienced during the removal of the device to be intense and almost unbearable. Pain additionally affected the type of work some men could partake in. Furthermore, the smell (odour) was reported as intense and difficult to ignore. It was reported to begin around the third and fourth day.

Sixty-six participants had masturbated or had sex within the 8-week abstinence period. Furthermore, 46% and 13% said that was very easy or somewhat easy, respectively, to abstain from sex or masturbation during the 8-week abstinence period.

In total there were twenty (20) AEs (in sixteen (16) people) out of 803 circumcisions, with an AE rate of 2.5% - although with withdrawals included the AE rate was higher than 5%.

The overall unit cost of VMMC has been determined to be R1320.41 prior to the introduction PrePex and R1272.04 after the introduction of PrePex device. At the average exchange rate for 2014 of R10.83 = US\$1, the overall unit cost is US\$121.92 per circumcision performed prior to the introduction PrePex and US\$117.46 per circumcision performed after the introduction of the PrePex device.

Recommendations Training should include a higher number of clients. Clients and their partners should be provided with both verbal / oral explanations and published material about pain and/or odour, as well as key messages regarding abstinence. Marketing material should include the fact that PrePex is mainly bloodless, sutureless, and has a good cosmetic result. Marketing material must not misinform clients about PrePex circumcision being painless and that all clients will be able to resume normal activity immediately, as this is not always the case. Stronger medication should be provided to clients for proper pain relief during the first 14 days, and an injectable anaesthetic should be used during device removal. PrePex circumcisions cannot be a standalone service, but must be scaled up at the same time as surgical circumcision.

I. INTRODUCTION

a. Background to the Study

i. *HIV in South Africa*

South Africa has been severely impacted by a generalised HIV/AIDS epidemic, with the highest number of people living with HIV in the world – millions of South Africans are living with the virus. South Africa with 0.7% of the world's population has 17% of the global burden of HIV infection.¹ HIV/AIDS accounts for 31% of the total disability-adjusted life years of the South African population; this has severely strained the public health system and is driving it towards collapse. Over the last decade great strides have been made in scaling up antiretroviral (ART) treatment with 3.1 million people receiving ART in 2015, from the estimated 6.4 million South Africans living with HIV.^{2,3}

Although there are signs that the epidemic may have reached its peak, the rate of new infections remains high and therefore there is an urgent need to intensify prevention efforts. Voluntary Medical Male Circumcision (VMMC) is an evidence-based HIV prevention strategy. The World Health Organisation (WHO) notes that the impact of male circumcision (MC) will be greatest in areas “where prevalence of heterosexually transmitted HIV infection is high, the levels of male circumcision are low, and populations at risk of HIV are large”.⁴ South Africa has many such locations that fit this criterion.

“South Africa bears the biggest burden of the world, providing (V)MMC in the public sector provides men with the opportunity of protecting themselves and their partners from HIV infection”

(A. Motsoaledi, 2010: Health Budget Speech)

Intensive HIV education and prevention message delivery and even free antiretroviral treatment have thus far failed to substantially decreased HIV sero-prevalence rates. There is a need to intensify prevention efforts and novel HIV prevention approaches are urgently needed in South Africa.

¹ Karim S, Churchyard G, Karim Q, Lawn S. (2009) HIV infection and tuberculosis in South Africa: an urgent need to escalate the public health response. *Lancet* **12; 374(9693): 921–933**.

² South African Department of Health (2014). Strategic Plan 2014/15- 2018/19

³ South African department of Health (2015) 7th South African AIDS Conference KwaZulu- Natal

⁴ WHO & UNAIDS (2007). *New data on male circumcision and HIV prevention: policy and programme implications*. *PLoS Medicine*.

ii. *Male Circumcision in South Africa*

While the evidence of the risk reducing impact of male circumcision is now accepted, in order to have a population level impact on HIV prevalence in South Africa a large number of HIV negative men would have to choose to undergo circumcision. The challenge lies in meeting such demand in South Africa where only surgeons, doctors and clinical associates (CAs) are allowed to perform circumcision surgery in clinics and hospital settings. A large number of health centres and clinics need to be equipped and improved to a level where minimum quality assurance standards for safe male circumcision service delivery can be met. For example, an evaluation of services provided at a public sector hospital in Soweto showed effective current service provision, with a need to improve capacity to meet future demand to achieve the public health impact of male circumcision interventions as part of a comprehensive package for HIV prevention⁵.

In the National Strategic Plan (NSP) for South Africa, “it is recommended that the Department of Health considers the effectiveness of male circumcision as an HIV prevention intervention and develop appropriate policies”⁶. The Government of South Africa included VMMC as one of five components of the HCT campaign of integrated prevention strategies with the goal of performing at least 2.5 million VMMC by 2015.⁷ Thus, the South African Government has fully embraced VMMC as a key prevention strategy and set forth a target of 5.3 million VMMCs for the next five years (2010-2015) in order to reach 80% of the eligible male population. However, currently there are numerous areas that are under-serviced.

In South Africa, the challenge lies in meeting the demand with the supply - where only surgeons, doctors and CAs are allowed to perform circumcision surgery in clinics and hospital settings. A large number of health centres and clinics need to be established, and others improved, and innovative ways to meet demand need to be found in order to scale-up VMMC procedures as part of a comprehensive HIV strategy.

Throughout Sub-Saharan Africa, national governments and NGOs are scaling up programmes to provide VMMC.⁸ Some of the barriers that they face include creating demand for VMMC, financing the health facilities necessary to provide VMMC and hiring the trained human resources necessary to perform the

⁵ de Bruyn G, Smith MD, Gray GE, McIntyre JA, Wesson R, et al. (2007) Circumcision for prevention against HIV: marked seasonal variation in demand and potential public sector readiness in Soweto, South Africa. *Implement Sci* 2: 2.

⁶ South Africa Department of Health. (2006). “HIV and AIDS and STI Strategic Plan for South Africa, 2007-2011”: p146.

⁷ South African National Department of Health. (2011). HIV and AIDS. Retrieved September 21, 2011, from <http://www.doh.gov.za/list.php?type=HIV and AIDS>

⁸ WHO, & UNAIDS. (2010). *Progress in male circumcision scale-up : country implementation and research update*.

procedure.^{9 10 11} In South Africa, the human resource challenge is perceived to be one of the limiting factors to meeting the government's goal of 2.5 million circumcisions. Currently, circumcision is a procedure that can only be performed by physicians and service providers are experiencing difficulties and hiring and retaining physicians to perform circumcisions. Boredom and fatigue, low levels of job satisfaction, and NGO salary limits are some of the reasons that VMMC service providers site as challenges for hiring and retaining physicians.

Human resource challenges in health care are not unique to VMMC nor are the solutions. In Sub-Saharan Africa task-sharing and task-shifting have been used for years to address human resource shortages in the health sector.¹² In many Sub-Saharan African countries new cadres of health professionals have been created including physician assistants, clinical officers, and nurse clinicians who substitute for physicians for both general medical and some surgical care including caesarean sections.¹³ South Africa, which has rapidly expanded the number of people under HIV therapy, is using task-shifting to allow nurses to both initiate and monitor patients on ART in which they are both prescribing medicine for patients initiating ART and changing medications for patients failing therapy.¹⁴ This task shifting allows the expansion of programmes without overburdening physicians. The CIPRA study, a randomised-trial comparing the management of ART patients by doctors and nurses, helped provide the evidence base to make the policy of nurse initiated ART possible.¹⁵

While nurses are allowed to perform VMMC in some countries, such as Kenya, where trained nurses have safely performed over 268,000 VMMCs¹⁶, VMMC is outside the current scope of practice of South African nurses. Professional and enrolled nurses are allowed to perform some of the procedures that

⁹ Herman-Roloff, A., Llewellyn, E., Obiero, W., Agot, K., Ndinya-Achola, J., Muraguri, N., & Bailey, R. C. (2011). Implementing voluntary medical male circumcision for HIV prevention in Nyanza Province, Kenya: lessons learned during the first year. *PLoS one*, 6(4), e18299. doi:10.1371/journal.pone.0018299

¹⁰ WHO, & UNAIDS. (2009). *Country experiences in the scale-up of male circumcision in the Eastern and Southern Africa Region : Two years and counting A sub-regional consultation Windhoek, Namibia. Agenda* (pp. 1-24). Windhoek, Namibia.

¹¹ WHO, & UNAIDS. (2010). *Scaling-up male circumcision programmes in the Eastern and Southern Africa Region Country update meeting to share lessons, explore opportunities and overcome challenges to scale-up A sub-regional consultation. Agenda* (p. 48). Arusha, Tanzania.

¹² Dovlo, D. (2004). Using mid-level cadres as substitutes for internationally mobile health professionals in Africa. A desk review. *Human resources for health*, 2(1), 7. doi:10.1186/1478-4491-2-7

¹³ Mullan, F., & Frehywot, S. (2007). Non-physician clinicians in 47 sub-Saharan African countries. *Lancet*, 370(9605), 2158-63. doi:10.1016/S0140-6736(07)60785-5

¹⁴ Colvin, C. J., Fairall, L., Lewin, S., Georgeu, D., Zwarenstein, M., Bachmann, M. O., Uebel, K. E., et al. (2010). Expanding access to ART in South Africa : The role of nurse- initiated treatment. *South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde*, 100(4), 210-2.

¹⁵ Sanne, I., Orrell, C., Fox, M. P., Conradie, F., Ive, P., Zeinecker, J., Cornell, M., et al. (2010). Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): a randomised non-inferiority trial. *Lancet*, 376(9734), 33-40. Elsevier Ltd. doi:10.1016/S0140-6736(10)60894-X

¹⁶ Curran, K., Njeuhmeli, E., Mirelman, A., Dickson, K., Adamu, T., Cherutich, P., Mavuso, T. K., et al. (2011). Innovative and Efficient Approaches for Meeting the Human Resource Needs of the Voluntary Medical Male Circumcision Scale-Up in Southern and Eastern Africa. *6th IAS Conference on HIV Pathogenesis, Treatment and Prevention*. Rome.

are part of VMMC such as suturing and administering local anaesthesia under the supervision of a physician.

iii. *Voluntary Medical Male Circumcision devices and PrePex*

Medical circumcision devices have the potential to accelerate delivery of male circumcision by making the procedure quicker, easier, more replicable, safer, and potentially more cost-effective. In addition to these factors that are likely to facilitate expansion of adult male circumcision programmes for HIV prevention and address some of the common capacity issues in countries with a high HIV burden, devices may be more acceptable to clients than a surgical approach in some circumstances. Devices are widely used for circumcision in infants with great success, but experience in adults is limited, particularly in countries in the sub-Saharan Africa region where rapid expansion of male circumcision programmes for HIV prevention is most urgent.^{17 18 19 20}

One device for adult male circumcision is PrePex, which the US Federal Drug Administration (FDA) recently approved. A similar endorsement was made by the World Health Organisation (WHO) is anticipated following the completion of safety trials²¹. The PrePex device is a novel medical device for an adult that compresses the foreskin with a two rings to block circulation distally, after which the foreskin becomes necrotic, and is easily removed. The PrePex device is bloodless and does not require injectable local anaesthesia in most cases, suturing, or a sterile setting. Compared to standard surgical circumcision, the total application and removal times are remarkably brief but it does require for the client to keep the device for 7 days.

After reviewing eight studies from three African countries the WHO Technical Advisory Group on Innovations in Male Circumcision concluded that the range and scope of clinical studies have met WHO requirements for evaluations of a device, and demonstrated that, for the purposes of HIV prevention, the PrePex device can efficaciously and safely circumcise healthy men over 18 years, when used by

¹⁷ The Potential Cost and Impact of Male Circumcision in Swaziland. (2009). Health Policy Initiative, Task Order, Futures Group International.

¹⁸ World Health Organisation. (2011). Framework for Clinical Evaluation of Devices for Adult Male Circumcision http://malecircumcision.org/programmemes/tools_guidelines.html

¹⁹ Barone, M. A., Ndede, F., Li, P. S., et al (). The Shang Ring Device for Adult Male Circumcision: A Proof of Concept Study in Kenya. *J AIDS* 2011;57:e7-12.

²⁰ Cheng, Y., Peng, Y. F., et al. (2009). A recommendable standard protocol of adult male circumcision with the Chinese Shang Ring: outcomes of 328 cases in China. *Zhonghua Nan KeXue* 15(7), 584-92.

²¹ Cheng, Y., Peng, Y. F., et al. (2009). A recommendable standard protocol of adult male circumcision with the Chinese Shang Ring: outcomes of 328 cases in China. *Zhonghua Nan KeXue* 15(7), 584-92.

suitably trained providers, and when surgical back-up facilities and skills are available to manage device displacements or early removals that could result in serious complications. Thus, the PrePex device has now been prequalified by the WHO.

As studies to determine the overall safety and efficacy of PrePex needed to gain WHO endorsement are nearing completion, it is important to conduct operations research to confirm the safety and acceptability of the PrePex device in routine use when circumcision is performed by mid-level providers and to determine how best to implement device circumcisions in national programmes.

iv. How could introduction of PrePex enhance South Africa's Programme

South Africa is currently using the forceps guided surgical method for providing VMMC. Circumcision devices, which make the procedure quicker, simpler and potentially more cost-effective, have the opportunity to make the provision of VMMC easier to scale-up, particularly because they can be used by non-physicians. Additionally, the use of a device may be more acceptable to potential clients, who often cite the fear of pain as a main barrier to getting circumcised. Devices are commonly used for circumcision in infants, but there is limited experience using devices for circumcision for adolescents and adults, particularly in Africa where circumcision for HIV prevention is rapidly being scaled up.

The WHO Framework for Clinical Evaluation of Devices for Adult Male Circumcision describes a minimum series of steps and clinical studies to evaluate the acceptability, clinical performance and safety of a new VMMC device in the country and setting of intended final use. These studies include clinical studies in the countries or settings of intended final use (initial case series, comparative studies and acceptability studies) and field studies in settings of intended final use. The information generated from this progression of clinical and programmatic research formed the basis for recommendations on use of the device in adult MC programmes in resource-limited settings. Furthermore, with a device, the procedure is simpler and faster compared to surgery because less surgical skill is needed, suturing, a time consuming portion of surgical circumcision is not required and procedures using both devices can safely be carried out by nurses, thus allowing task shifting.

b. Study Justification

Given limited financial and human resources to reach recommended MC targets in South Africa, it is imperative to take advantage of techniques that capitalise on efficiencies. In South Africa devices like PrePex, a nonsurgical method that can be performed by mid-level providers in a non-sterile setting could make it feasible to achieve recommended national targets with minimal burden on the healthcare system subsequently reducing the overall cost of human resource and infrastructure for VMMC. This pilot study generated quality data using objective criteria to determine the benefits, acceptability and risks of PrePex in South Africa. These data will assist the South African DOH with policy decisions and possible recommendations on the use and roll out of the device in adult male circumcision programmes including provider training, implementation of device circumcision, and messages for male clients and their partners in pre-procedure counselling sessions.

c. Goal, Objectives and Hypotheses of the Study

i. Study goal

To evaluate the acceptability and safety of the PrePex device for nonsurgical circumcision in routine clinical settings, as part of a comprehensive HIV prevention programme for healthy adult men in South Africa.

ii. Study objectives

There were four main objectives for this study:

1. To assess the feasibility and acceptance of clients and providers of the PrePex procedure in a routine clinical setting;
2. To assess the safety of the PrePex device when used by nurse providers in a routine clinical setting;
3. To assess the training needs of providers who place the PrePex device; and
4. To assess the cost of adding PrePex-based circumcisions to sites already providing surgical VMMC.

Thus the aims of the proposed pilot study were to:

1. Ascertain the training needs of mid-level providers, namely Enrolled Nurses under the supervision of Doctors, and the level of skill required to safely and effectively use PrePex for VMMC procedures;
2. Describe and assess the acceptability and reasons for acceptability of PrePex male circumcision amongst male clients and providers;
3. Describe and assess the safety of the PrePex device by the occurrence of clinical AEs, when circumcision is performed by Enrolled Nurses in South Africa; and
4. Derive per VMMC unit costs of circumcisions prior to and after introducing PrePex into facilities where a surgical circumcision programme is already established and fully functioning.

iii. Hypotheses

The following are the hypotheses, given the objectives of the study:

H₁: PrePex is both acceptable and feasible to clients and providers

H₂: The PrePex is safe to use when used by nurse providers in routine clinical settings

H₃: Introduction of PrePex-based circumcisions into facilities already conducting surgical circumcisions does not increase per circumcision unit costs at a facility by greater than 5%.

II. METHODOLOGY

This study was conducted in compliance with the protocol, as well as the applicable local regulations and guidelines as approved by the Ethics Committee at the University of the Witwatersrand. We recruited 803 men, aged 18 to 49 years. Study recruitment was TIME₀ (day of device application) and 56 days follow-up per participant. The study began on the 04 April 2014 and ended on 11 June 2015. There was two months of preparation and training prior to the fieldwork, with a further 3 months of data clean-up, report writing and dissemination of results after the fieldwork was completed.

a. Sample Size

The total number of male clients recruited for this study was 803. With a power of 80% and alpha 0.05, using the binomial exact test for small frequencies, a sample size of 803 and AE prevalence of 0.0175 had 95% confidence intervals of 0.0096 to 0.0292. Given the study budget, timeline and programme accrual in South Africa, a larger sample size with narrower confidence intervals was not feasible for recruitment. Thus, this sample size approach fixed the sample size based on what is feasible within the country and to estimate the confidence intervals around the observed AE rate. The total number of provider participants enrolled in the study was 9, including 6 Enrolled Nurses and three physicians.

b. Screening and Enrolment

Client participants were passively recruited among clients voluntarily seeking male circumcision services in the three selected sites, Zola Clinic, Katlehong North Clinic and Bophele Pele Orange Farm Clinic. Passive recruitment meant that outreach workers and staff did not actively go out and get clients for PrePex but instead offered both PrePex and blade-based circumcision to the client once the client came to the facility to undergo the circumcision procedure.

All clients received routine pre-circumcision services following the South African DOH protocol, including HIV testing, counselling, VMMC education and a brief physical examination.

Clients were informed of the opportunity to participate in a study, and those who were interested in learning more were directed to the Study Information Desk. There, prospective participants received a standard study information sheet that provided basic factual information about the pilot study.

Interested and eligible clients were screened for eligibility and assigned a Screen ID. Those who were eligible and interested reviewed the Client Consent Form with a study staff member. Those who provided signed consent to participate were enrolled and assigned a Study ID number. Clients who were eligible for surgical circumcision, but refused to enrol in the PrePex study or who were ineligible for PrePex were escorted to the surgical circumcision area of the clinic. The Enrolment Tracking Sheet was used to track the number of men receiving VMMC services, the number screening eligible and ineligible, and number of men that enrolled or refuse to enrol. Reasons for refusal to enrol in the study were also recorded. Other tracking tools to monitor participation and return visits were used, including the Study Activity Tracking Card.

If, following signed informed consent, further clinical examination results indicated that the participant was not suited for PrePex application; he was withdrawn from the study.

i. Client participant inclusion criteria

Potential participants received a medical history screening and a genital examination conducted by the PrePex provider to determine that they were in overall good physical health. Inclusion criteria included:

- Male between the ages of 18 to 49
- Uncircumcised
- Voluntarily seeking medical circumcision at one of the three study sites and wants to be circumcised
- Agrees to be circumcised using the study method, PrePex
- HIV sero-negative, confirmed by a rapid HIV test performed by the study counsellor before circumcision
- Penis fits into one of the five PrePex ring sizes
- Able to understand the study procedures and requirements
- Agrees to receive comprehensive pre and post circumcision care instructions
- Agrees to consent to not remove the device himself no matter what and to come back to the clinic if he changes his mind and want the device to be removed
- Agrees to return to the health care facility for scheduled series of follow-up visits (or as instructed) after circumcision, for a period of eight weeks
- Willing to have contact information used for study follow up (i.e., telephone number, address of residence, place of employment and other locator information)

- Has an activated mobile or landline telephone, or access to a mobile or landline telephone
- Agrees to photographs of the genital area document and medically manage moderate or severe AEs, in the rare event of their occurrence.
- Agrees to complete study surveys and medical evaluations in person at four time points:
 - Day 0 (pre-procedure; immediately post-device placement)
 - Day 7 (device removal)
 - Day 14 post-procedure
 - Day 28 post-procedure
 - Day 56 post-procedure
- Agrees to complete study telephone surveys at three time points:
 - Day 2 (device in situ)
 - Day 21 post-procedure
 - Day 28 post-procedure (no survey required; client will be sent SMS)
 - Day 35 post-procedure
 - Day 42 post-procedure
 - Day 49 post-procedure
- Able to communicate in English, Zulu or Sotho
- Capable and willing to provide written informed consent to participate

ii. Client participant exclusion criteria

Clients who did not meet the inclusion criteria described above and who had the following known medical conditions were excluded from the study:

- General Medical Conditions
 - Bleeding disorders or coagulation abnormalities
 - Uncontrolled diabetes
 - Uncontrolled hypertension
 - Clinical anaemia
 - Cognitive or psychiatric impairment
- Genital anatomic abnormalities
 - Phimosis and narrow prepuce opening
 - Paraphimosis

- Hypospadias
- Epispadias
- Tight frenulum
- Scrotal Hernia, Hydrocele and Undescended testis
- Other penile and scrotal structural abnormalities
- Active genital disease/infections
 - Active urethritis
 - Warts
 - Genital ulcers of any cause
- Other conditions, which in the opinion of the supervising circumcision physician, prevents the subject from undergoing a circumcision with the PrePex device

Clients who did not meet the study inclusion criteria or with contraindications for device circumcision were offered standard surgical circumcision (using the forceps-guided method) if appropriate. The number and reasons for such exclusions were recorded and in this report.

iii. Provider participant inclusion criteria

- Adult aged 18 or older
- Employed as a nurse or physician by CHAPS
- Trained in PrePex circumcision techniques for the current trial
- Able to understand the study procedures and requirements
- Agrees to complete study surveys and focus group discussions at four points:
 - During PrePex training
 - After PrePex training
 - At midpoint of study, following at least 10 weeks of client enrolment
 - At the conclusion of the study
- Able to communicate in English, Zulu or Sotho
- Capable and willing to provide written informed consent to participate

iv. Provider participant exclusion criteria

- Failure of PrePex circumcision training course

c. Informed Consent

Written informed consent was required for all participants. For Providers, the Provider Consent Form outlined the purposes, methods, risks, and benefits of the provider training evaluation, including abstraction of training proficiency records, and provider acceptability component of the study. The consent form included assurance that information providers offered would not be used for employment performance purposes, and that no harm or benefit would result from their participation. Study staff answered any questions posed by providers. Providers were reminded that participation was voluntary and the right to withdraw from the study without consequence was ever present.

For clients, eligible participants read the written consent form in English. Eligible participants were also given the opportunity to have any questions answered by study staff. Informed consent covered study procedures, potential risks, benefits, and contact persons for reporting complaints or concerns. Study staff explained the procedure and follow up visits in detail including the need to take photographs of the genital area in the rare event of a moderate or severe AE. Study staff told potential participants that the procedure would be classified as non-surgical VMMC and that the decision to become circumcised was permanent. Clients were informed that participation would assist the DOH to understand the best way to scale-up male circumcision and make it more accessible to men in South Africa. Study staff also notified potential participants that they had the right to withdraw from the study at any time; however, if they chose to withdraw from the study after the PrePex device has been placed, they would need to either complete the PrePex procedure or undergo surgical circumcision for medical reasons. Clients had the right to retract any data collected for research purposes upon withdrawal from the study.

A copy of the signed consent form was provided to participants. Another copy of the consent form was maintained in the site's study files in a locked file cabinet with access limited to study staff.

d. Device Placement

The PrePex device contains the following items: a placement ring (O-Ring Introducer) made of medical grade biocompatible plastic polymer that is highly used in the medical device industry; an inner ring made of medical grade biocompatible plastic polymer; and an O-Ring made of medical grade biocompatible elastic material.

The procedure was carried out in a clean, non-sterile environment. Providers applied anaesthetic cream to the eligible participant's penis immediately prior to the procedure and the penis was measured with the PrePex sizing plate to determine the size of the device to be used. The device placement site was disinfected, with the foreskin stretched back to expose the inner skin to the disinfection solution. The provider marked the circumcision line with a sterile skin marker and applied the appropriate size PrePex elastic ring to the placement ring and placed them on the shaft of the penis. The provider would grasp the top of the foreskin with gloved hands and dry gauze and stretch open the foreskin, applying the inner ring over the glans penis so that it would reach the corona of the glans (the base of the glans). The provider then approximated the elastic ring and placement ring to the inner ring. The foreskin was then adjusted to fit the circumcision line to the elastic ring, which was rolled over the foreskin to fit firmly around the inner ring to complete the procedure. The preparation and procedure time for the device application was measured and recorded.

At the end of the application procedure, Ibuprofen 400 mg (or the equivalent of another non-narcotic analgesic) was given to the participant to use at home if needed. The participant was asked to stay in the study site for one hour in order to monitor for post-procedure pain or complications. After the one hour observation period, the participant took part in a formal discharge session, where he was instructed to return at set follow up visits and to take painkillers in case of discomfort. The participant was also instructed to return to the study site in case of any unexpected event, for example if there was severe discoloration of the penis, signs of infection (purulence), severe or increasing pain, if the elastic ring moved, if the distal part of the foreskin detached, or any other significant concern that they may have had. All participants were provided with the phone number of the facility site coordinator that they could call at any time with questions or concerns. The participant were reminded to abstain from sex and to avoid masturbation.

On the seventh day following device application, the participant returned to the clinic to have the PrePex device removed along with the necrotic tissue of the distal part of the foreskin. The necrotised foreskin was removed using sterile scissors. The elastic ring was released after being cut with a scalpel

(surgical blade) and removed, and the inner ring was extracted using a spatula or gloved fingers. The provider would then examine the participant's genital area and determine if the results were within normal limits, and documented results in the Case Report Form. In the event of a complication meeting the case definition for a clinical AE, the provider documented the complication in the AE Case Report Form. The provider would then dress the wound with sterile gauze and secure the genital with adhesive tape. The participant would receive one dressing pad for home to change in case the dressing got wet. The preparation and procedure time for the device removal was measured and recorded. The participant was instructed to return to the study site in case of any unexpected event, to abstain from sex for eight weeks and to avoid masturbation. All reasons for removal of devices prior to Day 7 were documented in the Case Report Forms.

Complete healing was determined on Day 56, eight weeks following device placement, and was evaluated by visual inspection for complete epithelial covering of the wound.

e. Follow Up

i. *Follow-Up visits*

Each participant returned to the clinic on Day 7 to have the device removed. Following this, the client was required have two follow-up clinic visits to assess wound healing at 14 and 56 days after device placement. During both return visits, following device removal, the provider:

- Reviewed genital health and sexual activity and/or sexual function if applicable
- Examined penis and assess wound healing
- Reviewed AEs and SAEs, if applicable
- Reviewed concomitant medications, if applicable
- Provided HIV risk reduction counselling and condoms
- Scheduled additional follow-up visits, if necessary

The participant was instructed to return to the study site in case of any unexpected event, to abstain from sex for eight weeks (56 days) from the day of device placement, and to avoid masturbation.

The need to attend all scheduled clinic and study visits was emphasised to study participants during recruitment and enrolment and at each follow-up visit, phone call, and text message. If a participant

failed to appear for a scheduled clinic or study visit, up to five attempts to contact him were made to reach him by phone or SMS. Up to five additional attempts to follow-up participants would continue, including contacting the participant's alternate contacts or visiting his home to ensure as completed follow-up as possible with all participants. All missed appointments were rescheduled to a time that was convenient for the participant and consistent with clinic hours. All attempts to contact the participant will be recorded on a contact log in the participant's file. Attempts to contact the participant will be handled discretely to ensure confidentiality and privacy. Home visits may be attempted if a client fails to return to the clinic for device removal.

ii. Unscheduled visits

Additional visits sometimes occurred as needed for complications or AEs, or for wound healing that was delayed beyond 28 days. Men were told they should come for an unscheduled visit if they experienced medical events such as: difficulty urinating, increasing swelling with discoloration of the penis, signs of infection (purulence), severe or increasing pain, or any other significant concern. If any of these concerns were expressed by clients during study phone calls or text messages, the study staff had the physician supervisor onsite speak with the client by phone and recommend the appropriate course of action. During unscheduled visits, providers:

- Reviewed genital health and sexual activity and/or sexual function if applicable
- Examined penis and assess wound healing
- Reviewed AEs, if applicable
- Reviewed concomitant medications, if applicable
- Took photographs, if applicable
- Provided HIV risk reduction counselling and condoms
- Scheduled additional follow-up visits, if necessary

iii. Follow-up phone calls and messages

The study staff conducted follow-up phone calls with participants 3 days, 21 days, 35 days, 42 days and 49 days post-circumcision (post device placement). During the phone call, study staff would administer a standardised survey to assess participant healing, pain, discomfort, and satisfaction with the

procedure. A SMS text message was sent on Client Day 28. During all contacts with clients, the study team reminded clients of follow-up procedures and schedules, and would refer potential AE cases to the supervising physician.

f. Data Collection and Management

i. Data collection

Source documents for this study included, but were not limited to; screening and enrolment logs, informed consent forms, staff notes, medical notes, client CRFs, AE CRFs, surveys, participant reimbursement logs, programme and facility expenditure records, staff listings, commodity and equipment records, photographs and notes, and audio recordings and transcriptions from focus group discussions.

Clinical data collection included standard DOH clinical forms and study specific CRF and AE forms. The supervising physician onsite verified the completeness of medical forms. Cost data utilised study-specific cost data collection forms, combined with programmatic data collected prior to and during the study. Surveys and focus group discussions were administered by trained data collection staff. Once a survey form was completed, it was copied and given to a data entry clerk for data entry. The original form was retained in the participant file at the study site and the copy was stored in the locked CHAPS study office in a locked file cabinet.

The original client file, normally maintained by the clinic, contained all clinical documents. This source file was maintained securely at the site and was available only to the clinical providers and the study team. No names or other identifying information were collected on the various forms; only participant IDs were used for identification.

ii. Data entry

Once completed and verified, information contained on CRFs and AE forms in participant study folders was retained by the CHAPS study team for data entry. The data entry clerk at each site was responsible for data entry and the study coordinator was responsible for data management. Clinical data from the CRFs and AE forms was entered into a clinical database management system. Data-entry screens were

created for each form. For each question on the CRFs, the data entry screen contained a variable name, description, type and code list, if appropriate. All of the CRFs and AE forms were checked by the study coordinator for accuracy and quality control. Any inconsistencies were resolved with the help of the data entry clerk and study coordinator. The study coordinator documented the item with an apparent error; the original data stored in the data pilot, a description of the error/omission/inconsistency and revised data (if any). The study coordinator noted when the revision was made and the rationale for making the revision. The database was backed up on a daily basis.

All paper-based study forms were maintained in a secure, locked cabinet in the locked CHAPS study office and destroyed once the study was completed.

For the costing component of the study data from the facility surveys and information provided by CHAPS were entered directly into the costing model developed by the HPP research team. This model is a modified version of the DMPPT 1.0 costing model (Health Policy Initiative, 2010).

iii. Data management

Following data entry, the electronic files from the local data warehouse were uploaded by the data manager for inclusion in the central data warehouse at the end of each day. The study coordinator stored a back-up copy of the files on an encrypted external hard driver that was kept in a locked cabinet. The data manager uploaded all local files to a central data warehouse located on a password-protected computer.

The database was encrypted and maintained by the data manager in a central data warehouse.

The data manager performed continuous quality assurance checks to ensure that the database was cleaned and that there were no illogical responses. The data manager communicated with site staff to resolve the identified issues, if necessary. The data manager documented the item with an apparent error, the original data stored in the data pilot, a description of the error/omission/inconsistency, revised data (if any), noting who made the revision, when the revision was made, and the rationale for making the data change.

All databases were password protected and data was encrypted before transmission over public networks.

g. Measurement of Outcomes

i. Provider training evaluation

The assessment of PrePex training resulted from an abstraction of standard PrePex training materials that were part of the PrePex training curriculum, including training exams and trainee clinical assessments. Additional aspects of the training were explored through brief Provider Surveys that were self-administered immediately following the two-week training period, and again once they had gained more experience in using the PrePex device. The Provider Survey contained questions regarding providers' knowledge of the PrePex device, application procedures, and removal procedures; satisfaction with training; and recommendations to improve the training programme.

A focus group discussion and a structured questionnaire were administered with all the study clinicians to explore the strengths and weaknesses of the training, effectiveness of the training package and materials, satisfaction with the training and suggestions for improvement of the training and facilitation. Study clinicians were asked to answer the questionnaire before and after training, as well as after the first 75 procedures had been completed. The results and analysis of the three administered questionnaires informed the Focus Group Discussion (FGD) guide. The FGD was conducted at the end of the study with all study clinicians in order for researchers to explore these results in more depth.

ii. Provider proficiency and acceptability

Provider training, competency and initial acceptability were assessed. Following informed consent, service providers were asked to complete self-administered surveys to assess initial impressions of the device, acceptability of use, ease of use, perceptions of potential client acceptability, and training logistics issues. Each trainee provider was paired with another trainee, and each trainee received training as both PrePex primary providers and assistants (or secondary providers). All PrePex procedures in this group were closely supervised and tutored by the Master training team. When each trainee provider's PrePex skills were found acceptable by/through passing a formal training course, involving theoretical and practical tests given by the PrePex Master Training team, the provider was certified by the training team and permitted to participate in the study as a PrePex study provider.

A Provider Survey assessed providers' acceptance of the PrePex device following training, at the mid-point of the study. Survey questions focused on acceptability, ease of use, and providers' perceptions. Furthermore providers were interviewed to determine device acceptability, attitudes towards and experience with device circumcision, impact of offering male circumcision on clinical practice and barriers and facilitators of clinicians' implementation of device-supported circumcisions. They were interviewed before their training, post-training and after they completed 100 device-supported circumcisions.

Provider concerns and ideas regarding potential programmatic implementation of PrePex and future training recommendations were also solicited through focus group discussions. Topics that were introduced for discussion included logistics issues, areas to improve service delivery, impressions of task shifting, clinical waste management, infection prevention, client uptake, client communication issues, concerns regarding implementation, and future training recommendations.

iii. Client acceptability

The primary focus of the acceptability component of the study was to document attitudes towards and experiences with device circumcision from the provider, the client and the partner's perspective.

Using the Client Survey, clients were asked to provide their perspectives regarding the device before and immediately following the PrePex application (Day 0), midway during the week that the device remained in situ (between Day 2 and 5), and during device removal (Day 7). At each of these time points, clients were asked to rate comfort and pain, impressions of the device placement and removal procedures, and impressions of the device while in situ after application. During the week that the device was in place (Client Week 1), clients' self-reported overall emotional and physical comfort, pain, effect on activities of daily living, return to work, and overall satisfaction. Day 0, Day 7, Day 14, and Day 56 Client Surveys were self-administered onsite at the clinic site, unless clients preferred an interviewer to administer the survey. The Day 2 survey was interviewer-administered by phone.

At five time points during the healing process (Days 3, 21, 35, 42 and 49), clients were asked to complete a brief telephone survey regarding healing progress, satisfaction, and any sexual activity during the healing period. At the conclusion of the study, 8 weeks following PrePex placement and 7 weeks following PrePex removal, a final survey was conducted onsite to assess healing completion, satisfaction with cosmetic final results, healing time, and any residual complication on Day 56. Up to

two convenience samples (one at each site) of up to 10 clients each were asked to participate in a focus group discussion during the final visit (Client Day 56). The discussion explored clients overall impressions, and explore ideas for broader programmatic implementation, demand creation, and marketing approaches.

Furthermore, there were two (one at each site) focus group discussions (FGDs) of a minimum of 6 - 10 participants each with a group of those who opted for the surgical method exploring the reasons why they did not want to be circumcised using the PrePex device. In order for a more in-depth exploration of the reasons why men decided to circumcise or not circumcise with the PrePex device, questions for the FGD guides were adapted from preliminary results from the answers of the questionnaire survey. Acceptability of female partners was also assessed by interviewing female partners of men who are circumcised using the PrePex device, pre-procedure and 56 days post-procedure.

iv. Client safety

Eight hundred and three (803) clients were recruited and the safety of the device in the context of routine use by nurses and Doctors in South Africa were evaluated. All data collected from clients occurred following informed Client Consent procedures. The primary aim of the safety component was to monitor clinical AEs and device-related adverse incidents. Data on both general and device-related AEs were monitored using detailed Case Report Forms containing clinical records for each client. Clinical data was recorded at specific time points during PrePex application, immediately following application, and during the device removal procedure. The records and forms provided information on procedure and removal times, as well as any technical difficulties and complications experienced during the device application (Day 0) and removal processes (Day 7). Adverse Events classification of mild, moderate, or severe were clearly defined and were recorded on the AE CRF. AE definitions that were used were those as defined by PEPFAR. Clients' self-reported pain was recorded using a visual analogue scale (VAS), which was included in the PrePex Standard Operating Procedures (SOP) manual. The VAS was administered at four time points. These occurred before device placement, during device placement, 15 minutes after placement, and 60 minutes after placement. Client self-report of pain and any complications were solicited in the evening of Client Day 0 during a brief phone call to the client, and clients were encouraged to call in if they experienced pain. Additional visits in the first week occurred as needed for any problems or complications including but not restricted to bleeding, excessive swelling, pain, infection, difficult or burning on micturition, etc. Men were asked to come to the clinic immediately if they had these or any other problems that they thought were related to the

circumcision. If any potential complications or AEs warranting medical attention were reported during the phone call, the client was advised to return to the clinic for immediate medical evaluation.

A team of providers were on-call for the duration of the study to address any complications reported after clinic hours. Such instances were recorded in the CRF for the client and any AEs were documented on the AE CRF. The VAS was repeated during device removal.

To document any potential safety concerns, all clients were contacted once per week until the healing period was completed. If clients could not be reached on the first call, they were contacted every day until the client was reached. Providers were requested to record on the client's sheet if they were not able to reach the client by the end of each week. However, all attempts were made to establish contact with the clients; including contacting them using contact numbers of next-of-kin. These contacts involved administration of brief telephone survey to assess healing progress and inquire about sexual activity issues on Client Days 3, 21 and 35. On Client Day 28, an SMS was sent to the client reminding them to report any complications and abstain from sexual activity. At every encounter, a reminder to complete the next scheduled survey was given. During any telephone or SMS contact, if a client revealed or inquired about a medical complication, data collectors reported the concern to the medical team. A supervising physician consulted with the client by telephone, and advised the client to return to the clinic for a thorough medical evaluation if needed. All study clinicians and data collectors were thoroughly trained to use an abundance of caution for all medical issues reported by telephone, and to encourage clients to return for medical assessment for clinical concerns.

v. Costing

Costs were determined for the different categories as indicated below and compiled into data collection forms:

Personnel: The personnel costs were obtained by reviewing staff rosters that showed the titles of each staff member and their respective jobs. These were assessed in relation to the activities conducted within the VMMC programme by each staff cadre, as well as their pay scales. These costs also included the total hours and overtime hours worked by staff in the facility during the PrePex study implementation period and one year prior to the PrePex study implementation period. The levels of each member of staff were obtained from the human resources and/or finance departments at the facility or within the programme.

Time data was collected on five surgical procedures at each site, including pre-op and post-op activities, and used along with the time data collected on the PrePex procedure to facilitate allocation of personnel costs. In addition, five PrePex-based circumcisions at each study site were timed during the study. For each of these timings, the entire procedure, including group education, counselling, HIV and STI testing, physical exam, the circumcision procedure itself, and any associated activities were timed.

Drugs and supplies: Information on drugs, supplies and other consumables used in the VMMC programme were obtained from study implementation partners. In addition, information on the percentage and the number of adverse events needing specific drugs/supplies/other consumables and the price of each item used were obtained from the study implementation partners. The full lists of drugs, supplies and consumables used for VMMC were recorded in the data collection form.

Furniture and equipment: The furniture, equipment and other asset data were obtained from the asset register of the facilities implementing the pilot study. The cost of each piece of equipment, medical and non-medical, were obtained from the partners purchasing such inputs into the VMMC programme or from specific facilities. The cost of buildings was obtained from the partners, private housing agents or estimated based on current housing rates. Specific information includes purchase price, construction cost, or rental cost of each capital good (such as facility buildings, generators, vehicles, lab equipment etc.). Information on VMMC facility circumcision share, based on the service delivery model employed, were obtained and allocated for each of the capital items. The recommended WHO amortisation period for equipment and capital items was applied.

Consumables: The study used the list of commodities and supplies (set of disposable/reusable surgical instruments plus pack of consumables) recommended by WHO and which are being used in the South Africa model of conventional surgical male circumcision service delivery. A list of commodities and supplies for PrePex-based circumcisions was obtained from the PrePex manufacturer and was cross-checked against actual commodities and supplies utilised at each site during the study. In addition, information was obtained from each facility on the WHO recommended male circumcision emergency medical supplies. The unit cost of each category of commodities used for the VMMC programme at each site during and after the surgical procedure was estimated using prices from the study implementers.

Utilities: Utility costs include telephone, water, gas and electricity, maintenance of vehicles, and transport costs. The invoices for each utility were obtained from the accounts or finance department of the facility where available. Where no data were available at the facility, these were obtained from the study implementing partners.

Land and buildings: Building costs or annual rent equivalent, where applicable, was estimated by using current replacement values. The information on annual rent equivalent was obtained from facility managers or partners. In addition, the physical space utilised by each department including those being used for VMMC services, where measurable, was calculated using measuring devices. This information was used to estimate the cost of constructing the facility and to allocate indirect costs.

Volume of services: Information on general utilisation of services was obtained from programme registers and study documents. The nature of data collected included in-patient admissions for the overall facility, number of each type of VMMC performed (including the number of adverse events and their treatment) and total outpatient visits for all the conditions. Costs per circumcision performed were calculated with complications or adverse events both included and excluded. Adverse events costs were calculated in terms of emergency treatment including drugs, time, and personnel.

III. FINDINGS

a. Baseline and Patient Demographics and Information

Prior to being circumcised using PrePex, participants completed a pre-surgery questionnaire where they were asked questions about their socio-demographic characteristics as well as some information and questions regarding circumcision (in general as well as about PrePex in particular).

All participants were between the ages of 18 and 49 years old (Table 1). PrePex was only offered to men above the age of 18. Almost half of all participants (**44%**) were between the ages of 25 and 34 years, a further forty percent of participants were 18 to 24 years of age; while 15% were above the age of 35 years.

Table 1: Respondents' Ages (n=803)

Age	Frequency	Percentage
18-24 Years	323	40.2%
25-34 Years	356	44.3%
35-44 Years	108	13.5%
45 Years and Above	16	2.0%

Participants were asked about the highest grade or qualification they had completed (Table 2). None of the participants had completed less than Primary School, and the **majority at least had completed some high school**. Most had matriculated (68%), while 7% had a tertiary qualification.

Table 2: Highest Qualification (n=795)

Highest Qualification	Frequency	Percentage
Primary School	15	1.9%
Junior Secondary	176	21.9%
Senior Secondary	547	68.1%
Tertiary	56	7.0%
Don't Know	1	0.1%

Just under two thirds of all participants were working (45%) or studying (19%) (Table 3). Just under 20% stated that they were either looking for work or unemployed, 1 participants stated they had retired, and a further 1% stated that they took care of family or children or attended to the housework.

Table 3: Employment Status (n=803)

Employment Status	Frequency	Percentage
Working	359	44.7%
Going to School / Studying	153	19.1%
Looking for Work	135	16.8%
Retired	1	0.1%
Housework / Care for children or family	9	1.1%

Other	143	17.8%
Refuse to Answer	3	0.4%

Thirty-five percent of the total sample were unemployed. Of those participants who were employed (Table 4), 20% were students, 11% were labourers, 5% were in corporate and a further 5% were small business owners, while 5% were factory workers.

Table 4: Employment Type (for those who are employed) (n=763)

Employment Type	Frequency	Percentage
Unemployed	267	35%
Labourer	84	11.1%
Corporate	41	5.4%
Casual Worker	15	2%
Government Worker	14	1.8%
Domestic Worker	4	0.5%
Factory Worker	35	4.6%
Health Worker	4	0.4%
Small Business Owner	44	5.8%
Student	154	20.1%
Driver	38	5%
Teacher	3	0.4%
Other²²	60	7.9%
Refuse to Answer	1	0.1%

Religion of the participant was requested, **over two thirds (78%) were Christian**. The second largest groups (12%) stated that they did not have a religion, while 10 participants were Muslim and a further 56 classified themselves as “traditional” (Table 5).

Table 5: Religion (n=797)

Religion	Frequency	Percentage
I don't have a religion	96	12.0%
Christian	623	77.6%
Muslim	10	1.25%
Traditional	56	7.0%
Other	3	0.4%
Don't Know	9	1.1%

Almost two thirds of participants (61%) had a girlfriend or partner but did not live with them, while 21% participants were either married or lived with their girlfriend or partner. Only 18% of participants were not currently in a relationship (Table 6).

Table 6: Relationship Status (n=796)

²² Security, Retail, Sales, Playing Soccer, Catering/Chef, Dispatcher Clerk

Relationship Status	Frequency	Percentage
Not in a relationship	145	18.1%
Married	86	10.7%
Live-in Girlfriend / Partner	79	9.8%
Don't live with Girlfriend / Partner	486	60.5%

In order to assess participants social situation, they were requested to report on how many people lived in their household (Table 7), and also what source they got their water from (Table 8) and whether their homes had electricity (Table 9).

Only around 17% of participants had more than 6 members living with them in their homes, while 35% had 2 or 3 and further 32% either just had one person or had between 4 and 5 people living in their homes.

Table 7: Number of People in Household (n=797)

People in Household	Frequency	Percentage
1	128	16.0%
2-3	277	34.5%
4-5	253	31.5%
6-7	88	11%
>8	51	6.4%

Only 1% of participants got water from a community tap; while less than 1% got water from a borehole, river / dam or from collecting rain water. All other participants (97%) got water from a tap inside their home.

Table 8: Water Source (n=793)

Water Source	Frequency	Percentage
Tap water in house	775	96.5%
Tap water from community pump	8	1.0%
Borehole	5	0.6%
River / Dam water	4	0.5%
Collect rain water	1	0.1%

Thirty-six participants did not have electricity at home, while almost 95% stated that they did.

Table 9: Electricity at Home (n=798)

Electricity at Home	Frequency	Percentage
No	36	4.5%
Yes	762	94.9%

Participants' were asked to answer "True or False" to the statements that could show their knowledge on circumcision (table 10). The first statement asked participants whether or not men who are circumcised can never get a sexually transmitted infection. This was used to measure the participants'

knowledge of the protective effect that circumcision has to the transmission of the HI virus. Almost 93% of men stated that this was false. Although this is high, it was worrisome that 54 participants thought this statement was true and 3 participants did not know.

Participants were then asked to answer true or false to whether men who are circumcised can never get HIV. Ninety-seven percent (97%) stated that this was false, but twenty-two (22) participants thought this statement to be true.

Finally, participants were asked to answer true or false to if a man is circumcised, he does not need to use condoms. Although twenty-two (22) participants thought this statement to be true, the majority (97%) knew that this was not true.

Table 10: Circumcision Knowledge

	Frequency	Percentage
Knowledge of Circumcision's Protective Effect (n=802)		
False	745	92.8%
True	54	6.7%
Don't Know	3	0.4%
Knowledge of Whether Men who are Circumcised Can Ever get HIV (n=803)		
False	779	97.0%
True	22	2.7%
Don't Know	2	0.3%
Knowledge of Whether Men who are Circumcised Still Need to Use Condoms (n=800)		
False	777	96.8%
True	22	2.7%
Don't Know	1	0.1%

In order to understand the reasoning behind the decision making of why men undergo circumcision and their rationale for choosing between PrePex and surgical circumcision methods, both men who underwent PrePex and surgical circumcision were engaged in focus group discussions. In addition, women whose male partners underwent PrePex circumcision were interviewed.

In general, **all male participants regardless of area (Orange Farm, Katlehong and Zola) had background knowledge and information regarding circumcision.** The majority of male participants identified the benefits of male circumcision.

"The other benefits are that circumcision reduces the risk of contracting HIV by 60% amongst other things"

Katlehong, Male, PrePex

"The benefits include being at a less risk when it comes to STDs amongst other things but this however doesn't make us immune to the diseases, it just places

us at a lower risk. The way they explain it, in a way once I get circumcised then my life is no longer at an excessive risk of contracting HIV as compared to when I still have a foreskin. The presence of the foreskin make some susceptible to contracting these STDs as the foreskin absorbs all these diseases and I cannot rinse them off as it were”

Orange Farm, Male, PrePex

While it was clear that **many male participants understood that circumcision reduced their risk of contracting HIV and other related infections**, others recognised other added benefits:

“Talking about benefits, circumcision allows one to clean the penis properly and it brings about hygienic benefits.”

Further, male participants received information on circumcision from clinics when they went in to test for HIV: A few participants received information from advertisements and brochures.

“I got some of the knowledge here at this place [clinic] because they always group us into classes and educate us on everything that we need to know on circumcision. The sisters were very helpful in making us understand, plus there is an information brochure that one can take home with to read in more detail. I knew most of the information before I got circumcised and it was here that I got circumcised and they imparted a lot of information to me.”

Orange Farm, Male, PrePex

“I think most of the information was disseminated by Brothers for Life, I also got information from where I work because there was too much absenteeism and they decided to check people for HIV and they then said if we wanted to know more about HIV/AIDS we could ask and so I got information on MMC.”

Male, Surgical

One male received information on circumcision through a multitude of sources, which eventually convinced him to consider undergoing the procedure:

“There was always a lot of coverage on circumcision on TV and on the internet there were just too many articles on it. I took the decision because I had too much information about MMC. The recruiters, the media and the internet all convinced me to finally go ahead.”

Male, Surgical

In addition, the spread of knowledge among participants regarding the benefits of circumcision was through word of mouth from friends, family members, partners and recruiters.

“There were fieldworkers who told me about it, we met on the street and they introduced the subject and straight away I told them I was going to be at the clinic the very next day. I was invited to a secluded room before I met up with the counsellor and the nurses, in that room the attendants told me everything that I needed to know about circumcision, how it would benefit me and what its disadvantages would be. They also conducted lessons on proper condom use; they told us not to use our teeth to tear open condoms...”

Katlehong, Male, PrePex

“I would like to point out that there are recruiters from here who gave us all the information we needed and they answered all our questions. These recruiters can be found in more than one location [and] they explain everything in great detail and leave you feeling positive about circumcising.”

Male, Surgical

“It was my girlfriend who encouraged me to go on and get circumcised because I wouldn’t carry on with intercourse after the pain started. My girlfriend was the first person to ever talk to me about circumcision and from that point on I gave it some serious thought. I then decided to come to the clinic and they gave me more detail.”

Male, Surgical

Female partners of the male participants for both surgical and PrePex circumcision had heard of the benefits associated with circumcision. Many females identified that the risk of contracting HIV and other infections is minimized.

“If your partner gets circumcised, to a certain extent you both reduce the risk of contracting STDs and STIs and as a female you get a lower risk of contracting cervical cancer and other things along those lines. That was how I knew about it and that it is a good thing that he must do because it also grants me some protection as a female so that in future we can have healthy children and we can enjoy good health”

Katlehong, Female

Numerous female partners acquired information on circumcision from either clinics or through advertisements on billboards:

“I have heard about circumcision from the clinic and also read from the Billboards that circumcision it prevents a lot of sexual diseases like HIV penile and vaginal infections, and also that it was rolled out a prevention measure in clinics since HIV was so prevalent”

Zola, Female

“They [at the clinic] also mentioned that you should still continue using condoms even when you are circumcised”

Orange Farm, Female

Participants’ were asked to answer “Yes or No” to the question “Have you had sex in the past 3 months?” The majority (74%) had stated that they had. This includes those who stated they were married, living with a partner/girlfriend, as well as those who had partners/girlfriends but were not living with them.

Table 11: Had Sex in the Past 3 Months (n=790)

Participant Answer	Frequency	Percentage
No	196	24.4%
Yes	594	74.0%

In table 12 below, the number of partners that participants had in the past three months is shown. **Almost two thirds (60%) only had one partner over the past three months** – presumably their wives or partners. Eighty-three (83) had two sexual partners, while thirty-three (33) had between 3 and 6.

Table 12: Number of Partners Participant Had Sex with in the Past 3 Months (n=602)

Participant Answer	Frequency	Percentage
0	2	0.3%
1	484	60.3%
2	83	10.3%
3	25	3.1%
4	4	0.5%
5	3	0.4%
6	1	0.1%

Although just over 90% of participants stated that they had sex with their wife or girlfriend, **five had sex with a sex worker while 37 had sex with “other people”** (Table 13).

Table 13: People that Participants Had Sex with (n=638) *[More than one answer could be selected]*

Participant Answer	Frequency	Percentage
Wife	91	14.3%
Girlfriend	495	77.6%
Sex Worker	5	0.8%
Other	37	5.8%
Refuse to Answer	10	1.6%

Participants’ were asked to answer Yes or No to the question “Have you used a condom in the past 3 months?” (Table 14). Around two thirds of participants had, while one third of participants (36%) had not. Two participants refused to answer.

Table 14: Used Condom in the Past 3 Months (n=574)

Participant Answer	Frequency	Percentage
No	208	36.2%
Yes	364	63.4%
Refuse to Answer	2	0.3%

Over a third of participants used condoms to avoid HIV infection while another third was to avoid other STIs. Just under a quarter of participants also stated that they used condoms to avoid pregnancy (Table 15).

Three hundred and fifty two (352) participants whom had used condoms in the past 3 months had sex with their wives or girlfriends, three with a sex worker, and a further 36 participants stated “other”.

Table 15: Reasons Participants Used Condoms in the Last 3 Months (n=1917) *[More than one answer could be selected]*

Participant Answer	Frequency	Percentage
Avoid HIV Infection	693	36.2%

Avoid Sexually Transmitted Infections	669	34.9%
Prevent Pregnancy	460	24.0%
My Partner Insisted	33	1.7%
Everybody Else is Using One	3	0.2%
It Is Cleaner	2	0.1%
Other	47	2.5%
Don't Know	7	0.4%
Refuse to Answer	3	0.2%

Participants who had not used condoms were asked what the reason for this was (table 16). **Almost 15% of participants stated they did not use condoms because “they trusted their partners”, while just over 40% said they did not use condoms because they “loved their partner”.** Around 7% of participants said they “*did not have condoms*”, while just over 6% did not use condoms because their wife or partner “*was either pregnant or trying to fall pregnant*”.

Table 16: Reasons Participants Do Not Use Condoms (n=174) [More than one answer could be selected]

Participant Answer	Frequency	Percentage
I am married	3	1.7%
I trust my sex partner	26	14.9%
I love my sex partner	70	40.2%
I forget to use them when I am drunk	5	2.9%
Sex is better without condoms	6	3.4%
My sex partner doesn't want to use condoms	6	3.4%
My religious or traditional beliefs prevent me from using condoms	2	1.1%
Condoms irritate my/ my partner's skin	7	4.0%
I don't have any condoms	12	6.9%
Condoms are too expensive	1	0.6%
My wife or girlfriend is pregnant or trying to get pregnant	11	6.3%
I don't think using condoms are necessary	1	0.6%
I don't think about using condoms	4	2.3%
I do not like the way condoms feel	2	1.1%
Other	16	9.2%
Don't Know	2	1.1%

Participants were asked about their decision on why they decided to circumcise (Table 17a). **Over a quarter (29%) stated it was to reduce risk of HIV while a further quarter (29%) said it was to reduce the risk of other STIs.** Just under a quarter (20%) wanted to improve penis hygiene, 11% had always wanted to be circumcised, and another 8% wanted to improve their penis's appearance. A handful of

participants also noted that it was because they were encouraged by a partner, family member or friends. Seven participants stated they did it because they wanted to be seen as “modern”.

Table 17 (a): Reasons Participants Decided to Get Circumcised Prior to Doing the Circumcision (n=2444) [More than one answer could be selected]

Participant Answer	Frequency	Percentage
Reduced risk of HIV infection	713	29.2%
Reduced risk of STIs	716	29.3%
Improved penis hygiene	487	19.9%
Improved penis appearance	187	7.7%
My partner encouraged me	95	3.9%
My parent encouraged me	17	0.7%
My friends encouraged me	29	1.2%
I want to be more modern	7	0.3%
Religious or Cultural reasons	11	0.5%
I have always wanted to be circumcised	132	5.4%
Other	50	2.1%

While Table 17a provides an overall understanding of the reasons participants decided to circumcise, Table 17b examines the proportion of participants’ reasons for circumcision prior to being circumcised in relation to the sample size of 801. As was found in Table 17a, “the reduced risk of HIV infection” (89%) and “reduced risk of STIs” (89.4%) were the most significant reasons for why participants decided to be circumcised prior to performing the circumcision. This was followed by “improved penis hygiene” (60.8%).

Table 17 (b): Proportion of the “Reasons Participants Decided to Get Circumcised Prior to Doing the Circumcision” (n=801) [More than one answer could be selected]

Participant Answer	Frequency	Percentage
Reduced risk of HIV infection	713	89%
Reduced risk of STIs	716	89.4%
Improved penis hygiene	487	60.8%
Improved penis appearance	187	23.3%
My partner encouraged me	95	11.9%
My parent encouraged me	17	2.1%
My friends encouraged me	29	3.6%
I want to be more modern	7	0.9%
Religious or Cultural reasons	11	1.4%
I have always wanted to be circumcised	132	16.5%
Other	50	6.2%

Amongst FGD participants’ numerous men decided to undergo the circumcision procedure to safeguard themselves against infections such as HIV and STIs.

“I knew the pain would be there, I however weighed the pain of getting circumcised and the pain of living life with HIV/AIDS, I realised it would do me

good to experience the pain now and prevent suffering later in life if I contract the disease hence I got circumcised."

Male, Surgical

The fear of societal rebuke and being mocked by friends as well as wanting to avoid the stigma associated with not being circumcised encouraged male participants to get circumcised.

"I decided to get circumcised I dreaded the thought of being laughed by my peers if I lost my partner to a circumcised guy seeing that seemingly girls enjoy sex with circumcised guys."

Male, Surgical

"If I remained uncircumcised, I would be stigmatized and called names whenever the topic on MMC came on board. I decided to free myself of that burden and get circumcised so that communication with my peers would be on par. I wasn't going to be the odd one out. I can imagine having to hide away whenever I have to leak in the presence of a friend. It could have happened that I was going to start peeling away from the crew for fear of being marginalised and always picked on; hence I decided to go and get circumcised. It is worse in the rural areas with regards to discriminating against uncircumcised men."

Male, Surgical

The further possibility of losing female sexual partners as a result of the foreskin encouraged other male participants to get circumcised.

"What really got me to go and get circumcised was that I knew of the benefits of circumcision that it reduces the risk of contracting HIV and other STIs but what really prompted me [is] I have a girlfriend and she always mentioned that she was not happy with me having a foreskin, she kept on going on about it; well I always knew that I would go."

Zola, Male, PrePex

Both PrePex and surgical participants discussed the reasons why they opted for their chosen method of circumcision. Many of the PrePex participants were informed about the device as a result of knowing someone from the clinic.

"My sister encouraged me, she works here at the clinic and she gave me all the information that I needed and she also influenced my decision to opt for the PrePex. I didn't tell my girlfriend before, she was however happy after I had already circumcised because in a way she had always encouraged me to do so. She did encourage me before but I never took heed mostly because I couldn't bear the pain after the bad experiences that I had seen those before me endure"

Katlehong, Male, PrePex

The main reason women encouraged their partners to circumcise was related to hygiene, health and pleasure. Female partners were in consensus that it was not hygienic for men to have a foreskin as they

felt especially uncomfortable engaging in oral sex. Further, penetrative sex was seen to be less enjoyable than if their male partner was circumcised.

“One other thing is when a male person takes a bath and he still has a foreskin it is not easy for him to clean his penis thoroughly, and it doesn’t become clean because you will still find that there are still some germs that is left inside the penis”

Orange Farm, Female

“He becomes better in terms of sexual performance so in a way it made sense that he gets circumcised so that we could be exposed to lower risks of infection and yet enjoy sexual pleasure...I have heard that the male also gets a boost on sexual endurance by virtue of getting circumcised.”

Katlehong, Female

Female partners used various methods in order to encourage and convince their partners to undergo VMMC. This ranged from refusing to perform oral sex to constantly focused discussions on the topic. **Many females encouraged their partners to go for circumcision by engaging in conversations regarding circumcision benefits following a television advertisement** on the topic while others insisted upon practising safe sex as a couple.

“I initiated the discussion because it started with my mother taking my last born brother to the clinic and he did it and he was fine, then our son also did it and he was also fine, so then I told him that he should also go and circumcise because from what I have heard it helps in reducing the risks of contracting sexually transmitted diseases and he told me that he was scared but I kept on talking to him because he was over 40 years and my other brother has also done it at Bara hospital and he was also over 40 years. So I am the one who kept on hammering the idea to him... one thing that influenced him was that his best friend was also not circumcised and they convinced each other to do it together.”

Zola, Female

“We decided that in order for us to have a healthy relationship we should go and test for HIV test and it became negative and then he said that in order for us to live a better life he should go and do circumcision.”

Katlehong, Female

“He was bothered as to why [we] used condoms- explained to him that the reason we are using condoms is that I don’t feel safe having unprotected sex because you are not circumcised.”

Orange Farm, Female

The motivation and reassurance from one female helped to convince her male partner despite the fear they both experienced regarding the procedure.

"I also had to motivate him as he was scared of the fact that he might die in the process. I did admit that the thought is scary but that doing it at the clinic was the safer option. I talked him out of the traditional circumcision route."

Katlehong, Female

A strategy used by one female partner was to enlist the additional help of nurses at clinics in order to persuade her partner to consider circumcision by explaining the benefits of circumcision.

"When we got to the clinic (because we were also going to test for HIV), I approached one of the senior nurses and explained to her that I came with my partner to test for HIV and I also want him to circumcise but he doesn't understand the importance of it, can she as a professional talk to him and try to make him understand. She talked and managed to get through to him"

Orange Farm, Female

The issue of which method of circumcision male participants chose and the reasons for their choice was raised in the FGD. **Most men chose PrePex as a method because of its absence of needles, stitches and blood loss.** The experiences of men who underwent surgical circumcision convinced many men to choose PrePex:

"In my case the needles and the fact that I was going to get stitches always made me reluctant to get circumcised because mostly my body doesn't respond well to stitches because at times it swells up and takes longer to heal hence I was reluctant to get circumcised".

Orange Farm, Male, PrePex

"I also asked around from my peers and one of them said that they had an adverse event in that the sutures ruptured and others would say that the anaesthetic wore off prematurely. Well I have had sutures before and I know how painful they can get so I decided to try PrePex, seeing that there were no stitches involved and it was neater."

Zola, Male, PrePex

PrePex had the added benefit of allowing men to continue working without requiring them to change their work schedules:

"They said that PrePex allows one to work freely compared to the surgical method, all I would have to do was wait for the 7 day period and then come back and remove the device. I am a very industrious person and PrePex would fit my schedule pretty well hence I took it up."

Zola, Male, PrePex

"I decided to go with it since it would not affect my work schedule."

Zola, Male, PrePex

"PrePex is a blessing, it allows one to get on with their business as if nothing is wrong, in my case I managed to service a vehicle on the same day that I put the

PrePex on, I wouldn't have been able to do this had I went for the surgical MMC."

Katlehong, Male, PrePex

Conversely, **male participants who chose surgical circumcision over PrePex circumcision did so as a result of the amount of time it takes to heal after the procedure.** The additional two weeks healing period hindered them from choosing PrePex.

"The benefits amongst other things are that one can install the PrePex and immediately get on with their day to day activities, on the other hand, I compared the 8 weeks PrePex healing period to the 6 weeks of the surgical healing period and as such I concluded that those 2 weeks were just too long for my liking."

Male, Surgical

The **prospect of having to wear the device for seven days was seen as an inconvenience and thus was unfavourable among the participants.** Further, PrePex was seen as an inconvenience given that they had to go back to the clinic to remove the device.

"I enjoyed the fact that I could literally take the bandages off the next day unlike with PrePex where it stays on for 7 days."

Male, Surgical

"I lost interest in the PrePex because of the fact that the device still has to be removed... that to me is time wasting. Surgical MMC is a once off affair and once it is done that's it,"

Male, Surgical

Men who knew participants who had undergone PrePex circumcision were discouraged by the pain experienced during the procedure.

"The PrePex device is a bit scary and worse I have heard that it is a bit painful when you have to go back and remove it."

Male, Surgical

One male participant **expressed his reluctance to undergo a procedure that is new and still requires testing:**

"It was basically just the fear of the unknown, in South Africa PrePex is relatively still a new concept and I wasn't going to be the guinea pig to be piloted on. I can imagine being the first victim of the negative results that it may bring about. No thank you; I will rather leave the pioneering to others."

Male, Surgical

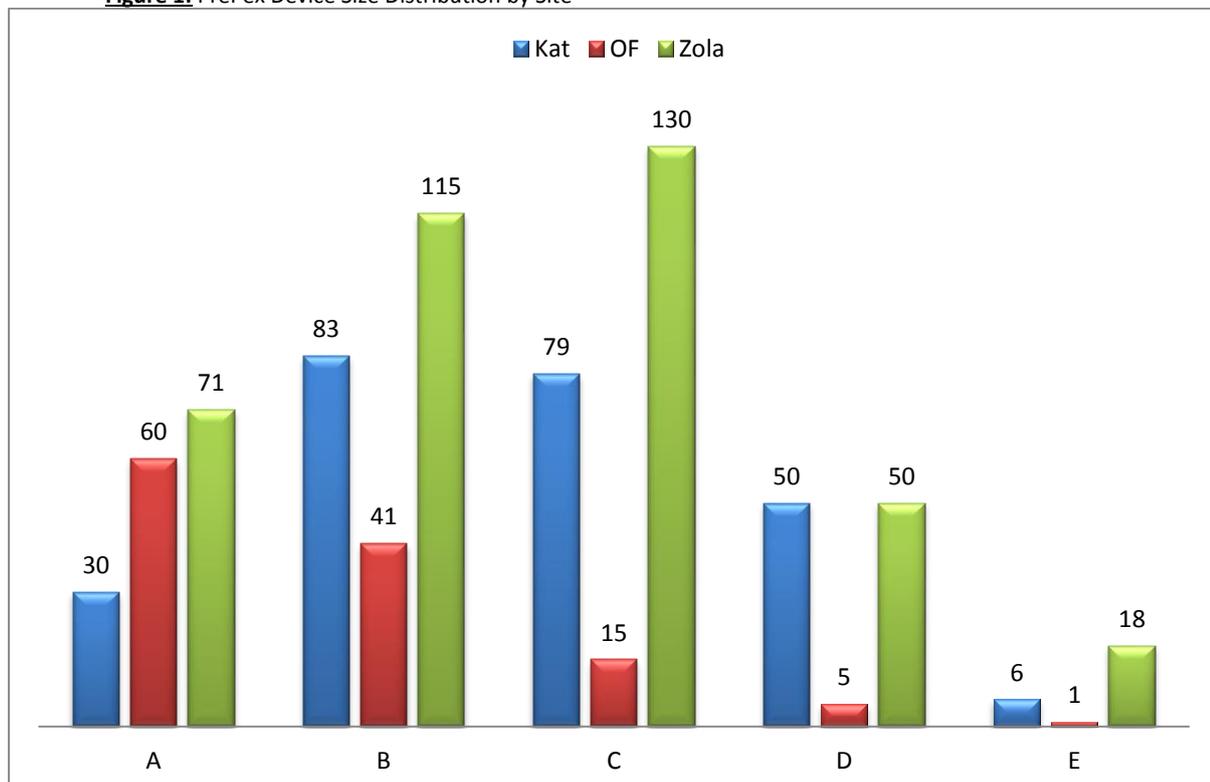
The biggest concern men had about being circumcised was that they were worried that they may not like the way their penis feels (37%), followed by there may be a medical complication (6%) and that the healing time was too long (6%), and that it would be hard not to masturbate or have sex (6%) (Table 18).

Table 18: Concerns Participants Had on Being Circumcised Prior to Doing the Circumcision (n=219) [More than one answer could be selected]

Participant Answer	Frequency	Percentage
Procedure may be painful	17	7.8%
I might not be able to work or be active	5	2.3%
My partner might not approve	1	0.5%
My family/friends might not approve	1	0.5%
There might be a medical complication	13	6.0%
The healing time (6 weeks) is very long	13	6.0%
It will be hard to not have sex or masturbate for 6 weeks	12	5.5%
Sex might not feel the same	5	2.3%
I may not like the way my penis looks	3	1.4%
I may not like the way my penis feels	81	37.0%
I could die from the procedure	2	1.0%
Other	66	30.1%

Figure 1 below shows the distribution of PrePex sizes by site. In Orange Farm the greatest number of clients were size A, followed by size B; in Katlehong the greatest number of clients were size B, followed by size C; and in Zola the greatest number of clients were size C, followed by size B.

Figure 1: PrePex Device Size Distribution by Site



b. Safety and Efficacy of the PrePex Device

i. Moderate and severe adverse events

The primary aim of the safety component of the study was to monitor clinical Adverse Events (AEs) and device-related adverse incidents. Data on both general and device-related AEs were monitored using detailed Case Report Forms (CRF) containing clinical records for each client. Clinical data was recorded at specific time points during PrePex application, immediately following application, and during the device removal procedure. The records and forms provided information on procedures, as well as any technical difficulties and complications experienced during the device circumcision procedure. Adverse Events classification of mild, moderate, or severe were clearly defined and were recorded on the AE CRF.

Clients were told to come in to the clinic for any additional visits, or unscheduled follow-ups, in the first week if required for any problems or complications including but not restricted to bleeding, excessive swelling, pain, infection, difficulty or burning on urination, etc. Men were asked to come to the clinic immediately if they had these or any other problems that they thought could be related to the circumcision. If any potential complications or AEs warranting medical attention were reported during the phone call, the client was advised to return to the clinic for immediate medical evaluation.

AE definitions that were used were those as defined by PEPFAR.

In total there were twenty (20) AEs (in sixteen (16) people) out of 803 circumcisions, with an **AE rate of 2.5%**.

ii. *Study withdrawals and AE case descriptions*

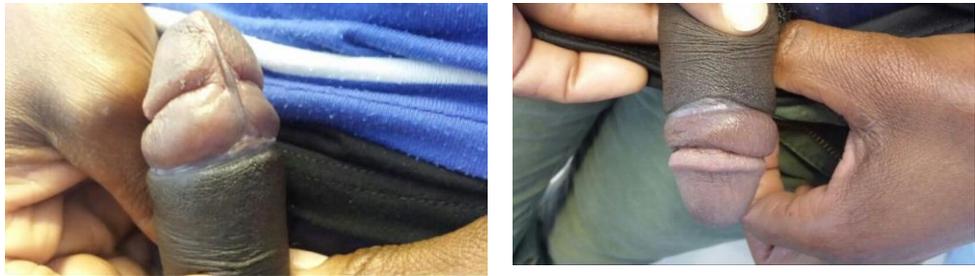
There were a number of clients who were withdrawn before application of device:

- **Client 102 – Orange Farm (2 April 2014):** Client 102 was enrolled in the study and was found to have Balinitis/Posthitis by the clinicians. As a result, the PrePex device could not be applied and he went home to think about a surgical circumcision.
- **Client 206 – Katlehong (7 April 2014):** Client 206 was enrolled in the study and was found to have Genital Warts by the clinicians. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 217 – Katlehong (16 April 2014):** Client 217 was enrolled in the study and was found to have Genital Warts by the clinicians. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 218 – Katlehong (17 April 2014):** Client 218 was enrolled in the study and was found to have Genital Warts by the clinicians. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 124 – Orange Farm (6 May 2014):** Client 124 was enrolled in the study and was found to have an Infectious/traumatic ulcer by the clinicians. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 130- Orange Farm (12 May 2014):** Client 130 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied. The client did not have a surgical circumcision.
- **Client 133- Orange Farm (14 May 2014):** Client 133 was enrolled in the study and it was found that he had a tear in his foreskin. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 139- Orange Farm (22 May 2014):** Client 139 was enrolled in the study and was found to have an ulcer by the clinicians. As a result, the PrePex device could not be applied. The client did not have a surgical circumcision.
- **Client 142- Orange Farm (22 May 2014):** Client 142 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.

- **Client 144- Orange Farm (22 May 2014):** Client 144 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 148- Orange Farm (23 May 2014):** Client 148 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 178- Orange Farm (4 July 2014):** Client 178 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 187- Orange Farm (15 July 2014):** Client 187 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 192- Orange Farm (15 July 2014):** Client 192 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied. Status of surgical circumcision is not specified.
- **Client 198- Orange Farm (18 July 2014):** Client 198 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 519- Orange Farm (15 August 2014):** Client 519 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 521- Orange Farm (22 August 2014):** Client 521 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 522- Orange Farm (22 August 2014):** Client 522 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 532- Orange Farm (11 November 2014):** Client 532 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 732 – Katlehong (9 January 2015):** Client 732 was enrolled in the study, client left clinic before placement- before seeing clinician for clinical exam and device size.

- **Client 763 – Katlehong (10 April 2015):** Client 763 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 551- Orange Farm (13 April 2015):** Client 551 was enrolled in the study and it was found that there was a “lack of fitting” of the study device. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.
- **Client 765- Katlehong (13 April 2015):** Client 765 was enrolled in the study and it was found that he had “tight foreskin”. As a result, the PrePex device could not be applied and the client had a surgical circumcision instead.

The descriptions and pictures below describe all the withdrawal and AE case studies that occurred during the study:

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 101)	2 April 2014	31	28 May 2014	Moderate	Swelling	Client returned to the clinic on day 56 for his final follow-up and still had moderate swelling. He was advised to elevate and compress the penis. 

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (client 204)	3 April 2014	29	-	-	Not contactable	Client 204 was enrolled in the study and had the PrePex™ device applied on Thursday 3 April. The client returned for a regular device removal visit on 10 April. The client was withdrawn from the study as he was not contactable for/unwilling to complete the telephonic interviews.
Katlehong (client 222)	23 April 2014	40	12 May 2014	Moderate	Infection	Client had moderate infection on day 19 (after device removal). Client was given oral antibiotics which resolved the infection completely.
Katlehong (client 226)	30 April 2014	27	-	-	Device removed by his GP	Client 226 was enrolled in the study and had the PrePex™ device applied on Wednesday 30 April. The client informed the study team that he had to travel to Cape Town for a work conference before day 7, and that he would get the device removed at his doctor. Both the nurse and the call centre agent called the client and told him to return to the clinic for an early removal but the client refused. The study team, including the chief medical officer for Prepex tried to contact him on numerous occasions but he would put the phone down on them. The research coordinator reached him on 9 May and the client said that he had had the device removed at his GP on day 7 and that he was fine and did not require any follow up visits.

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (client 034)	8 May 2014	31	9 May 2014	Severe	Pain / problems voiding	<p>Client 034 was enrolled in the study and had the PrePex™ device applied on Thursday 8 May. In the early hours of 9 May (day 1), the client experienced terrible pain and had difficulty urinating. As a result, he phoned the ambulance and the paramedic removed the device and took the client to Chiawelo clinic. He was seen by a doctor in the Urology department who reported that the client's foreskin was swollen. Later on that day the client went back to Zola clinic and for an examination and declined a surgical circumcision, saying that he no longer wanted to be circumcised. The client returned to Zola clinic again on 12 May (4 days after placement) with swelling and blisters on his foreskin (above the original placement site of the device), threatening to contact the newspaper (Daily Sun) with his story. Both the chief medical officer for the Prepex study and a study doctor performed a surgical circumcision under local anaesthetic as the foreskin was in the early stages of necrosis. A modified dorsal slit circumcision was performed and the client is expected to make a full recovery with no further complications.</p> <div style="display: flex; justify-content: space-around;">   </div>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (client 265)	28 May 2014	28	20 June 2014	Moderate	Insufficient skin removal	Client returned to the clinic on day 23 after device removal, with the prepuce partially covering the glans when flaccid, although surgical correction was found to be unnecessary.
Zola (client 061)	28 May 2014	35	3 June 2014	-	-	Client 061 was enrolled in the study and had the PrePex™ device applied on Wednesday 28 May. He returned to the clinic for removal on day 6 (3 June) as he felt the device was ready for removal. The device was removed with the foreskin and everything is fine. No AEs.
Katlehong (client 210)	15 April 2014	26	22 April 2014	Severe	Pain	Clinician administered a ring-block in order to remove the device on day 7 as the client experienced severe pain.

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 121)	5 May 2014	20	-	-	Self-removal	Client 121 was enrolled in the study and had the PrePex™ device applied on Monday 5 May. The call centre agent was not able to contact him for the telephonic follow-ups as the number he provided did not exist. The client did not return on day 7 (12 May) for removal, so the CHAPS driver went to the clients house twice on the 13 th May but he was not home – the CHAPS driver got the phone number of his neighbour. The call centre agent contacted the client on his neighbour’s phone on 14 May and he said that he had removed the device himself at 6pm on the day it was placed due to pain (day 0; 5 May). He told the call centre agent that he no longer wants to be circumcised and that is why he didn’t return to the clinic. After much persuasion, the call centre agent managed to convince him to return to the clinic (for a check-up, risk of infection, compensation etc.) and he confirmed his address on the phone. When the CHAPS driver arrived at his house shortly after the call centre agent had spoken to the client, he had run away. The client has never come back to the clinic and was withdrawn from the study.

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (client 243)	12 May 2014	35	19 May 2014	Severe	Paraphimosis / swelling	<p>Client 243 was enrolled in the study and had the PrePex™ device applied on Monday 12 May. He returned for his removal on day 7 (19 May) as per normal but was very swollen (he did not report the swelling during his telephonic follow-up calls). The client had to undergo a surgical circumcision due to the swelling. The chief medical officer for the Prepex study indicated that the swelling could either have been caused by the wrong sized device being placed or due to the client fiddling with the device/masturbating. A study doctor listed the following problem in his AE report: ‘paraphimosis developed after foreskin retracted on the device’. The surgical circumcision was performed with no complications and the client is expected to make a full recovery with no further complications. The client has been withdrawn from the study.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 138)	20 May 2014	41	23 May 2014	Severe	Self-removal	<p>Client 138 was enrolled in the study and had the PrePex™ device applied on Tuesday 20 May. He removed the device himself on day 2 (22 May) as he couldn't urinate and was in terrible pain and returned to the clinic on 23 May. He underwent a surgical circumcision at the clinic and is expected with recover full no further complications. The client was withdrawn from the study.</p> 

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 140)	22 May 2014	30	28 May 2014	N/A	Self-removal	<p>Client 140 was enrolled in the study and had the PrePex™ PrePex device applied on Thursday 22 May. The client was in terrible pain since day 4. On day 6 (28 May) he could no longer tolerate the pain, so his father, a traditional circumciser, removed part of his foreskin. The client came to the clinic on the same day (day 6) with the device still in place and some of his foreskin remaining. He was given a ring block and the device was removed normally with the remaining foreskin. A full recovery is expected with no further complications.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 145)	22 May 2014	20	N/A	N/A	Self-removal	Client 145 was enrolled in the study and had the PrePex™ device applied on Thursday 22 May. He did not arrive for his removal on day 7 (29 May) so the call centre agent called him and he said that he had been in terrible pain today (day 7) and that he had tried to call the call centre but couldn't get through, and had sent a please call me with no response. He removed the device earlier today (day 7) with a scissor. The study fieldworker phoned him and arranged for the CHAPS driver to fetch him but he was not home when the CHAPS driver got there. The call centre agent then phoned him and he said that we would go to the clinic the next day (day 8) but never arrived. The call centre agent has tried to call him several times but his phone is off. The client has been withdrawn from the study.
Katlehong (client 259)	21 May 2014	24	-	-	Client relocated	Client 259 was enrolled in the study and had the PrePex™ device applied on Wednesday 21 May. The client returned for a regular device removal visit on 28 May (day 7) and informed the study team that he was relocating to Natal and wouldn't be able to return for follow-ups. The client was withdrawn from the study.
Katlehong (client 272)	5 June 2014	32	6 June 2014	N/A	Early removal	Client 272 was enrolled in the study and had the PrePex™ device applied on Thursday 5 June. He told the clinic staff that he was awaiting news about a job he had applied for in KwaZulu Natal province. When the call centre agent called him for his day 1 follow-up on Friday 6 June, he informed her that he got the job and will be relocating to KZN immediately. As a result, he returned to the clinic on 6 June (day 1) for an early removal and a surgical circumcision. The client was withdrawn from the study.

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (client 619)	16 July 2014	35	18 July 2014	Severe	Pain	Client 619 was enrolled in the study and had the PrePex™ device applied on Wednesday 16 July. He contacted the clinic and the call centre saying that he has been in severe pain since the placement to the point that he can't walk (called on day 2, 18 July). One of the Professional Nurses conducted a surgical circumcision to remove the device and the foreskin on day 2. Client was withdrawn from the study.
Zola (client 094)	13 June 2014	25	17 June 2014	N/A	Early removal	Client 094 was enrolled in the study and had the PrePex™ device applied on Friday 13 June. He reported severe pain on day 3 (16 June) during his telephonic interview so one of the PrePex Nurses advised him to return to the clinic to get more pain killers. He returned to the clinic on day 4 (17 June) still in severe pain so the clinical team removed the device as per a regular PrePex removal since the foreskin was already dead and ready to be removed.  

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (client 287)	30 June 2014	19	6 July 2014	Severe	Pain & problems voiding	Client 287 was enrolled in the study and had the PrePex™ device applied on Monday 30 June. He phoned the emergency CHAPS number on Saturday 5 July (day 5) at 23h00 saying that he was in severe pain and couldn't urinate as there was a white substance (sloughing) blocking the urethra. The CHAPS Senior Administrative Assistant advised him to take pain killers and wait until Sunday morning to be seen by a CHAPS clinician but he didn't want to because he would then need to urinate because of the water. He called again at 4h30 saying that he could no longer take the pain and that we was going to the hospital. The client went to Union hospital in Alberton and underwent a surgical circumcision. The chief medical officer for Prepex then saw the client later on that morning and said that he was fine and would heal properly. No photos were taken of the AE while the device was still in place. The client has been withdrawn from the study.

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 517)	13 August 2014	22	14 August 2014	Moderate	Self-removal	<p>Client 517 was enrolled in the study and had the PrePex™ device applied on Wednesday 13 August. The client tried to remove the device himself and returned to the clinic on day 1 (14 August) with a displaced device and swelling. The clinic team removed the device as well as the foreskin surgically. The client was withdrawn from the study.</p> <div style="display: flex; justify-content: space-around;">    </div>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (client 520)	20 August 2014	35	22 August 2014	Moderate	Self-removal	<p>Client 520 was enrolled in the study and had the PrePex™ device applied on Wednesday 20 August. He removed the device himself on day 1 (21 August) after having sex with device on. He said that he was drunk and after having sex the device had moved so he took it off. He returned to the clinic for a surgical circumcision the next day (22 August). The client has been withdrawn from the study.</p> 

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (client 602)	10 July 2014	35	4 th September 2014	N/A	Delayed wound healing	 <p data-bbox="1131 710 2184 917">Client 602 placed the PrePex™ device on the 10th of July 2014 and the device was removed on the 17th July. Client returned to the clinic for his final follow-up (day 56) on the 4th of September 2014. It was on his day 56 that the clinician diagnosed him with “delayed wound healing”. He will return to the clinic for follow-ups until he has healed completely.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (Client 690)	13 October 2014	22	17 October 2014	Severe	Early removal (day 4)/ Severe Pain	 <p data-bbox="1131 858 2190 975">Client 690 placed the PrePex™ device on the 13th of October 2014 and the device was removed on the 17th October 2014, his day 4 of wearing the PrePex device. Client complained of severe pain. He was also ready for the device to be removed.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola Client (700)	17 Oct 2014	41	22 Oct 2014	Severe	Early removal/severe pain	 <p data-bbox="1131 837 2190 981">Client 700 placed the PrePex™ PrePex device on the 17th of October 2014 and the device was removed on the 22nd October 2014, his day 4 of wearing the PrePex device. Client complained of severe pain. He was also ready for the device to be removed.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (Client 705)	22 October 2014	30	24 October 2014	Severe	Early removal	 <p data-bbox="1131 726 2184 965">Client 705 placed the PrePex™ device on the 22nd of October 2014 and the device was removed on the 24th October 2014. Client reported that he was involved in a “fight” that resulted in the complete removal of the device on the 23rd of October in the evening. The client returned to the clinic on the 24th of October to have his foreskin removed surgically (due to pain and swollen glands). The client has been withdrawn from the study.</p>

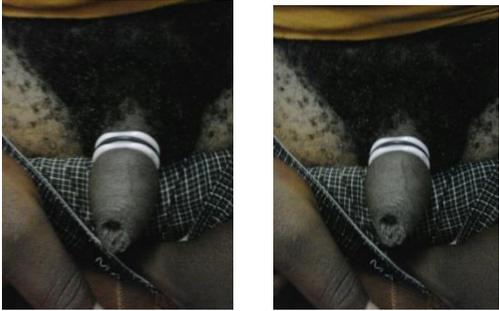
Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (Client 632)	28 July 2014	24	22 September 2014	N/A	Delayed wound healing	<p>Client 632 placed the PrePex™ device on the 28th of July 2014 and the device was removed on the 4th of August 2014. When the client returned to the clinic for his day 56 on the 22 of September 2014 “delayed wound healing” was discovered. The clients’s wound was treated and he was told to return to the clinic for a check-up. He will return to the clinic for follow-ups until he has healed completely. It is expected for him to heal fully.</p> <p>No pics are available for this client.</p> <p>Client was fully healed at week 9.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (Client 688)	8 October 2014	24	24 October 2014	N/A	Infection	 <p data-bbox="1131 790 2184 997">Client returned to the clinic on Day 16 for a check up as his wound had puss in it. Client 688 was seen on the 24th of October for a dressing as the client had puss in his wound. Bactroban and fragile were used for dressing the client. He returned to the clinic on the 31st of October and the dressing was removed. The wound was healing and no puss was present.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (Client 679)	7 October 2014	37	2 December 2014	N/A	Delayed wound healing	 <p data-bbox="1133 799 2175 911">Client returned client on day 56 (2 December 2014) and presented with delayed wound healing. Client was dressed with Bactroban. He was also given bactroban ointment to use at home.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Zola (Client 836)	08/01/15	21	22 January 2015 (day 14)	N/A	Swelling	 <p>Client went to clinic on day 14 as he noticed that his penis was swollen. The clinician told him to keep his penis elevated. Swelling continued until day 42. Client returned to clinic on day 42 and the clinician gave him pain killers and pressure bandages. Client will be monitored.</p>
Orange Farm (Client 538)	3 February 2015	24	-	-	-	<p>Client was in another province on his day 7 and was awaiting transport back to Johannesburg. Client did not return to clinic on day 7 for removal but returned to clinic on day 9 for removal.</p> <p>No pictures available.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (Client 744)	3 February 2015	29	Day 7 10 th Feb	Severe	pain	<p>Client was in severe pain early in the morning of his day 7 (10th Feb). He called an ambulance and was taken to Natalspruit hospital. The nurse went to the hospital with removal kit for the client on the morning of his day 7 (10th Feb). She could not locate client in the hospital. Client's name was in the register for admittance but was MIA in the ward that the nurse was waiting for him. The study Nurse returned to Natalspruit the next day (11th Feb) and was told that the device was removed surgically at the hospital. Client returned to Natalspruit for follow-ups. The nurse and the doctor called client 836 to follow up, and client reported that he was healing well.</p> <p>No pictures available.</p>
Zola (860)	11 February 2015	21	25 February 2015	N/A	Insufficient skin removed	<p>Client returned to Zola Clinic for his Day 14 follow-up. It was discovered that he had insufficient skin removed. Had to remove it surgically.</p> <p>No Pictures available</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Orange Farm (548)	6 March 2015	25	13 March 2015	N/A	Self-removal	<p data-bbox="1131 391 2181 587">Client placed on day 0 (6 march 2015). Client removed device when he returned home on day 0. On his day 7 he re-attached the device to his penis. Client reports that he removed the device on day 0 as it was extremely painful. Client returned to clinic and still wanted to be circumcised. He had surgical circumcision. Client has been withdrawn from the study.</p> <div data-bbox="1131 624 1630 935">  </div> <p data-bbox="1131 970 1592 999">Client has been circumcised surgically.</p>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (766)	13 April 2015	20	24 April 2015	N/A	Self- Removal	<p>Client did not return to clinic on his removal day (20 April 2015). The recruiter and PrePex Counsellor from Katlehong drove around the area he said he lived looking for him after being unable to reach him by phone. The call centre agent also tried calling him several times to no avail. Finally, four days after his removal day, the recruiter from Katlehong tracked him down. Client 766 had removed the device himself. No bleeding or infection were present. All in all it was a “perfect self-removal”. No surgical correction was required.</p> <div data-bbox="1131 707 2161 1069"> </div>

Location/site of surgery	Date of placement	Age of client (years)	Date when AE first diagnosed by clinician	Severity (Severe or Moderate)	Adverse Event	Clinical details – brief description of event, timing (before or after device removal, days from placement [=Day 0] or hours from placement if less than 1 day), management, and final outcome. As possible, please provide photographs of AE
Katlehong (779)	21 April 2015	22	05 May 2015 (day 14)	N/A		<p>Severe swelling on day 14, nurse could not distinguish if there was insufficient skin removed. He returned to the clinic 1 week later on the 13th May 2015 for a follow-up. The nurse ruled it severe swelling but was healing nicely.</p>  <p>Photograph on the right: Day 23: Frenulum slightly open but not septic</p> <p>Photograph on the : Day 23: Client healed on top (penis)</p>

iii. Efficacy of the PrePex device

In total there were three Enrolled Nurses, three Professional Nurses, two Clinical Associates, and two Physicians in the provider teams who were supervised by the Operations Director (a qualified Physician). All providers were CHAPS employees who had extensive experience in doing forceps-guided circumcision and who had been trained and qualified to conduct circumcisions using PrePex. One Enrolled Nurse had 3 to 5 years' experience in circumcision, and the other had over 5 years' experience. Two Professional Nurses also had 3 to 5 years' experience in circumcision, while one had less than a year. Furthermore, while one physicians had between 1 and 2 years, the other had more than 5 years' experience. One Clinical Associate had less than a year of experience, while the other had between 1 and 2 years.

Four providers out of the ten had not heard about PrePex before joining the study. Out of the six that had heard about PrePex before the study, two had heard about it from either the website, materials, or marketing; while four had heard about it from Professional contact. Furthermore, one had worked with PrePex before (one of the Clinical Associates) while the remaining five who had heard about PrePex prior to the study had not.

a. Feasibility and provider acceptability of PrePex

At first impression (before being trained) two providers said that the PrePex seemed very favourable while two said it seemed somewhat favourable. Four of the ten providers were neutral to the device, while a further two were somewhat unfavourable to it. Furthermore, five of the providers all felt that at first impression (before being trained) the PrePex device seemed very easy to use, four said it looked somewhat easy, while the final providers thought it looked neither difficult nor easy to use. Furthermore, seven providers felt very confident that they would master the skill of using PrePex for circumcision, while the remaining providers felt somewhat confident.

During the focus group discussions PrePex providers had mixed reactions when they were first introduced to the device. Their reactions ranged from intrigue and curiosity to concern. **The providers were concerned about the safety implications of the device for potential clients as well as the lack of control exercised over most of the procedure.**

"I was worried because when I heard it's a device that the patient will take home, my worry was what if they get home and start fiddling with it because now you would have no control over what happens during the seven days, and you will only see them after seven days so basically that was my main worry"

“For me I was scared because I wondered how this thing is going to work, is it safe to use what are the risks infections”

Another initial thought on the PrePex device was one of intrigue in the device’s potential to minimize adverse effects of male circumcision.

“Well I think from my side is almost what they said it’s just that as they were presenting the device I was worried because they didn’t report any adverse events that came with the device and as medical person I know that in everything there is always a positive a negative side, so I was concerned if there will be any complication or the outcome and how bad can they be so that was my main worry”

After providers had been trained and had been implementing PrePex, they were again requested to answer a survey questionnaire. Only two out of the 10 providers completed this section. At this stage providers were asked what their impressions of the PrePex device was. At this stage one of the providers said their impressions were very favourable, while the other said they were neutral.

For providers, a key benefit of using the PrePex device for VMMC was the assurance of a needle and stitch-free procedure as well as the lack of blood loss. This assurance can recruit men who would not consider circumcision because of such barriers:

“You know what is good about the PrePex device is that we are still losing a lot of men when we do surgical circumcisions who are scared of the needles, and some of them are just scared of the word “stitch” and some they don’t want to see blood so we would have those people that PrePex can bring in by assuring them that there is no blood loss and stitches, so already you can attract that small group that is still hesitant to come and circumcise”

“I think it might not be a huge number but any addition is good so for those that we are losing because they are scared of pain they will come up... I think it would really increase the numbers, it would make a difference because there is no such thing as a low number”

Providers were overall very impressed with the cosmetic result of circumcisions with the PrePex device:

“Cosmetic effects of PrePex are way better than the surgical so if a guy likes to look good then he wants his penis also to look good then he will definitely opt for PrePex, and I think it will also appeal to those who are health conscious and interested in their wellness.”

“It looks very neat because it doesn’t have any scars, like cosmetically as there were no stitches”

Similar to the discussed benefits, a significant difference highlighted was the elimination of bleeding during PrePex circumcision.

“We eliminate the bleeding complications because you don’t cut so you won’t have your haematomas, and that excessive bleeding experienced during surgery”

An **additional benefit that providers noted was that the PrePex device did not require the sterile environment that a surgical circumcision demands.** Instead the preparation for PrePex circumcision is more simplistic:

“because with surgical there is a set of preparations that you need to do before the procedure takes place you have to prepare the packs, put the patient on the bed scrub him, inject him, there is a lot to do. With PrePex the sterility is less and it is a non-sterile procedure and it is less complex it is actually very simple”

PrePex is **seen as more cost effective** than surgical circumcision as less consumables are used in the process. Additionally there is less room for complications with the PrePex method of circumcision.

“Actually when you put surgical vs. PrePex in terms of the cost effectiveness with PrePex we actually use less consumable’s and also the risks are very minimal unlike the exposure that we have in surgical like glands injuries, burns from using the diathermy and the anaphylaxis that caused by using the injection, so you can see that with surgical there is a lot of consumables that are being used so PrePex is good in terms of cost effectiveness and it has less complications.”

Numerous drawbacks regarding the PrePex procedure were identified. Among them **was the challenge of using a limited PrePex Sizing plate:**

“We also have the challenge of the limited size of the PrePex and the eligibility criteria which is very strict.”

“We only had sizes from A to E and sometimes you will find a patient who has a small penis or a big one and they wouldn’t fit into the sizes...”

Similar to initial thoughts regarding the PrePex device, **providers expressed discomfort with clients going home with the device. Further, monitoring clients on the day of the device’s removal would be difficult if there is an increase in PrePex uptake.**

“I think for me there is a bit of uneasiness because there is that seven days where you don’t know if this guy will come back, or if he is going to try and temper with it or even remove it himself, you don’t actually know what is happening with the circumcision that you have started”

There was a general concern amongst providers about the lack of control associated with allowing clients to go home for seven days with the device attached.

“I don’t have any guarantee that he will come back so that I can remove it professionally.”

However, **other providers noted that clients were given sufficient information about the procedure and what was expected of them during the seven day waiting period before device removal.** Thus clients had a responsibility to ensure their own safety.

“You know what I think they are given enough and clear information I don’t know what else we should do, unless if we were to call them every day to remind them; but they are given information from the counselling to the provider and again when they leave they are given an instruction chart and we also give them our numbers that if there is anything they should call us, at some point we have done our job and I don’t think there is anything further we can go with this”

The additional two-week healing period discouraged several clients from participating in the PrePex circumcision procedure.

“It takes a long time because a patient has to come in on a Monday and then come back the next Monday and wait seven weeks to go back to having sex, so it’s not easy to sell it because already we are struggling with the six weeks, we have serious problems where by a person will be like “Iyo six weeks no thank you”, so now you are adding another two weeks to make it eight weeks”

Despite the concern, providers were convinced that most clients do return for the removal of the PrePex device.

“A lot of them do come back in fact I don’t think throughout the study there was a patients who disappeared but there is always that uncertainty that are they all going to come back”

An additional concern was that dealing with a large number of clients on one day could cause difficulties in keeping track of clients who need the device to be removed especially men who do not return after seven days.

“But my worry about that is that with PrePex you have to be updated about who is coming when and if we do a high number of PrePex clients per day, who is going to sit there and make sure that everybody is back because for me it doesn’t seem like it’s a logical process you can provide in your busiest time, yes it might help but it will be time consuming because you will have to go through all the files to check who came and who didn’t and what are

their reasons for not coming so now you will have to call and check on them, for busy time it would not work.”

b. Ease of use

Two providers were also asked about ease of use after having used the PrePex device for half of the procedures required to complete the study (400). One of the providers said that it was very easy while the other said it was neither easy nor difficult.

During the focus group discussion **several providers stated that they liked the efficiency and speed of the device’s placement procedure**, highlighting the benefit of not seeing clients for infected related problems.

“It was very fast, the patient comes in and few minutes they are out because with some of the providers it would take about 2-3 minutes to insert the ring, the client doesn’t wait long for the procedure you will only see them when they come on their scheduled check-up dates for you to see if its granulating well, so I guess for me I like the speed about it with regards to the inserting and the removal its way faster than the surgical”

c. Procedure time

The average procedure time showed that the device was quick and easy to use. **Once providers were proficient in the use of PrePex circumcisions with the device took on average 30 minutes.**

d. Provider preferences

When asked prior to being trained how they felt PrePex would compare to standard surgical circumcision prior to being trained, **eight stated that “PrePex is far superior to standard surgical circumcision”**, one stated that “PrePex is somewhat superior to standard surgical circumcision”, and the last provider stated that “PrePex is equivalent to surgical circumcision”.

The same question was asked to two providers after they had been trained and had done half of the required circumcisions using PrePex that was required to complete the study (400). At this stage one provider stated that “PrePex is far superior to standard surgical circumcision”, and one provider stated that “PrePex is equivalent to surgical circumcision”.

c. Client Acceptability and Satisfaction

The primary focus of the acceptability component of the study was to document attitudes towards and experiences with device circumcision from the provider, the client and the partner's perspective.

Using the Client Survey, clients were asked to provide their perspectives regarding the device procedure. Clients were asked to rate comfort and pain as well as impressions of the device procedure. On the day of procedure, after 24 hours post-procedure, every day in the first week, and once a week for 8 weeks after the procedure, client surveys were administered onsite at the clinic site, unless clients preferred an interviewer to administer the survey.

At the conclusion of the study, 8 weeks following PrePex VMMC procedure, a final survey was conducted onsite to assess healing completion, satisfaction with cosmetic final results, healing time, and any residual complication on Day 56.

Participants were also asked whether they were specifically concerned about being circumcised with PrePex prior to undergoing the procedure. Over 95% of participants were not (Table 19).

Table 19: Whether Participants were concerned about Being Circumcised with PrePex Prior to Doing the Circumcision (n=802)

Participant Answer	Frequency	Percentage
Yes	35	4.4%
No	767	95.5%

Of those who did have concerns about being circumcised with PrePex (Table 20), just over a quarter (29%) were concerned the procedure would be painful, 22% were worried that there may be a complication, and 14% were worried that the healing time was too long, and a further 8% were concerned that they would not be able to work or be active.

Table 20: Reasons Participants were concerned about Being Circumcised with PrePex Prior to Doing the Circumcision (n=59) *[More than one answer could be selected]*

Participant Answer	Frequency	Percentage
Procedure may be painful	17	28.8%
I might not be able to work or be active	5	8.5%
My partner might not approve	1	1.7%
My family/friends might not approve	1	1.7%
There might be a medical complication	13	22.0%
The healing time (8 weeks) is very long	8	13.6%
It will be hard to not have sex or masturbate for 8 weeks	5	8.5%
Sex might not feel the same	4	6.8%
I may not like the way my penis feels	2	3.4%
I could die from the procedure	2	3.4%

Other	1	1.7%
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Participants were also asked whether they felt that it would be easy to talk about PrePex with their sexual partners, family and friends (Table 21). **Most believed it would be very easy to speak about PrePex to their sexual partners (72%), family (92%) and friends (96%).** While around two percent of participants thought it would be very difficult or somewhat difficult to talk to their sexual partners, family and friends.

Table 21: How Easy Participants believed it would be to talk about PrePex Prior to Doing the Circumcision

	Frequency	Percentage
How easy would it be to talk to your sexual partner about PrePex (n=792)		
I do not have a sexual partner	175	21.8%
Very easy	583	72.6%
Somewhat easy	13	1.6%
Neither easy nor difficult	4	0.5%
Somewhat difficult	7	0.9%
Very difficult	9	1.1%
Don't know	1	0.1%
How easy would it be to talk to your family about PrePex (n=800)		
Very easy	739	92.0%
Somewhat easy	21	2.6%
Neither easy nor difficult	5	0.6%
Somewhat difficult	13	1.6%
Very difficult	16	2.0%
Don't know	6	0.8%
How easy would it be to talk to your friends about PrePex (n=798)		
Very easy	771	96.0%
Somewhat difficult	7	0.9%
Neither easy nor difficult	3	0.4%
Somewhat difficult	6	0.8%
Very difficult	6	0.8%
Don't know	5	0.6%

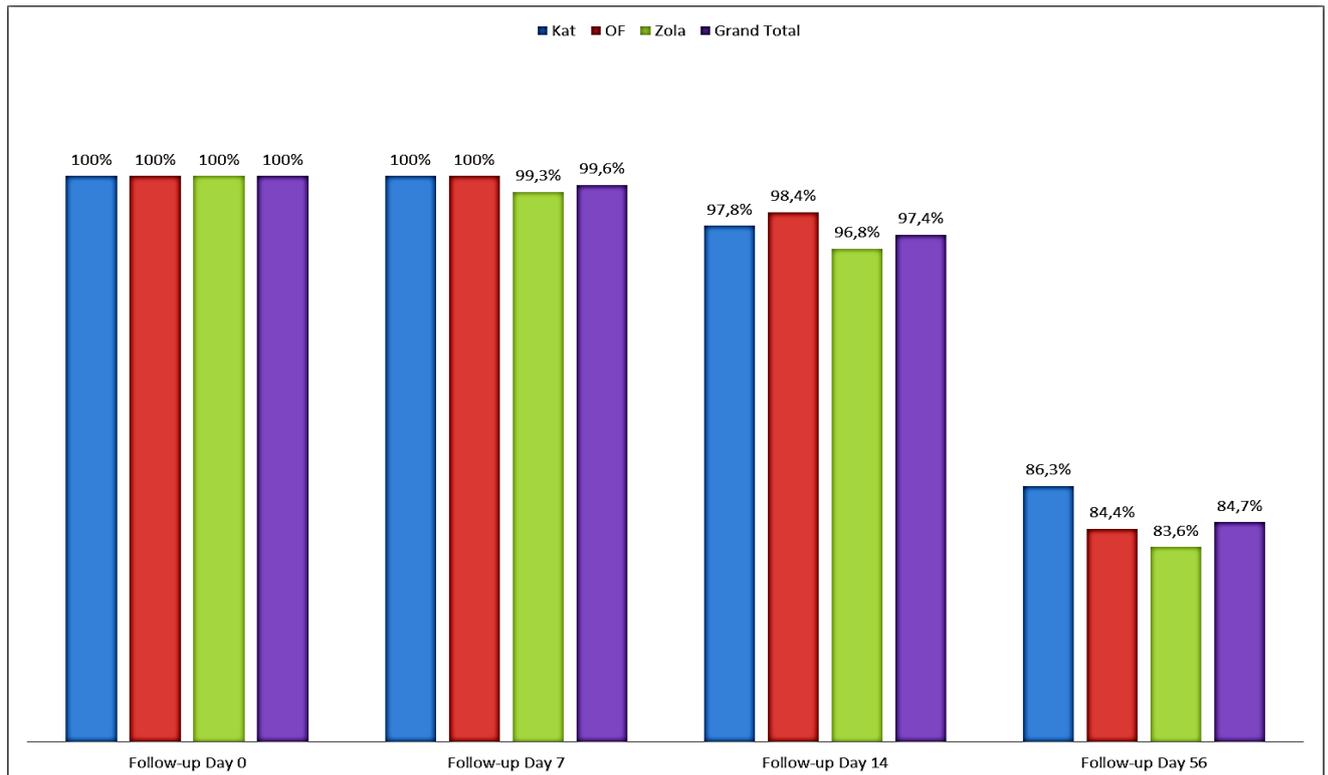
i. Desire for PrePex and Loss to Follow-Up

a. Number of eligible clients and refusal for study participation

In total 15 865 people went to the clinic to access circumcision services during the study period, however only 5 500 of these were between the ages of 18 and 49 years. **Of the 5 500 clients who were between the ages of 18 and 49 years, 828 (15.1%) people were both eligible and opted to have circumcision done using the PrePex device.** However, there were 25 withdrawals from the study.

Almost all clients came back for removal on Day 7 (Figure 2), with a few exceptions that required the call centre agent to contact them a few times for them to come to the facility to have the device removed. Over 95% of clients returned on day 14, and **around 85% returned on the final day of follow-up (Day 56).**

Figure 2: Percentage Distribution of Clients who Completed Day 7, 14 and 56 Follow-Ups



ii. Reported pain

Pain was reported using a visual analogue scale (VAS) both during and after the PrePex device circumcision procedure prior to removal. Once the PrePex device was removed, participants were asked whether they felt pain at each follow-up visit as well as at each telephonic survey (Table 22).

At no point in time before and during device placement did any of the participants report the highest score possible (10 = “hurts as much as you can imagine”), and the **eight of the participants scored the pain score higher than a 2 (“hurts just a little bit”) device placement and 32 participants five minutes after device placement, and 30 participants one hour after device placement** - while the remaining participants stated that they were very happy and were not hurting.

Table 22: Reported pain at before and during device application

Pain Score	N	%
Pain before the application of PrePex (n=793)		
Very happy, no hurt	793	100.0%
Hurts just a little bit	0	0.0%
Hurts a little more	0	0.0%
Hurts a whole lot	0	0.0%
Hurts as much as you can imagine	0	0.0%
Pain during the application of PrePex (n=793)		
Very happy, no hurt	785	97.8%
Hurts just a little bit	8	1.0%
Hurts a little more	0	0.0%
Hurts a whole lot	0	0.0%
Hurts as much as you can imagine	0	0.0%
Pain five minutes after device application, but before the removal of PrePex (n=796)		
Very happy, no hurt	759	94.5%
Hurts just a little bit	32	4.0%
Hurts a little more	0	0.0%
Hurts a whole lot	0	0.0%
Hurts as much as you can imagine	0	0.0%
Pain one hour after device application, but before the removal of PrePex (n=795)		
Very happy, no hurt	759	94.5%
Hurts just a little bit	30	3.7%
Hurts a little more	0	0.0%
Hurts a whole lot	1	0.1%
Hurts as much as you can imagine	0	0.0%

On day 7, at device removal, 11% of participants stated that the pain had been so bad during the preceding 7 days that they had wished that they had not circumcised with PrePex, even though 91% stated that they had experienced pain in the preceding 7 days while wearing the device.

On day 56, during the questionnaire that was administered, participants were asked to answer whether the pain they experienced during the healing period was what they expected. **Sixty-three percent (63%)** said that a lot less painful than what they expected, while **14 participants** stated that it was more or a lot more painful than what they had expected.

Men who underwent PrePex circumcision found that the PrePex device placement did not hurt initially. **Most experienced no pain after device placement. However, they began to experience pain after the first two days:**

“The first two days were fine but it wasn’t until the 3rd day that the pain started and I suspect that the pain killers that we get are not the strongest around.”

Zola, Male, PrePex

“There wasn’t any pain initially until the 3rd day then everything changed I couldn’t wait for the 7th day so they could remove the device, I was literally dying on the 6th day. I was impressed with the gentle manner in which the device was removed.”

Katlehong, Male, PrePex

Further the **pain was much more severe at night than during the day**. This was mainly due to erections experienced by men at night. **Numerous men complained of additional pain during urination:**

“The first day was just as the script said that there was no pain, the 3rd day at night then the device kicks in and starts cutting into the flesh and the pain starts... It is a better because there are no razors involved”.

Zola, Male, PrePex

“The pain is excruciating especially in the 3rd day and I also say the tablets were ineffective. The evenings were also the worst; it is not as bad in the afternoon as it is in the evening”.

Zola, Male, PrePex

“They explain to you as they install the device that there will be no pain, you would feel nothing at the point of installation. The pain only says hello on the 2nd to the 3rd day and as they have already said, the erections at night are very common.”

Katlehong, Male, PrePex

“The pain was worse when I had to relieve myself. At times I would think that they may have used a small size device on me.”

Zola, Male, PrePex

Men found that the **pain subsided substantially after the PrePex device was removed**. Only a few participants continued to experience pain after the device was removed.

“After the device was removed and a week later I was all good, within two weeks I was all healed, there was just minimal pain which was a small reminder of the fact that I had circumcised but otherwise I was sorted in two weeks. I even told them that I was healed when they made the follow up call after two weeks”

Orange Farm, Male, PrePex

However, some found that **the pain intensified after a week following device removal**: Increased pain experienced after the procedure can be due to the failure to abstain from sexual intercourse during the eight week waiting period that is required:

“The pain when removing the device was more severe than the initial 7 days collectively, I contemplated just asking them to leave the device intact for a while longer because I couldn’t bear the pain, I also asked to be allowed to smoke marijuana before they could proceed because the pain was too much. The pain was really bad but the random erections didn’t really help much. Two weeks after the device was removed I tried having sex and it was just a horrible experience, the erections were painful but wearing a condom was a mission on its own, I tried penetrating her but that was just impossible, the pain wouldn’t allow me to have sex.”

Orange Farm, Male, PrePex

“It took a while, I suppose around 3 weeks. At times I felt as if the pain intensified after I would have taken pain killers”

Orange Farm, Male, PrePex

Numerous men found the pain experienced during the removal of the device to be intense and almost unbearable. Their thoughts after the procedure however were positive as they reflected on PrePex circumcision.

“They took about 12-15 minutes to remove the device on me but only around 5 minutes to remove it from the rest of the guys. I felt the pain as they touched me to remove the device and the pain was unbearable. Anyway the pain subsided after the device was removed but then again the trauma of having had the device lasted for about two days after it had been removed, it took some adjusting for me to get used to once again not having the device installed on me. After all is done, the penis becomes really smooth and good looking, it becomes so clean and the smell disappears immediately after you clean the wound”

Orange Farm, Male, PrePex

Conversely, some men did not experience the removal of the device as painful:

“The removal of the device wasn’t painful as such, and yes I was worried building up to the day about how exactly they would remove the device and on the Monday and the nurse did a good job, she asked me to lie down on the bed and before I knew it she was done and I hardly felt any pain”

Orange Farm, Male, PrePex

There were **feelings of regret amongst a few men who chose PrePex as a circumcision method as opposed to surgical circumcision.** This, they explained, was because of the amount of pain that they experienced whilst wearing the device and during its removal.

“I did get to that point of regretting, I thought to myself perhaps the pain would have been less had I circumcised surgically. I felt better when one guy that got circumcised with me at the same time but the surgical route, told me that his pain was way greater than mine and he also said that his pain lasted longer than mine. His wound got swollen immediately as you would

have expected as with any other wound but it wasn't the case in mine because I had about 2 days of calm before the storm. PrePex is good and after I removed the device the pain went away oh well I felt some minor pain last week but this was inside the urinary tract. There is still some pain when touching the penis...it still feels as if the device is still present but remotely so well it is negligible nonetheless"

Orange Farm, Male, PrePex

Men who held this view were however, able to acknowledge PrePex as a viable circumcision option.

In order to numb the pain, men used the painkillers that they received from the clinic. The **painkillers were however ineffective** and they continued to experience pain. Pain medication prescribed by the clinic was experienced as ineffective at decreasing the pain, thus most men resorted to increasing their doses or using stronger medication:

"It feels as if the device blocks the urinary tract somewhat but I have to say that day 3 is the most painful. Yes the pain is there and the tablets are not strong enough and they failed me and at some stage I regretted having gone through with the procedure."

Zola, Male, PrePex

"I was advised to take 2 pain killers and I took 3 instead and I just wanted to sleep it off."

Zola, Male, PrePex

"The pain killers do not help with the pain, [and] it only gets better if you clean the penis with salty water which also helps with the swelling."

Katlehong, Male, PrePex

Pain additionally affected the type of work some men could partake in. Work requiring men to sit for long periods led to discomfort and pain.

"I think that also depends on the type of work that you do, in my case I play the guitar, and I have to sit down in order to play it, the sitting part is what caused most of the discomfort".

Zola, Male, PrePex

Only a few of the participants found the pain to be bearable:

"I don't have a problem with it; it is only when I got erections that I felt pain. It tightens up against the device when you get an erection."

Katlehong, Male, PrePex

"I have to say that the pain was bearable and the only time the pain was severe was when I had an erection."

Orange Farm, Male, PrePex

iii. Odour

The smell (odour) was reported as intense and difficult to ignore. It was reported to begin around the third and fourth day:

“The smell is a very bad one and it over powers Savlon, it is impossible to ignore it. I would even ask those near me if they didn’t smell anything foul and they always said no they didn’t, it seems the smell would only be felt the one person who is going through the healing period. I asked a different person and still no one could smell it”

Zola, Male, PrePex

“There was a smell but Dettol antiseptic always killed it off, it would however always come back at intervals but the Dettol was always at hand to get rid of it. Oh and yes the smell would be a tad offensive to anyone sharing the bed with you.”

Katlehong, Male, PrePex

“I think it (foul smell) starts on the 3rd day... advised to use Savlon antiseptic to clean our wounds. They said one must use regular soap water to bath but the water must have Savlon antiseptic in it. I was uncomfortable using soap only because soap made it itchy and uncomfortable.”

Zola, Male, PrePex

“In those 7 days, the smell that brews up is unbearable but well it could all be minimized by cleaning the penis about 3 times daily. Compared to the surgical MMC, the PrePex smells bad, as for the surgical guys, they said they only had to clean up but not to curb a foul smell.”

Katlehong, Male, PrePex

iv. Resuming normal activity

When participants were asked on day 7 (on the day that the device was removed) how they would rate their ability to conduct routine activities since they had done the PrePex circumcision **82% of participants stated that it was very easy while 11% stated that it was somewhat easy.**

Importantly, PrePex allowed for men to continue with their work soon after device placement:

“PrePex allows one to get on with their business the very following day”.

Orange Farm, Male, PrePex

Further, **PrePex allows men to work after the procedure, thus a convenient option:**

“Surgical would be more painful- I think it would have been more painful like from what I saw my brothers going through, and it would have also required him to take day off from work from the very first day of the surgery. PrePex is the best way to do circumcision because you can still be able to carry on with your day to day duties.”

Orange Farm, Female

Sixty-six participants had masturbated or had sex within the 8 week abstinence period, while 1 stated they did not know and another 1 participant refused to answer. A further 17% of participants did not answer the question at all. Furthermore, **46% and 13% said that it was very easy or somewhat easy, respectively, to abstain from sex or masturbation during the 8-week abstinence period**. However, 9% and 7% respectively stated that it was somewhat difficult and very difficult to abstain.

While majority of the participants did not have a problem abstaining from sexual intercourse during the duration of the healing period, **few female participants found that it was difficult for them and their partners to abstain from sexual relations**.

Some succumbed to temptation despite knowing that the penis was not yet fully healed and engaging in sexual intercourse could allow for infections and spread diseases. Despite this, female partners motivated their partners to abstain for the remaining weeks:

“Difficult for him and at times it was also difficult for me but then I said to him like that time when we had to abstain before we got married and he kept saying no it's not the same.....laughing... because at that time I didn't know anything about sex and now I know, and at that time we didn't sleep in the same bed; I remember after seven weeks and he said to me he is fine he is healed, and I looked at his penis and it looked fine like it was healed and we had a sexual encounter during that seven weeks but after that I was so scared, and I said to him you need to call the PrePex people and tell them what you have done and ask if what we did was wrong. He did and they told him that we shouldn't have done it but he still insisted that he was okay and then I told him that maybe we should rather have sex during the day so that we can see if something can go wrong and I would also see your facial expression if something is wrong, but we didn't do it like we used to it would just be a brief sexual encounter because he was getting frustrated and short tempered and he kept on telling me that but I am healed, and I told him that we should rather wait for the 8 weeks”

Orange Farm, Female

“It was not being able to have sex because I think PrePex it takes longer than surgical, so that also affected him a lot but as you know for us women we can manage to abstain for that period and he would keep on telling me that he is fine and I would refuse telling him that we have to wait until the time that he was given at the clinic”

v. *Acceptability of PrePex amongst providers*

Providers' general perceptions of performing circumcision using the PrePex device were positive. Many enjoyed the experience of PrePex circumcision and gained new skills.

"I really enjoyed it and I have managed to add another skill on top of the knowledge that I had."

As already highlighted, learning new skills was an aspect that encouraged providers to accept the use of PrePex device for circumcision. **One provider acknowledged that learning more about the device allowed for the dissolution of the stigma that was attached to it.**

"For me it was about learning a new skill which is always good and for me it also took away the stigma that I always had about the devices, so it was good to see a device that could produce a good end product so yeah it really changed my mind-set about devices."

Providers went on to **suggest that marketing PrePex device should broaden its target market in order to reach men in smaller towns and rural areas where there is a lack of information on new and alternative circumcision procedures.**

"They should just scale up what they are doing now because it is very good and coming from a small town where we don't have as much information they should just scale-up their advertising."

Numerous providers had initial professional concerns regarding the use of PrePex device for VMMC:

"At the beginning most of us were not happy of course later on I heard a lot of them saying that they were finally getting used to using the device, so I think I could also talk on their side that everybody is loving it and the nurses are loving the fact that it is so fast, of course we are different as providers some will be comfortable with this method and others with a different method but having said that most of them are really comfortable using PrePex other than surgical because of the benefits."

Providers recognised that there were differences in opinion about the use and methods of the device. **Most agreed that despite being misinformed about the pain expectancy during the procedure, the benefits of PrePex device made them supportive of its use.**

“I guess they were like me like we were not happy about the fact that the pain issue was not explained but most of them as they were getting used to it, they started believing in the product and I have also heard that over time most clients got better because they were given brufen”

Most providers felt positively about the DOH including PrePex in the VMMC programme. However, they suggested that PrePex be offered in conjunction with surgical circumcision.

“I would say especially if DOH would want to include in the VMMC program, they should make sure that the site has surgical services so that we address the situations like when the client tried to remove the device and end up with a complication we can the opt for surgical circumcision to correct the complication....”

Providing clients with two methods of circumcision, surgical circumcision or PrePex circumcision can positively deal with the large amounts of men that come in to clinics to be circumcised. **The PrePex procedure allows for faster service whereas surgical circumcision is a time consuming process that demands more staff.**

“Definitely they should like as I said we are doing mass volumes so let me make an example like in winter we have like 10 to 14 years old who are going to make up about 80% of your clientele for the day, so it would be nice that the 20% that would be able to do PrePex can just go because it will be faster and the clients will come in and go, and even if they can come back on day seven even if we are busy PrePex doesn’t need a lot of bays like with the surgical, two providers like a nurse and a doctor or a nurse and a CA can deal with this 20% while the rest of the staff is busy with the ones that don’t even qualify for the PrePex.”

Furthermore, **providing PrePex as an option in conjunction to surgical circumcision provides men with an alternative circumcision option to that of traditional circumcision methods or paying general practitioner fees.**

“This would be a good option because even before people didn’t have a lot of choices because you would either go to the traditional circumcision or you go to the private GPs and pay money, then free and safe circumcision came in and now you can have more options with PrePex so I definitely think it should be added.”

“I think they should because it’s a good option for those clients who are really scared of seeing blood and people do really have phobia that is a fact.”

vi. *Participants' opinions*

a. **Cosmetic results and client satisfaction**

By the 56th (last) day of follow-up **79% of the clients stated that they were very satisfied with the PrePex circumcision they had undergone**, while 6 participants and 9 participants respectively were very dissatisfied and somewhat dissatisfied.

Table 23: Reported satisfaction with the healing process at Day 56 (n = 679)

	N	%
Day 56 (n=680)		
Very satisfied	631	78.6%
Somewhat satisfied	30	3.7%
Neither satisfied not dissatisfied	3	0.4%
Somewhat dissatisfied	9	1.1%
Very dissatisfied	6	0.8%

Only two of the participants regretted doing surgical circumcision after seeing the results of peers who circumcised with PrePex circumcision. This was mostly because of the amount of time and effort it took for men to tend to the wound as a result of surgical circumcision:

"I decided against it but I regretted when my brother did the PrePex thing and he looked awesome."

Male, Surgical

Further, **participants acknowledged that PrePex had a better cosmetic outcome compared to surgical circumcision as well as the added benefit of being able to go to work.**

"Surgical MMC leaves behind marks showing where the stitches used to be but PrePex leaves no trace whatsoever. The results are smooth and flawless."

Male, Surgical

"I do like the surgical but PrePex leaves a better looking result, no traces of stitches, it looks smoother. For some people there would be great discomfort as the stitches start coming off and they may have to rush back to see the nurses. Honestly I prefer PrePex to surgical MMC."

Male, Surgical

b. **Participant and provider recommendations**

Although two participants stated that they would not recommend PrePex, **74% and 8% respectively stated that they would strongly recommend or recommend circumcision with PrePex to another male who was thinking about getting circumcised.** Furthermore, 53% of participants had already recommended PrePex to someone they knew or had met.

While male participants who circumcised with PrePex were satisfied with their choice they gave recommendations on changes to the device. Men additionally elaborated on what they disliked about the PrePex procedure and device.

Consistent with the majority of the findings among male participants, **suggestions revolved around the amount of pain experienced:**

“The removal is the most painful and I even suggested they should inject us when they remove the device. Everything else is fine except the part when they remove the device.”

Orange Farm, Male, PrePex

“I think it would work better if they use a razor to cut along the rim of the device instead of using a pair of scissors to cut it off. It is the scissors that makes the whole thing painful.”

Zola, Male, PrePex

Some of the **participants disliked the width of the rubber band and suggested that it should be thinner**, assuming that this would shorten the number of days the device should be worn:

“The only thing that I did not like about the PrePex is the rubber band; it should be made thinner than it is at the moment because if it is thinner then it will cut into the skin quicker. Maybe if they make it thinner then we wouldn’t have to wear the device for 7 days and it may happen that maybe on the 4th or 5th day then it would have finished cutting the foreskin.”

Katlehong, Male, PrePex

“I really like the PrePex method but maybe they can speed up the process by making the elastic rubber band that they use a little thinner. This could perhaps shorten the 7day initial period which is a bit too much if you think about it and at some point one feels that the pain is too much but the results are really worth it.”

Katlehong, Male, PrePex

“Our skins react differently and for some of us that rubber band on the device was not the most comfortable, it really hurt. My wound had become septic”

Orange Farm, Male, PrePex

Men further **suggested that they found it difficult to keep their penis in an elevated position during the seven days before device removal:**

“I didn’t like the fact that we had to keep the penis in an upright position.”

Orange Farm, Male, PrePex

The providers did not concur on the recommendation for PrePex. Reasons for not recommending PrePex circumcision was because of the pain involved, smell and additional weeks involved in healing. These providers would only recommend PrePex if an anaesthetic was applied before device removal and stronger pain killers were administered during device wear. Among those who would recommend PrePex, the main reason was that it caters for men afraid of needles and is an alternative to surgical circumcision.

In their recommendations of the use of PrePex device, providers differed in opinion. Many did not recommend its use because of the pain involved in the procedure:

“No I wouldn’t let me tell you an example I had a friend who wanted to circumcise and he asked me about both procedures, and I told him if you are in hurry rather do the surgical circumcision because you are the very first day and obviously if you would also follow the instructions you will be fine and you will not get any of the adverse events, because the risks and pain of surgical circumcision are way less than how they would be perceived; and again with PrePex within the first seven days when a patient is at home they are feeling an excruciating pain.”

Others recommended that medication be given to clients for the pain.

“I would say yes but only if they would allow anaesthetic injection during removal.”

The main reason providers recommended and supported the use of PrePex device was because of its elimination of needles, stitches and blood.

“With PrePex healing takes 7 weeks and the surgical is six weeks, so we will have the guys that will opt for surgical only because of the lesser time for healing period and some will go for PrePex only because they don’t want to see blood, needles and stitches or because they have seen how their friends healed.”

Identified groups of men who are not suited to use PrePex device were those who could not refrain from sexual intercourse for the eight week period following the removal of the device, men who could not handle the pain involved in the procedure, and men who were not psychologically stable:

“We need to have a way of assessing men psychologically thoroughly before we can put them on PrePex, because if we get a guy who is a drug addict who is going to go home with the device and when he gets high, he thinks he can just remove the device so I think that is the breaking point of PrePex as we really need to make sure that the guy is mentally fit to be able to adhere to the PrePex rules.”

Men who are suited to use PrePex device are those who can handle the pain, men who fear needles, stitches and blood and men who are prepared to abstain for eight weeks.

“Some will go for PrePex only because they don’t want to see blood, needles and stitches or because they have seen how their friends healed.”

d. Provider Training and Training Evaluation

A group of ten providers - two Doctors, two Clinical Associates, three Enrolled Nurses, and three Professional Nurses - were trained in the use of the device. One Senior Clinical staff member was also trained to act as a monitor for the implementers and act as backup. Provider training was done by a Master Training team consisting of Clinicians associated to the manufacturer and 2 senior CHAPS trainers with many years of VMMC training experience. Each trainee provider was paired with another trainee, and each trainee received training as both PrePex primary providers and assistants (or secondary providers). Thus all Doctors and Clinical Associates were trained as Primary Providers, as well as assistants and all nurses, were also trained as Primary Providers and assistants.

The assessment of PrePex training was created from an abstraction of standard PrePex training materials that are part of the PrePex training curriculum, including training exams and trainee clinical assessments. When each trainee provider’s PrePex skills were found acceptable by passing a formal training course, involving theoretical and practical tests given by the PrePex Master Training team, the provider was certified by the training team and permitted to participate in the study as a PrePex study provider.

A Provider Survey assessed providers’ acceptance of the PrePex device following training, and at the end of the study. Survey questions focused on acceptability, ease of use, and providers’ perceptions on client acceptability. Furthermore providers were interviewed to determine device acceptability, attitudes towards and experience with device circumcision, impact of offering male circumcision on clinical practice and barriers and facilitators of clinicians’ implementation of device-supported circumcisions. They were interviewed before their training, post-training and after the study has been completed.

i. Strengths and weaknesses of the training

In order to improve the training on PrePex circumcision and to better improve service delivery to clients, **providers suggested that understanding how much pain will be experienced and at what stage in the procedure can help them prepare their clients more effectively.**

“...so we then understood that the pain is there and when you are with your clients you would know how to prepare them that there is no pain when you are placing but they will start to experience pain as the days go by.”

“I wish they could have explained to us more that people would come back because of pain I would have been prepared”

“...so if you tell them that you will start experiencing pain at this stage that will also protect you as the provider that you did not lie.”

One provider mentioned that counsellors who were involved in the procedure began to better prepare the clients with regards to pain expectations.

“Only in the beginning when the study started but as it progressed you would see them only complaining about pain and that would be on the last day and that became normal knowing that there is some kind of pain and the counsellors also started to changed their story when they saw what was actually going on with other clients”

ii. Satisfaction with the training

a. Post training but prior to PrePex implementation

After training had been completed (but prior to providers implementing PrePex circumcisions), providers were once again requested to answer a survey questionnaire. Providers were asked whether they felt prepared to implement PrePex – four providers felt very prepared while one provider was somewhat prepared. Furthermore, two providers were neutral while a further two felt somewhat unprepared. Providers were then asked whether they felt confident about their PrePex application skills. Seven providers stated that they felt very confident / certain, while one provider was somewhat confident/certain, and another one provider was neutral. When asked about their overall PrePex skills, seven providers felt very confident/certain, while the remaining providers felt somewhat confident/certain.

Most of the providers felt that the time of the training was inadequate, and did not feel confident in their skills, after the training had been completed but prior to the commencement of the study.

b. Post training and after PrePex implementation

After providers had been trained and had been implementing PrePex, they were again requested to answer a survey questionnaire. At this stage providers were asked whether they felt prepared to implement PrePex outside of the study – two out of the three providers that answered this question felt very confident to do so while one felt somewhat confident. Furthermore, **two providers felt very confident in their overall and application skills, while one provider felt somewhat confident; and all felt very confident in their removal skills of the PrePex device.**

Furthermore, one provider was very satisfied with their PrePex skills and enjoyed working with PrePex very much, another was somewhat satisfied with their skills and somewhat enjoyed working with the device, and the final provider that answered neutral to both these questions.

iii. Suggestions for training other health professionals

Providers stated that they were well trained to handle and perform the PrePex circumcision procedure; however **they all felt that they were not informed adequately with regards to pain experienced by clients during the procedure. They were under the impression that clients would not experience any pain using the PrePex device, indirectly misleading their clients with regards to pain:**

“in terms of the procedure I would say well they equipped us quite well and everything, I guess while training I did not anticipate people feeling so much pain because I remember the first day when I was inserting the device it was so exciting like wow, this is so easy and nice and when they came back on the day of the removal “Oh my God” they were in so much pain. There would be those ones who are strong enough to handle the pain and some are not, so honestly, for me I did not anticipate it; I thought it was pain free from start to finish. I guess it was also my fault because it doesn’t really make sense how a person cannot have pain when there is swelling but with the execution we were well equipped I must say.”

“When we were training we were also told there is no pain and when our clients started to experience pain they would blame us that we were the ones that were causing pain because we were not doing it correctly, so it was even a challenge for ourselves because we were not gaining the confidence because when you remove the device the client is in pain so it

end up being as if we know nothing and we are incompetent, of which the statement that we were told was wrong from the beginning that there is no pain so with time and after we had compared notes amongst us we then realised that it was not our fault and even the trainer admitted that the pain is there”

One provider expressed concern about the possibility of losing the trust of clients and members within their respective communities because of the provision of misleading information on how much pain will be experienced during the procedure.

“Once the clients experience the pain that we said it’s not there, it will be like we are shooting ourselves in the foot because they will go back to the community and tell that it is very painful and we won’t be trusted anymore because they will say I didn’t expect any pain and yet I had experience an excruciating one”

Providers were in consensus that **all medical healthcare professionals with knowledge on circumcision are capable of performing the procedure as long as they are properly trained.** Furthermore, the procedure is relatively simple, and thus **allows for nurses to perform the procedure and in certain situations even assist the providers with placing the device:**

“I don’t think the doctors need to supervise nurses, for me I was taught by the nurse some of the techniques of inserting properly, especially because there is no bleeding and any risks involved so why not let the nurses lead the process.”

Importantly, it **was expressed that persons who place and remove the PrePex device should have prior knowledge on circumcision to be able to perform the procedure.**

“They should also have a surgical circumcision knowledge and background, because you have to know what you are doing you can’t just take somebody who has no medical background so it has to be somebody who has worked in a circumcision environment and who has a general knowledge on circumcision.”

Training personnel apart from medical doctors to perform the procedure can be especially beneficial where there is a shortage of doctors.

“For me I see PrePex playing a bigger role in areas where they have shortage of doctors because you will find that in those areas MMC is lacking because of the shortage of staff, it doesn’t consume a lot of time to do it and as a result nurses can do more circumcisions with it, but in clinics where there are doctors it can serve as a support for surgical circumcision I don’t see it playing a major role there unless clients opt for it; but in rural areas where there is a shortage of doctors it can be pushed as a main service.”

Another provider expressed slight concern over the need for nurses to be adequately trained and prepared to handle any complications that may arise from the implementation of the device.

“After seeing the kind of adverse events that it can bring so I still think that if they roll it out to the rural areas they should first be trained for surgical because the very same clients that have done the PrePex might come back with a complication that might require surgical...”

By involving more nurses in the PrePex procedure, the demand for governmental doctors will be decreased which will then allow for more men to receive circumcision services in clinics.

“I think they could sell it in that way that you know what nurses you will be an independent service provider within the clinic because with surgical you are an assistant you are not independent and now PrePex will give you a responsibility and as nurse I would feel more proud to do something on my own without somebody having to always check up on me.”

Again, **providers felt that nurses could be trained to use PrePex device because of its easy use.**

“With surgical there is always that thing that a mistake can happen but with PrePex what mistake can you do, I have never seen an insertion that was not properly done or a removal that was not properly done, chances of causing harm to the client are less.”

e. Costing

Overall unit costs for VMMC were calculated prior to and after the introduction of the PrePex device in clinical facilities already conducting VMMC. Unit costs were also estimated by cost drivers (direct clinical labour, support staff, medicine and consumables, continuous quality improvements (CQI), overhead, training, equipment and vehicles). For a breakdown of overall unit costs and unit costs by cost drivers please refer to Table 1 below.

Table 24: Per unit costs of VMMC by cost component

Description of cost component	Per unit cost prior to PrePex™	Per unit cost after PrePex™ introduction
Per VMMC cost	\$121.92	\$117.46
Clinical Labor	\$50.73	\$39.37
Support Staff	\$39.44	\$26.92
Consumables	\$14.76	\$12.64
Equipment	\$3.14	\$3.14
Overhead	\$8.77	\$7.75
Vehicles	\$0.52	\$0.41
QA_QC	\$4.56	\$3.65

i. Overall unit cost

The overall unit cost of VMMC has been determined to be R1320.41 prior to the introduction PrePex and R1272.04 after the introduction of PrePex device. At the average exchange rate for 2014 of R10.83 = US\$1, the overall unit cost is US\$121.92 per circumcision performed prior to the introduction PrePex and US\$117.46 per circumcision performed after the introduction of the PrePex device. Since the cost per circumcision performed is lower after the introduction of the PrePex device, there is no incremental cost incurred after the introduction of PrePex.

This decrease in the per unit cost of VMMC can be attributed to two main factors; i) the total number of clients receiving VMMC services increased considerably after the introduction of the PrePex device and ii) the total expenditure incurred remained fairly constant.

- i. The **total number of clients increased by 25 percent after the introduction of PrePex**. In the year prior to the introduction of PrePex 16 158 clients received VMMC services in all three sites in South Africa. After the introduction of PrePex the total number of VMMC clients increased to 20 217. Since the unit costs are determined by dividing total costs by the total number of clients, such a substantial increase in the total number of clients greatly impacted the unit costs per VMMC after the introduction of PrePex.
- ii. **Even though the total number of clients increased considerably, the total expenditure decreased after the introduction of PrePex**. As we can see in Table 1.2, in the year prior to the introduction of PrePex, the total expenditure incurred was approximately US\$ 1.9 million (R21million) while the total expenditure incurred after the introduction of PrePex was approximately US\$ 1.8 million (R20.5million), thus resulting in a unexpected 4 percent

Table 25: Total costs of VMMC by cost component

Description of cost component	Total expenditure prior to PrePex™	Total expenditure after PrePex™ introduction
Total costs	\$1,970,000.96	\$1,897,838.72
Clinical Labor	\$819,631.53	\$796,019.62
Support Staff	\$637,252.68	\$544,205.77
Consumables	\$238,565.48	\$255,490.82
Equipment	\$50,726.87	\$63,469.81
Overhead	\$141,767.99	\$156,596.30
Vehicles	\$8,346.61	\$8,346.61
QA_QC	\$73,709.79	\$73,709.79

decrease in total expenditure. This decline in expenditure is attributable entirely to a decline in both direct and indirect labour after the introduction of PrePex. The only additional labour hired

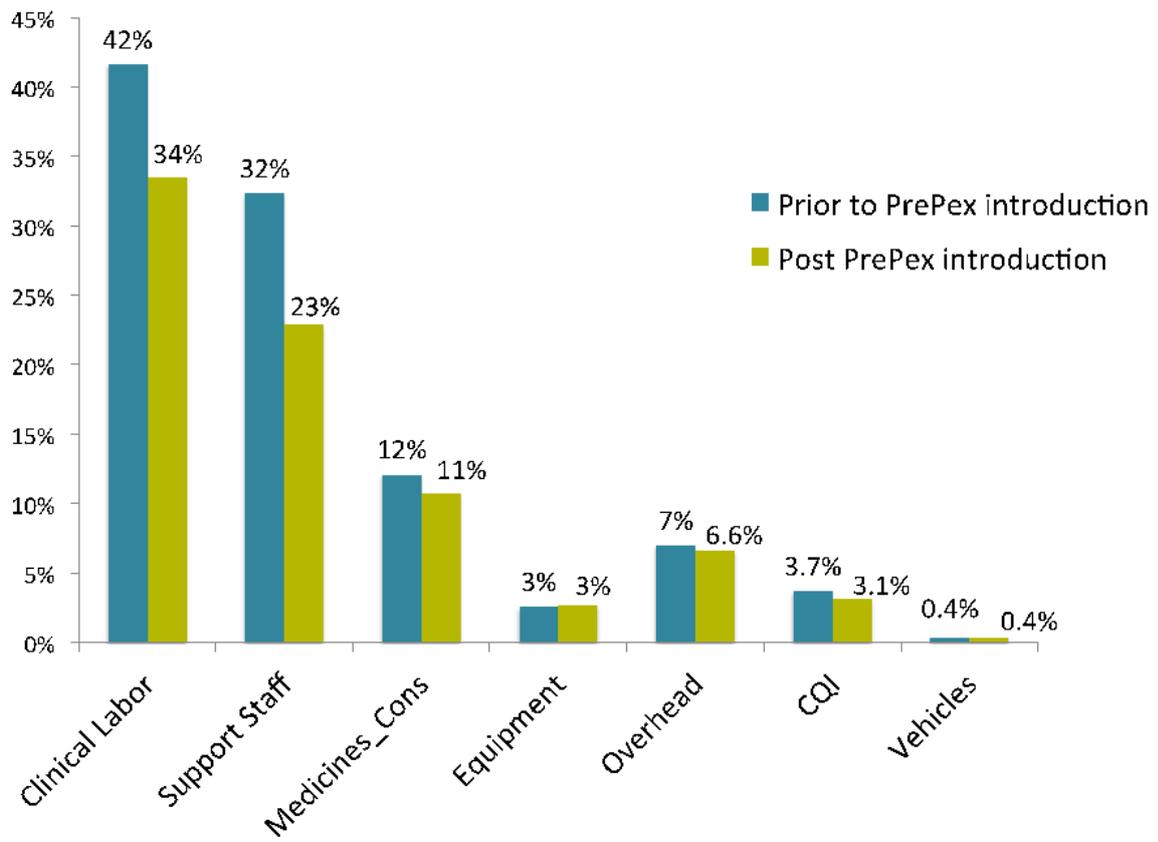
after the introduction of PrePex was one additional lab technician in Zola clinic. There was a decrease in the number of counselors in Katlehong clinic, as well as a reduction in the number of auxiliary nurses in both Katlehong and Orange Farm clinics. Lastly, two part-time enrolled (staff) nurses in Orange Farm clinic were reduced to one enrolled (staff) nurse after the introduction of PrePex. All other clinical staff in all three facilities remained the same.

Additionally, all other expenditures, namely equipment, overhead costs, CQI, and vehicles – remained the same with the exception of expenditures on medicines and consumables. The total expenditure on medicines and consumables in the year prior to the introduction of PrePex was US\$ 238 565 (approximately R2.5 million). **After the introduction of PrePex the total expenditure on medicines and consumables increased to US\$ 255 491 (approximately R2.7 million), resulting in a 7.1 percent increase in expenditure on medicines and consumables after the introduction of PrePex.**

ii. Unit cost by cost component

As we can see in Figure 1, cost drivers account can be ranked in the same order in terms of the proportion of per unit cost that are attributable to cost drivers. **The largest cost driver is clinical labour; prior to the introduction of PrePex direct labour i.e. clinical staff accounted for 42% of the per unit cost per circumcision performed while after the introduction of PrePex clinical staff accounted for 34% of the per unit cost per circumcision performed.** Support staff is the next source of costs, accounting for 32% and 23% of the unit cost per VMMC prior to and after the introduction of the PrePex device respectively. All other cost components remain the same, with a small increase in the cost of medicines and consumables.

Figure 3: Cost Drivers in terms of Proportion of Per Unit VMMC Costs prior to and after the Introduction of PrePex



IV. DISCUSSION, CONCLUSION AND RECOMMENDATIONS

a. Provider Training, Proficiency and Acceptability

Most providers felt equipped and confident to conduct PrePex circumcisions after the initial training, although one was neutral on both accounts. However, all providers felt that the time period of the training was inadequate and should have been longer to ensure that skills were properly learned. Initially, providers were mostly favourable towards the device, although two providers were not favourable at all – although even prior to commencing the study, all providers thought that the device looked easy to use.

Once providers had been conducting PrePex circumcisions for a few months (after a total of 400 PrePex circumcisions had been completed), providers stated that they were all very confident in their removal skills but less so in their application skills.

One of the key complaints that the providers had in terms of the training is that they felt misinformed about the level of pain the clients would endure. During the training the providers were told that clients would not have any pain, but once they had begun doing the circumcisions found that many clients in fact experienced very high levels of pain – especially during the removal process. This raised a professional concern, as providers were worried that clients would not trust the providers given that they were providing incorrect and misleading information about the level of pain they would experience.

Another key concern raised by the providers was the lack of control they would exercise over most of the “procedure”, given that the device is worn for seven days. Providers expressed discomfort with clients going home with the device and mentioned that monitoring clients on the day of the device’s removal would be difficult if there is an increase in PrePex uptake. They believed that dealing with a large number of clients on one day could cause difficulties in keeping track of clients who need the device to be removed especially men who do not return after seven days. In fact a number of withdrawals from the study were clients who had either tampered with the device prior to removal, or those who had simply decided not to return to remove the device. A handful of these clients were never seen again, and it is not known what the end result of the circumcision was.

Another limitation foreseen by the providers was the challenge of using a limited PrePex Sizing plate, which meant that a number of clients would not be able to be circumcised using the PrePex device. Of the actual clients that underwent circumcision using PrePex - in Orange Farm the greatest

number of clients were size A, followed by size B; in Katlehong the greatest number of clients were size B, followed by size C; and in Zola the greatest number of clients were size C, followed by size B.

Providers did feel that the procedure was simple enough that with the correct training, at a lengthened time than what was provided to them, lower cadres of health professionals would be able to perform circumcision using the PrePex device – but with the mention that a doctor would still need to be present for supervision as well as in the event that surgical removal of the device was required. Providers, however, felt that any cadre of health professional that would be trained in using the PrePex device would need to have prior knowledge of circumcision or be provided the full circumcision training and not solely on PrePex.

Furthermore, for providers, a key benefit of using the PrePex device for VMMC was the assurance of a needle and stitch-free procedure as well as the lack of blood loss. This assurance can recruit men who would not consider circumcision because of such barriers. Due to the sutureless circumcision, providers were extremely impressed with the cosmetic result of the PrePex circumcision – and felt that this too would increase the likelihood of recruiting men to consider circumcision with the PrePex device.

Another potential benefit as mentioned by the providers was the fact that a sterile environment is not needed to perform circumcisions using the PrePex device, which all providers thought would help in providing circumcisions in areas that do not have surgical facilities. This, together with the perceived decrease in cost due to the decrease in the number of consumables used, made providers believe that PrePex could help in scaling up circumcisions in South Africa faster than providing surgical circumcision alone. Providing clients with two methods of circumcision, surgical circumcision or PrePex circumcision can positively deal with the large amounts of men that come in to clinics to be circumcised. Furthermore, providers perceived the PrePex procedure allows for faster service whereas surgical circumcision is a time consuming process that demands more staff.

The providers did not concur on the recommendation for PrePex. Reasons for not recommending PrePex circumcision was because of the pain involved, smell and additional weeks involved in healing. These providers would only recommend PrePex if an anaesthetic was applied before device removal and stronger pain killers were administered during device wear. Among those who would recommend PrePex, the main reason was that it caters for men afraid of needles and is an alternative to surgical circumcision.

The main reason providers recommended and supported the use of PrePex device was because of its elimination of needles, stitches and blood. According to providers, identified groups of men who are not suited to use PrePex device were those who could not refrain from sexual intercourse for the eight week period following the removal of the device, men who could not handle the pain involved in the procedure, and men who were not psychologically stable.

Most providers felt positively about the DOH including PrePex in the VMMC programme. However, they suggested that PrePex be offered in conjunction with surgical circumcision. Furthermore, providing PrePex as an option in conjunction to surgical circumcision provides men with an alternative circumcision option to that of traditional circumcision methods or paying general practitioner fees.

b. Client Acceptability and Safety

Prior to undergoing the PrePex circumcision only 5% of clients reported to being worried about the circumcision – participants were mainly scared about possible pain that they would endure or a complication / adverse event (AE) that would occur. However, in reality, participants generally felt that the pain they experienced during the healing period was what they expected. Sixty-three percent (63%) said that a lot less painful than what they expected, while 14 participants stated that it was more or a lot more painful than what they had expected. Men who underwent PrePex circumcision found that the PrePex device placement did not hurt initially. Most experienced no pain after device placement. However, they began to experience pain after the first two days. Further the pain was much more severe at night than during the day. This was mainly due to erections experienced by men at night. Numerous men complained of additional pain during urination. Most men found that the pain subsided substantially after the PrePex device was removed, but that the pain intensified after a week following device removal. Numerous men found the pain experienced during the removal of the device to be intense and almost unbearable. Some of the men did complain that the medication provided at the clinic was ineffective in subsiding the pain they experienced, and many had to increase the dosage or take stronger medication. Furthermore, over and above pain experienced, clients complained of an odour between day 0 (application) and day 7 (removal), and began around the 3rd or 4th day – clients complained that the odour was intense and distinct. For some, the pain and odour did affect their return to normal activities and work.

However, when participants were asked on day 7 (on the day that the device was removed) how they would rate their ability to conduct routine activities since they had done the PrePex circumcision 82% of participants stated that it was very easy while 11% stated that it was somewhat easy. For most, PrePex allowed for men to continue with their work soon after device placement.

With regards to resuming sexual activities and masturbation - sixty-six participants had masturbated or had sex within the 8-week abstinence period. Furthermore, 46% and 13% said that it was very easy or somewhat easy, respectively, to abstain from sex or masturbation during the 8-week abstinence period. However, 9% and 7% respectively stated that it was somewhat difficult and very difficult to abstain. This means that over half did not find it difficult to abstain from either sexual intercourse or masturbation, although close to a 5th of participants found it very difficult and some did not stick to the stipulation that they must abstain from sexual intercourse. However, partners of the clients found it very difficult to abstain from sexual intercourse during the 8 weeks post-procedure. Some partner stated that they had in fact had intercourse with their partners even though they knew that the penis was not yet fully healed and engaging in sexual intercourse could allow for infections and spread diseases.

Most participants believed it would be easy to tell friends, family and partners about circumcision with PrePex; meaning that participants and their kin would presumably not have a problem with circumcision being done with the device. In fact, a number of participants had already recommended circumcision with the PrePex device to friends by the time the last interview was conducted with them as they were all extremely satisfied with the results. Many of the participants were particularly impressed with the cosmetic results of circumcisions done with the PrePex device.

In total 15 865 people went to the clinic to access circumcision services during the study period, however only 5 500 of these were between the ages of 18 and 49 years. Of the 5 500 clients who were between the ages of 18 and 49 years, 828 (15.1%) people were both eligible and opted to have circumcision done using the PrePex device. However, there were 25 withdrawals from the study.

In total there were twenty (20) AEs (in sixteen (16) people) out of 803 circumcisions, with an AE rate of 2.5%. This, however, does not include the withdrawals due to loss to follow up as well as due to the fact that some of those that underwent PrePex circumcisions required surgical removal of the device. Though these clients were withdrawn from the study, they were continuously monitored. These would increase the number of AEs to 45 out of 828 recruited clients, increasing the AE rate to 5.4%.

c. Costing

Based on the data available for this costing study, results indicate that there are no incremental costs of introducing PrePex-based circumcisions in clinical settings where surgical VMMC is already provided.

While in this study there were no incremental costs, it is possible that incremental costs in other settings might also be negligible. This is largely due to the fact that no additional expenditure due to equipment or overhead costs is likely to be incurred as a result of introducing PrePex. It is important to bear in mind that here we are assuming that PrePex-based circumcisions will be introduced in sites already performing surgical VMMC. With respect to sites that have been newly established to provide PrePex-based circumcisions, the findings of this study will likely not apply since in the case of new sites, additional equipment will have to be purchased.

Furthermore, the additional costs of adding PrePex in clinical VMMC settings may be minor since the costs of conducting VMMC using the PrePex device is considerably less than the items required for surgical MC. In the estimates included in this study, the cost per circumcision using PrePex was estimated to be approximately US\$ 102.25 while cost per surgical circumcision was estimated to be approximately US\$ 160.

Lastly, while direct labour might have to increase as the critical mass of total circumcisions increases, since circumcisions using the PrePex device can be conducted using non-physicians, it is possible that the total cost of labour for circumcision using PrePex will not increase as dramatically as the total number of circumcisions increases. However, additional research with a larger sample size of facilities needs to be conducted to verify these findings.

d. Recommendations

- Training should include a higher number of clients in order for providers to feel fully comfortable in the application and removal skills after the training and prior to commencing circumcisions using the PrePex device on their own.

- Clients and their partners should be provided with both verbal / oral explanations (reiterated before, during and after device application and removal) and published material that specifically states what they could expect and what to do if they have pain and/or odour, as well as key messages regarding abstinence.
- Marketing material should include the fact that PrePex is mainly bloodless (although some blood can sometimes be seen), sutureless, and has a good cosmetic result. However, marketing material must not misinform clients about PrePex circumcision being painless and that all clients will be able to resume normal activity immediately, as this is not always the case.
- Providers and clients should be told about the likely levels and time periods of pain that clients will endure from application until after the removal of the device – including on day 2 or 3, at removal, and during the first 7 days after the removal of the device.
- Stronger medication should be provided to clients for proper pain relief during the first 14 days, and an anaesthetic should be used during device removal.
- PrePex circumcisions cannot be a standalone service, but must be scaled up at the same time as surgical circumcision. All PrePex teams must also be proficient in conducting surgical circumcisions, and at least one qualified doctor should be included in all teams. This is to assure that when a complication arises, the proper medical attention and requirements are met. This will also assure that clients who are not eligible or do not want circumcision with the PrePex device are still able to undergo circumcision.

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