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TANZANIA PREPEX™ ACCEPTABILITY AND SAFETY STUDY (TZ-PASS)

TECHNICAL REPORT



ACCELOVATE



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ACRONYMS AND ABBREVIATIONS

AE	adverse event
C	counselor
CI	confidence interval
FDA	U.S. Food and Drug Administration
FGD	focus group discussion
GCP	good clinical practice
HPV	human papilloma virus
IQR	interquartile range
IRB	institutional review board
JHU	Johns Hopkins University
LTFU	loss to follow-up, lost to follow-up
MC	male circumcision
MCHIP	Maternal and Child Health Integrated Program
MRCC	Medical Research Coordinating Committee
MOHSW	Ministry of Health and Social Welfare
NIMR	National Institute of Medical Research
RA	research assistant
STI	sexually transmitted infection
TAG	technical advisory group
TZ-PASS	Tanzania PrePex™ Acceptability and Safety Study
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
VAS	visual aid score
VETA	Vocational and Educational Training Authority
VMMC	voluntary medical male circumcision
WHO	World Health Organization

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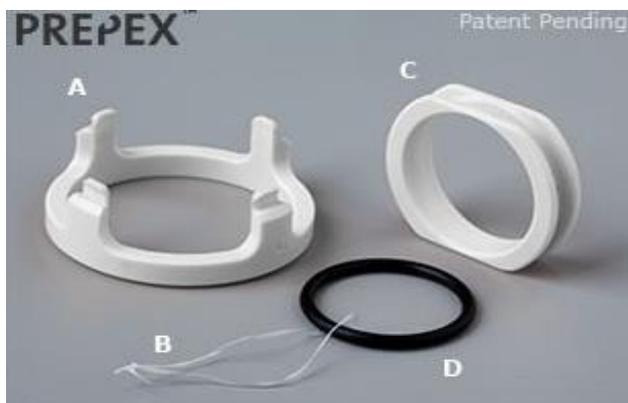
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SUMMARY OF FINDINGS

- A total of 3,309 clients attended nine study sites for services for VMMC during the study. Of these, 1,495 (45.2 percent) were adults aged 18 and above.
- Of 1,495 adults, 1,108 clients (74 percent) opted for circumcision using the PrePex™ device after being told offered the two methods of circumcision. Of these clients, 1,029 were from implementation phase of the study and were included in the analysis.
- Of 1,029 clients who opted for PrePex™ circumcision during the implementation phase, 870 (84.5 percent) were eligible for PrePex™ circumcision.
- One hundred fifty-nine clients (15.4 percent) did not meet inclusion criteria. HIV infection was the primary reason for exclusion, restricting 90 HIV-positive clients (56.6 percent of clients not meeting inclusion criteria). Overall HIV prevalence among adults attending circumcision services was 8.7 percent.
- The median age of clients who came for VMMC, opted for the procedure, and were found eligible for PrePex™ circumcision was 23 years (range 18–49 years).
- Of 870 eligible clients, 862 placements (99 percent) were successful. One client changed his mind on the way to the placement room. Three clients could not fit in any of the five PrePex™ device sizes. Placements were unable to be completed for four clients due to other anatomical conditions.
- Of 862 clients with successful placement, 31 clients (3.6 percent) were terminated from the study for various reasons and 29 were lost to follow-up.
- Of 802 clients who completed all visits, 785 (97.9 percent) were declared completely healed by Day 42. Of 802 clients that completed Day 42 medical exams, only 794 were interviewed. Of 794 clients interviewed for Day 42, 91.2 percent reported being satisfied with their wound's healing progress.
- Of 794 clients interviewed for the Day 42 Survey, 77 clients (9.7 percent) reported having had sex or masturbated before Day 42.
- The acceptability of the PrePex™ procedure was high; 99 percent of clients who returned for device removal reported being satisfied with the device and device procedures.
- Moderate to severe adverse events (AEs) were reported among 22 of 862 clients, for an AE rate of 2.5 percent [CI: 1.6, 3.8]. Delayed wound healing, excessive or insufficient skin removal, problems voiding, hematoma, swelling and edema, pain, infection, abdominal pain, diarrhea, and fever were reported as moderate to severe AEs.

BACKGROUND AND RATIONALE

Three independent prospective randomized controlled trials conducted in South Africa, Kenya, and Uganda demonstrated the efficacy of VMMC in preventing heterosexual acquisition of HIV infection in uninfected men by up to 60 percent (Gray et al. 2007; Auvert et al. 2005; Bailey et al. 2007). In 2007, based on the results of the three trials and past epidemiologic data, the World Health Organization and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended promotion of male circumcision (MC) as part of a comprehensive HIV prevention package (World Health Organization 2012b). Subsequent studies (Wawer et al. 2011; Mehta et al. 2013) have confirmed the value and persistence of MC protection against HIV infection. Additional studies have shown that MC not only reduces the prevalence and incidence of HIV but also of high-risk human papillomavirus infection in men, and provides partial protection against HPV transmission to female partners (Castellsagué et al. 2002; Tobian et al. 2009). Modeling exercises illustrate that over time, circumcision may confer a 46 percent reduction in the rate of male-to-female HIV transmission in high-prevalence settings by contributing to reduction of overall community HIV prevalence (Hallett et al. 2011). VMMC is targeted for scale-up in 14 countries with generalized heterosexual HIV epidemics and low MC rates, including Tanzania (Ehrhardt 2014).



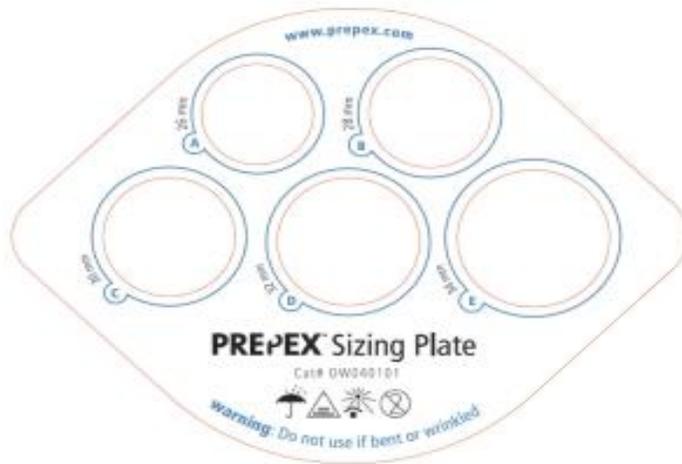
KEY A: Placement ring. B: Verification thread.
C: Inner ring. D: Elastic ring.

PrePex™ is a nonsurgical male circumcision system that uses a plastic and rubber device to help remove the foreskin without injections or stitches. The device is worn for seven days.

It is hypothesized that MC devices may accelerate delivery of VMMC by making the procedure quicker, easier, more replicable, safer, and potentially more cost-effective (World Health Organization 2012a). MC via such devices may also be attractive to potential clients who have concerns about or are otherwise reluctant to be surgically circumcised. One promising device for adult MC is PrePex™, which the U.S. Food and Drug Administration (FDA) recently cleared and which has received prequalification from the WHO. The PrePex™ device has been evaluated in eight studies conducted in Botswana, Lesotho, Rwanda, South Africa, Uganda, and Zimbabwe involving about 2,400 device placements (Bitega et al. 2011; Mutabazi et al. 2012; World Health Organization 2013a; Duffy et al. 2013; Njeuhmeli et al. 2014; Galukande et al. 2014; Feldblum et al. 2014; Mutabazi et al. 2014; Kigozi et al. 2014). Circumcision was

successfully completed in 99.5 percent of clients on whom the PrePex™ device was placed, and

the rate of AEs in these studies was 1.7 percent. Only 0.4 percent of AEs were severe; the rest were mild or moderate.



The World Health Organization (WHO) Technical Advisory Group (TAG) on Innovations in Male Circumcision concluded that the PrePex™ device is “clinically efficacious in male circumcision and safe for use among healthy men 18 years and older when used by trained mid-level providers in public health programs, provided that surgical backup facilities and skills are available in 6–12 hours to manage events that could lead to serious complications” (World Health Organization 2013b).

In Tanzania, since 2009, following the evidence on the protective effect of circumcision against HIV, the Tanzanian government, in collaboration with technical partners, has scaled up adult VMMC services in 12 priority regions with low circumcision rates and relatively high HIV prevalence; Iringa, Njombe, and Tabora are three of these regions. As of August 2015, more than 480,000 adolescents and adults had been circumcised with the WHO-recommended VMMC package at fixed and outreach sites, during campaigns, or during routine service delivery, in the three regions. As a strategy to scale up VMMC, the WHO preapproved PrePex™, a nonsurgical device for adults 18 to 49 years of age for VMMC (World Health Organization 2013b).

Given the limited financial and human resources available to reach the recommended VMMC targets in Tanzania, it is prudent to take advantage of techniques that capitalize on efficiencies. Use of devices such as PrePex™, which accomplish VMMC nonsurgically and can be performed by mid-level health care providers in a nonsterile setting, may make it more feasible to achieve recommended national targets with a lesser burden on the health care system than surgical circumcision. Use of PrePex™ may subsequently reduce the overall cost of human resource and infrastructure for VMMC (Duffy et al. 2013; Njeuhmeli et al. 2014).

Objective

The Tanzania PrePex™ Acceptability and Safety Study (TZ-PASS) was a pilot study aimed to generate quality data using objective criteria to determine the benefits, acceptability, and risks

of the PrePex™ device for nonsurgical circumcision in routine clinical settings in three regions in Tanzania.

The study examined clinical outcomes, healing time, and client and partner views on the experience of circumcision with this device. Clients who chose not to be circumcised using PrePex™ were asked why they made that decision; health care providers were asked about their experience in providing VMMC using the PrePex™ device. Incremental costs of integrating PrePex™ into the existing VMMC program were assessed.

Study Phases

TZ-PASS had three phases: a training phase, a two-week run-in phase, and an implementation phase.

Training Phase

Training of Research Assistants

The Tanzania PrePex™ study started on May 25, 2014. Before data collection commenced, a week-long training of 13 research assistants was held. Thirteen research assistants were trained on: study-specific procedures; how to use tablets for data collection; good clinical practice (GCP), mainly as it applied to obtaining informed consent; and basic human research ethics. Training was divided into theory and practical sessions. After classes ended, the 13 research assistants were divided into two groups for practical sessions during the run-in phase in two facilities at Makambako and Mafinga hospitals.

After the run-in phase was completed and sites began operations, research assistants were allocated to the various sites in Iringa and Njombe, two research assistants per site. After two months of study implementation, it was determined that low VMMC-yield study sites would be closed and that three new sites would open in the Tabora region. The introduction of this region required adding four research assistants to staff the new sites; some of the original research assistants were required to remain in the Iringa and Njombe at closed sites in order to document follow-up visits. The additional four research assistants were recruited, trained, and mentored by the existing research assistants. Over the study period, 17 research assistants were used in all.

Training of Health Care Providers

Five technical staff were trained in Rwanda on how to provide circumcision using the PrePex™ device. Three trainees were Jhpiego staff members, and two were from the Tanzania Ministry of Health and Social Welfare. Later, these Rwanda participants trained other health care providers

in facilities participating in TZ-PASS. TZ-PASS trainees for the PrePex™ circumcision course were selected by their respective hospital managements, from among already-trained VMMC service providers and counselors, who had been trained per the national guideline for provision of VMMC services. There were three PrePex™ circumcision course trainings. The first batch of participants attended counseling training, where six PrePex™ counselors were trained. The second and third batches were for “operators” (health care providers who would circumcise using the device), 20 of them in all, with, four from each of the PrePex™ study sites. These trainings lasted three days each, with Day 1 dedicated to the theory of the procedure, protocols for completing study medical forms, and a model demonstration, and Day 2 and Day 3 dedicated to practice on clients at the two practical sites, Makambako Town Hospital and Mafinga District Hospital. Thirty participants were trained from five sites: Makambako Town Hospital, Lugoda Hospital, Mafinga District Hospital, Ilula Mission Hospital (a designated district hospital), and Iringa Regional Hospital, a referral hospital.

Knowledge acquisition was assessed using competency-based exams. All participants correctly answered at least 85 percent of the assessment questions required for PrePex™ qualification. Skills of both counselors and PrePex™ providers were assessed using competency-based checklists. Counselors were expected to perform the skills involved in conducting group education and individual counseling and screening for PrePex™ eligibility; PrePex™ providers had to place and remove the PrePex™ device. To qualify, a provider had to perform each step correctly and follow the sequence consistently in at least 15 of 20 placements and ten of 15 removals. The training was conducted by the Jhpiego Tanzania PrePex™ trainer with support from four other PrePex™ providers, all trained in Rwanda. The PrePex™ master trainer from Rwanda, who also attended the training, oversaw the theory and practical sessions.

Health Care Provider Inclusion Criteria

- Adult aged 18 or older.
- Employed as a doctor, nurse, counselor, or clinical officer by Jhpiego or the Tanzania Ministry of Health and Social Welfare (MOHSW).
- Trained in PrePex™ circumcision procedures for the current trial.
- Able to understand study procedures and requirements.
- Agreed to complete study surveys and participate in focus group discussions (FGDs) at the conclusion of the study.
- Able to communicate in English and Kiswahili.
- Able and willing to provide written informed consent to participate.

Run-in Phase

During the run-in phase, VMMC clients who provided consent were circumcised using the PrePex™ device. The purpose of this phase, which included completion of all planned TZ-PASS procedures and data collection tools, was to identify and resolve any problem related to planned study procedures, data collection instruments, the data management system, and participant flow at the respective study sites. No data from the run-in phase were analyzed.

Implementation Phase

Clients who provided consent to participate in both the procedure and the study were circumcised using the PrePex™ device. The purpose of the implementation phase was to collect information on the acceptability and safety of PrePex™ circumcision in Tanzania and the cost of integrating the PrePex™ device into Tanzania's existing VMMC program.

Client Recruitment

Client recruitment commenced during the run-in phase, starting at two sites and expanding to other sites, gradually, as the research assistants learned to interview and enter data correctly and as providers were certified to perform PrePex™ circumcision. General VMMC demand creation was conducted in communities, while specific recruitment for the study and for circumcision with the PrePex™ device was done only at the study site. The run-in phase started at Makambako and Mafinga hospitals on June 4 and 5, 2014, respectively. Other sites followed (Table 1).

Table 1. Open and Closure Dates for PrePex™ Study Sites

Hospital	Start date		Closure date
	Run-in phase	Implementation phase	
Ilula Mission Hospital	June 26, 2014	June 30, 2014	October 11, 2014
Iringa Regional Hospital	June 26, 2014	June 28, 2014	October 11, 2014
Lugoda Hospital	June 19, 2014	June 23, 2014	October 11, 2014
Mafinga District Hospital	June 5, 2014	June 16, 2014	August 25, 2014
Makambako Town Hospital	June 4, 2014	June 16, 2014	October 11, 2014
Kibena District Hospital	July 21, 2014	July 21, 2014	October 11, 2014
Kitete Regional Referral Hospital	No run-in phase	August 18, 2014	October 27, 2014
Nzega District Hospital	No run-in phase	August 18, 2014	October 27, 2014
Igunga District Hospital	No run-in phase	August 18, 2014	October 27, 2014

Client Flow in PrePex™ Study Sites

When clients reported to a clinic for VMMC, they were processed following standardized VMMC procedures. First, VMMC risks and benefits were discussed in group education sessions; these were segregated by age, with separate sessions for adults and adolescents. During adult sessions, counselors discussed general facts about VMMC and HIV, then introduced the two methods of circumcision offered at the clinic—the surgical method and the nonsurgical method using PrePex™. When a client showed interest in PrePex™ circumcision, a sticker was placed in his file to flag him for study procedures. Clients interested in surgical circumcision proceeded through normal VMMC client channels. Clients interested in PrePex™ but found not eligible for it were advised to go for surgical circumcision. A research assistant administered the study consent procedure and a preprocedure interview to those found eligible; other study-specific procedures followed. Each client was informed of all study requirements and given a client reminder card listing dates to return to the clinic for follow-up visits. In addition, all clients were advised to come back at any time in case of problems. Appendix I provides a diagram of client flow at health facilities on Day 0, recruitment day.

Methodology

Study Design and Sampling

TZ-PASS was a single-arm, open-label, prospective cohort study employing a mixed-methods approach. It was conducted from June to October 2014. To complete the sample size for the study, 845 clients were required. The total sample size planned and achieved for both qualitative and quantitative study is listed below (Table 2). This report presents the quantitative findings from this study.

Table 2. TZ-PASS Planned and Achieved Sample Size

Population	Planned sample size	Achieved sample size
VMMC clients circumcised using the PrePex™ device	40 during the run-in phase 805 during the implementation phase	76 during the run-in phase 862 during the implementation phase
VMMC clients circumcised, enrolled in the study, and sampled into FGDs	1 FGD per site	7 FGDs
VMMC clients opting for surgical circumcision	100 clients	89 clients
VMMC clients opting for surgical circumcision	1 FGD per site	1 FGD
Female partners of men circumcised using the PrePex™ device (interview)	40 female	57 female

Population	Planned sample size	Achieved sample size
Female partners of men circumcised using the PrePex™ device, sampled into FGDs	1 FGD per site	7 FGDs
Provider trainees	30 (20 operators and 10 counselors)	30 (20 operators and 10 counselors)
Provider trainees sampled into FGDs	3 FGD (1 per region)	1 FGD
Community leaders sampled into FGDs	1 FGD per community	5 FGDs

Study Tools

Various tools were used to collect data during TZ-PASS. Data collection was administered by counselors, health care providers, and research assistants (Table 3).

Table 3. Data Collection Tools

Timing	Data collection tool	Who collected ^d
Day 0	Eligibility Checklist	C
Day 0	Preplacement Survey	RA
Day 0	Placement Form	HCP
Day 0 ^a	Survey of Men Who Refused the PrePex™ Device	RA
Day 2	Day 2 Survey	RA
Day 2	Day 2 Medical Follow-Up Form	HCP
Day 7	Day 7 Preremoval Survey	RA
Day 7	Day 7 Medical Follow-Up Form	HCP
Day 7	Day 7 Removal Form	HCP
Day 7	Day 7 Post-Removal Survey	RA
Day 7 ^a	Sexual Female Partners Survey	RA
Day 42	Follow-Up Visit Survey	RA
Day 42 ^b	Follow-Up Medical Form	HCP
	Focus Group Discussions	
	Men circumcised by PrePex™	RA
	Female partners of men circumcised by PrePex™	RA
	HCPs performed PrePex™ circumcision	RA
	Village leaders and influential people in the community	RA
All visits ^c	Adverse Event Report	HCP
All visits ^c	Moderate or Severe Adverse Event Report	HCP
All visits ^c	Device Adverse Event Report	HCP

^a Issued on the day of refusal but corresponding interview conducted at clients' convenience. ^b Filled out on Day 42, 49, and any other follow-up visits. ^c Filled out during any visit where there was an AE or device AE. ^d C = Counselor. HCP = health care provider. RA = research assistant.

Eligibility Checklist: This was collected by the VMMC counselor after client counseling. The form was used to screen for the client's TZ-PASS eligibility.

Preplacement Survey: The research assistant collected this during the first visit after the client was found eligible for the study but prior to device placement. The survey collected client demographic details, including household characteristics and knowledge on MC (e.g., reasons for coming to facility, reasons for opting for PrePex™, and knowledge about sex and condom use).

Placement Form: The health care provider filled this out during the PrePex™ placement procedure. The placement form covered: patient clinical condition prior to placement; time required for device placement; analgesics and anesthetic used prior to placement; size of the device used and ease of device placement; any AEs occurring during placement; and pain rating at 2 minutes, 15 minutes, and 30 minutes post placement. The form also documented noncompleted placements and their causes.

Survey of Men Who Refused PrePex™ Device: Men who opted for surgical circumcision over PrePex™ were surveyed in a random sample. The survey aimed to collect demographic characteristics; assess whether the men had heard about PrePex™ before coming to the health facility; asked men about their sources of information about PrePex™; documented the distance from their residence to the health facility; and asked them to give possible reasons for refusing a PrePex™ circumcision.

Day 2 Survey: Forty-eight hours after device placement, this survey assessed a client's progress and comfort since placement. There were four main parts. The first part addressed daily living with the device in situ, probing for: information on physical comfort with the device in place; physical comfort around other people with the device in place; experience with cleaning the penis with the device in place; client ability to pursue routine and daily activities with the device in place; and possible AEs. The second part of the Day 2 Survey concerned odor and the client's experience with odor (e.g., when noticed, by whom, and whether it affected daily activities). Clients were also asked whether close friends or relatives had noticed odor. The third part of the Day 2 Survey collected information about pain, including the level of pain and how it had affected daily activities, and asked clients whether they could recommend PrePex™ circumcision to close friends or relatives, specifically with respect to the pain they had experienced. The final part of the Day 2 Survey asked clients whether they had required assistance in bathing or penis cleaning, who had provided that assistance, and whether they had masturbated or had sex since device placement.

Day 2, 7, and 42 Medical Follow-Up Visit Forms: Health care providers collected these during the Day 2, Day 7, and Day 42 visits, as well as during any others that clients required. The forms

collected results from the client physical examination, provided a medical review before and during the visit, noted medicines prescribed, and documented wound healing.

Day 7 Preremoval Survey: Collected on the removal day (Day 7), this survey aimed to assess client comfort and any difficulties experienced since the last visit. The survey collected the same information collected during the Day 2 Survey, with the addition of a section asking clients whether they had discussed the PrePex™ device with others.

Removal Form: Health care providers completed this tool during the removal procedure on Day 7. It captured any AEs that occurred during device removal, the time required for device removal, the ease of device removal, and any occurrence of pain at 2 and 15 minutes after device removal.

Post-Removal Survey: Research assistants administered this survey after the device was removed, with the aim of collecting data on client perceptions of all device procedures, from placement to removal. The survey also gave clients the opportunity to provide feedback on how to improve the PrePex™ circumcision procedure.

Follow-Up Visit Survey: Research assistants used this tool to collect information during clients' last visit, on Day 42. A truncated version of the Day 2 and Day 7 surveys, this one: collected information about physical comfort, penis cleaning, and ability to pursue daily activities; asked whether clients had needed post-procedure assistance and whether clients had masturbated or had sex during healing; and had clients rate their satisfaction with the overall healing progress.

Female Sexual Partner Survey: Sampled female sexual partners of men who were circumcised using PrePex™ provided information for this survey aimed at assessing partners' opinion about PrePex™. The survey collected partners' demographic information and their opinions about the PrePex™ device and their experience about caring for their partner post circumcision. Partners were asked whether they liked or did not like the PrePex™ circumcision and whether they would recommend surgical circumcision or circumcision using PrePex™. The survey was scheduled with the sexual partners up to 30 days post removal, at their convenience.

Adverse Events Report: Health care providers filled out this tool any time an AE was reported. The form collected the AE time and type, the level of severity, and the likelihood of relationship between the AE and the PrePex™ device.

Moderate or Severe Adverse Event Report: Health care providers filled these out at any time during the study when a moderate or severe AE was noted. The report collected data on when the moderate or severe AE occurred, the type of AE, and how it was treated.

Device Adverse Event Report: This tool was completed when the AE report suggested that the AE was related to the PrePex™ device. Information was collected on the AE type and timing.

Study Visits

Each client circumcised by a PrePex™ device as part of the study was asked to complete at least three follow-up visits to the health facility after the placement. The first follow-up visit was to occur on Day 2 after device placement and was aimed mainly at observing client progress and at tracking any post-placement AEs. The second follow-up visit was to be conducted on Day 7 post placement, with the aim of removing the device and monitoring for AEs. Clients who did not attend the first and second follow-up visits were traced using the phone number and physical address. Ten attempts to call and physical visits at different times were required before declaring the client was declared lost to follow-up (LTFU) for the Day 2 and Day 7 follow-up visits. The third follow-up visit, on Day 42 after device placement, aimed to assess the healing stage of the client's wound as well as to monitor for post-removal AEs. If a client did not attend the third follow-up visit, five attempts were made to telephone him and physically trace him before declaring him LTFU. However, the study allowed and encouraged clients to return at any time during the study in the event of AEs while wearing the device or after removal.

Study Geographic Area

The study was conducted in hospitals that had high volume (in terms of number of clients) and that met criteria for a health facility's participation in a PrePex™ acceptability and safety study in Iringa, Njombe, and Tabora regions of Tanzania.

Site Inclusion Criteria

For a health facility to become a TZ-PASS site, it had to meet the following criteria:

- The facility must be able to provide surgical circumcision within six hours of a PrePex™ placement attempt, in cases where the PrePex™ procedure was not successful.
- Its personnel must have the capacity to medically manage severe AEs.
- Its health care providers must be trained in the use of the PrePex™ device.
- It must have the capacity to perform all aspects of the PrePex™ procedure within the study time frame (i.e., with follow-up of at least 42 days).

Study Population

To evaluate the acceptability and safety of the device, TZ-PASS explored different populations, including: VMMC clients circumcised using the PrePex™ device; VMMC clients who opted for surgical circumcision; female partners of men circumcised using PrePex™; community leaders;

and health care providers who were trained on PrePex™ and who performed both PrePex™ and surgical circumcisions.

PrePex™ Clients

This group comprised VMMC clients who chose to be circumcised using PrePex™ and who were enrolled in the study. The study recruited healthy, HIV-negative males aged 18 to 49 who were seeking VMMC services at participating health facilities in Tanzania. Men seeking VMMC were asked, after group education, to participate in the study. Clients were given the opportunity to choose between surgical VMMC and VMMC using PrePex™. Only clients who met study eligibility criteria and who signed (or thumb printed) two copies of informed consent forms were qualified for enrollment. There were no special public announcements or promotions for PrePex™ circumcision services outside health facilities.

Client Inclusion Criteria: Men to be circumcised using the PrePex™ device during the study period needed to meet all of the following criteria:

- Aged 18 to 49.
- Uncircumcised, with foreskin fully intact.
- Voluntarily seeking medical circumcision at one of the four study sites.
- Agreed to be circumcised using the PrePex™ device.
- HIV seronegative, confirmed by a rapid HIV test performed by the study counselor before circumcision.
- Able to fit penis into one of the five PrePex™ ring sizes.
- Able to understand study procedures and requirements.
- Agreed to follow comprehensive pre- and post-circumcision care instructions.
- Agreed to return to the health facility for scheduled follow-up visits (or as instructed) after circumcision, for a minimum six weeks.
- Willing to have contact information used for study follow-up (i.e., telephone number, address of residence, and other locator information).
- Agreed to permit the genital area to be photographed to document and medically manage moderate or severe AEs, in the potentially rare event of their occurrence.
- Agreed to complete study surveys and medical evaluations in person at a minimum of six time points.
- Able to communicate in English or Kiswahili.
- Able and willing to provide written informed consent to participate.

Client Exclusion Criteria: These were as follows:

- Positive HIV status.
- Known bleeding disorders.

- Known diabetes or hypertension.
- Anatomic genital abnormalities or injuries (e.g., phimosis, paraphimosis, tight or torn frenulum, hypospadias, epispadias).
- Narrow foreskin opening.
- Active genital infection.
- Dermatitis of the foreskin.
- Warts on the glans or on the inner surface of the foreskin.
- Active infectious disease impairing health.
- Any physical or mental condition that, in the opinion of the supervising VMMC provider, likely would prevent the client from undergoing circumcision using the PrePex™ device or participating in complete follow-up.

Female Partners

This component of the study population comprised wives, girlfriends, or other female partners of the clients who chose circumcision using PrePex™. After the client had healed from his circumcision, his female partner was asked to participate in interviews and later FGDs on her views of PrePex™ and MC.

Clients Not Choosing PrePex™

Men who came to a study site for VMMC and who were circumcised but who declined the PrePex™ device for their circumcision procedure were asked to complete a questionnaire exploring their reasons for choosing surgery over PrePex™ for MC. Some of these men were invited to attend FGDs to express their views about the procedure.

Community Leaders

The study considered, as community leaders, individuals thought to occupy positions of authority or respect within their community (e.g., clergymen, council members, village leaders, elders). It was expected that they would be able to anticipate and provide insight into community views on the use of PrePex™ for MC. Several community leaders in the areas served by participating clinics were asked to participate in FGDs.

Health Care Providers

Health care providers included the doctors, nurses, and clinical officers performing circumcisions using the PrePex™ device for the study. Participating providers were asked to respond to a survey and/or attend a FGD at the end of TZ-PASS.

PrePex™ Study Site Orientation

Before the study, local and regional government officials, selected influential community leaders, regional medical officers, and district medical officers were oriented to study policy and procedures in formal meetings in each TZ-PASS region. After obtaining permission at regional level, meetings were held within districts; all leaders were invited. In the district, meetings and presentations were done at health facility level, with all providers told about the study and oriented to it, both providers performing VMMC and those not involved.



Picture 1. Session of Iringa and Njombe Regional Administration Leaders Attending a PrePex™ Orientation at Vocational and Educational Training Authority (VETA) Hall in Iringa Town

Data Entry and Uploading

Data entry was done using both paper-based and electronic tools (i.e., tablets). All study surveys were collected using tablets, with paper questionnaires as backup in case of device malfunction or power outage. All medical forms were filled in by health care providers for easy reference and review. Then the forms were given to research assistants, who entered them onto the tablets and uploaded the data to the PrePex™ database daily. The database could be accessed only by authorized personnel.

Ethical Considerations

An ethical clearance to conduct the study was granted by the Medical Research Coordinating Committee (MRCC) of the National Institute for Medical Research (NIMR), with certificate reference number NIMR/HQ/R.8a/Vol. IX/1702, and by the Johns Hopkins University (JHU)

Institutional Review Board (IRB), with certificate reference number IRB00005379. All participants signed two copies of the consent form, one for their own reference and another for study reference. Study participants were given one copy of the consent to take home.

Data Security and Confidentiality

Study procedures and interviews were completed one client at a time to ensure confidentiality. Clients were given an option to select whether they preferred that their provider be male or female. All completed study forms were stored in a locked metal cabinet in a room that only the research team could access. All forms with client identifiers, including consent forms and client locator forms, were stored separately from other study information, to protect client identities. All study forms were assigned a study ID for confidentiality, and the master file containing study IDs and personal information was kept in the Jhpiego office, away from the health facilities. After each client completed the study forms and procedures, the file containing his information was removed from the health facility and kept at the local Jhpiego regional office for security and confidentiality. Survey information collected using tablets was password protected for security. In addition, as soon as the interview was completed, the data was sent directly to the server; no client information remained on the tablets.

FINDINGS

Client Enrollment

During the study time period, a total of 3,309 clients attended the four study sites for VMMC services, 1,495 of them (45.2 percent) adults. Among adults who came for VMMC services, 1,108 of clients (74 percent) opted for PrePex™ circumcision after learning about the two methods. During the TZ-PASS run-in phase, 79 clients were enrolled; during the implementation phase, 1,029 clients were enrolled. For analysis, data was analyzed only for the 1,029 implementation-phase clients. Of these, 870 clients (84.5 percent) were eligible for PrePex™ circumcision, and all went for placement except one (who changed his mind on the way to the placement room). Three clients did not meet the sizing qualification, and medical conditions prevented placement completion for another four clients. Thus, of 869 attempted placements, 862 (99.2 percent) resulted in successful circumcision with PrePex™.

Eligibility Checklist (n = 1029)

As mentioned in previous sections, clients were evaluated according to specific criteria for inclusion and exclusion. Only those who met all required criteria were enrolled. Of the 1,029 who expressed interest, 154 (15 percent) were found not eligible for the PrePex™ study after assessment according to the inclusion and exclusion criteria.

Table 4. TZ-PASS Client Inclusion Criteria, with Number and Percentage of Clients

Criteria	Number	Percentage
Inclusion Criteria Group 1 (n = 1029)		
<i>Client answers "yes" to any the following criteria</i>		
Is the client aged 18 through 49 years old today?	1,024	99.5
Was the result of the HIV screening negative?	939	91.2
Is the client voluntarily seeking circumcision at this facility?	1,028	99.9
Does the client agree to be circumcised with PrePex™?	1,019	99.0
Inclusion Criteria Group 2 (n = 926)		
<i>Client answers "yes" to any the following criteria</i>		
Does the client understand Kiswahili?	926	100
Is the client willing and able to abstain from sexual activity for six weeks?	926	100
Does the client agree to complete all study visits at this clinic?	905	97.7
Is the client willing to have contact information used for study follow-up?	917	99.0
Is the client willing to answer survey questions?	918	99.1

Inclusion criteria used a phased approach (Table 4). Men were first assessed against the criteria in Inclusion Group 1; those who failed to meet these criteria were dropped. Those who met Inclusion Group 1 criteria were then assessed against Inclusion Group 2 criteria. About 8.8 percent of clients who opted for PrePex™ were dropped due to HIV infection. Clients who opted for circumcision using the PrePex™ device but who were more than 49 years of age were also excluded. Another approximately 2.3 percent of clients who opted for circumcision using PrePex™ did not agree to complete all study visits at the clinics because of their schedules and were therefore excluded from TZ-PASS.

Men who met all Group 1 and Group 2 inclusion criteria were reviewed against a list of disease/disorder and then anatomical exclusion criteria. Nine clients were excluded due to phimosis, paraphimosis, or adhesion of prepuce to glans; seven due to hydrocele; five due to active genital infection; and five because of other conditions (e.g., cyst on foreskin, genital sore/ulcer, or narrow, short, or tight foreskin). Three were excluded because their foreskin was not intact.

Table 5. TZ-PASS Client Exclusion Criteria, with Number and Percentage of Clients

Criteria	Number	Percentage
Exclusion Criteria Group 1 (n = 903)		
Is the client under treatment for diabetes?	1	0.1
Is the client under treatment for hypertension	1	0.1
Is the client under treatment for any bleeding disorder?	1	0.1
Does the client have an active infectious disease impairing health?	1	0.1
Exclusion Criteria Group 2* (n = 902)		
Foreskin is not intact	3	0.3
Phimosis, paraphimosis, adhesion of prepuce to glans	9	1.0
Tight frenulum	2	0.2
Hypospadias, epispadias	1	0.1
Hydrocele	7	0.8
Scrotal hernia	0	
Other genital anomaly	3	0.3
Active genital infection	5	0.6
Warts on the glans or inner surface of foreskin	1	0.1
Other conditions (e.g., cyst on foreskin, genital sore/ulcer, narrow foreskin, short foreskin, tight foreskin)	5	0.6

* Some clients had multiple exclusion criteria

Preplacement Survey (n = 863)

All eligible clients who consented to participate in the study were interviewed before going for PrePex™ device placement—mainly to collect demographic information and assess their views about VMMC in general and about the PrePex™ circumcision in particular. A total of 863 clients

were surveyed (. includes the information of the one client who changed his mind about PrePex™ circumcision on the way to the placement room).

Demographics of PrePex™ Clients

Demographic information, including client age, marital status, religion, and occupation, was collected and analyzed from the preplacement survey forms.

Age

The mean age of clients who came for VMMC services, opted for PrePex™, and were found eligible for PrePex™ circumcision was 25.3 years (range 18 through 49; Table 6).

Marital Status

Most clients eligible for PrePex™ had never been married (i.e., 62.5 percent of all clients who opted and were eligible); 37.2 percent of all eligible clients were married (Table 6, Figure 2).

Religion

Religion was among the demographic characteristics assessed before service provision (Table 6). The majority (84.7 percent) of all clients who came for VMMC and who opted for PrePex™ and were found eligible were Christian. Some said they had no religion or were Muslim (11.9 percent and 3.4 percent, respectively).

Occupation

The main economic or income-generating activity of clients who opted for PrePex™ circumcision and were found eligible was assessed (Table 6). Clients were divided into two major groups. One group was self-employed in farming (34.5 percent of those who opted and were found eligible); the other group comprised those working either full time or part time in an organization (30.5 percent of those who opted and were found eligible). A number of clients were in school (13 percent of all who opted for PrePex™ and were found eligible).

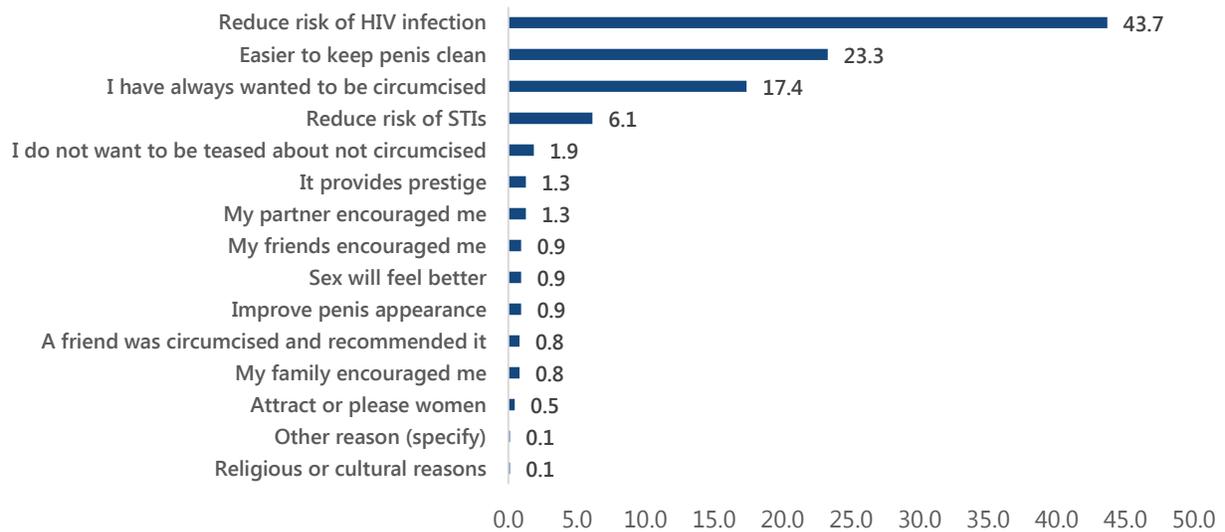
Table 6. Sociodemographic Factors of Men Who Were Eligible for PrePex™ Circumcision (n = 863)

Sociodemographic factor	Number	Percent
Age, mean [SD]	25.3 [7.2]	
Education level		
No formal education	180	20.9
Primary education	538	62.3
Secondary education	121	14.0
College and above	24	2.8

Sociodemographic factor	Number	Percent
Marital status		
Never married	539	62.5
Married/live with partner	321	37.2
Divorced	3	0.4
Religion		
No religion	103	11.9
Christians	731	84.7
Muslim	29	3.4
Occupation		
Employed	263	30.5
Farming	298	34.5
Business (self-employed)	187	21.7
Student	112	13.0
Handicapped/cannot work	2	0.2
Missing	1	0.1
Total	863	100.0

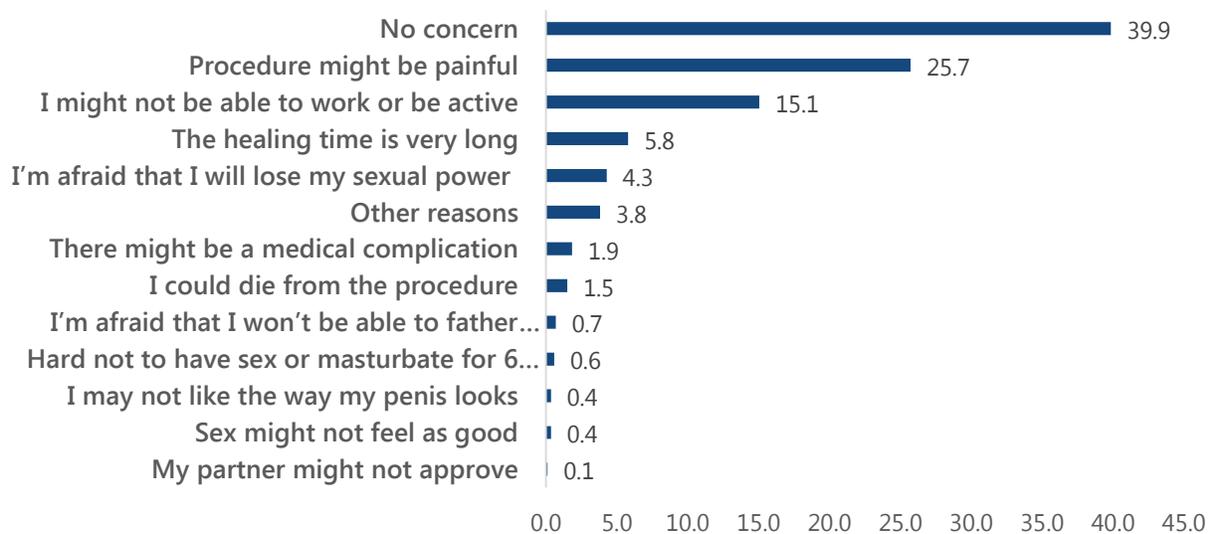
Main Reason for Coming for VMMC

Clients were asked their main reason for seeking VMMC services (Figure 2). Reduction of HIV infection risk was reported by close to 43.7 percent of all clients who came for VMMC services in health facilities offering PrePex™ services. Other factors identified as the main reason were reported as the ease of penis cleaning (23.3 percent of men who came for VMMC services) and the fact that men wanted to be circumcised (reported by 17.4 percent).

Figure 2. Reasons Clients Sought VMMC Services during TZ-PASS (n = 863)

Main Concerns about VMMC

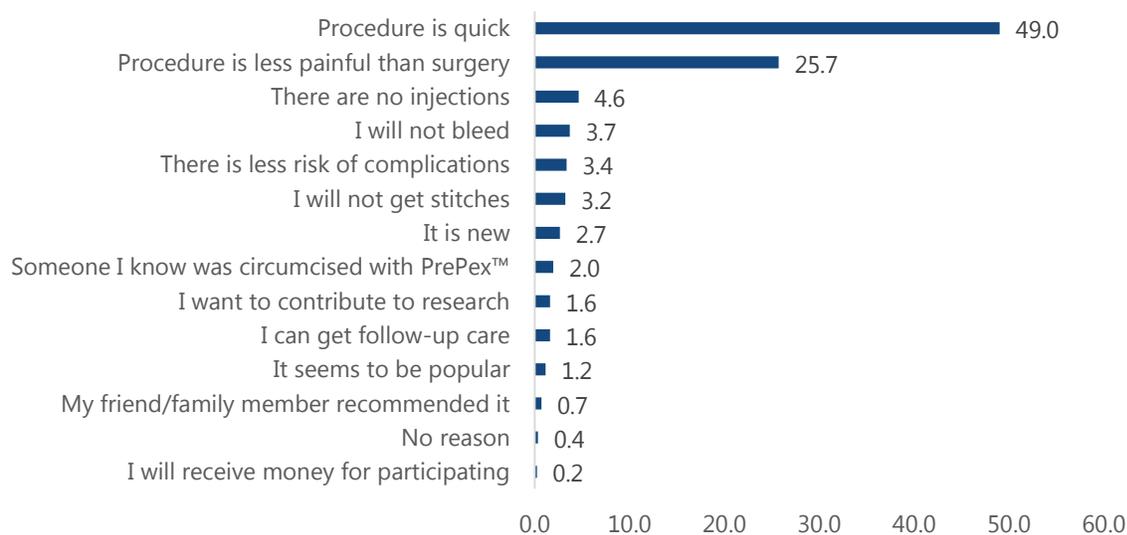
Men were also asked to list whether they had any concerns about VMMC services (Figure 4). About 40 percent of men who came for the VMMC services in health facilities offering PrePex™ circumcision reported having no concerns with the service. Pain during the procedure and the ability to work after the procedure were the main reported concerns of men who came for the VMMC services who opted for and were eligible for PrePex™ services.

Figure 3. Main Client Concerns about VMMC during TZ-PASS (n = 863)

Reasons for Opting for PrePex™ Circumcision

All clients who reported to opt for PrePex™ circumcision were interviewed before the procedure to determine their main reasons for opting for PrePex™ circumcision (Figure 5). About half of all clients who opted for PrePex™ (49.2 percent) reported making the choice out of a belief that the procedure would be quicker than a surgical procedure. The second most-reported reason for choosing PrePex™ circumcision among all who opted for it was the belief that the procedure would be less painful (25.8 percent). Other reasons for selecting the PrePex™ procedure are shown below.

Figure 4. Reasons Clients Sought Circumcision during TZ-PASS (n = 863)



Clients' Main Concerns about PrePex™ Circumcision

PrePex™ circumcision is a new method of circumcision for these three regions; potential clients received information about the procedure only after arriving at the health facility. Among all clients who reported for VMMC and opted for PrePex™ circumcision, 70 percent reported having no concern about it. However, about 9 percent of clients who opted for PrePex™ were worried that the procedure might be painful. Other concerns, although in lesser percentages, were about: not being able to work; healing time; medical complications; not being able to be active; the need for six weeks of sexual abstinence; potential for sex not to feel as good; and potential lack of approval by female sexual partners.

Successful PrePex™ Device Placement Procedures (n = 862)

A total of 870 clients agreed to participate in circumcision using the PrePex™ device. One client changed his mind on the way to the placement room, thus 869 clients went for device placement. Of all placement attempts made, 862 were successful; seven were not. Of these

seven, three clients could not complete PrePex™ placement due to fit (the smallest device size was too large), and the remaining four had other conditions that made placement difficult. All study analyses were based on the 862 successful placements. Clients were interviewed and assessed during placement procedures. Clinical conditions, fidelity to protocol, AEs and pain during placement, size of device used, and ease of placement were assessed.

Clinical Conditions Prior to Device Placement

Among who met eligibility criteria, temperature, weight, and blood pressure were measured. Blood pressure was normal in all clients who opted for PrePex™ and who were ready for the procedure; their average temperature was 36.6° C and their average weight 60 kilograms. Vital signs were assessed before placement was commenced.

Protocol Adherence during Placement

Protocols were observed to ensure that study guidelines were followed. Four preplacement elements were completed: local anesthetic cream was applied, a circumcision line was marked on the penis, topical disinfectant was applied, and analgesics were administered. During the TZ-PASS implementation, each of these four preplacement procedures was observed more than 97 percent of the time.

Adverse Events during Placement

Clients were observed and interviewed if they reported any AEs during device placement. Sixteen AEs were reported (Table 7).

Table 7. Adverse Events during Device Placement during TZ-PASS

Type of AEs	Number
Pain	10
Bleeding	2
Damage to the penis	1
Difficulty with placement	1
Reaction to anesthetic cream	1
Reaction to analgesic medication	1

Of 16 reports of AEs during device placement, 10 were pain. Two clients reported bleeding during device placement.

Pain during Placement

Since pain was the most-reported AE it was also assessed at different stages (Table 8). Pain was assessed using a visual analog scale (VAS) within 2 minutes, 15 minutes, and 30 minutes of device placements.

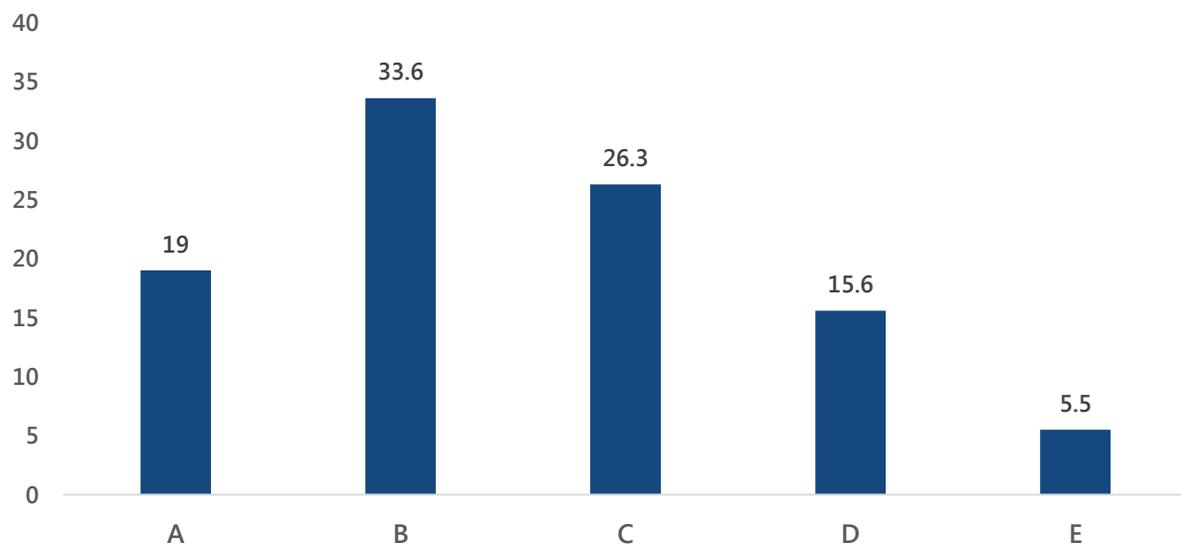
Table 8. Pain Assessed by Visual Analog Scale at 2, 15, and 30 Minutes after PrePex™ Device Placement during TZ-PASS (n = 862)

	Pain during placement		
	2 minutes	15 minutes	30 minutes
VAS 0	844	859	861
VAS 2	17	3	1
VAS 4	1	0	0

The VAS pain scores revealed decrease in pain level over time. Eighteen clients reported a VAS score above zero at 2 minutes. At 15 minutes, only three clients reported VAS above zero, and only one client reported VAS above zero at 30 minutes post placement.

Device Size

All sizes of PrePex™ devices used were recorded to learn the distribution of sizes (Figure 5). Devices were labeled in sizes A through E, with A being the smallest. The most-used size was B (used by 33.6 percent of all clients circumcised using the PrePex™ device). The second most-used size was C (used by 26.3 percent of all clients circumcised using the device). The least-used device size was E (used by only 5.5 percent of clients).

Figure 5. Sizes of PrePex™ Device, Used for Circumcision during TZ-PASS (n = 862)

Device Size by Regions

TZ-PASS was undertaken in Iringa, Tabora, and Njombe regions of Tanzania. Because the PrePex™ devices used in the study came in different sizes, an analysis was undertaken to understand the variation in PrePex™ device size used by region (Table 9 on the following page).

Table 9. Variation of PrePex™ Device Size by Region among PrePex™ Clients during TZ-PASS (n = 862)

PrePex™ size small to large	Number (percent)			Total
	Iringa region	Njombe region	Tabora region	
A	53 (18)	81 (30)	30 (10)	164 (19)
B	96 (33)	103 (39)	91 (30)	290 (34)
C	91 (31)	53 (20)	83 (28)	227 (26)
D	28 (13)	26 (10)	70 (23)	134 (16)
E	16 (5)	4 (2)	27 (9)	47 (5)
Total	294 (100)	267 (100)	301 (100)	862 (100)

Assessment showed variation in PrePex™ device sizes used by region ($p < 0.001$). The smaller size was more widely used in Njombe, the large sizes more widely used in Tabora.

Ease of Device Placement

Health care providers were surveyed in addition to clients on the ease of device placement. Almost all providers trained on PrePex™ circumcision reported completing device placement procedures as “easy.” Approximately 96 percent of all placements done were reported as having been “very easy.” One health care provider reported a “somewhat difficult” experience in one placement procedure.

Day 2 Survey (n = 844)

Of 862 clients for whom placement was successful, 11 clients were terminated from the study. The remaining 851 returned after 48 hours for an assessment and were interviewed for the Day 2 Survey, with data for seven clients missing due to data collection error (forms were not saved before electronic transmission and were lost). The TZ-PASS analysis was based on the 844 clients who completed Day 2 Survey form. At the same time, health care providers trained on PrePex™ circumcision performed a medical checkup on each client.

Physical Comfort

As part of the Day 2 Survey, clients were interviewed on their physical comfort and comfort around people with the device in situ (Table 10).

Table 10. PrePex™ Clients’ Physical Comfort and Comfort around People during TZ-PASS (n = 844)

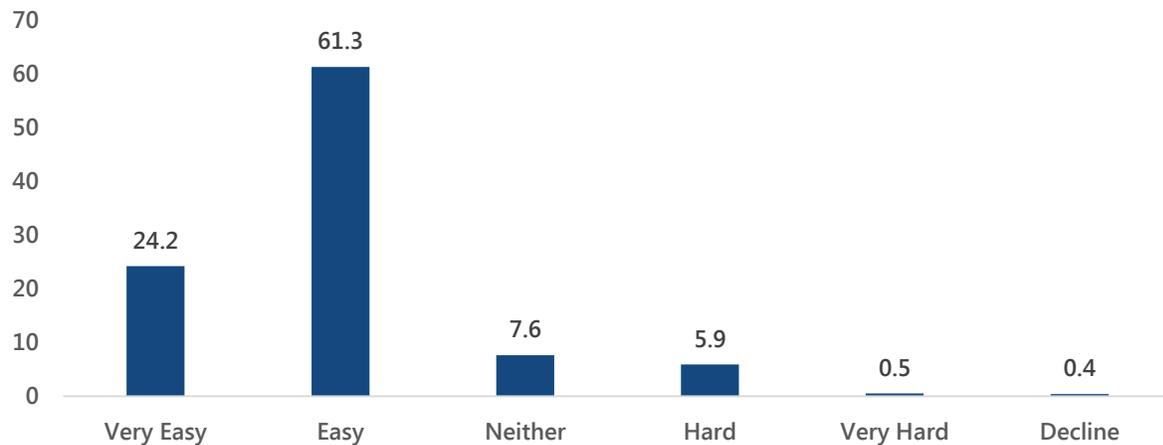
Rate	Percentage	
	Physical comfort	Comfort around people
Very comfortable	21.5	29.7
Comfortable	73.9	65.0
Uncomfortable	4.0	5.0

Rate	Percentage	
	Physical comfort	Comfort around people
Very uncomfortable	0.6	0.2
Total	100	100

The Day 2 Survey revealed that clients who had been circumcised using the PrePex™ device and who returned had felt both physically comfortable (94.7 percent) and comfortable around people with the device in situ (95.4 percent).

Ease of Penis Cleaning

Figure 6. Ease of Penis Cleaning Reported by TZ-PASS PrePex™ Clients during Day 2 Survey (n = 844)



During the Day 2 Survey, clients were also asked to rate the ease of penis cleaning with the device in situ. More than 85 percent of clients reported it easy—61.3 percent “easy” and 24.2 percent “very easy” to do so (Figure 6).

Odor within 48 Hours

During their 48-hour visit at the health facility, 177 clients (21 percent of those who returned for this visit) reported having noticed an odor. However, of all clients who reported odor, none stated that they found the odor so unpleasant that they would not recommend PrePex™ to close male friends or relatives.

Pain within 48 Hours

One hundred and sixty two clients (19.0 percent of all those who returned for the Day 2 Survey) reported pain. Two clients (0.4 percent) of those returning for the 48-hour assessment, reported pain so unpleasant that they would not recommend PrePex™ circumcision to close male friends or relatives.

Day 2 and Day 7 Follow-Up Medical Visits

On Day 2 and Day 7, in addition to taking surveys, TZ-PASS followed up to assess client progress medically and to record any AEs. While 851 clients returned for the 48-hour medical assessments, 829 returned for planned Day 7 medical visits. Four clients came for an additional unscheduled visit (repeat visits).

Pain Assessed by Visual Analog Scale

VAS revealed that the proportion of patients reporting pain decreased between Day 2 and Day 7 (Table 11). Report of pain was slightly higher on Day 2, with 19 percent of clients experiencing pain on Day 2 and 16.8 percent on Day 7. The four clients returned for an additional unscheduled visit reported little pain (3 reported no pain and 1 “hurts little more”).

Table 11. PrePex™ Clients’ Visual Analog Scale Scores for Pain and Odor Noticed during Day 2, Day 7, and Unscheduled Medical Visits during TZ-PASS

Category	Day 2 visit	Day 7 visit
VAS pain level	n = 851	n = 829
No hurt	689 (81.0)	690 (83.2)
Hurts little bit	156 (18.3)	126 (15.2)
Hurts little more	5 (0.6)	9 (1.1)
Hurts even more	1 (0.1)	4 (0.5)
Odor		
No odor	674 (79.2)	433 (52.2)
Slight odor	177 (20.8)	393 (47.4)
Strong odor	0	3 (0.4)
Total	100	100

Odor during Medical Visits

Odor was noticed more on visits on Day 7 than on Day 2, with odors reported as “slight” among 47 percent (on Day 7) and 21 percent (on Day 2).

PrePex™ Device Pre-removal Visit, Day 7 (n = 831)

All clients who returned for a Day 2 visit were supposed to come for a removal visit on Day 7. A total of 831 were examined by the provider. During Day 7 visits, three types of surveys were conducted by research assistants (pre-removal, removal and post-removal). The Pre-removal survey was conducted among 765 clients as this instrument was not initially included in the local IRB approval so its use was delayed until about a week after the implementation phase started. Clients were interviewed; their clinical condition and ability to conduct routine activities were assessed; and the device was removed. For several reasons, 20 clients (2.4 percent) were terminated from the study before removal.

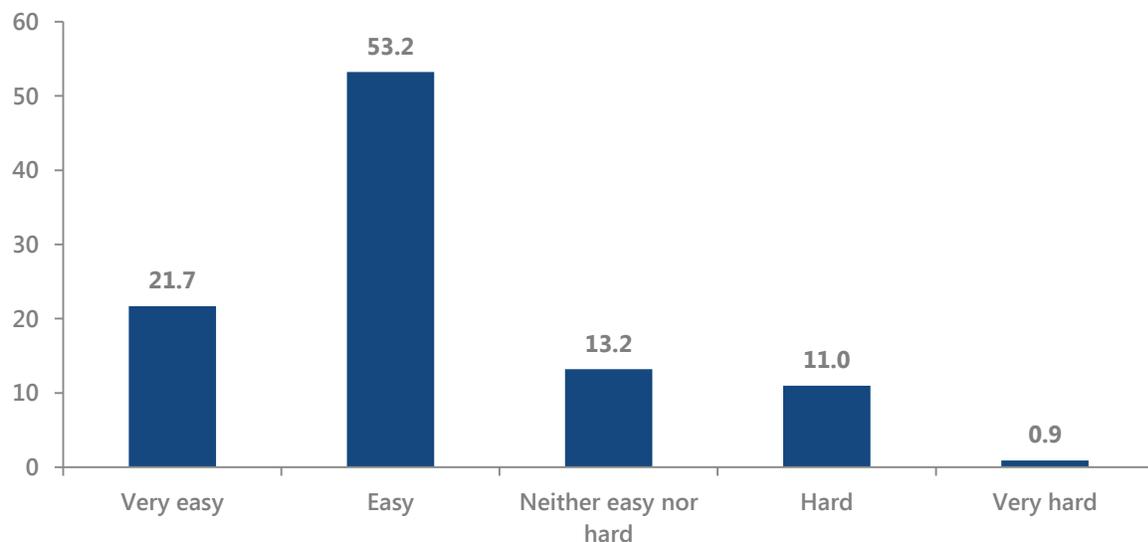
Visit Date

Although clients were supposed to return on Day 7, they were given the flexibility to come before then if the need arose. Nonetheless, most PrePex™ clients (97 percent of those who returned for removal) presented themselves on Day 7, the planned removal day. For varying reasons, 2.4 percent of clients requested early removal of the device. Another 0.6 percent returned late for removal.

Rating the Ease of Penis Cleaning

Just before the devices were removed, clients were interviewed to track their experience and feelings. All clients were asked to participate in the Day 7 Preremoval Survey. On the day of device removal and just before the device was removed, clients were again asked to rate the ease of penis cleaning (Figure 7).

Figure 7. Ease of Penis Cleaning on Day 7, before the Device Was Removed, Reported by PrePex™ clients during TZ-PASS (n = 765)



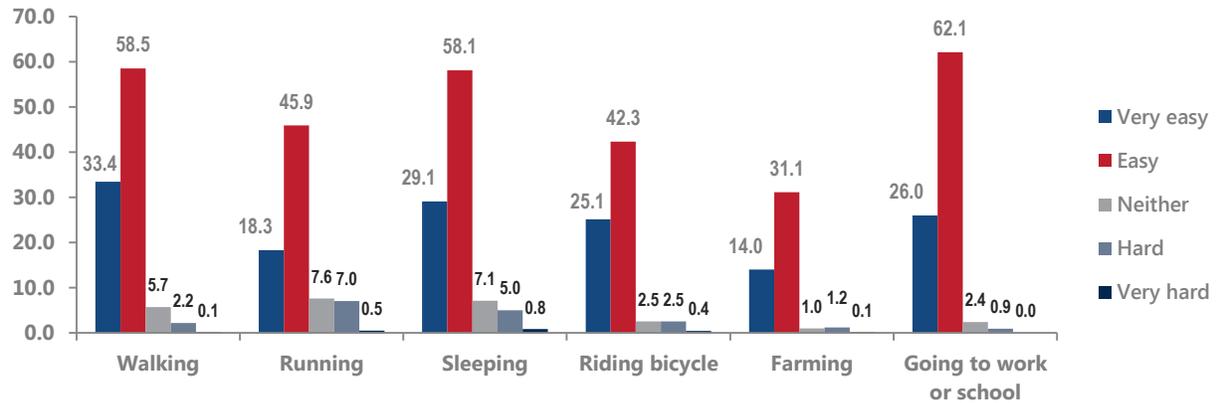
More than 70 percent of clients who came for removal and who were interviewed for the Day 7 Preremoval Survey reported the penis as being “easy” to clean. About 11 percent rated the cleaning “hard,” 0.9 percent as “very hard.”

Ability to Do Daily Activities

Before device removal, clients who had been circumcised using the PrePex™ device were asked to rate their ability to pursue their daily activities (Figure 8). Farming, riding a bicycle, and running were the least easy activities for men to pursue without problems while wearing the

device. Walking, sleeping, and going to work or school were reported to be easily done by men with the device in place.

Figure 8. Ability to Pursue Daily Activities As Reported by PrePex™ Clients on Day 7, before Device Removal, during TZ-PASS (n = 765)



Odor on Removal Day

A total of 531 clients (69 percent) reported experiencing odor from their penis during removal visits. About five of these clients considered the odor so unpleasant that they regretted choosing PrePex™ circumcision; one said he would not recommend PrePex™ circumcision to a close male friend or relative.

Pain on Removal Day

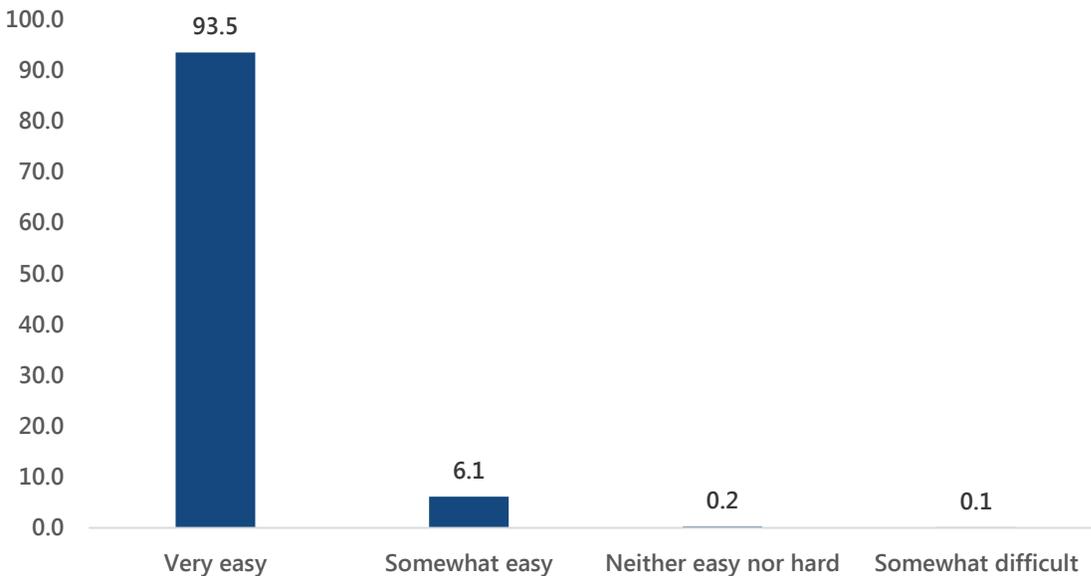
On removal day, 460 clients (60.0 percent) reported experiencing pain before removal. Of these, seven clients (1.5 percent) reported that the pain was so unpleasant that they regretted choosing PrePex™ circumcision, and two (0.4 percent) reported pain so unpleasant that they would not recommend PrePex™ to a close male friend or relative. Pain during removal was reported by 321 clients of all clients surveyed (41.9 percent).

Day 7 Removal Form (n = 831)

Rating Ease of Removal

Health care providers were interviewed in addition to clients. Providers were asked to rate the ease of device removal (Figure 9).

Figure 9. Health Care Provider Rating of the Ease of Removing the PrePex™ Device during TZ-PASS (n = 831)



Health care providers rated the device removal process “very easy” in 93.5 percent of cases—“somewhat easy” in 6.2 percent of removals. Some difficulty was reported (via ratings of “somewhat difficult” and “neither easy nor hard”) in less than 1 percent of removals. In some cases, as judged appropriate by health care providers, eight clients slated for device removal (1 percent) were given analgesics prior to that procedure.

Conditions before and during Removal

Swelling was the most-reported of conditions experienced since the 48-hour visits; it was reported by 39 clients (5 percent of all clients who returned for removal). Other conditions reported are shown below (Table 12). Pain was the most-reported condition during device removal; it was reported by 330 of 831 clients (39.7 percent of all clients who came for removal). Other conditions reported during device removal were penis damage and bleeding.

Table 12. Conditions of Clients since Last Visit and Conditions during Removal Visit among PrePex™ Clients during TZ-PASS (n = 831)

	Number	Percent
Conditions before Removal		
Swelling	39	5
Blisters or ulcers	4	0.5
Others	5	0.6
Conditions during Removal		
Pain	330	39.7
Penis damage	1	0.1
Bleeding	1	0.1

Visual Analog Scale Pain Score during Device Removal

During device removal, as noted, pain was commonly reported; it was measured using the VAS.

Table 13. Visual Analog Scale Pain Score at 2 and 15 Minutes after Device Removal among Those Circumcised Using PrePex™ during TZ-PASS (n = 831)

VAS pain score	2 minutes		15 minutes	
	Number	Percent	Number	Percent
No hurt	525	63.2	809	97.3
Hurt a little bit	253	30.6	21	2.6
Hurt a little more	32	3.9	0	0
Hurts even more	20	2.4	1	0.1

When pain was reported during device removal, the level seemed to be lower than during previous assessments and to decrease over time (Table 13). At 2 minutes, for example, 253 clients (30.6 percent of those who returned for removal) reported that it “hurt a little bit,” while 21 clients (2.6 percent) gave the same evaluation after 15 minutes. “No hurt” was reported by about 525 clients (63.2 percent) at the 2-minute assessment and by 809 clients (97.3 percent) after 15 minutes.

Satisfaction with the Circumcision Experience

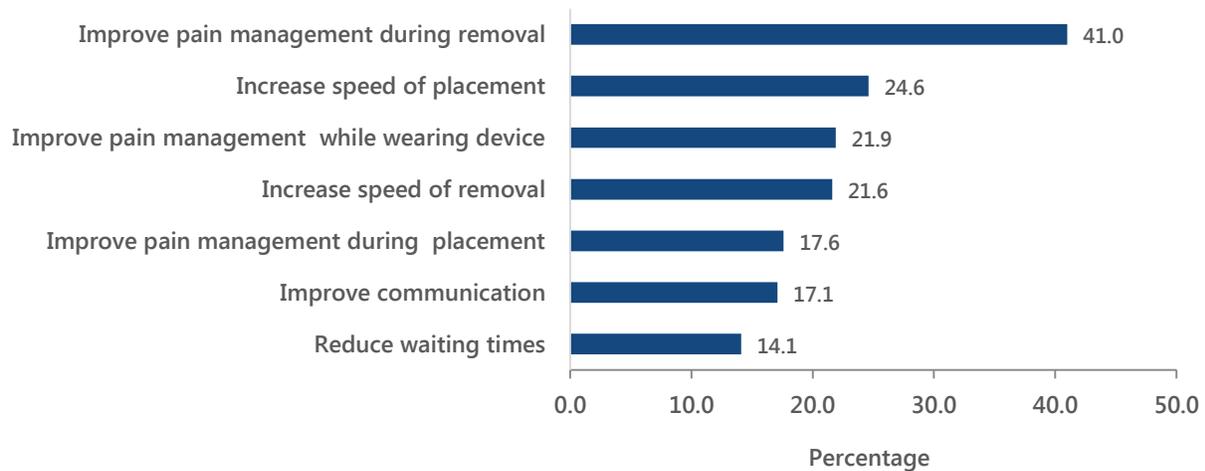
After the device was removed, clients were asked to measure their level of satisfaction. About 86 percent of clients who turned up for removal reported to be “very satisfied” with the PrePex™ procedures after the device was removed, while an additional 13 percent reported being “satisfied” with the procedure. Only 0.9 percent were “neither satisfied nor dissatisfied.”

Day 7 Post-Removal Survey (n = 732)

What Can Be Done to Improve PrePex™ Services?

On the day the device was removed, after removal, clients spent 30 minutes in observation then were asked to participate in the post-removal survey. Ninety-nine clients left without completing the post-removal survey, leaving 732 clients. The results of these interviews on their opinion of how PrePex™ circumcision services could be improved is presented in Figure 10.

Figure 10. Client Opinions on How to Improve PrePex™ Device Services during TZ-PASS (n = 732)



The most-reported area identified for potential improvement was around pain management during device removal (reported by 41 percent of clients who were circumcised using the PrePex™ device and who returned for device removal). The second most-reported area was around placement speed (suggested by 24 percent of all clients who were circumcised using PrePex™ and who returned for device removal). Percentages were similar (21 percent) around two additional potential areas for improvement: pain management during device placement and removal time.

Day 42 Follow-Up Medical Visit (n=802) and Survey (n=794)

Of the 831 clients who had come for removal, 29 clients (3.5 percent) were LTFU. Of these, 794 completed the Day 42 Follow-Up Visit Survey, while 802 completed the medical follow-up form. Before being assessed on wound healing by a trained health care provider, research assistants sought their feedback on clients' physical comfort, ease of penis cleaning, and satisfaction with wound healing since their last visit to the health facility. Of the 802 clients who returned on Day 42, 776 (96.8 percent) returned on the planned visit day, while the rest returned after.

Physical Comfort

Asked to rate their physical comfort since their previous health facility visit (Table 14 on the following page), 785 clients reported that they had been physically comfortable. Eight clients reported that they had not been physically comfortable.

Table 14. Physical Comfort during Follow-Up Visit after Device Removal among PrePex™ Clients during TZ-PASS (n = 794)

Rate	Number	Percentage
Very comfortable	680	85.7
Comfortable	105	13.2
Uncomfortable	7	0.9
Very uncomfortable	1	0.2

Ease of Penis Cleaning

Clients were asked how they rated the ease of penis cleaning (Table 14). Some 95 percent reported that it was “easy” to clean the penis, with 74.6 percent reporting it “very easy.” About 0.9 percent of clients who returned for the Day 42 follow-up visit reported that it was “hard.”

Table 15. Ease of Penis Cleaning Reported during the Day 42 Follow-Up Visit among PrePex™ Clients during TZ-PASS (n = 794)

Rate	Number	Percentage
Very easy	594	74.6
Easy	160	20.4
Neither easy nor hard	32	4.2
Hard	4	0.5
Very hard	3	0.4
Missing	1	—
Total	794	100

Satisfaction with Wound Healing

Clients were interviewed to determine their level of satisfaction with wound healing (Table 16). About 88.4 percent of all clients interviewed for the Day 42 Follow-Up Visit Survey reported being “very satisfied” with the healing of their wounds, and an additional 9.9 percent were “satisfied.”

Table 16. Satisfaction with Wound Healing Expressed during the Day 42 Follow-Up Visit Survey by PrePex™ Clients during TZ-PASS (n = 794)

Wound Healing Satisfaction	Number	Percentage
Very satisfied	701	88.4
Satisfied	79	9.9
Neither satisfied nor dissatisfied	11	1.4
Dissatisfied	1	0.1
Very dissatisfied	1	0.1
Missing	1	—
Total	794	100

As reported post removal, 1.4 percent were “neither satisfied nor dissatisfied” with their wound healing. One client reported being “dissatisfied” and one “very dissatisfied.” Data for one man were missing from the server, perhaps due to uploading errors and/or poor Internet connection.

Day 42 Medical Follow-Up (n = 802)

All clients were informed about all visits and were required to come to all, including follow-up medical visits to assess wound healing. For the visit known as the Day 42 Medical Follow-Up, 802 clients attended. Of these, all were seen by the provider for the medical exam and data was collected and analyzed from 794 clients. Data from the interview data from 8 clients was not available for analysis. Interview data was collected on tablets and sent to a central server, at which time it was deleted from the source tablet. This data did not reach the server and the data from these clients either was lost due to data collection error (not saving file before sending) or not collected.

Conditions Presented during the Day 42 Medical Follow-Up

During the Day 42 Medical Follow-Up, very few clients reported AEs or reported having experienced one since their last visit to the health facility. Pain on erection was the AE most commonly reported by clients as having been experienced since their last visit to the health facility; during the Day 42 medical examination itself, pain was the most-reported AE. Of those who had some complaints during the Day 42 Medical Follow-Up, four clients (0.5 percent) were prescribed medication during the visit. Other conditions that were reported to have occurred since the previous clinic visit or during the exam are below (Table 17).

Table 17. Conditions Experienced since Previous Health Facility Visit and Presented during the Day 42 Medical Follow-Up by PrePex™ Clients during TZ-PASS (n = 802)

Conditions since Last Visit	Number	Percentage
Pain on erection	9	1.1
Hematoma	1	0.1
Infection	2	0.2
Other	1	0.1
Conditions during Examination		
Pain	6	0.7
Discharge	1	0.1
Painful swelling	1	0.1
Enlarged lymph nodes	1	0.1
Hematoma	1	0.1

Wound Healing

A core component of the Day 42 Medical Follow-Up was to assess the wound healing stage. Trained health care providers observed clients to evaluate wound healing.

Table 18. Wound Healing Stage Observed during Day 42 Medical Follow-Up among PrePex™ Clients during TZ-PASS (n = 802)

Wound Healing Stage	Number	Percentage
Normal skin	785	97.9
Skin completely closed; may lack pigmentation or be reddened	6	0.7
Wound edges and center filled in; surrounding tissues intact and not reddened	10	1.2
Wound bed filling with pink granulating tissue; slough present; free of necrotic tissue; minimum drainage and odor	1	0.1
Total	802	100

Assessments confirmed that for 785 clients (97.9 percent of the 802 clients who returned and completed the Day 42 Medical Follow-Up), the wound was healed, with normal skin. For 17 clients (3 percent), wounds were reported not fully healed (Table 18).

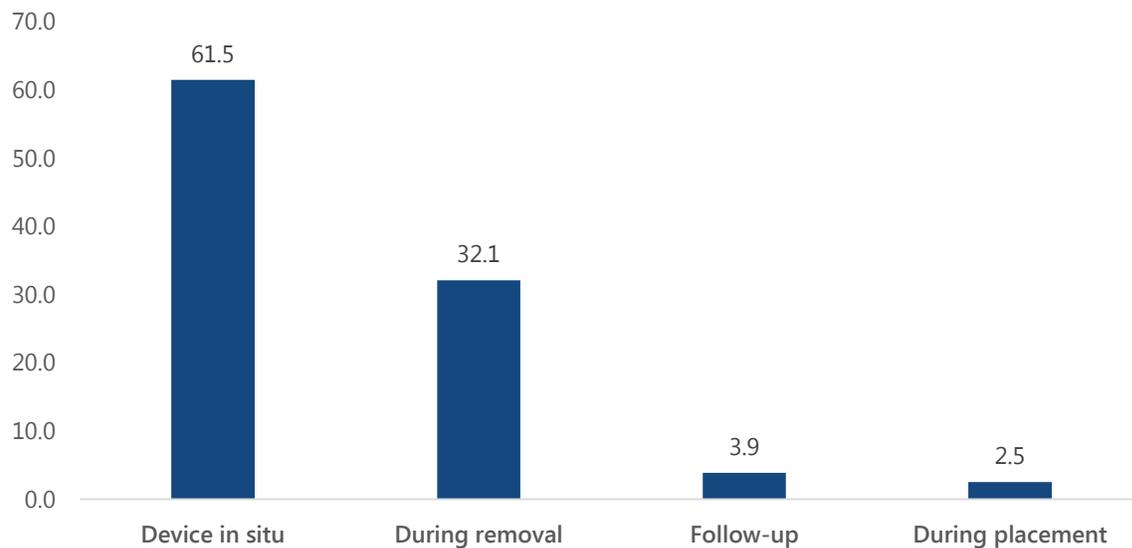
Adverse Events during TZ-PASS

The definition of an “adverse event” in this study is similar to the one used by the FDA; the term indicates any undesirable experience associated with the use of a medical product in a patient. During TZ-PASS, an AE included any undesirable experience occurring after the PrePex™ circumcision and before the study closed.

In all stages of TZ-PASS, clients were asked to report any AEs experienced at any time during the course of the study. In addition, at all visits, both scheduled and unscheduled, clients were observed by trained health care providers alert to any potential AEs. All AEs experienced by clients were reported, and all reported adverse events were properly documented on the Adverse Event Report form, noting the type of AEs, the number of occurrences, their severity, and their relation to the PrePex™ procedure.

Occurrence of Adverse Events

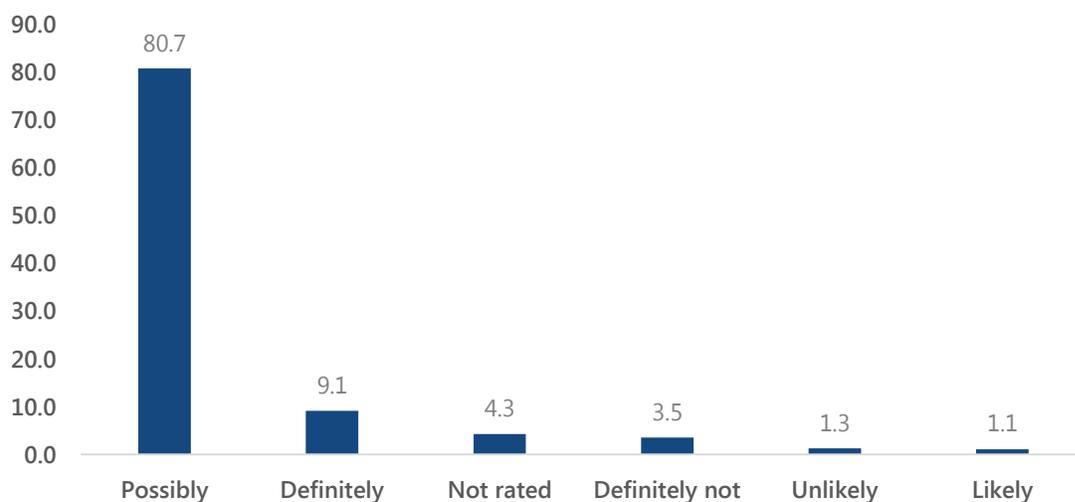
AE occurrence was assessed at all visits—namely, during device placement, while the device was in situ, and during and after device removal. Some 1,187 AEs were reported by 578 clients across all visits. The mean number of AEs reported was 1.8 per client across all visits. The highest number of AEs reported was eight across all visits, and that number was reported by two different clients.

Figure 11. Occurrence of Adverse Events in PrePex™ Clients during TZ-PASS (n = 1187)

Of all reported AEs, 61.5 percent occurred when the device was being worn (through the 24 hours after device placement and before device removal). The second largest proportion of AEs was reported during device removal (32.1 percent of all reported AEs). Periods after removal and during placement together accounted for only 6.4 percent of AEs reported (Figure 11).

Provider Reports of Adverse Events Related to the PrePex™ Device

In addition to surveying clients on AEs, health care providers were asked whether they believed that reported AEs were related to the device (Figure 12).

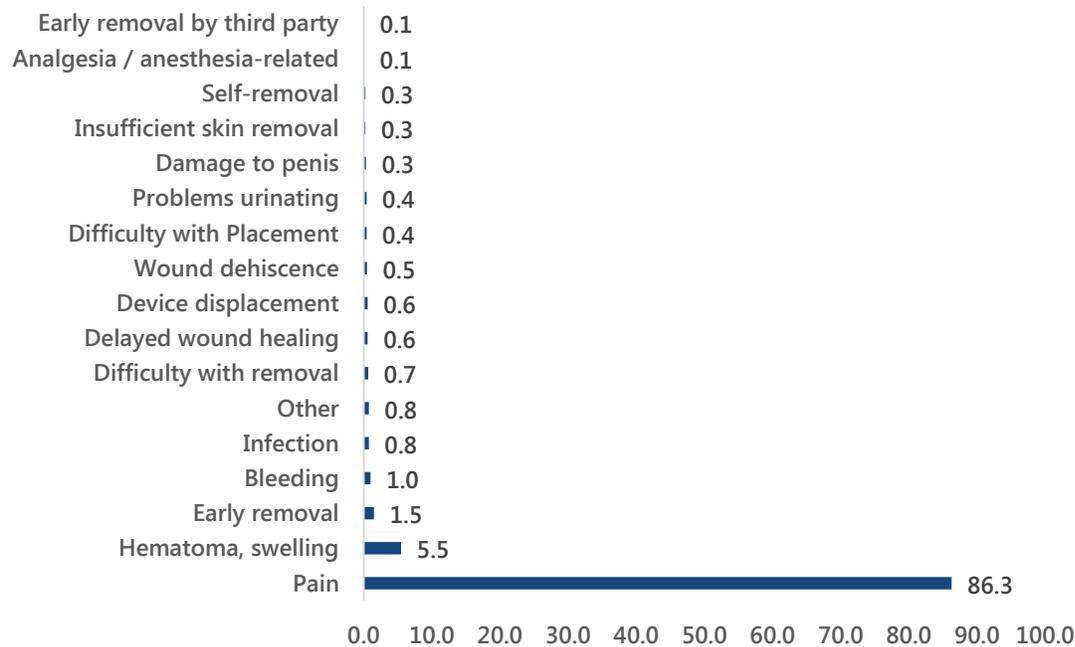
Figure 12. Relationship of Adverse Events to PrePex™ Device (n = 1187)

Of all 1,187 reported AEs, health care providers thought that approximately 80.7 percent were “possibly” related to the PrePex™ device and that 108 (9.1 percent) of them were “definitely” related.

Types of Adverse Events

At each visit, clients were interviewed by both the research assistants and trained PrePex™ providers to elicit reports of any AE experienced since the preceding visits well as during their health facility visit (Figure 13).

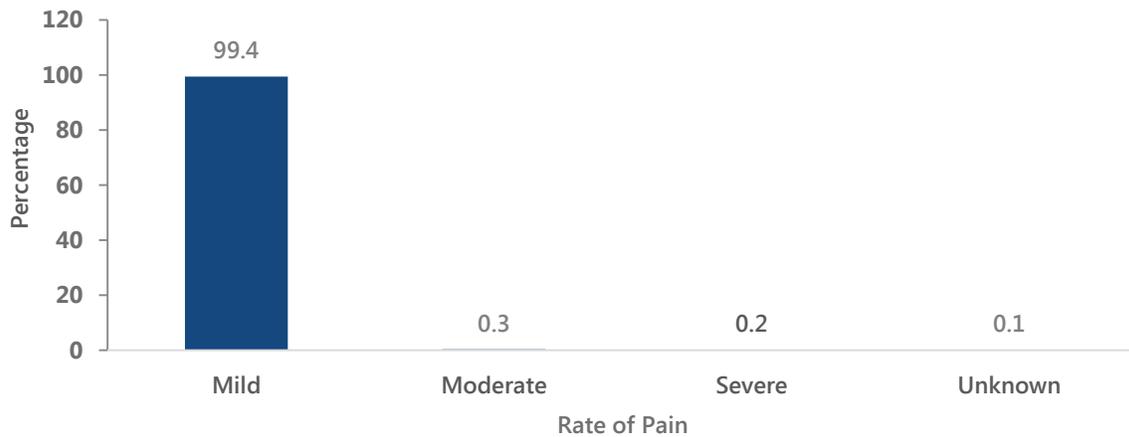
Figure 13. Distribution of Types of Adverse Events among PrePex™ Clients during TZ-PASS (n = 1187)



Pain was the most commonly reported AE, comprising more than 86.3 percent of all those reported. Hematoma, swelling, and edema were reported by 5.5 percent of clients. No other type of AE comprised more than 1 percent of AEs reported.

Severity of Pain

Pain was the most commonly reported AE among all clients circumcised using the PrePex™ device. Pain and all other AEs were recorded according to severity (Figure 14). Occurrences scoring above VAS zero, or where the client reported that an AE was more than mild in severity, were recorded on the Moderate or Severe Adverse Event Report form. Of reported instances of pain, 99.4 percent were considered "mild," and no further actions were taken. In about 0.5 percent of occurrences, pain was scored as "moderate" or "severe," requiring further action.

Figure 14. Severity of Pain among PrePex™ Clients during TZ-PASS (n = 1024)

Moderate or Severe Adverse Events

In addition to recording all reported AEs from all visits, TZ-PASS documented all AEs reported as moderate or severe and all pain considered as moderate or severe on a Moderate or Severe Adverse Event Report form. Twenty-two moderate or severe AEs were recorded across the 862 placements, for an AE rate of 2.5 percent [CI 1.6, 3.8].

Types of Moderate or Severe Adverse Event

Types of moderate or severe AEs were recorded, as was the timing of these occurrences. Among all 22 moderate or severe events (Table 19), seven occurred after the device was removed, nine while the device was in situ, and six during removal. During removal, there were two cases of infection and one case each of pain, hematoma, and problems in urinating, all recorded during removal. AEs recorded while the device was in situ included three cases of pain, two of hematoma, three of problems in urinating, and one of insufficient skin removal. Clinicians judged most post-removal AEs as resulting from delayed wound healing; there were two cases of this, two cases of insufficient skin removal, and one case each of hematoma or swelling, pain and abdominal pain with fever and diarrhea, and problems in urinating, all of which occurred during device removal.

Table 19. Types of Moderate or Severe Adverse Events and their Timing among PrePex™ Clients during TZ-PASS

Type of adverse event	With device in situ	During removal	Follow-up	Total
Hematoma, edema, or swelling	2	1	2	5
Infection	0	2	0	2
Insufficient skin removal	1	0	2	3
Delayed wound healing	0	0	2	2
Abdominal pain and diarrhea	0	1	0	1
Pain	3	1	1	5

Type of adverse event	With device in situ	During removal	Follow-up	Total
Problems in urinating	3	1	0	4
Total	9	6	7	22

Pain and hematoma were the most-reported moderate to severe AEs, each reported five times. Problems in urinating were also reported as a moderate to severe AE four times. Insufficient skin removal was reported three times, and severe infections occurred twice at device removal. Delayed wound healing after Day 42 was reported by two clients, both declared moderate to severe AEs. One client experienced severe abdominal pain and diarrhea and was hospitalized (Table 19).

Treatment of Moderate and Severe Adverse Events

All moderate or severe AEs were assessed and treated as required. About 38 percent of all moderate or severe AEs reported were found, after assessment by trained PrePex™ providers, not to need treatment. A total of 10 AEs (45.5 percent of all moderate and severe AEs) required surgery; 23 percent required other medical treatment. The remaining 12 percent required both surgery and medical treatment.

Clients' Partners Survey

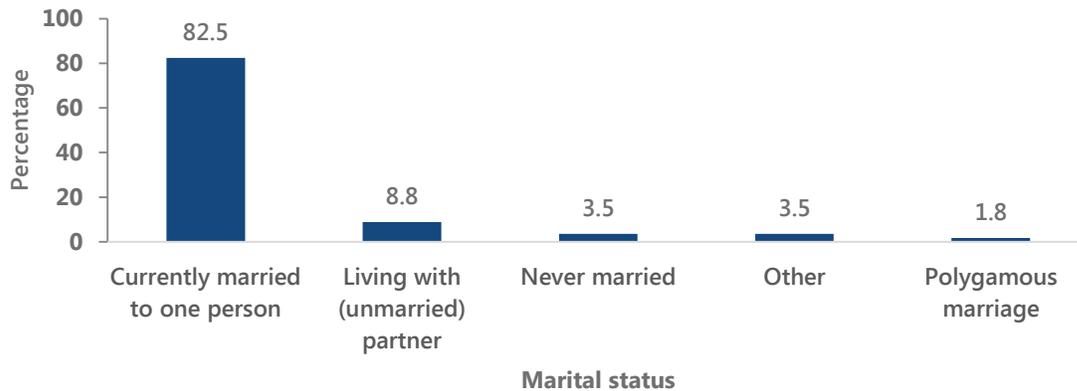
In addition to interviews with and observations of PrePex™ clients, TZ-PASS interviewed their female partners to determine their satisfaction, especially with penis appearance, after circumcision using the PrePex™ device and completion of all procedures. Fifty-seven women were interviewed.

Characteristics of Clients' Partners

Age: The mean age of female partners of PrePex™ clients was 27 years, ranging from 17 to 44.

Highest Education Level Attained: Most female partners had completed their primary education, with more than 73 percent reporting primary education as their highest level of education completed. About 12 percent had never had formal education; 7 percent reported having completed secondary school.

Figure 15. Percentage Distribution of Marital Status of Female Partners of PrePex™ Clients during TZ-PASS (n = 57)



Marital Status: The majority of female partners of men who had been circumcised using the PrePex™ device reported having been married at the time of the interview (Figure 15), with approximately 82.5 percent reporting that they were married to a single person. More than 3.5 percent reported that at the time of interview they had never been married.

Satisfaction with Penis Appearance: Clients' female partners were asked whether they were satisfied with the appearance of their partner's penis after completion of the procedure. Female partners reported being satisfied with penis appearance. More than 89.0 percent reported being "very satisfied," while about 8 percent reported being "satisfied." About 2.0 percent were not willing to respond to the question.

A Survey of Men Not Choosing PrePex™ Circumcision

As part of TZ-PASS, 89 men who opted for surgical circumcision over circumcision using the PrePex™ device were interviewed to understand their reasons for not choosing PrePex™.

Sociodemographic Characteristics of Men Not Opting for PrePex™ Circumcision

Age: The median age of men who came for VMMC services and who opted for surgical over nonsurgical circumcision was 22 (range 18 to 45 years).

Marital Status: Most men who opted for surgical over nonsurgical circumcision were unmarried. Those who reported being "never married" comprised about 69.7 percent of all interviewed men who opted for surgical circumcision (Table 20). Those married to one or more persons amounted to 29.2 percent of interviewed men; 1.1 percent were divorced.

Table 20. Sociodemographic Characteristics of Men Choosing Surgical Circumcision during TZ-PASS

Sociodemographic factor	Number	Percent
Age, mean [SD]	23 [5.8]	
Occupation		
Employed	14	15.7
Farming	39	43.8
Business	22	24.7
Student	13	14.6
Handicapped	1	1.1
Marital status		
Never married	62	69.7
Married	26	29.2
Divorced	1	1.1
Distance from health facility		
<1 km	16	18.0
1–5 km	29	32.6
5–10 km	20	22.5
>10 km	22	24.7
Decline/don't know	2	2.3
Total	89	100.0

Occupation: Men choosing surgical circumcision were asked about their main economic activity (Table 20). About 43.8 percent were engaged in farming activities, while about 15.7 percent were employed, on either a permanent or temporary basis, in an organization or office. About 14.6 percent of men who opted for surgical circumcision were students, while those employed were 15.7 percent, with farmers accounting for 43.8 percent.

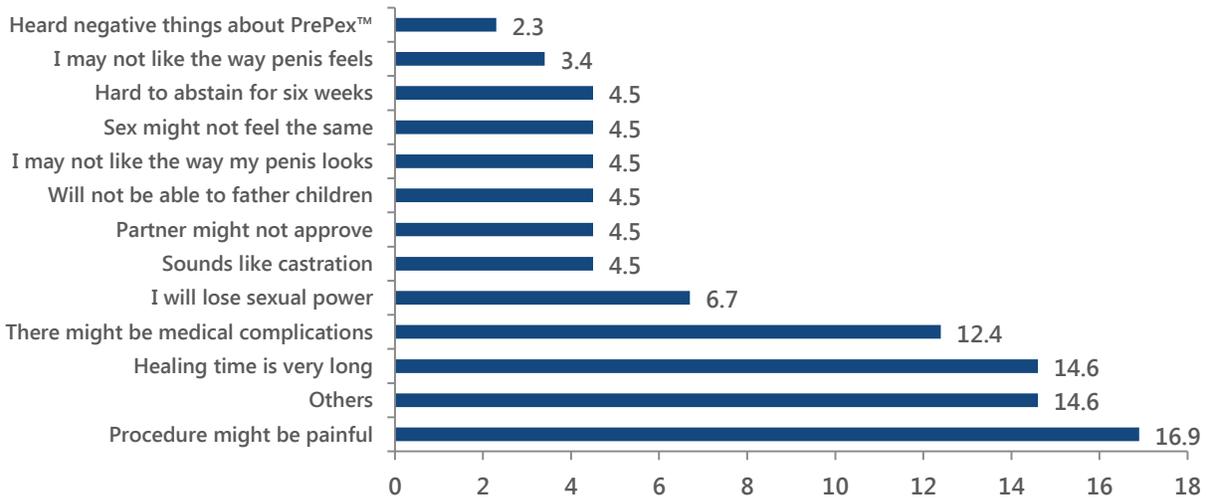
Distance from the Health Facility: TZ-PASS explored the distance between the health facility providing VMMC services and the client's place of residence, with a goal of understanding whether distance from a health facility might have influenced the choice of the circumcision method (Table 20).

More than half of interviewed men who opted for surgical circumcision lived within 5 kilometers of the health facility that provided their VMMC services; 18 percent lived within a kilometer. Approximately one quarter of interviewed clients (24.7 percent) reported living more than 10 kilometers from the health facility providing VMMC services.

Reasons for Not Opting for PrePex™ Circumcision

After being presented with a few facts, respondents were asked about the reasons for their choice (Figure 16).

Figure 16. Distribution of Reasons for Not Opting for PrePex™ among VMMC Clients during TZ-PASS (n = 89)



Among all interviewed respondents, 29.2 percent reported being worried, after learning about circumcision with the PrePex™, that the procedure would “take too long” as their reason for not opting for circumcision using the device. About 19.1 percent reported their reason as concern over potentially not being able to be active and work after the procedure; 18.0 percent cited the inconvenience of wearing the device. Additionally, 16.9 percent, 14.6 percent, and 12.4 percent opted against PrePex™ for fear that the procedure might be painful, that time for healing would be too lengthy, or that there might be medical complications, respectively. Other reported concerns related to potential loss of sexual power (6.7 percent) and potential partner disapproval (4.5 percent).

DISCUSSION

Client Age

The majority of other PrePex™ studies have involved men aged 18 and above, and in this study, the mean age was 23 years (range 18 through 49). A similar age range was reported in studies done in Uganda and Kenya, reported by Galukande et al. (2014) and Feldblum et al. (2014). A longer age range (18–54) was reported by a study in Rwanda (Mutabazi et al. 2014); a shorter age range was used for a study in Uganda (18–24), reported by Kigozi et al. (2014).

Inclusion and Exclusion Criteria

Clients for TZ-PASS were subjected to series of inclusion and exclusion criteria, as for PrePex™ studies reported from Rwanda and Uganda by Bitega et al. (2014) and Mutabazi et al. (2014) respectively. A total of 6.5 percent of clients were not eligible for PrePex™ circumcision in Uganda (Galukande et al. 2014); in Tanzania, clients who were not eligible, per the eligibility checklist, constituted 15.4 percent.

Placement and Removal Procedures

During TZ-PASS, all placements and removals were done by trained health care providers at static sites. In a similar study in Kenya, approximately two-thirds of all placement procedures were performed by nurses and one-third by clinical officers, and procedures were performed both at stationary sites and through outreach services (Feldblum et al. 2014). For the TZ-PASS placement procedure, oral analgesics were administered and anesthetic cream was applied prior to placement. A study in Kenya reported that only anesthetic cream was routinely applied prior to placement (Feldblum et al. 2014).

Device removals were scheduled seven days post placement. For several reasons—either because of AEs or upon a client’s request—removal was on Day 5 or Day 6 for about 3 percent of clients. Some clients (0.9 percent) had late removals, on Day 8. The Kenya study reported removals on days 5, 6, 8, or 9 for men with and without an AE (Feldblum et al. 2014). In Uganda, 99 percent of all clients circumcised using the PrePex™ device returned for removal within five to seven days, as expected (Galukande et al. 2014).

Pain Assessment

The placement procedure was done with minimal pain; only 1.1 percent reported AEs. Assessment for pain at 2 minutes post placement had a mean and median VSA score 0.04 and 0 respectively (IQR 0–4) on a scale of 0–10. The Kenya study reported similar median scores, with

differences in IQR and a maximum pain score of 2 (Feldblum et al. 2014); in TZ-PASS, the maximum pain score was 4. The Uganda study also reported generally no pain on placement (Galukande et al. 2014); a study in Rwanda outlined that pain was minimal, except for brief pain reported during removal (Bitega et al. 2011).

Pain was more often reported during removal. Assessment 2 minutes post removal showed mean and median scores of 0.9 and 0 respectively with IQR 0–6 on a scale of 0–10. The Kenya study reported relatively higher level of pain during removal, with mean and median pain scores of 5.3 and 5 and IQR 4–6 (Feldblum et al. 2014). Self-reported mean and median pain scores at erection when the device was worn were 0.7 and 0 respectively, with IQR 0–6, which was relatively less than during the Kenya study, which reported 3.2 and 3 respectively for mean and median self-reported pain scores (Feldblum et al. 2014).

Safety

AEs were reported among 22 men, yielding an AE rate of 2.5 percent [CI 1.6, 3.8]—relatively lower than reported in the Kenya study. There, AEs were reported at 5.9 percent [CI 3.8, 8.5] (Feldblum et al. 2014). Two studies completed in Uganda reported AE rates of 1.9 percent and 1.8 percent among men circumcised using the PrePex™ device (Galukande et al. 2014; Duffy et al. 2013). Compared to surgical circumcision, risks of moderate or severe AEs were 3.1/100 and 3.5/100 in HIV-positive and HIV-negative participants, as reported by a study in Kenya. These results were similar to the PrePex™ results reported by Kigozi et al. (2008).

In TZ-PASS, two device displacements were reported (0.2 percent of all placements), requiring surgical circumcision, while in Kenya, displacements were reported at a rate of 1.2 percent (Feldblum et al. 2014). Data from the TZ-PASS showed that 28 clients (3.2 percent of all clients who completed placement) were reported to have returned to the health facilities for unscheduled visits while the device was being worn; 27 clients (3.2 percent of all clients) returned for unscheduled visits post removal. In Kenya, Feldblum et al. (2014) reported 193 unscheduled follow-up visits after Day 42 (31 percent of participants).

Post-Circumcision Abstinence and Sexual Activity

Most clients who returned on Day 42 (90.3 percent) reported not having had sex or masturbated since their last visit. Feldblum et al. (2014) observed similar results, with 88.1 percent of clients reporting not having had sex post circumcision visit. Comparing PrePex™ and surgical circumcision, clients who had had surgical circumcision were observed to engage early in sexual activity; 30.7 percent reported having started having sex at Week 3 to Week 4 post procedure (Hallett et al. 2011).

Time for Complete Healing

An estimated time for wound healing with normal skin was 35 days, or about five weeks post removal, with the probability of a client being completely healed at 0.97 (i.e., 97 of 100 men). Feldblum et al. (2014) reported that the probability of being completely healed was less than half (0.44, or 44 out of 100 men). An earlier healing time was reported after a Rwanda study—that is, average healing time of 21 days post removal (Bitega et al. 2011). Another study reported a mean 31 days to heal post removal (Mutabazi et al. 2014). It seems that there is no difference between healing time after circumcision using the PrePex™ device and after surgical circumcision, according to studies in Kenya; 95.8 percent, 91.3 percent, and 94.0 percent of men who were circumcised by surgery healed within 42 days after circumcision per Kigozi et al. (2008), Hallett et al. (2011), and Odoyo (2014), respectively.

Acceptability

Acceptability was high, with 99 percent of all clients who returned for removal reporting satisfaction with the procedure. In addition, only 0.6 percent and 0.4 percent of PrePex™ clients in TZ-PASS reported pain on Day 2 and Day 7 visits and said they would not recommend PrePex™ circumcision to a close male friend or relative. Feldblum et al. (2014) reported similarly; 99 percent of clients were satisfied with the appearance of their penis and would recommend circumcision using the PrePex™ device to a male friend or family member. A Uganda study reported that the PrePex™ device was favored by 60 percent of potential clients and that 90 percent reported after use that they would recommend it to male friends or relatives (Galukande et al. 2014).

CONCLUSION

The PrePex™ device was well accepted by adult males in three regions in Tanzania, with the majority (74 percent) opting for a PrePex™ circumcision when offered a choice. HIV infection was the primary reason for exclusion from TZ-PASS, with 8.8 percent of clients being excluded from this study after a positive HIV screening. The majority of health care providers determined that the device was “easy” or “very easy” to use, with only a single provider having difficulty during one single placement. The placement procedure was conducted with minimal pain; only 2.5 percent of clients reported AEs. AE rates were higher when device was in situ (61.5 percent) and during removal (32.1), but only 3.9 percent of AEs were reported during follow-up; the vast majority of AEs were pain related (86.3 percent). The overall AE rate was 5 percent, with moderate to severe AEs reported among 22 of 862 clients. PrePex™ is an efficient, safe, and acceptable method of adult circumcision in three regions in Tanzania.

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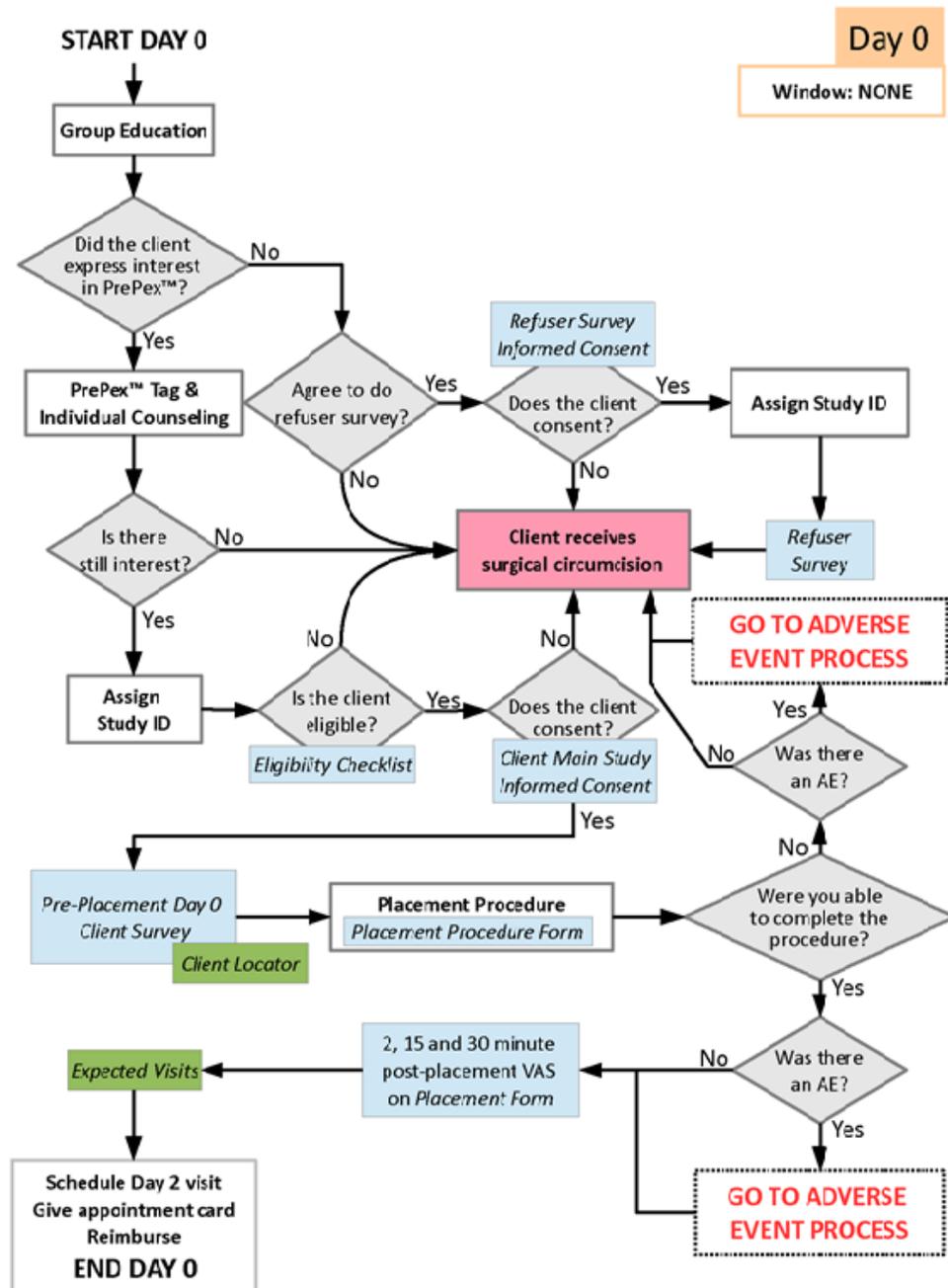
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APPENDICES

APPENDIX I: CLIENT FLOW ON RECRUITMENT DAY



PrePex™ Study
Flowcharts, Version 1.8
Modified: April 22, 2014

APPENDIX II: NAMES OF HEALTH CARE PROVIDERS TRAINED ON THE PREPEX™ CIRCUMCISION PROCEDURE

Region	District	Hospital	Provider	Provider sex	Provider cadre
Iringa	Iringa MC	Iringa Regional	Adelaide Ndanga	F	Nurse midwife
Iringa	Iringa MC	Iringa Regional	Dennis Fischer	M	Clinical officer
Iringa	Iringa MC	Iringa Regional	Illuminata Sanga	F	Nurse midwife
Iringa	Iringa MC	Iringa Regional	Victoria Mlowe	F	Nurse midwife
Iringa	Kilolo	Ilula Mission	Erasto Rite	M	Medical officer
Iringa	Kilolo	Ilula Mission	Luka Chimoto	M	Nurse
Iringa	Kilolo	Ilula Mission	Rahabu Mbilinyi	F	Nurse midwife
Iringa	Kilolo	Ilula Mission	Winnie Msumba	F	Nurse midwife
Iringa	Mufindi DC	Lugoda	Aurelia Kikoti	F	Nurse midwife
Iringa	Mufindi DC	Lugoda	Emmaculate Ngollo	F	Clinical officer
Iringa	Mufindi DC	Lugoda	Frolidos Kisakali	M	Clinical officer
Iringa	Mufindi DC	Lugoda	Upendo Sweke	F	Nurse midwife
Iringa	Mafinga TC	Mafinga District	Christina Sanga	F	Clinical officer
Iringa	Mafinga TC	Mafinga District	Graceana Olomy	F	Nurse midwife
Iringa	Mafinga TC	Mafinga District	Gwerino Kaguo	M	Nurse
Iringa	Mafinga TC	Mafinga District	Proserpina Kalanje	F	Clinical officer
Njombe	Makambako TC	Makambako Town	Eliezey Kalinga	M	Clinical officer
Njombe	Makambako TC	Makambako Town	Joyce Sote	F	Nurse midwife
Njombe	Makambako TC	Makambako Town	Julius Kiowi	M	Paramedical/other
Njombe	Makambako TC	Makambako Town	Oberd Mwashikumbulu	M	Clinical officer

APPENDIX III: NAMES OF COUNSELORS TRAINED ON THE PREPEX™ CIRCUMCISION PROCEDURE

Region	District	Hospital	Counselor	Counselor sex	Counselor cadre
Iringa	Iringa MC	Iringa Regional	Honoratha George Matilya	F	Enrolled nurse
Iringa	Iringa MC	Iringa Regional	Marietha Mkinga	F	Enrolled nurse
Iringa	Kilolo DC	Ilula Mission	Sayuni Godfrey Lyamuya	F	Enrolled nurse
Iringa	Kilolo DC	Ilula Mission	Monica Adoleza	F	
Iringa	Mafinga TC	Mafinga District	Aida Samweli Mnyawami	F	Nurse midwife
Iringa	Mafinga TC	Mafinga	Aloisia Ngungulu	F	Nurse midwife
Iringa	Mufindi DC	Lugoda	Beatrice Jackson Ng'ande	F	Enrolled nurse
Iringa	Mufindi DC	Lugoda	Odina Andreas Mdemu	F	Medical attendant
Njombe	Makambako TC	Makambako Town	Rehema Raphael Mlyuka	F	Enrolled nurse
Njombe	Makambako TC	Makambako Town	John Kajange	M	Nurse midwife

APPENDIX IV: SUMMARY OF N AT EACH DATA COLLECTION POINT

Timing	Data collection tool	Who collected	n	Comment
Day 0	Eligibility Checklist	C	1029	870 eligible.
Day 0	Pre-placement Survey	RA	863	Of 870 eligible, 3 did not fit device (device too big), additional 4 devices not placed due to anatomical reasons.
Day 0	Placement Form	HCP	862	One client decided not to have PrePex just before placement
Day 2	Day 2 Medical Follow-Up Form	HCP	851	11 participants terminated between placement and Day 2
Day 2	Day 2 Survey	RA	844	Missing data for 7 clients due to data collection error (electronic forms not saved before transmission).
Day 7	Day 7 Preremoval Survey	RA	765	Data collection delayed because form was initially submitted for local IRB approval and local IRB approval was required before it could be used)
Day 7	Day 7 Removal Form	HCP	831	Additional 20 participants terminated between Day 2 and Day 7
Day 7	Day 7 Medical Follow-Up Form	HCP	828029	Missing data for 2 participants.
Day 7	Day 7 Post-Removal Survey	RA	732	Clients completed device removal, recovered for 30 minutes then went for research interview. 99 clients left without completing survey.
Day 7	Sexual Female Partners Survey	RA	57	
Day 42	Follow-Up Visit Survey	RA	794	8 were lost due to data collection error (electronic forms not saved before transmission)
Day 42	Follow-Up Medical Form	HCP	802	31 terminated; 29 lost to follow up

C= Counselor; RA= Research assistant; HCP=Health care provider



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