

PrePex™ Acceptability Protocols: Mozambique & Botswana Review of Key Issues

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Mary Glenshaw, CDC Botswana

Beverly Cummings, CDC Mozambique

Overview

- Objectives
- Comparison of Botswana & Mozambique Protocols
- Inclusion, Exclusion Criteria
- Primary Endpoints & Data Collection Themes
- Data Collection Tools

Objectives

- Goal: evaluate **SAFETY** and **ACCEPTABILITY** of PrePex™ in routine VMMC clinical settings in Botswana and Mozambique*
- Objectives
 1. Determine training needs of PrePex™ providers
 2. Describe client and provider acceptability
 3. Describe and assess safety when PrePex™ VMMC performed by nurse providers
 4. Describe cost effectiveness of PrePex™ circumcision
(Mozambique only)

**Note- these are 2 distinct studies, NOT a multi-country study*

Comparison of Mozambique and Botswana Protocols

	Botswana	Mozambique
Sample size	1000 in 2 sites	500 in 2 sites
Key Objectives	<ul style="list-style-type: none"> -Training evaluation -Provider acceptability -Client acceptability 	<ul style="list-style-type: none"> -Training evaluation -Provider acceptability -Client acceptability -Cost effectiveness
Population	Urban, peri-urban	Urban
Locations	Existing VMMC clinics	Existing VMMC clinics
Phases	<ul style="list-style-type: none"> -Preparation -Implementation 	<ul style="list-style-type: none"> -Preparation -Implementation
PrePex™ Providers	<ul style="list-style-type: none"> -Surveys -Focus groups 	In-depth interviews
Non-PrePex™ Providers	(None)	-Focus groups
Clients	<ul style="list-style-type: none"> -Surveys -Telephone surveys -Focus groups (PrePex clients) 	<ul style="list-style-type: none"> -Surveys -Telephone surveys -Focus groups (PrePex refusers)

Comparison of Mozambique and Botswana Protocols

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Client Inclusion Criteria

- Male between the ages of 18 to 49
- Uncircumcised
- HIV sero-negative
- Voluntarily seeking medical circumcision at one of the two study sites and wants to be circumcised with PrePex™
- Penis fits into one of the five PrePex™ ring sizes
- Has access to a cell/mobile phone
- Agrees to photographs of the genital area *to document and medically manage moderate or severe AEs*
- Capable and willing to provide written informed consent to participate
- Agrees to complete study surveys and medical evaluations **in person** at designated time points
- Agrees to complete study **telephone** surveys at designated time points
- Able to communicate in official languages

Botswana and Mozambique

Botswana only

Mozambique only

Client Exclusion Criteria

- General Medical Conditions
 - Bleeding disorders or coagulation abnormalities
 - Uncontrolled diabetes
 - Uncontrolled hypertension
 - Clinical anaemia
 - Cognitive or psychiatric impairment
- Active genital disease/infections
 - Active urethritis
 - Warts
 - Genital ulcers of any cause
- Genital anatomic abnormalities
 - Phimosis and narrow prepuce opening
 - Paraphimosis
 - Hypospadias
 - Epispadias
 - Tight frenulum
 - Scrotal hernia, hydrocele and undescended testis
 - Other penile and scrotal structural abnormalities
- Other conditions, prevents circumcision with the PrePex™

Botswana and Mozambique

Botswana only

Mozambique only

Provider Criteria

- Inclusion
 - Employed as a nurse or physician by implementing partner or MOH
 - Trained in PrePex™ circumcision techniques for the current trial
 - Agrees to data collection at designated time points:
 - During PrePex™ training
 - After PrePex™ training
 - At midpoint of study, following at least 10 weeks of client enrollment
 - At the conclusion of the study
 - Able to communicate in official languages
 - Capable and willing to provide written informed consent to participate
- Exclusion
 - Failure of PrePex™ circumcision training course

Botswana and Mozambique

Botswana only

Mozambique only

Research Data Collection Tools

- *PRE-TESTING*
 - *Materials Pre-test Consent Form*
- *PROVIDER TOOLS*
 - *Provider Consent Form*
 - *Employee Confidentiality Agreement*
 - *Provider Survey*
 - *Provider Focus Group Discussion Guide* (PrePex™ providers)
 - *Provider Focus Group Discussion Guide* (non-PrePex™ providers)
 - *Provider In-depth Interview Guide*
- *CLIENT TOOLS*
 - *Study Information Sheet*
 - *Client Consent Form*
 - *Client Survey*
 - *Telephone script*
 - *Client Telephone Survey*
 - *SMS Text message script*
 - *PrePex™ client Focus Group Discussion Guide*
 - *PrePex™ “refuser” Focus Group Discussion Guide*

Botswana and Mozambique

Botswana only

Mozambique only

Non-Research Tools

- *TRACKING, ANALYSIS and ADMIN TOOLS*
 - *Screening Verification Form*
 - *Enrollment Tracking Form*
 - *Data Collection Tracking Form*
 - *Data Analysis Shell Tables*
 - *CDC Incident Report Form*
 - *Study Withdrawal/Termination Form*
 - *PrePex™ Device Manufacturer Information*

Botswana and Mozambique

Botswana only

Mozambique only

Clinical Data Collection Tools

- *Materials & Supplies*
 - *PrePex Placement Kit*
 - *PrePex Removal Kit*
 - *Removal Tools Specifications*
 - *Wound Dressing Specifications*
 - *Materials Modules*
 - *Infection Prevention and Waste Management*
 - *Equipment for Male Circumcision Sites*
 - *Emergency Medical Supplies*
 - *HTC and STI Management*
- *Clinical Management Tools*
 - *PrePex™ Placement Checklist*
 - *PrePex™ Removal Checklist*
 - *PrePex™ Discharge Checklist*
 - *Case Report Form (CRF)*
 - *Day 0 CRF*
 - *Day 0 VAS Pain Scale (3 time points)*
 - *Day 7 Removal Visit CRF*
 - *Day 7 VAS Pain Scale*
 - *Day 42 Final Review Visit*
- *Adverse Events Definitions, Grading, and associated Reporting Forms*
 - *During Device Placement*
 - *While Device is In Situ*
 - *During Device Removal*
 - *After Device Removal*
 - *Device-related AE definitions*
- *Unscheduled Visit Reporting Forms*
 - *Day 0-7*
 - *Day 8-42*
 - *Day 43 and beyond*

Botswana and Mozambique

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Provider Assessments: Primary Endpoints & Themes

- Provider training evaluation
 - Length of training
 - Knowledge of procedure, methods, theory
 - Duration of procedures
 - Competency scores, examinations, observations
 - Satisfaction
 - Expectations
 - Self-Efficacy
 - Recommendations for training improvement
- Provider acceptability
 - Ease of use and duration of procedures
 - Problems encountered during procedures and post-procedure care
 - Preferences for PrePex™ or surgical methods
 - Self-efficacy in procedure
 - Enjoyment of procedure
 - Recommendations for healthcare cadres
 - Recommendations for future programming

Botswana and Mozambique

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Client Assessments: Primary Endpoints & Themes

- Client acceptability and satisfaction:
 - Pain
 - During application, while in situ, during removal, after removal.
 - Time for participant to return to normal activity, including work.
 - Physical comfort
 - Self-care
 - Abstinence
 - Discussions with partner, friends, family, community
 - Religious or cultural issues
 - Cosmetic result
 - Recommend SMC and specifically SMC by PrePex™ to others
 - *Reasons for refusal (focus group discussion)*
- Client safety
 - Mild, moderate, severe AEs (by person, event)
 - Detailed AE description (type, severity, time of detection, relatedness to MC, device)
 - AEs are defined by standardized definitions included in the PrePex™ SOP
 - Self-reported complications
 - Unscheduled visits

Botswana and Mozambique

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Provider Data Collection Time Points

Phase	Preparatory	Implementation		
Component	Initial Provider Acceptability	Training Evaluation	Mid-Point Provider Acceptability	Final Provider Acceptability
Timeframe	During training	After training	Midpoint, ~Week 10	End of study
	Before training	After training	After 50 MC	

Client Data Collection Time Points

Phase	Implementation: Client Acceptability and Safety							
Client Day	0	3	7	14	21	28	35	42
	0	2	7	14	21	28		42
Method	<ul style="list-style-type: none"> -Client survey -Medical examination -PrePex™ placement -VAS pain scale -AE eval -Follow-up phone call 	<ul style="list-style-type: none"> -Phone survey 	<ul style="list-style-type: none"> -Client survey -Medical examination -PrePex™ removal -VAS pain scale -AE eval 	<ul style="list-style-type: none"> -Clinic visit, survey -Phone survey 	<ul style="list-style-type: none"> -Phone survey 	<ul style="list-style-type: none"> -Phone survey -Clinic visit, survey 	<ul style="list-style-type: none"> SMS text 	<ul style="list-style-type: none"> -Client survey -Medical examination -PrePex™ removal -Cosmetic result -AE eval -Client focus group