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

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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

<table>
<thead>
<tr>
<th></th>
<th>Botswana</th>
<th>Mozambique</th>
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</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>1000 in 2 sites</td>
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<tr>
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<tr>
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<td>-Surveys</td>
<td>In-depth interviews</td>
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<td></td>
<td>-Focus groups</td>
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<tr>
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<td>Clients</td>
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<td></td>
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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 prepucial 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
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*  
*Botswana only*  
*Mozambique only*
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
Botswana only
Mozambique only
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
Botswana only
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## Provider Data Collection Time Points

<table>
<thead>
<tr>
<th>Phase</th>
<th>Preparatory</th>
<th>Implementation</th>
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<tbody>
<tr>
<td><strong>Component</strong></td>
<td><strong>Initial Provider Acceptability</strong></td>
<td><strong>Training Evaluation</strong></td>
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<tr>
<td><strong>Timeframe</strong></td>
<td><strong>During training</strong></td>
<td><strong>After training</strong></td>
</tr>
<tr>
<td><strong>Before training</strong></td>
<td><strong>After training</strong></td>
<td><strong>After 50 MC</strong></td>
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</tbody>
</table>

- **Preparatory** time frame is during training and before training.
- **Implementation** time frames are after training and mid-point (~Week 10) and after 50 MC.
# Client Data Collection Time Points

## Implementation: Client Acceptability and Safety

<table>
<thead>
<tr>
<th>Phase</th>
<th>Client Day</th>
<th>0</th>
<th>3</th>
<th>7</th>
<th>14</th>
<th>21</th>
<th>28</th>
<th>35</th>
<th>42</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>7</td>
<td>14</td>
<td>21</td>
<td>28</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td>-Client survey -Medical examination -PrePex™ placement -VAS pain scale -AE eval -Follow-up phone call</td>
<td>-Phone survey</td>
<td>-Client survey -Medical examination -PrePex™ removal -VAS pain scale -AE eval</td>
<td>-Clinic visit, survey -Phone survey</td>
<td>-Phone survey</td>
<td>-Phone survey</td>
<td>SMS text</td>
<td>-Client survey -Medical examination -PrePex™ removal -Cosmetic result -AE eval -Client focus group</td>
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