

# Adverse Events Following Circumcision with the PrePex™ Device in Tanzania

## Authors and Affiliations

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The voluntary medical male circumcision (VMMC) program in Tanzania started in 2009 and is being implemented in 12 priority regions. The goal is to circumcise 2.1 million adolescent boys and men by 2017. Innovations, such as circumcision devices like PrePex™, may assist in accelerating the scale-up of VMMC programs. Therefore, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), through the United States Agency for International Development (USAID), supported the Strengthening High Impact Interventions for an AIDS-free Generation (AIDSFree), Maternal and Child Health Integrated Program (MCHIP), and Accelovate Projects to undertake the first Tanzania PrePex™ Acceptability and Safety Study (TZ-PASS) in-country.

## Clients' Inclusion Criteria

To qualify to be circumcised using the PrePex™ device during the study period, adult men were required to:

- ▶ Be between the ages of 18 to 49
- ▶ Agree to be circumcised using PrePex™
- ▶ Be confirmed as HIV-negative by a rapid HIV test performed by the study counselor prior to the circumcision
- ▶ Fit penis into one of the five PrePex™ ring sizes.

## Clients' Exclusion Criteria

Adult males did not qualify for the study if they:

- ▶ Were HIV-positive
- ▶ Had known bleeding disorders
- ▶ Had anatomic genital abnormalities or injuries (phimosis, paraphimosis, tight or torn frenulum, hypospadias, epispadias)
- ▶ Narrow foreskin opening
- ▶ Had active genital infections and/or an infectious disease impairing health.



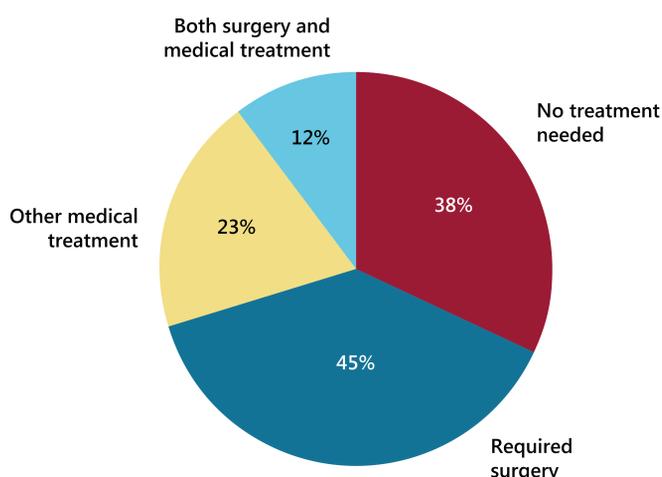
## Results

- ▶ 875 participants were eligible for circumcision using the PrePex™ device during the study period.
- ▶ Device placements were successful in 866 participants.
- ▶ 100% of participants returned for follow-up visits.
- ▶ There were a total of 22 (2.5%) moderate and severe adverse events reported including hematoma, swelling, infection, delayed wound healing, pain, problems urinating, abdominal pain and diarrhea, and insufficient skin removal.
- ▶ Of the 22 AEs:
  - 59% (13) were moderate
  - 41% (9) were severe.

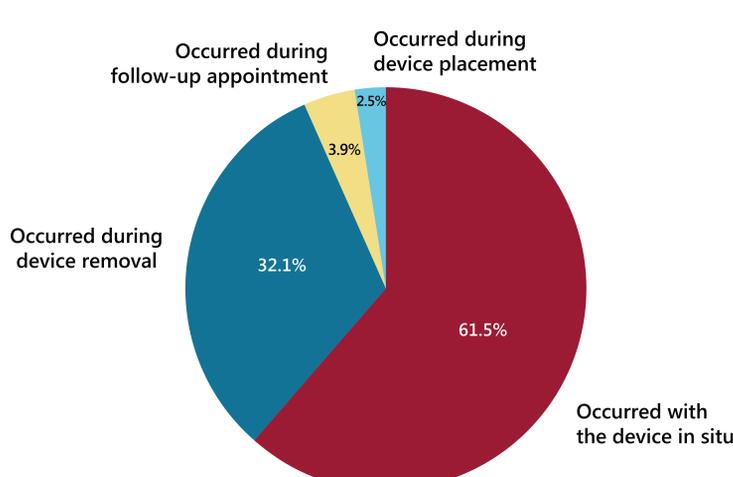
## Treatment of Moderate and Severe Adverse Events

Among 22 moderate or severe AEs, clinical management was as follows:

Treatment of AE Occurrences



Timing of AE Occurrences



Types of Moderate or Severe Adverse Events and Timing among Men Who Were Circumcised Using PrePex™ in Three Tanzanian Regions, 2014

Type of AE	Device in Situ	Device Removal	Post-Removal	Total
Pain	3	1	0	4
Infection	0	2	0	2
Hematoma, swelling, edema	2	1	2	5
Trouble urinating	3	1	0	4
Insufficient skin removed	1	1	2	4
Delayed wound healing	0	0	2	2
Abdominal pain, diarrhea, fever	0	0	1	1
<b>Total</b>	<b>9</b>	<b>6</b>	<b>7</b>	<b>22</b>

## Conclusion

- ▶ The AE rate in this study was low and similar to other safety and acceptability PrePex™ studies in sub-Saharan Africa.
- ▶ Pain was found to be the most common moderate/severe adverse event, highlighting the need to explore pain management alternatives.
- ▶ Clients need to be appropriately and adequately educated on signs and symptoms of common AEs after placement of the device, since the majority of AEs occur while the client is wearing the device.
- ▶ Because 45% of the AEs required surgery to manage, there is a need for surgical capacity/availability at sites that provide PrePex™ services.

