Swaziland’s VMMC Adverse Event Reporting System

Jonathan Grund
Centers for Disease Control and Prevention
Atlanta, GA USA

AIDS 2012 - Turning the Tide Together
Outline

• Swaziland’s VMMC Program
• Adverse Event Management and Definitions
• Adverse Event Triage and Management System (AETMS)
• Notification Process and Nurse Training
• Conclusion
Swaziland and VMMC

- Swaziland’s HIV prevalence: 31% among adults (18-49 yrs.)
  - Low VMMC prevalence: 16%

- *Soka Uncobe* “Circumcise and Conquer”
  - 5-year strategy into 1-year campaign
  - 33 total sites
  - Doctor-led with task-sharing
  - Minimum VMMC package offered, with recommended post-op reviews on day 2/7
  - Informed about 24-hour “MC Help Line”
VMMC and AEs

• VMMC is a minor surgical procedure that involves risk
  • Some AEs are expected, even when surgery is conducted in sanitary conditions by trained providers

• AE monitoring to ensure appropriate clinical management

• Timely identification, proper management, and accurate reporting of AEs is critical for quality and safety
## Adverse Events Definitions

<table>
<thead>
<tr>
<th>Adverse Event Type</th>
<th>Timing of initial diagnosis</th>
<th>Severity of Initial Diagnosis</th>
</tr>
</thead>
</table>

### Infection (IN)
- Infection was diagnosed:
  - □ Within the 30 days post-operative = Code B
  - □ Greater than 30 days post-operative = Code C
- □ Mild erythema and minimal serous discharge from wound
- □ Only topical antibiotics used
- □ Infected area less than 1 cm in length

### Pain (PA)
- Pain was noted:
  - □ Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A
  - □ After discharge from clinic and up to 30 days post-operative = Code B
- □ Mild discomfort

*Any Severe AE must be reported immediately to the EPR*
Adverse Event Triage and Management System (AETMS)

• AETMS was staffed by nurses hired to work at the Emergency Preparedness and Response (EPR) dept.
• Designed to complement in-person follow-ups on day 2 and 7
• Goal of the AETMS/EPR was to:
  • Address client questions and concerns
  • Facilitate transfer of clinical information
  • Improve accuracy and completeness of data collection
Nurse Training

- Trained in telephone triage of symptoms
- Address complications in order of decreasing severity
- Focus on AEs most likely to become severe:
  - Bleeding, voiding difficulty, pain, and infection
  - Algorithms designed to determine need for emergency intervention
- Algorithms approved by MoH, Soka Uncobe physicians, and National MC Task Force
Post-Operative VMMC Patient

**VMMC site**
- Routine post-op reviews
- Emergency reviews

**AE Diagnosis, Treatment, Reassessment**

**EPR VMMC Help-Line**

- Patient returns directly to VMMC site
- Patient calls for assistance

**Patient sent to VMMC site; Coordination of care**

**General or Urological Surgery Consultation**

**Routine and AE Reports; VMMC Database**

**Hospital (referral site)**

**Transport**

**Patient sent to hospital; Coordination of care**
Nurse Algorithm: Post-Operative Voiding Difficulties (*Inability to Pass Urine*)

- **Are you able to pass urine?**
  - **No**
  - **Yes**
    - **Do you have poor stream, dribbling, or incomplete emptying of bladder?**
      - **No**
      - **Yes**
        - **Do you have dressing on?**
          - **No**
          - **Yes**
            - **Inform health center of incoming patient and suspected AE**
          - **No**
            - **Yes**
              - **Find out client’s location and send vehicle**
    - **Find out client’s location and send vehicle**
  - **Yes**
    - **Go through post-operative instructions**

*PEPFAR*
Conclusion

• AE monitoring is necessary for the success of a VMMC program
• Adherence to measurable and time-based AE definitions is needed for standardization
• Timely monitoring, communication, and response to all AEs is required
• A telephone-based AE Management System may be useful at identifying life-threatening post-operative complications
Acknowledgments

• Ministry of Health, Swaziland
• Swaziland National AIDS Program
• CDC/PEPFAR Swaziland
• EPR Department
• USAID
• Jhpiego
• Futures Group
• JSI Swaziland

Thank you!
jgrund@cdc.gov