



# PEPFAR

U.S. President's Emergency Plan for AIDS Relief

## Swaziland's VMMC Adverse Event Reporting System

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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”





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# 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

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Adverse Event Type	Timing of initial diagnosis	Severity of Initial Diagnosis		
		Mild (1)	Moderate (2)	Severe (3) *
		*Any Severe AE must be reported immediately to the EPR		
<b>Infection (IN)</b>	<b>Infection was diagnosed:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Within the 30 days post-operative = Code B</li> <li><input type="checkbox"/> Greater than 30 days post-operative=Code C</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Mild erythema and minimal serous discharge from wound</li> <li><input type="checkbox"/> Only topical antibiotics used</li> <li><input type="checkbox"/> Infected area less than 1 cm in length</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Purulent discharge from wound</li> <li><input type="checkbox"/> Oral or IV antibiotics needed</li> <li><input type="checkbox"/> Infected area greater than one cm in length</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Abscess</li> <li><input type="checkbox"/> Severe cellulitis</li> <li><input type="checkbox"/> Wound necrosis</li> <li><input type="checkbox"/> Severe wound disruption</li> <li><input type="checkbox"/> Tissue loss</li> </ul>
<b>Pain (PA)</b>	<b>Pain was noted:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Intra-operative or immediately post-operative (prior to discharge from clinic) = Code A</li> <li><input type="checkbox"/> After discharge from clinic and up to 30 days post-operative = Code B</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Mild discomfort</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Moderate discomfort</li> <li><input type="checkbox"/> Pain requiring interruption of operation for additional local anesthetic</li> <li><input type="checkbox"/> Pain resulting in inability to work or cancellation of normal activities lasting for 4-7 days.</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Pain resulting in early termination of MC or general anesthesia</li> <li><input type="checkbox"/> Pain severe enough to result in inability to work or cancellation of normal activities for at least 8 days</li> </ul>



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# 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





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# 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

Patient returns directly to VMMC site

Patient calls for assistance

### VMMC site

- Routine post-op reviews
- Emergency reviews

Patient sent to VMMC site;  
Coordination of care

Transport

## EPR VMMC Help-Line

Patient sent to hospital;  
Coordination of care

### AE Diagnosis, Treatment, Reassessment

Severe AE Data

Severe AE Data

Routine data

Severe AE Data

Routine data

Patient Referral/ Transfer

### Hospital (referral site)

### General or Urological Surgery Consultation

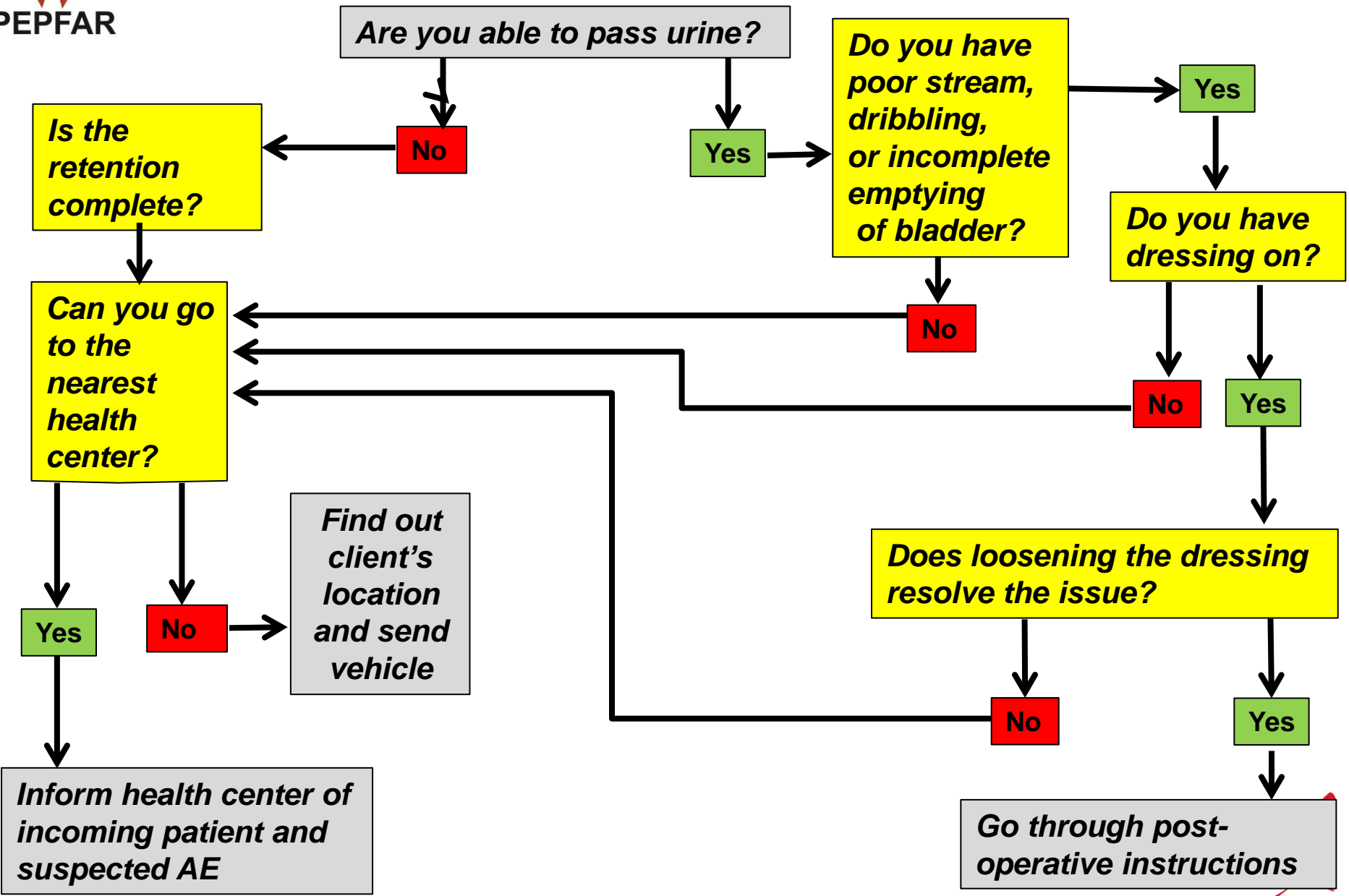
### Routine and AE Reports; VMMC Database





# Nurse Algorithm: Post-Operative Voiding Difficulties (*Inability to Pass Urine*)

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# 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

PEPFAR

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

***Thank you!***  
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