PEPFAR Safety Monitoring: Global Adverse Event Reporting and Response

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VMMC and Safety

- Prevention intervention in young, healthy males
- Safety paramount, continued vigilance crucial
- AEs a reality in the context of MC
  - provider error
  - screening error
  - client/parent misinformation or behavior
  - none of the above
- Temporal but not causal association
- AE identification and reporting enables programs to learn and improve programs
- Processes country-defined; meant to support MOH
PEPFAR Resources for Safety Assurance

- Informative tools
- External quality assessment
- SIMS
- Continuous quality improvement
- Notifiable AE surveillance
Resources for Safety Assurance
what does each give us?

• Informative tools
  – procedural guide
  – standardized definitions and classifications
  – AE recognition, prevention and management
  – WHO guidance documents

• External quality assessment

• SIMS

• Continuous quality improvement

• Notifiable AE surveillance
Resources for Safety Assurance
what does each give us?

• Informative tools
• External quality assessment/SIMS
  – adherence to global quality standards
  – site and staff characteristics
  – equipment and supplies information
  – quality of services
  – quality of data
• SIMS
• Continuous quality improvement
• Notifiable AE surveillance
Resources for Safety Assurance

what does each give us?

• Informative tools
• External quality assessment
• SIMS
  – Consent
  – Linkage to care and treatment
  – AE management and documentation
  – Clinical follow up
  – QA/QI
• Continuous quality improvement
• Notifiable AE surveillance
Resources for Safety Assurance

what does each give us?

• Informative tools
• External quality assessment
• SIMS

• Continuous quality improvement
  – ongoing internal assessment at site-level
  – focused on site, or team, depending on service delivery model
  – each site evaluates its own situation and decides which changes can most improve service delivery
  – fosters a culture of improvement

• Notifiable AE surveillance
Resources for Safety Assurance
what does each give us?

• Informative tools
• External quality assessment
• SIMS
• Continuous quality improvement
• Notifiable AE surveillance
  – track serious AEs and death
  – review management
  – determine relatedness to MC
  – identify rare but serious events
  – communicate to stakeholders, eg WHO
## Notifiable AEs 2014-16

<table>
<thead>
<tr>
<th>AEs</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>105</td>
</tr>
<tr>
<td>Related to MC</td>
<td>84</td>
</tr>
<tr>
<td>Deaths (tetanus)</td>
<td>8</td>
</tr>
<tr>
<td>Bleeding</td>
<td>19</td>
</tr>
<tr>
<td>Necrotising infections debridement skin graft</td>
<td>23 18 6</td>
</tr>
<tr>
<td>Tetanus</td>
<td>10</td>
</tr>
<tr>
<td>Fistula</td>
<td>12</td>
</tr>
<tr>
<td>Injury</td>
<td>30</td>
</tr>
</tbody>
</table>
## Lessons and Actions: Examples

<table>
<thead>
<tr>
<th>Finding</th>
<th>Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single use kit quality</td>
<td>• Quality improvement</td>
</tr>
<tr>
<td></td>
<td>• Encourage use of reusable kits</td>
</tr>
<tr>
<td>Inadequate pain control</td>
<td>• Standardized anesthetic dosing</td>
</tr>
<tr>
<td>Undiagnosed bleeding disorders</td>
<td>• Enhanced screening</td>
</tr>
<tr>
<td></td>
<td>• Earlier referral</td>
</tr>
<tr>
<td>Necrotising infections</td>
<td>• Broad spectrum antibiotics</td>
</tr>
<tr>
<td></td>
<td>• Need for debridement</td>
</tr>
<tr>
<td>Tetanus</td>
<td>• Better coverage for males</td>
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<tr>
<td></td>
<td>• Assure protection with PrePex</td>
</tr>
<tr>
<td></td>
<td>• Enhanced wound care counseling</td>
</tr>
<tr>
<td>Glans injury with FG in &lt;15 years</td>
<td>• Mandate DS for &lt;15 years</td>
</tr>
<tr>
<td>No emergency equipment or training</td>
<td>• Equipment and training added</td>
</tr>
<tr>
<td>No parental consent for minors</td>
<td>• Policy RE consent for minors</td>
</tr>
<tr>
<td>Poor/inconsistent documentation</td>
<td>• Standard forms and training</td>
</tr>
</tbody>
</table>