Update: Notifiable AEs (NAEs) & 2nd Edition Adverse Event Action Guide

Renee Ridzon, MD

Office of the U.S. Global AIDS Coordinator and Health Diplomacy & U.S. Centers for Disease Control and Prevention
VMMC and Safety

• Prevention intervention in young, healthy males
• HIV incidence in most settings decreasing
• Further decreased incidence likely with 90-90-90 and combination prevention
• For current young clients, HIV risk may be very low by the time they reach their mid 20’s
• Safety must be paramount, continued vigilance crucial
VMMC and Reality

• AEs a reality in the context of MC
• AEs associated with MC from:
  – provider error
  – screening error
  – client/parent misinformation or behavior
  – none of the above
• Temporal but not causal association
• Need to decrease number and severity as much as possible
• Ensuring identification and reporting enables programs to learn and improve programmes
Introduction of Reporting of NAEs

• To learn and track serious AEs and death
• Review of management
• Determine relatedness to MC
• Identify
  – rare but serious events
  – AEs associated with MC not previously identified with MC
  – opportunities for programme improvement
• As of Q4 FY2016, will be PEPFAR’s only AE reporting process (MER AE reporting being discontinued)
Reporting of NAEs

• Identify
  – rare but serious events (necrotising infections)
  – AEs associated with MC not previously identified with MC (tetanus)
  – Opportunities to improve programmes and guidance (enhanced guidance on management of bleeding)
Next Steps with NAEs

• Interviews with field teams
• Development of easier-to-use reporting tools
• Simplification of communication chain
• Simplification/shortening of forms
• Increased transparency with feedback to country teams
• Final report to country teams
• Feedback welcome!
Purposes of AE Action Guide

• Reduce incidence of AEs in MC by providing guidance on how to avoid them
• Improve outcomes of AEs by providing guidance on safe and appropriate management
• Facilitate standardized reporting of AEs
• Support monitoring of the quality and safety of programmes
Why a New Edition?

• Experience with AEs seen in context of VMMC programmes and programmatic needs
• Introduction of devices
• Lessons learned from reporting and management of notifiable AEs and deaths
AE Guide, 2nd Ed. What’s Old?

- Standardized definitions for AEs
- Standardized severity classifications
- Management guidance
- Atlas of AEs associated with surgery
AE Guide, 2nd Ed. What’s New?

• Definition and management of AEs associated with WHO-prequalified MC devices
• Timing scheme for device-related AEs
AE Guide, 2nd Ed. What’s New?

- Infection chapter includes tetanus and serious necrotising infection
- Additional information on bleeding and bleeding dyscrasias
AE Guide, 2\textsuperscript{nd} Ed. What’s New?

- Guidance on infection control
- Local anaesthetic dosing charts modified

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Lignocaine 2.0% alone (20 mg/ml)</th>
<th>Lignocaine 2.0% / Bupivacaine 0.5% mix (20 mg/ml; 5.0 mg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starting dose-2.0 mg/kg</td>
<td>Max dose-3.0 mg/kg</td>
</tr>
<tr>
<td>20 $\textsuperscript{kg}$</td>
<td>2.0 ml</td>
<td>3.0 ml</td>
</tr>
<tr>
<td>25 $\textsuperscript{kg}$</td>
<td>2.0 ml</td>
<td>4.0 ml</td>
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<tr>
<td>30 $\textsuperscript{kg}$</td>
<td>2.5 ml</td>
<td>4.5 ml</td>
</tr>
<tr>
<td>35 $\textsuperscript{kg}$</td>
<td>3.0 ml</td>
<td>5.0 ml</td>
</tr>
<tr>
<td>40 $\textsuperscript{kg}$</td>
<td>4.0 ml</td>
<td>6.0 ml</td>
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<tr>
<td>45 $\textsuperscript{kg}$</td>
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<tr>
<td>50 $\textsuperscript{kg}$</td>
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<td>7.5 ml</td>
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<tr>
<td>55 $\textsuperscript{kg}$</td>
<td>5.5 ml</td>
<td>8.0 ml</td>
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<tr>
<td>60 $\textsuperscript{kg}$</td>
<td>6.0 ml</td>
<td>9.0 ml</td>
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<tr>
<td>65 $\textsuperscript{kg}$</td>
<td>6.5 ml</td>
<td>10.0 ml</td>
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<tr>
<td>70 $\textsuperscript{kg}$</td>
<td>7.0 ml</td>
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</tr>
<tr>
<td>75 $\textsuperscript{kg}$</td>
<td>7.5 ml</td>
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<tr>
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<tr>
<td>85 $\textsuperscript{kg}$</td>
<td>8.5 ml</td>
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</tr>
<tr>
<td>90 $\textsuperscript{kg}$</td>
<td>9.0 ml</td>
<td>13.5 ml</td>
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</tbody>
</table>

\textsuperscript{Bupivacaine should not be used in anyone weighing under 30 kg}
AE Guide, 2\textsuperscript{nd} Ed. What’s New?

- Policies and responsibilities for reporting AEs
- Color-coding to the charts

<table>
<thead>
<tr>
<th>ADVERSE EVENT</th>
<th>MILD</th>
<th>MODERATE</th>
<th>SEVERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL: Bleeding</td>
<td></td>
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<tr>
<td>Surgery</td>
<td>Bloodstained B/C-BL: Blood-stained dressings or underwear, no active bleeding. Small amount of bleeding from minor clot disruption when changing dressings that is controllable with new dressings or 5-10 minutes of manual pressure measured on a clock.</td>
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<tr>
<td>Device</td>
<td>A2-DD: NA</td>
<td>A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal that does not require surgical intervention to correct, either because the device can be removed, repositioned, or replaced with a new device.</td>
<td>A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that requires surgical intervention to correct, or requires hospitalization or transfer to another facility to clinically manage.</td>
</tr>
<tr>
<td>DD: Device Displacement</td>
<td>A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure.</td>
<td>A1-PA: Client expresses discomfort and is not able to cooperate well with procedure.</td>
<td>A1-PA: Client rates pain as very severe.</td>
</tr>
<tr>
<td>IN: Infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery (B/C-IN) and Device (A2/C-IN)</td>
<td>B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention otherwise.</td>
<td>B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral.</td>
<td>B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or...</td>
</tr>
</tbody>
</table>
AE Guide, 2\textsuperscript{nd} Ed. What’s New?

• Encouragement for site staff to identify and report situations/behaviors that result in safety risk
• Additional material in appendix
  – Management of bleeding/haematoma
  – Safe injection
  – Charts that can be used as job aids
• Atlas of device-related AEs
AE Guide-Final Notes

• Availability
  – www.malecircumcision.org (guide)
  – Printed material (guide and atlas)

• Will continue to be informed by learning and experience from the field

• Feedback welcome
Acknowledgements

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