



Improving Quality VMMC

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

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&

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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?

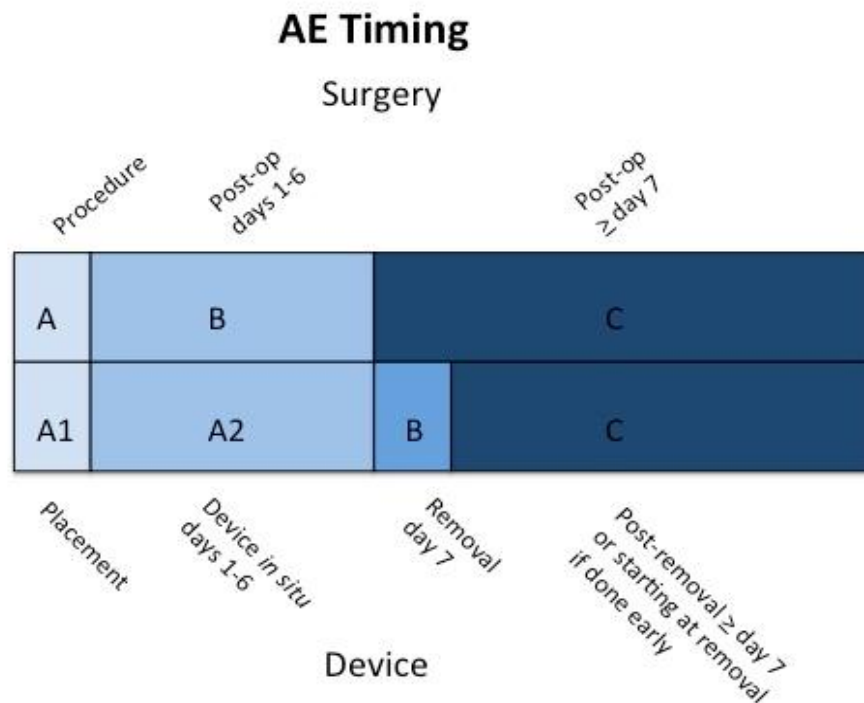
- Experience with AEs seen in context of VMMC programmes and programmatic needs
- Introduction of devices
- Lessons learned from reporting and management of notifiable AEs and deaths

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?

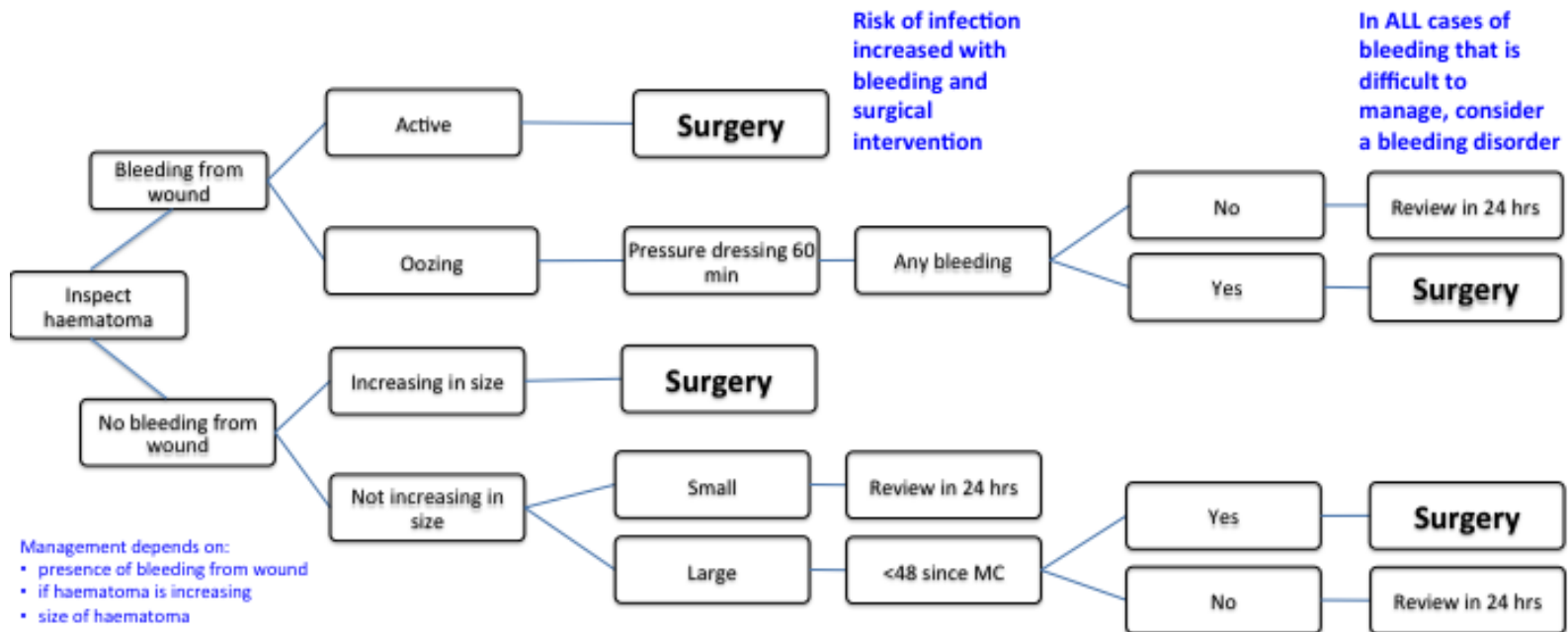
- Definition and management of AEs associated with WHO-prequalified MC devices
- Timing scheme for device-related AEs



AE Guide, 2nd Ed. What's New?

- Infection chapter includes tetanus and serious necrotising infection
- Additional information on bleeding and bleeding dyscrasias

Management of penile haematoma after circumcision, MC sites
Surgical exploration by experienced providers only



AE Guide, 2nd Ed. What's New?

- Guidance on infection control
- Local anaesthetic dosing charts modified

Weight (kg)	Lignocaine 2.0% alone (20 mg/ml)		Lignocaine 2.0% / Bupivacaine 0.5% mix (20 mg/ml; 5.0 mg/ml)	
	Starting dose-2.0 mg/kg	Max dose-3.0 mg/kg	Starting dose-1.5 / 0.3 mg/kg	Max dose-2.0 / 0.5 mg/kg
20	2.0 ml	3.0 ml	Bupivacaine should not be used in anyone weighing under 30 kg	
25	2.0 ml	4.0 ml		
30	2.5 ml	4.5 ml		
35	3.0 ml	5.0 ml	2.0 ml / 2.0 ml	3.0 ml / 3.0 ml
40	4.0 ml	6.0 ml	2.0 ml / 2.0 ml	3.5 ml / 3.5 ml
45	4.5 ml	6.5 ml	2.5 ml / 2.5 ml	4.0 ml / 4.0 ml
50	5.0 ml	7.5 ml	2.5 ml / 2.5 ml	4.5 ml / 4.5 ml
55	5.5 ml	8.0 ml	3.0 ml / 3.0 ml	5.0 ml / 5.0 ml
60	6.0 ml	9.0 ml	3.0 ml / 3.0 ml	5.5 ml / 5.5 ml
65	6.5 ml	10.0 ml	3.5 ml / 3.5 ml	6.0 ml / 6.0 ml
70	7.0 ml	10.5 ml	3.5 ml / 3.5 ml	6.5 ml / 6.5 ml
75	7.5 ml	11.0 ml	4.0 ml / 4.0 ml	7.0 ml / 7.0 ml
80	8.0 ml	12.0 ml	4.0 ml / 4.0 ml	7.5 ml / 7.5 ml
85	8.5 ml	12.5 ml	4.5 ml / 4.5 ml	8.0 ml / 8.0 ml
90	9.0 ml	13.5 ml	5.0 ml / 5.0 ml	8.5 ml / 8.5 ml
			5.5 ml / 5.5 ml	9.0 ml / 9.0 ml
			6.0 ml / 6.0 ml	

AE Guide, 2nd Ed. What's New?

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

ADVERSE EVENT ☒	MILD ☒	MODERATE ☒	SEVERE ☒
BL: Bleeding ☒			
Surgery ☒	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. ☒	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure measured on a clock, and requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound. ☒	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary. ☒
Device ☒	A2-DD: NA ☒	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. ☒	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. ☒
DD: Device Displacement ☒			
Device ☒	A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. ☒	A1-PA: Client expresses discomfort and is not able to cooperate well with procedure. ☒	A1-PA: Client rates pain as very severe. ☒
IN: Infection ☒			
Surgery (B/C-IN) ☒ and ☒ Device (A2/C-IN) ☒	B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other	B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral	B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or

AE Guide, 2nd 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

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