

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

AEs	Number
Total	105
Related to MC	84
Deaths (tetanus)	8
Bleeding	19
Necrotising infections	23
debridement	18
skin graft	6
Tetanus	10
Fistula	12
Injury	30

Lessons and Actions: Examples

Finding	Action(s)
Single use kit quality	<ul style="list-style-type: none"> • Quality improvement • Encourage use of reusable kits
Inadequate pain control	<ul style="list-style-type: none"> • Standardized anesthetic dosing
Undiagnosed bleeding disorders	<ul style="list-style-type: none"> • Enhanced screening • Earlier referral
Necrotising infections	<ul style="list-style-type: none"> • Broad spectrum antibiotics • Need for debridement
Tetanus	<ul style="list-style-type: none"> • Better coverage for males • Assure protection with PrePex • Enhanced wound care counseling
Glans injury with FG in <15 years	<ul style="list-style-type: none"> • Mandate DS for <15 years
No emergency equipment or training	<ul style="list-style-type: none"> • Equipment and training added
No parental consent for minors	<ul style="list-style-type: none"> • Policy RE consent for minors
Poor/inconsistent documentation	<ul style="list-style-type: none"> • Standard forms and training