

Strengthening Safety through Surveillance: Notifiable Adverse Events in the U.S. President's Emergency Plan for AIDS Relief's Voluntary Medical Male Circumcision Program Through 2020



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BACKGROUND

- Circumcision reduces males' risk of heterosexual HIV acquisition by ~60%¹⁻³
- The President's Emergency Plan for AIDS Relief (PEPFAR) has supported over **28 million** voluntary medical male circumcisions (VMMCs) through 2021
- PEPFAR monitors the following adverse events (AEs), initially through adhoc reports and, beginning in 2014, systematically through the Notifiable Adverse Event Reporting System (NAERS)
 - **Deaths** (reported in NAERS since 2014)
 - **Hospitalization ≥ 3 days** (since 2015)
 - **Penile injury/amputation** (since 2015)
 - **Permanent deformity or disability** (since 2015)
 - **Tetanus** (since 2015)
 - **Circumcision device displacement** (since 2020)

METHODS

- Standardized forms are used to report notifiable adverse events (NAEs)
- Detailed case investigations by physicians further classify diagnoses and determine NAE relatedness to the VMMC procedure
- NAE reports submitted to PEPFAR since the first ad-hoc report in 2011 through December 2020 were reviewed from 14 countries (Botswana, eSwatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe)

RESULTS

- **14 countries reported 446 clients** with NAEs; 394 (88%) were determined VMMC-related, 37 (8%) were unrelated, and 15 (3%) were unknown (Figure 1)
 - **56 deaths** reported, 24 (43%) were determined VMMC-related, **54% of these from tetanus**
 - The remaining 390 NAEs were non-fatal with 95% VMMC-related
 - **Infection was the most common** cause of hospitalization with **175 severe non-tetanus infections**
 - **26 cases of tetanus, 13 of which were fatal**
 - **40 glans injuries** and **51 fistulas**
 - **70 clients** with severe **bleeding**
 - **4** circumcision **device displacements**
- Of clients with a reported NAE, 236 (53%) were among clients aged 10-14 years (Figure 2).

Figure 1

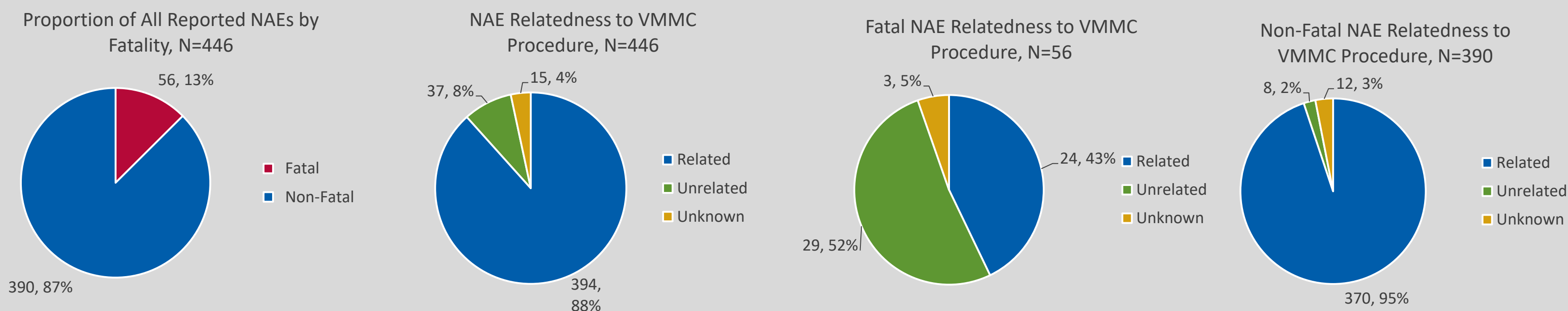
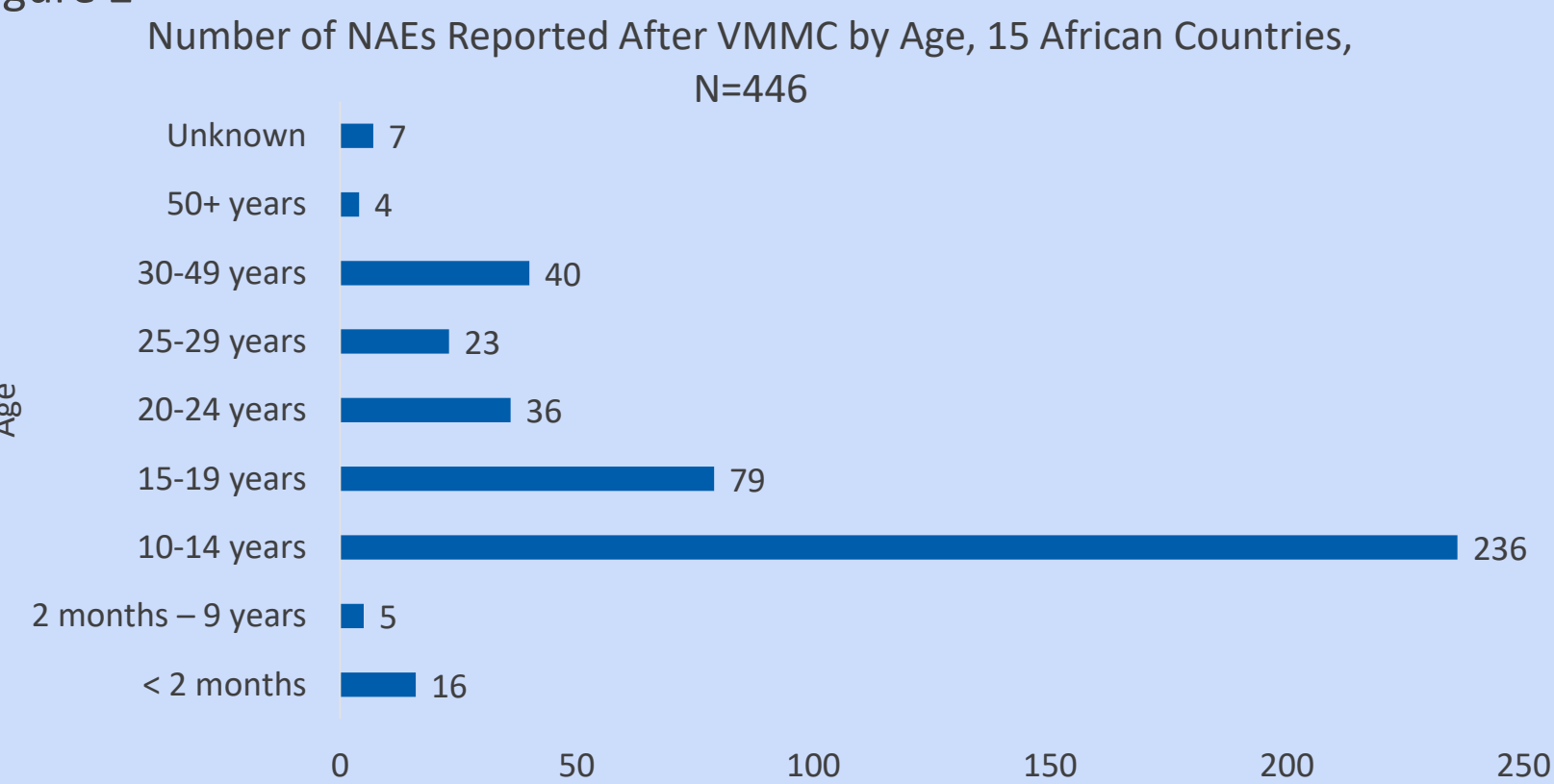


Figure 2



CONCLUSIONS

Although it is not possible to eliminate all AEs from surgical interventions, surveillance of rare but serious AEs can identify safety concerns and guide programmatic improvement. Several policy changes were made based on NAERS findings to improve program safety including:

- **Updated guidance on surgical technique** to decrease risk of glans injuries and fistulas
- **Restricting VMMC eligibility** to clients ≥15 years old
- Improving **tetanus prevention practices**

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