

Notifiable adverse events associated with Medical Male Circumcision in Kenya

*Elijah Odoyo-June¹, Kawango Agot², Nandi Owuor³, Christine Kisia⁴, Boaz Otieno-Nyunya¹, Paul Musingila¹, Vincent Ojiambo⁴, Norah Talam⁵, Hellen Muttai¹, Kennedy Serrem⁷, Martin Sirengo⁷

1. Division of Global HIV & TB, U.S. Centers for Disease Control and Prevention (CDC), Kenya, 2. Impact Research and Development Organization, Kisumu, Kenya 3. JHPIEGO 4. WHO Kenya Country Office, 5. USAID Kenya East Africa Office 6. KEMRI/Walter Reed Project, Kericho, Kenya 7. Kenya Ministry of Health National AID & STD control Program (NASCOP)

CORRESPONDING AUTHOR: Elijah Odoyo-June, E-Mail: yed0@cdc.gov, P.O Box 606, 00621 Nairobi, Kenya

Presenting Author: Paul Musingila, Email: yto3@cdc.gov

Introduction

Background:

Since 2008, Kenya's voluntary medical male circumcision (VMMC) program collects monthly data on moderate and severe adverse events (AE) to monitor safety. In 2014, PEPFAR supported Kenya to introduce an additional AE reporting system which requires notification of a limited number of serious AEs occurring within 30 days post-circumcision. The notifiable AEs (NAE) must meet following criteria;

- Tetanus
- Death
- Complete or partial amputation of the penis
- Hospitalization for >3 days
- Associated with probable permanent disability or deformity

Objective: To share Kenya's experiences with reporting notifiable AEs.

VMMC Program Context

Methods of circumcision:

- Forceps guided for 15+yrs
- Dorsal slit for 10-14 year olds
- Transition to Dorsal slit method for all clients 10+yrs was done in Jan 2018
- Mogen Clamp for Early Infant MC for babies aged 0-60 days
- PrePex device at passive roll out stage while ShangRing is in Active AE surveillance stage of introduction

Cumulative VMMCs done nationally since 2008 to date is approximately 1.7 Million

Methods

The notifiable AE reporting system uses standard forms to investigate, follow-up and report on serious AEs.

Photographs of AE lesions are taken periodically until healing is complete to:

- Monitor progress of healing
- Evaluate effectiveness of management
- Serve as records of the clinical course and final outcomes
- Serve as case studies for learning purposes

Incidence of preventable AEs (e.g. penile injuries due to inappropriate use of forceps guided method and tetanus) are used as proxy indicators of non-compliance with program guidelines.

We reviewed notifiable adverse events reported in Kenya's VMMC program from 2014 to 2017.

Results

NAEs were reported in 25 out of 661,653 MCs performed from August 2014 to August 2017 and 24% were associated with non-compliance.

Table 1: Penile glans injuries associated with non-compliance (6)

Type of NAE	Cases reported	Clients age range	Compliance issue	Outcome
Complete or partial amputation glans	5	10-12 years	Inappropriate use of forceps guided method	Permanent anatomical deformity of glans
Non-fatal tetanus following PrePex	1	15 years	2 nd requisite dose of tetanus toxoid was not given	Full recovery after prolonged inpatient management

NAEs not associated with non-compliance (19)

4 Deaths:

- 1 death due to tetanus in a 15 year old boy
- 1 infant death following repair of glans injury under general anesthesia
- 3 newborn infant deaths due other underlying conditions unrelated to VMMC
- 3 non fatal tetanus cases
- 2 cases after surgical VMMC in boys 12 and 13 years, respectively
- 1 case of non-fatal tetanus after PrePex circumcision in a 19year old man
- 3 urethral fistulae in boys 10-12 years;- Closed through natural healing
- 1 penile glans injury during Mogen clamp circumcision in a newborn baby
- 8 hospitalizations for 3 or more days; (including 2 severe bleeding, 1 necrotizing fasciitis, and 5 other previously undiagnosed medical conditions)

Conclusions

The NAE reporting system has enhanced understanding of AEs and revealed cases of serious AEs associated with non-compliance or undiagnosed underlying medical conditions. VMMC programs should implement enhanced NAE reporting systems to monitor lapses in compliance with program safety standards and for learning purposes. Programs introducing new methods of circumcision should expand their scope of NAEs to include previously undescribed AEs.

Kenya's VMMC program Context

Geographic scope:

Kenya's VMMC program targets non-circumcising communities within 11 counties mainly in the western regions, which also bear the heaviest burden of HIV

