

Patterns and Predictors of Adverse Events Over Six Years of the VMMC Program in Tanzania

Authors and Affiliations

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Voluntary medical male circumcision (VMMC) services have been scaled-up in 14 priority eastern and southern African countries; as of September, 2015 8.9 million VMMCs for HIV prevention have been performed in priority countries with support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Although most VMMC programs track and report adverse events (AEs) regularly, factors associated with AEs are often not well documented. To address this PEPFAR, through the U.S. Agency for International Development's (USAID) Strengthening High Impact Interventions for an AIDS-free Generation (AIDSFree), Accelovate and Maternal and Child Health Integrated Program (MCHIP) Projects, implemented by Jhpiego, examined factors associated with AEs in the Iringa, Njombe, and Tabora regions of Tanzania, including the safety of the procedures and patterns and predictors of AEs in VMMC.

Why Are Patterns and Predictors of AEs Important?

- ▶ Knowledge of factors that contribute to AEs assist to design programmatic/technical interventions to prevent future AEs.
- ▶ AEs often act as a proxy for quality, it is vital to know how to prevent AEs.
- ▶ Programs with low rates of AEs build clients' trust and potentially create demand for services from future clients.
- ▶ VMMC is an elective procedure for health clients, it is vital to prevent avoidable AEs.

Adverse Events in VMMC

- ▶ May occur even in optimal surgical conditions with well-trained providers because of client anomalies or environmental factors
- ▶ Rates tend to be low; for example, AE rates in the three 2005/06 VMMC random control trials ranged from 1.5% to 3.8%.

VMMC in Tanzania

- ▶ Services initiated in 2009 in 12 regions with high HIV prevalence and low VMMC coverage
- ▶ PEPFAR, through USAID-managed AIDSFree, Accelovate, and MCHIP Projects, supports VMMC programs in three regions in Tanzania: Iringa, Njombe, and Tabora
- ▶ WHO issued a cautionary note on the use of the forceps guided (FG) method for young adolescents on July 1, 2014; PEPFAR issued a policy against the use of FG in males under the age of 15 on July 30, 2014.

Methods

- ▶ Conducted retrospective review of moderate/severe AEs using client level data from 2009-2015
- ▶ Reviewed age of clients, types/severity of AEs, service modalities, and surgical techniques
- ▶ Chi-square test used for statistical significance
- ▶ Mild AEs were excluded from analysis.

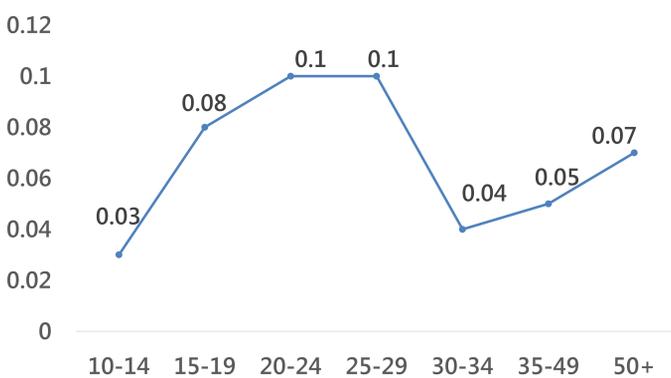
Results

- ▶ 497,259 clients circumcised during review period (2009-2015)
- ▶ 274 intra-operative AE incidents from 497,259 clients (a rate of 0.06%)
- ▶ 1,209 post-operative AE incidents from 365,957 follow-up clients (a rate of 0.33%).

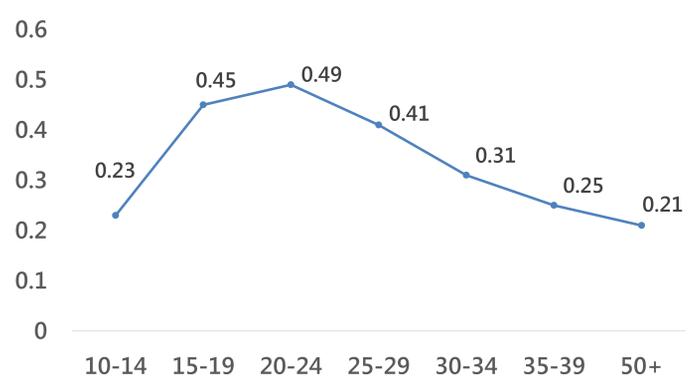
Intra-Operative AEs in 10-14 Year Olds

Description	N	Denominator	%
Total intra-op AE rate in all age groups	274	497,259	0.06
Total AEs among 10-14 years	65	245,118	0.03
AEs with description among 10-14 years	30		
Glans injuries or lacerations in 10-14 years	19	30	63.3

Trend of Intra-Operative AE Rates, by Age



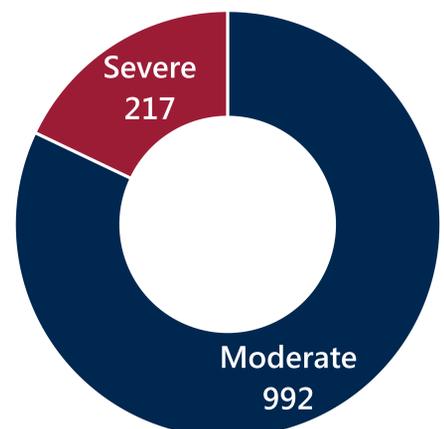
Trend of Post-Operative AE Rates, by Age



Adverse Event Rates by Service Delivery Model

Service Delivery Model	Intra-Operative AE Rates			Post-Operative AE Rates		
	AE #	VMMC #	AE %	AE %	Returning #	AE %
Campaign	241	368,590	0.07	951	275,296	0.35
Mobile	0	16,363	0.00	12	12,347	0.10
Outreach	7	63,507	0.01	106	45,824	0.23
Routine	26	48,779	0.05	113	32,490	0.36
Total	274	497,259	0.06	1,182	365,957	0.30
X ²		38.5331			38.7687	
p value		<0.001			<0.001	

Post-Operative AEs, by Severity



- Moderate, n = 992/1,209 = 82%
- Severe, n = 217/1,209 = 18%
- Total (Mod/Severe) = 1,209/365,081 = 0.33%

Adverse Event Rates by Surgical Method

Service Delivery Model	Intra-Operative AE Rates			Post-Operative AE Rates		
	AE #	VMMC #	AE %	AE %	Returning #	AE %
Forceps-Guided	271	437,927	0.06	1115	316,960	0.36
Dorsal Slit	3	58,364	0.01	66	48,232	0.14
Total	274	496,291	0.06	1181	365,192	0.32
X ²		30.6437			61.7252	
p value		<0.001			<0.001	

Limitations

- ▶ Analysis based on only three regions; may not be applicable to other countries
- ▶ Possibility of AE underreporting
- ▶ Post-operative AEs can only be recorded if client completes follow-up
- ▶ Because there are no AE descriptors listed from 2009-2012, analysis of AE type was limited.

Conclusion

- ▶ Intra- and post-operative AE rates are low (<1%) across all service delivery methods
- ▶ AE rates did not differ at routine and non-routine sites demonstrating comparable quality
- ▶ Glans injuries were rare but were significantly higher among 10-14-year-olds. All clients were circumcised by the FG Method
- ▶ Lower rates of other intra- and post-operative AE rates with the dorsal slit surgical technique compared to the FG surgical technique
- ▶ Underscores need to adhere to PEPFAR policy guidelines on use of age-appropriate surgical methods for VMMC (dorsal slit for 10-14-year-olds and adolescents with immature anatomy).

