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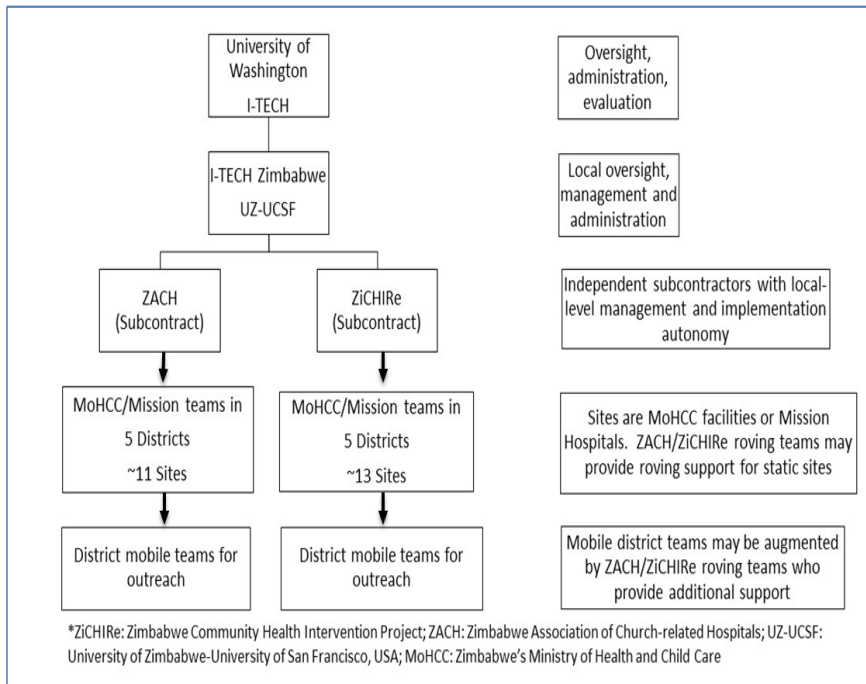
TRUST BUT VERIFY: IS THERE A ROLE FOR ACTIVE SURVEILLANCE IN MONITORING AES IN LARGE-SCALE VMMC PROGRAMS?

Background

- ZAZIC's integrated voluntary medical male circumcision (MC) program (Figure 1) aims to create safe space to identify and manage adverse events (AEs), acknowledge surveillance weaknesses, and introduce quality assurance (QA) strategies.

- From October 2014 - September 2017, ZAZIC conducted 205,847 MCs. Most MCs took place in outreach locations (schools, rural clinics, tents). Passive surveillance recorded a moderate and severe AE rate of 0.2% and 95% follow-up visit adherence, suggesting program safety.
- However, other MC programs and trials in the region report significantly higher AE rates.
- Therefore, to increase confidence in AE identification and improve reporting, we conducted a careful review of program data on AEs and conducted observations of VMMC reviews with VMMC clinicians to help motivate positive changes in both AE identification and program documentation.

Figure 1: ZAZIC Organizational Model



Methods

ZAZIC implemented a mixed-method, quality assurance activity in 6 purposively-selected, high volume MC sites that included:

1. Retrospective review of 3 months (October-December 2016) of routine AE data comparing recorded to reported AEs in VMMC registers, client intake forms (CIF), monthly return form (MRF) and District and Health Information System (DHIS2);

Figure 2: Form for Tandem GS and Site Team Reviews

Prospective Activity: AE Review Form – client MC follow-up review

Site name _____ Date _____ Site type: Outreach Mobile Static

Reviewer _____ Dates of in-person reviews observed _____ Cadre of person observed: nurse doctor

MC follow-up reviews	Client order																								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Client review characteristics																									
Review Day	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	
AE identified by site staff	Y N																								
Actual AE present	Y N																								
AE type identified correctly	Y N																								
AE severity identified correctly	Y N																								
AE reviewed with staff	Y N																								

TOTAL NUMBER OF AEs IDENTIFIED BY SITE STAFF: _____ TOTAL NUMBER OF AEs IDENTIFIED BY ZAZIC STAFF _____

Notes _____

2. 100 prospective, tandem, post-operative MC reviews with a gold-standard (GS) ZAZIC clinician working alongside site-based MC clinicians; and
3. Brief interviews with site staff about AE documentation.

GS clinicians provided in-person mentoring, support, and feedback before concluding site-based activities. A ZAZIC vehicle facilitated reviews. As per MoHCC guidelines, reviews were typically conducted on post-operative days 2 or 7.

Results

Findings from the Prospective and Retrospective Reviews

- AEs identified using active prospective surveillance are considerably higher than passive surveillance: observations suggest AE rates from 1-5% (Table 1). Retrospective record review found AEs not recorded nor reported across all forms consistently (Table 1). Most observed AEs were infections among clients under age 15. There was no evidence of missed severe AEs resulting in permanent impairment or morbidity. Follow-up reviews for routine days 2 or 7 appear considerably less than expected.

Table 1. Results from Prospective and Retrospective AE Review

Site	Prospective			Retrospective: AEs Reported Oct-Dec 2016, by Source					
	# Tandem Reviews	# AEs	AE Rate	VMMC Register	CIF	Logbook	In/Out Patient	DHIS2	MRF
1	95	5 Mod	5%	0	1	0	0	1	0
2	91	4 Mod	4%	1	1	1	1	0	1
3	99	3 Mod 1 Sev	4%	0	1	1	2	0	0
4	100	5 Mod	5%	0	0	1	0	0	1
5	100	3 Mod 2 Sev	5%	0	0	0	0	0	0
6	100	1 Mod	1%	5	3	2	4	0	5

Results

Potential Undiagnosed AEs

Table 2. Comparison of Retrospective AEs to AEs Observed in Routine QA

Site	Reported Passive Surveillance: Oct 2014-Sept 2017			Observed Active Surveillance AE Rate: Oct 2016-Dec 2016 (b)	AEs Expected** Oct 2014- Sept 2017 (a·b)
	AEs*	MCs (a)	AE Rate		
1	10	14707	0.1%	5%	735
2	22	13892	0.2%	4%	556
3	30	8174	0.4%	4%	327
4	31	17908	0.2%	5%	895
5	25	11242	0.2%	5%	562
6	39	6727	0.6%	1%	67

*Moderate and severe AEs; **AEs expected (a·b) was calculated by multiplying the number of MCs reported over the passive surveillance period (a) by the observed active surveillance AE rate (b)

Results

- AE rates from prospective review (actual) were higher than those documented from retrospective data (reported).
- Therefore, we used the actual AE rates to estimate the number of AEs that could have been identified from previous VMMC if similar active surveillance and QA measures had been implemented (Table 2).
- It is possible that 3,142 AEs could have been missed through routine program implementation. It is unlikely that this phenomenon is unique to ZAZIC.
- AEs identification and reporting may be weak throughout the region leading to significant underreporting.

Lessons Learned

- This intensive QA activity required additional financial, transport, and human resources over routine program monitoring.
- Reported AE rates appear quite low in these settings; actual AE rates appear considerably higher than expected.
- For rural clients, follow-up is difficult due to expensive transport and long distances
- On the system level, lack of vehicle and staff shortages contribute to poor follow-up.
- Rural health center nurses need training in AE identification, management, and reporting; staff may remain with no records nor forms for VMMC clients due to centralized AE reporting.
- Schools may not allow reviews during school hours.
- Maintaining clean wounds appears difficult for younger clients requiring parental/guardian involvement in care.

Conclusion

ZAZIC promotes quality assurance and patient safety as top priority for its VMMC implementation. Therefore, ZAZIC aims to implement several initiatives to strengthen program quality:

1. Launch a Quality Improvement Task Force;
2. Expand this QA initiative with broader continuous active surveillance to all sites;
3. Further risk reduction strategies focused within school settings as young boys, ages 10-14, currently comprise the majority of ZAZIC MCs;
4. Provide additional vehicles to facilitate client follow-up;
5. Reinforce clear expectations with regard to recognition and reporting of AEs (Adverse Events Surveillance System SOP) at national and district levels;
6. Increase intensive training on recognition, management and reporting of AEs for all clinicians, with targeted efforts for rural nurses.

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