health

Department:
Health
REPUBLIC OF SOUTH AFRICA

VOLUNTARY MEDICAL MALE CIRCUMCISION

Standard Operating Procedures (SOPs) for Management and Reporting of Adverse Events

South Africa

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DEFINITION OF TERMS

Adverse Events (AEs) Adverse events (AEs) related to male circumcision: any injuries, harm, or undesired outcomes occurring during or following male circumcision that would not have occurred if the client had not undergone the procedure. AEs can be classified by severity, timing, and type. AE reporting provides data required for monitoring of service delivery and patient safety.

Continuous quality improvement (CQI): a management philosophy that organizations use to reduce waste, increase efficiency, and increase internal (meaning, employees) and external (meaning, customer) satisfaction. It is an ongoing process that evaluates how an organization works and ways to improve its processes.

CQI framework: an organization's roadmap for improving its services, capacity, and outcomes. It guides the organization and its key collaborators and stakeholders through the process of monitoring services and using data as part of everyday practice to improve outcomes.

External quality assessment (EQA) of VMMC programs: site visits by an external body, often accompanied by Department of Health officials and implementing partner staff, to review and observe how individual VMMC sites perform against pre-determined criteria, using standardized tools.

Proficiency testing) (EQA): inter-laboratory comparison to determine if the HIV testing service can provide the correct test status.

Quality assurance (QA): a part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality control/process control (QC): a material or mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.

Quality improvement (QI): a part of quality management focused on increasing the ability to fulfil quality requirements

Quality management system: a system to direct and control an organization with regards to quality.

ABBREVIATIONS AND ACRONYMS

AE	Adverse Events
CDC	Centre for Disease Control and Prevention
CQI	Continuous Quality Improvement
DOH	Department of Health
EQA	External Quality Assessment
GP	General Practitioner
HAST	HIV, AIDS, STI and TB
HIV	Human Immuno-deficiency virus
IP	Implementing Partner
IPC	Infection and Prevention Control
M&E	Monitoring and Evaluation
MMC	Medical Male Circumcision
NDOH	National Department of Health
OTH	Online Training Hub
PEPFAR	The U.S. President's Emergency Plan for AIDS Relief
PSI	Patient Safety Incidence
QA	Quality Assurance
QI	Quality Improvement
RSA	Republic of South Africa
SOP	Standard Operating Procedure
US	The United States of America
USAID	United States Agency International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organisation

"Any injury, harm or undesired outcome that occurred during or following the male circumcision procedure, that would not have occurred if the client had not undergone the procedure at that time. This includes not only events related to any error in screening or medical practice, but those in which no error occurred."

--Adverse Event Action Guide

1. PURPOSE OF AE MONITORING AND REPORTING

Why do we Monitor AEs?

- VMMC is a preventive surgical intervention, and it is necessary to minimize related adverse events (AEs)
- High rates of AEs and poor management greatly affect demand for VMMC

2. ADVERSE EVENT MANAGEMENT, MONITORING AND REPORTING

The following mechanisms and processes have been implemented for the management, monitoring and reporting of all AEs:

- Standard Operating Procedures (SOPs) for management and reporting of AEs
- The list of MC-related AEs, as well as definitions of the respective severity levels, can be found in Adverse Event Action Guide for Voluntary Medical Male Circumcision (VMMC) by Surgery or Device 2nd Edition, 2016
- Standalone MMC register updated to collect data on type of AE and follow up
- AE register and follow up register

Standard Operating Procedures (SOPs) for management and reporting of AEs

The SOPs for reporting of AEs, also referred to as the AE Monitoring and Reporting Logical Framework, explain the importance of applying the correct management and reporting of each individual case of AE. The SOPs also provide guidelines to VMMC providers, programme managers and site managers on the correct process to follow in dealing with all types and severity of AEs.

Reports of AEs provide data necessary to conduct monitoring of service delivery, safety, programme progress and patient outcomes. AEs should be reported according to national department of health guidelines, and regardless, programmes should continue internal AE reporting for quality control. Reporting systems should include clear guidance on:

- Moderate and Severe AEs are expected to be reported through standard reporting mechanisms regardless of the appearance of relatedness; AEs will be reported according to their Severity as follows:

1. Mild AEs should be appropriately documented in the MMC register and reported monthly to the national MMC programme team.
2. Moderate AEs to be documented and reported on monthly basis
3. Severe AEs, for purposes of reporting, will be split into two, notifiable severe AEs and notifiable Ultra severe AEs.
    - **Notifiable Severe Adverse Events**: Notifiable severe adverse events are defined as those AEs requiring the Transfer/referral (to another facility or department) for complications and or hospitalisations. Refer to severe AE notification algorithm **Figure 1 on page 11**

      Notifiable Ultra-Severe Adverse Events: Notifiable ultra-severe adverse events are defined as the following:
    - death
    - complete or partial amputation of the glans or shaft of the penis
    - laceration of the glans
    - tetanus, including non-fatal cases
    - any AE that results in disability that is likely permanent
    - any AE that results in anatomic deformity that is likely permanent
    - any AE that results in hospital admission for ≥3 days

FIGURE 1. Severe Adverse Event Reporting

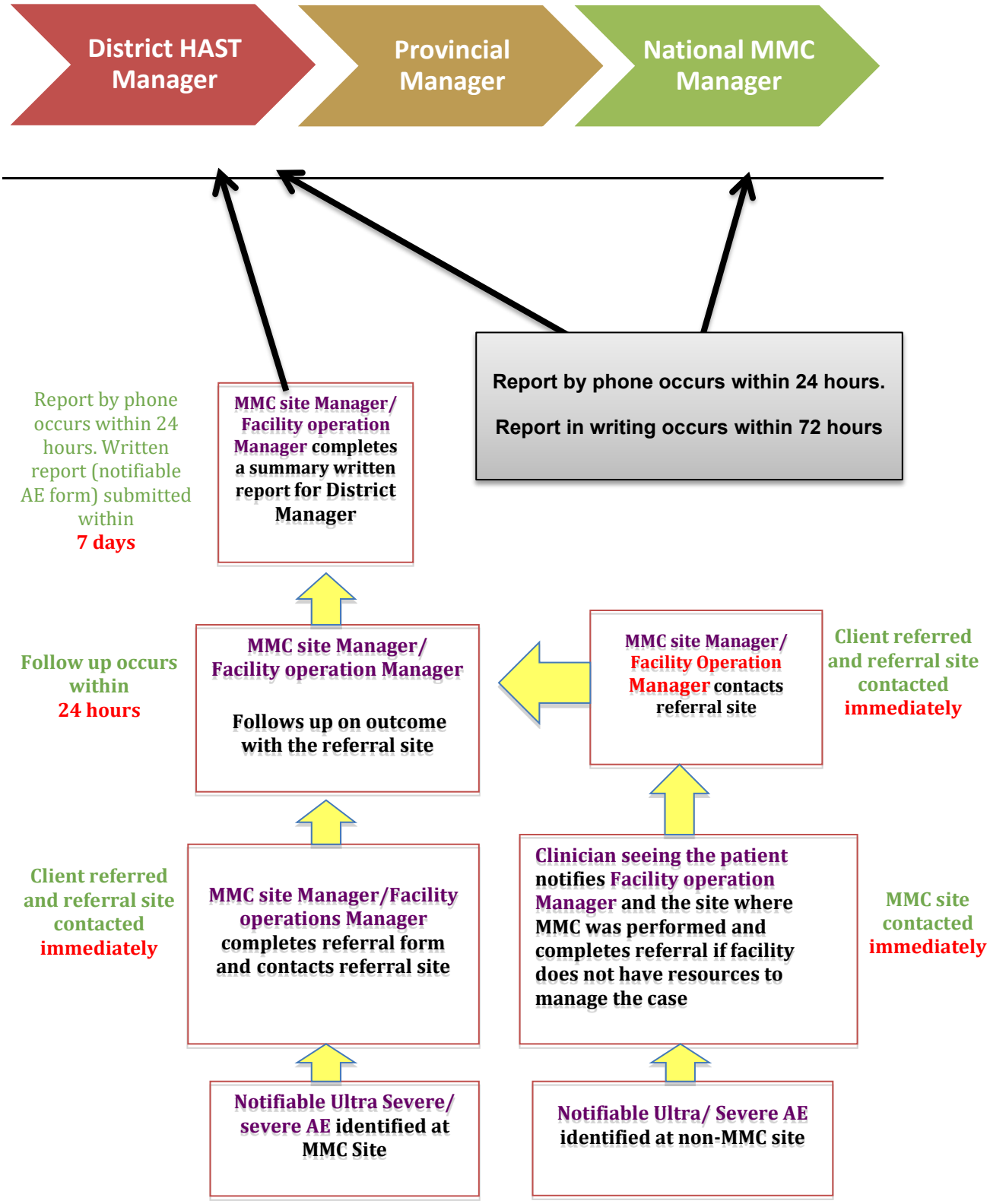

Figure 1. Notifiable Severe Adverse Event Reporting

MMC in traditional settings (High Season)

- The MMC programme is currently assisting EC and MP province with safe circumcision
- RTC and SFH in perform MMC in EC working through agreements with the House of Traditional Leaders (HOTL)
- RTC deliver MMC to support traditional circumcision schools in Nkangala district, Mpumalanga via the Ngoma Forum
- Traditional Male Circumcision (TMC) settings are approached as an entry point for HIV prevention and safe circumcision by providing medical male circumcision in the traditional settings (MMC-T)
- Guidelines recommended for MMC-T:
  - Health screening – all initiates (by health professionals)
  - Have clear referral pathways – for those with medical problems
  - Encourage medically trained doctors and nurses to assist (surgical removal and wound care)
  - Raise awareness at community level on these issues
  - Customary Initiation Bill

3. TRENDS OF SEVERE ADVERSE EVENTS (SAES) REPORTED FROM 2013 - 2019

In 2013, there was only one case reported and recorded on the PEPFAR tracking sheet for severe notifiable adverse events (NAEs) including one death caused by Haemorrhage. This case was noted as likely related to the MMC procedure performed. During 2014, most cases reported were glans injury and SAEs related to the procedure being performed as well as infection post-procedure during client follow-up assessment visits. There was unfortunately another case of death noted in 2015, as a motor vehicle accident after having undergone VMMC procedure. Patient Safety Incidents (PSI) include any adverse events, death or health symptoms that develop after undergoing operative procedure and therefore death should always be documented as an SAE even when it is found to be unrelated to the procedure. Following investigation by the PEPFAR VMMC implementing partner, the case of death was reported as unrelated to the actual MMC procedure. The other case reported in 2015 was of glans injury.

In 2016, there were 3 cases of glans injury, and this was attributed to the use of forceps-guided method (FCG) procedure previously used in the programme and this how now been phased out from MMC and replaced by the safer method of Dorsal Slit (D/S) technique. There was 1 case of death reported in 2016 (epileptic seizure), found to be unrelated to MMC procedure after client history information was gathered by the AE investigation officer.

There were 4 cases of glans injury reported in both 2017 and 2018 on the PEPFAR report on AEs, with the other reasons being infection, bleeding and fistula as other predominant types of AE. Recent cases of AEs reported up until 2019 include glans injury and severe infection often caused by incorrect application of wound care or poorly managed client follow-

ups, poor personal hygiene, unclean living conditions, lack of running water, or poor application of wound dressing.

1. HOW WE WILL IMPROVE MONITORING OF AES AND QUALITY

The following recommendations are suggested to avoid AEs and improve AE management:

- Appreciate that AEs are bound to occur but need mitigation measures
- Deliberate efforts needed to prevent and improve management of AEs
- Conduct regular reviews to understand cause and respond appropriately
- Proper assessment of eligibility
- Establish clear reporting channels and tools for Adverse Events (AEs)
- Ensure that providers have acceptable VMMC clinical training, emergency management, Basic life support (BLS) and AE management training, as well as refresher training for DOH doctors and VMMC providers to avoid unnecessary admissions and improve the diagnosis and management of AEs.
- Supply facility casualties with telephone numbers to contact when having a circumcision complication. A 24-hour call centre contact number needs to be provided to all clients with designated clinicians available to provide support post-op.
- Improve communication to client on wound care, and emphasise do NOT use home remedies and make sure parents are present when explaining wound care to younger clients.
- DOH facility staff need to be hands-on and support VMMC sites with handling client check-ups, and reports must be included in the patient's files at all MMC sites.
- Conduct meaningful follow up of clients

External Quality Assurance (EQA):

The National Department of Health (NDOH) Medical Male Circumcision (MMC) Programme with the support from World Health Organization (WHO) will be conducting External Quality Assessments (EQA) in selected facilities during August and September 2019. The national South Africa EQA will be led by NDOH in cooperation with WHO, a specialized agency of the United Nations that is concerned with international public health. The forthcoming EQA will be the largest ever undertaken within the national SA VMMC programme and was made possible through support and funding from the Centre for Disease Control and Prevention (CDC) the leading national public health institute of the United States.

A list of 90 sites for the national EQA exercise will include CDC, USAID and RT35 sites (including sites funded from provincial tenders).

The main objective of the upcoming EQA exercise is to check whether QA standards are adhered to and to identify gaps that could be remedied through implementation of CQI. Sites that have been quality assured through recent CDC/USAID EQA exercises may not be selected.

In the longer-term, we aim to achieve the following:

- Strengthen MMC Quality monitoring mechanisms at all levels within national MMC programme.
- Enhance ownership of continuous quality improvement (CQI) by MMC site managers, at all MMC sites.
- Establish District-led functional CQI teams to sustain CQI activities in each district, and build capacity for CQI at all DOH facilities and sites providing MMC services.
- Document and share best practice for delivery of quality MMC services.

Following the above exercise, the national EQA task team will work with WHO to compile feedback reports that include recommendations for the improvement of service safety and quality as a basis for ongoing continuous quality improvement (CQI) and other interventions that will improve MMC service provision.

What sets the current WHO EQA exercise apart from previous editions recently conducted within the national MMC programme is that previous models focus more on PEPFAR MMC provider sites whereas this EQA will examine a much wider selection of MMC providers including PEPFAR, RT35 sites, sites funded from provincial tenders, and MMC delivered by DOH within public health facilities, etc.).

This will be the largest study ever conducted before with significant long-terms gains than previous PEPFAR-led models with the longer term goals including the revitalization of existing CQI teams and establishment of new CQI teams at all sites.

We will generate sites EQA reports to present the findings and recommendations (clearly as DOH task teams/CQI teams), describing the ongoing process of CQI after EQA; and there will be greater cooperation between national and subnational levels of DOH to address gaps identified and strengthen QA mechanisms in the programme.

Implementation of Continuous Quality Improvement (CQI)

The CQI training will strive to ensure the development of skills and knowledge on how to apply the CQI approach and tools in routine implementation of VMMC services so that safe, high quality VMMC services are provided at all health facilities. A phased approach to the CQI training plan will be adopted for implementation, with the aim of capacitating VMMC service providers with the necessary skills required. During this process we will identify and collaborate with existing PEPFAR and DOH-led CQI teams; Centres of Excellence (COEs);

and sites that have completed institutionalisation of CQI within a DOH facilities, and therefore already applying CQI tools and methodology.

2. PHASED APPROACH TO CQI

CQI is being rolled out in a phased approach:

A phased approach methodology is a process whereby project implementation takes place in stages. This phased approach will follow a wave sequence spread methodology or 'slice of the system' approach, whereby CQI implementers who have experience in improving VMMC services in the country are utilised to conduct CQI trainings and spread better VMMC care delivery to other sites within the same sub-district, utilising the same methodologies and tools. A process was started in recent months to standardize the tools to be used for MMC service provision, CQI site assessment and reporting.

The utilisation of this approach is key as it can assist in overcoming resistance to change and allow for participants to master new skills. It also allows for the lessons that are learned in early phases to be incorporated into later phases.

3. CQI AND AE REPORTING TRAINING LAUNCH

To launch the CQI and AE management training, findings from the WHO EQA will serve as reference and guidance for the identification of sites to be covered during the first phase of training. In this phase, facilities in PEPFAR transitioning districts and in high volume priority provinces namely, Gauteng, Kwa-Zulu Natal, Mpumalanga, North West, Eastern Cape and Limpopo will be prioritised for CQI training.

Commonly, VMMC service delivery in South Africa is provided through the following sites:

- Fixed Sites: Hospitals, Community Health Centers, Clinics, General Practitioners
- Outreach Sites: Roving teams, Captured audiences
- Mobile Sites: Camps, far to reach areas
- Sites can be further classified as DoH, Implementing Partner and General Practitioner (GP) sites.

All of the above sites offering VMMC services will be considered for CQI training. The inclusion and exclusion criteria for this process will include the following benchmarks:

A site will only be classified as CQI trained if it has two or more team members who have undergone the training and are still present at the particular site.

4. SELECTION OF PERSONNEL

From the identified sites, a minimum of 2 members will be selected for training. The cadre of staff to be trained includes:

- Doctors
- Clinical officers
- Nurses
- Data capturers
- HCT counselors
- Housekeeping assistants
- Demand creation personnel

5. CQI AND AE REPORTING TRAINING WORKSHOPS

Personnel working at VMMC sites will undergo theoretical CQI training to gain an understanding and knowledge of CQI processes before applying it at facility level. The training will be conducted in the form of clustered workshops with a total number of participants not exceeding 35 per workshop. There will be 2 participants from each identified facility as well as 5 additional VMMC-affiliated participants from the province. Thereafter, a baseline assessment of each site will be conducted which will inform the level of CQI support. It is envisaged that the CQI and AE reporting training will be supported by the district MMC microplan conditional grant funding, with additional support for venue sought from regional training centres (RTC) when required and MMC programme partners when available.

6. CQI SUPPORT VISITS

Before the CQI training workshops, **baseline assessments** of each site will be conducted in order to establish the status of the site performance against set standards; this will be used as a benchmark in future re-assessments to determine whether the particular site is improving after CQI support visits. During these support visits, trainees will be provided with direct mentorship and support to enable them to: identify gaps for improvement, form quality improvement teams, apply quality improvement methodologies, test and implement changes, analyse and utilise their own data to improve the quality of care, and scale up best practices through shared learning.

The level of intensity of the CQI post-training support visits will be determined by the score that a site achieves on their baseline assessment, against the following set site performance standards:

1. Leadership and Planning
2. Management systems
3. Infrastructure, equipment, environment and supplies
4. Registration, group education and IEC
5. Individual counselling for VMMC procedure and HCT
6. Surgical Procedure
7. Infection prevention and control
8. Monitoring and Evaluation (M&E)

1.1. LEVEL 1: INTENSE SUPPORT

Sites in this group will receive CQI support on monthly basis until they improve to light support. Intense support will be provided to sites with significant gaps, or those that achieve the following results on the baseline assessment:

- Scoring less than 70% on surgical VMMC procedure.
- Scoring less than 70% for infection control.
- Scoring less than 50% average compliance with all components / indicator.

1.2. LEVEL 2: LIGHT SUPPORT (REVISIT 4 TIMES A YEAR)

Sites in this group receive CQI support visits quarterly. These are sites with moderate gaps or sites selected based on the following criteria:

- Scoring >70% but <85% for VMMC procedure and/or
- Scoring >70% but < 85% for infection control and/or
- Scoring >50% but <70% average compliance with all quality standards.

1.3. LEVEL 3: COLLABORATIVE SUPPORT (REVISIT EVERY 6 MONTHS)

Sites in this group receive CQI support visits twice yearly. These are sites with minimal gaps or sites selected based on the following criteria:

- Scoring >85% for VMMC procedure and/or
- Scoring >85% for infection control and/or
- Scoring >80% average compliance with all quality standards.

Comprehensive reports on CQI trainings follow up and evaluation will be generated by implementing partners and submitted to NDoH. The national MMC programme will compile a combined overarching report on CQI training outcomes.

7. PROVINCIAL LEARNING SESSIONS

It is important for VMMC providers to convene from time to time and have learning sessions to collectively share experiences from their work areas. During these sessions, 1 province specific learning session, lasting 3 days, will be held for each province – with 2 held for each

of the priority provinces. Each learning session will be attended by two representatives from each site that has undergone CQI training, as well as 6 additional attendees from each province.

8. ADDITIONAL RESOURCES FOR IMPROVED OUTCOMES IN MMC

The national MMC programme employs the following additional resources to improve outcomes from MMC services and compliance by all MMC providers:

- **Online Training Hub (OTH):** the OTH is an eLearning platform that provides classes, resources, and communities of practice to help clinicians advance their skills and knowledge around performing voluntary medical male circumcision (VMMC). The OTH covers the didactic, theoretical VMMC information currently learned through in-person workshops. All providers are required to complete the OTH training and this requires attainment of an 80% pass mark in all 7 modules.
- **General Practitioner (GP) on-boarding guidelines:** a standard set of rules for all GP's providing MMC services to follow that allows for measures to be taken in the case of non-compliance. The guidelines apply laterally to all providers performing MMC.
- **Patient Safety Incidence (PSI):** the CQI process and mechanisms employed for AE recording and monitoring will be more closely aligned and integrated within the internal quality monitoring systems at DOH facilities, including the PSI systems and committee structures, and in accordance with the requirements of the Office of the Standards of Compliance.
- **The National QA and CQI Implementation Framework** is currently being updated to reflect the processes and workings of the national MMC team within the broader quality monitoring and control mechanisms of the DOH, PSI and Office of the Standards of Compliance.
- **Knowledge Hub:** online repository for disseminating standard MMC tools, guidelines and SOPs

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