

SOUTH AFRICAN NATIONAL GUIDELINES FOR VOLUNTARY MEDICAL MALE CIRCUMCISION (VMMC) ON GENERAL PRACTITIONER'S (GP) CONTRACTING

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ABBREVIATIONS

AE	Adverse event
CQI	Continuous quality improvement
DoH	Department of Health
GP	General practitioner
GPP	Good Pharmacy Practice
HPCSA	Health Professional Council of South Africa
HTS	HIV testing services
IPC	Infection and prevention
M&E	Monitoring and evaluation
OTH	Online Training Hub
SARS	South Africa Revenue Service
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

PURPOSE/OBJECTIVES OF THESE GUIDELINES

The Voluntary Medical Male Circumcision (VMMC) general practitioner (GP) contracting guidelines have been compiled to ensure that GPs provide MMC services in a safe, efficient and cost-effective way. The quality of services provided by GPs will be monitored and maintained at very high levels by Provincial and National VMMC Managers.

CONSIDERATIONS FOR SELECTING GPS

It is required that when selecting GPs to partner with, organisations must aim to broaden their reach to as wide a catchment area as is feasible, by selecting partners in different areas of the city. Contracting of many GPs in the same area splits the access points of clients looking for VMMC services. This could mean lower client volumes-to-site/clinics ratios, and in this scenario the practices may not benefit from economies of scale of high-volume client flow and the sustainability of the model maybe jeopardized.

The GP practice should have adequate electronic management systems in place to be able to adhere to stringent requirements and quality standards, and offer a comprehensive package of the minimum services required by the Department of Health. This system must be auditable.

It is a requirement to contract GPs that have undergone VMMC training and deemed proficient in providing VMMC and other HIV prevention services. The GP must have a trained and certified HIV Counsellor employed or contracted to offer and perform HIV testing services (HTS)

OBLIGATIONS OF THE GP

- To comply with all applicable South African Government regulations including all the applicable requirements and guidelines relating to the National VMMC programme such as reporting and external quality assurance assessments, including data quality assessments and continuous quality improvement activities.
- To keep confidential all information, records, tests or disclosures of a medical or personal nature, relating to the client during the course of rendering any service to them. GPs are however required to release information to relevant



bodies during investigation of adverse events (AEs) or for further clinical management of the client.

- To demonstrate accountability in terms of maintaining private medical records of patients including HIV status.
- To be solely responsible for ensuring that they keep themselves fully informed of any amendments, variations and/or additions to the World Health Organization (WHO) and South African Department of Health (DOH) National Guidelines relevant to the provision of VMMC services.
- To provide VMMC services to eligible males who are 10 years of age and older, and ensuring that the required consent processes are in place and according to the quality standards set out in the WHO and DoH VMMC implementation and clinical guidelines.
- To offer HTS to 100% of the VMMC clients as part of the MMC service and ensure referral of HIV positive clients for treatment and care services. However, HIV testing is not compulsory to receive VMMC.
- To educate clients on the benefits of VMMC using DoH approved materials and guidelines referenced by this statement to improve clients' knowledge about the partial protective effect of VMMC and the need for safe sexual practices following MMC through the use of dual protection, including condoms and other safe sex strategies.
- To provide pre- and post- VMMC counselling, including informed consent for MMC, abstinence counselling during the healing period and risk reduction.
- To ensure that all AEs are properly managed and accurately reported. Should it emerge that AE's have not been adequately reported, the contract between the appointed service provider may be terminated immediately at the discretion of DoH.
- To ensure the use of clinical algorithms and quality standards as per the WHO and NDoH VMMC clinical guidelines for the management and performance of MMC surgical and device-based procedures.
- To ensure VMMC health services waste is managed according to the WHO and NDoH guidelines.
- To ensure access to follow-up services of two (2), seven (7) and fourteen (14) days after the provision of VMMC services to all patients.
- To provide appropriate and adequate staffing as well as on-going training, mentoring and supervision of staff to ensure high quality delivery of the package of VMMC services.
- To ensure that all staff have enrolled and completed training with the Online Training Hub (OTH) system.



- To ensure that all staff working in the practice have legally binding written contracts of employment that includes reference to normal working hours, total remuneration, leave policy, and all other terms and conditions of employment.
- To ensure that all staff are and remain registered with all applicable professional health councils, authorities and/or bodies in accordance with all applicable laws and regulations. Copies of proof of such registration in respect of all or any of the staff shall be made available to the DoH upon request.
- To ensure access to and create demand for VMMC services among males between the ages of 15-34 years of age, including site-specific social mobilization and collaboration with community and clinic-based partners that can help build demand.
- To ensure that quality Monitoring and Evaluation (M&E) records and systems are maintained in compliance with DoH reporting standards.
- To comply with occupational and environmental health and safety processes that meet legislative requirements.
- To adhere to DoH VMMC infection control and waste management protocols.

NATIONAL VMMC PROGRAM POLICY VIOLATIONS

The following shall constitute National VMMC policy violations:

1. The use of sedation or general anaesthesia
2. No client post circumcision follow-up as per protocol
3. No emergency supplies, equipment and trained staff on site
4. No HIV testing recommended and provided (HIV testing is not compulsory)
5. No written informed consent retained for clients or parental/guardian consent for minor clients
6. No immediate reporting of any death or severe adverse event as per protocol in Appendix A
7. VMMC performed in clients aged <10 years
8. Clients not receiving written instructions on recommended post-procedure wound care that explicitly address the risk of wound infection including the danger of using traditional remedies for wound care
9. To only use surgical methods and devices approved and/or pre-qualified by WHO and the NDoH. All circumcisions regardless of age of client should be conducted using the dorsal slit method
10. Not maintaining clinical skills as demonstrated through participation in routine trainings (e.g. procedure refresher and emergency management training every



- 2 years) or using untrained support staff to deliver the package of VMMC services (e.g. using a layperson to perform HTS)
11. Not adhering to infection and prevention (IPC) practices
 12. Double counting VMMC reported to different stakeholders or falsifying records (e.g. reporting ghost VMMCs)
 13. Removing client records from DoH facilities or any other VMMC site where they were performed
 14. Failure to engage in continuous quality improvement (CQI) visits or failure to make improvement on remedial actions between CQI visits

CONSEQUENCES FOR POLICY VIOLATIONS

Should a Policy Violation occur the appointed Service Provider shall be obligated to take immediate remedial action. This remedial action shall take the form of: remedial training, mentoring and supervision by the Service Delivery Partner(s) clinical staff to ensure high quality service. Remedial action should ideally focus on reviewing internal systems and processes to identify gaps. Methodology for this is provided in the CQI guidelines. Providers should conduct regular in-service trainings on MMC service delivery guidelines and protocols and should include clinical guidelines, HIV and MMC counselling guidelines, In-service communication guidelines as well as wound care and follow-up guidelines. The appointed service provider shall agree to conduct audits of its own staff and that of its Service Delivery Partner(s) to ensure that such remedial has taken place and report such to the district DoH. Failure of which shall constitute a breach of this Contract.

Should the proportion of AEs fall outside the range of 2% and if there is no reporting of any severe notifiable AE's, the Contract between the appointed Service Provider can be terminated immediately at the discretion of PDoH.

The NDOH have outlined consequences for policy violations as per national GP contracting guidelines and RT35 stipulations, which takes the stance of suspending services or blacklisting GPs until corrective measures have been satisfactorily implemented.

Failure by an MMC provider to satisfactorily implement any of the stipulated remedial actions will result in the immediate termination of services by the National Department of Health.

OPERATIONAL READINESS REQUIREMENTS

ADMIN REQUIREMENTS

1. Medical degree (MBChB or equivalent)
2. Valid registration with the Health Professional Council of South Africa (HPCSA)
3. Valid and adequate medical indemnity insurance
4. Valid dispensing license as issued by DoH if practice will be participating in dispensing activities
5. Valid and adequate business or property insurance that cover medicine stock losses due to fire, storms, theft and other events apart from mass destruction events
6. Valid tax clearance certificate issued by the South Africa Revenue Service (SARS)
7. VMMC OTH certificate
8. Training certificate in VMMC surgical procedure (not older than 2 years)
9. Facility readiness assessment report
10. Bank details

PROCESS REQUIREMENTS

- The practice should be operational a minimum of 20 hours per week
- All GPs must be provided with targets
- Proper administrative processes are in place that demonstrate effective financial, personnel, asset and information management
- There is a proper filing system that demonstrates good record-keeping
- Proper stock management and dispensing processes are followed according to Good Pharmacy Practice (GPP). These processes include ordering, receiving, issuing, security, control and disposal
- A minimum level of occupational and environmental health and safety processes are in place to meet legislative requirements

APPROVALS AND STRUCTURAL REQUIREMENTS

- Approved by District DoH or relevant funder

SOPS, GUIDELINES, POLICIES AND JOB AIDS

1. National VMMC Guidelines
2. Informed Consent Process



3. VMMC Surgical Manual (WHO or National)
4. VMMC Register
5. Client Record Forms
6. Surgical Register
7. Guidelines and Protocols for Medical Emergencies
8. Anaesthetics Dosing Guidelines
9. Immediate Post-Operative Care
10. Post-Operative (return visit) Follow-up Protocol
11. Post-Operative Wound Care Written Instructions
12. Adverse Event Prevention and Management Guidelines
13. Adverse Event Reporting Flow
14. Adverse Event Register
15. HIV/AIDS Risk Reduction Counselling guidelines
16. HIV Testing Services Guidelines
17. HIV Testing Services Register
18. HIV Testing Quality Control Register
19. STI Diagnosis and Treatment
20. TB Screening Guidelines
21. Infection Prevention and Control Guidelines
22. Blood-borne Pathogen Exposure, including Post-exposure Prophylaxis (PEP) Guidelines
23. Waste Management Guidelines
24. Patient Rights Charter
25. Staff Job Descriptions
26. Minutes from Quality Improvement Team Meetings
27. Inventory (Stock) cards

INFRASTRUCTURE

1. Reception area
2. Doctors consulting rooms
3. Private counselling rooms
4. Pre-op examination room
5. Operating room with scrubbing area
6. Recovery room/space
7. Storage space for supplies
8. Fit-for-purpose dispensary that meets temperature, access, fire safety, receiving of medicines, delivery and refrigeration requirements (for dispensing doctors)
9. Waste management area
10. Adequate water supply

11. Adequate lighting
12. Internet access
13. Security for staff and patients and be clean
14. Accessible to people with disabilities

SUPPLIES, EQUIPMENT AND CONSUMABLES

- VMMC kits (according to NDoH specifications and from DoH approved suppliers)
- Lignocaine (1% or 2%) and/or Marcaine (0.5%)
- Disposable needles (23g and 24g)
- Disposable syringes (5ml, 10ml, and 20ml)
- Disposable cannulas (16g, 18g and 20g)
- Gloves (examination, surgical, and utility of different sizes)
- Plastic disposable aprons
- Waste bins (for contaminated and non-contaminated waste)
- Colour-coded bin liners (red and black)
- Sharps disposal containers
- Decontamination buckets
- Handwashing/rub facilities at appropriate places
- Iodine/Betadine solution
- Chlorine/sodium hypochlorite (Jik)
- Soap (plain/medicated/detergent)
- Hand towels/disposable paper towels
- Wall thermometer
- Temperature control charts
- HIV testing kits
- HIV testing quality control samples
- Fridge
- Freezer
- Air conditioners
- Surgical beds
- Diathermy machine
- Anaesthetic (“bedside”) trolley with a drawer

EMERGENCY SUPPLIES

EQUIPMENT AND INSTRUMENTS

- Emergency Trolley
- Emergency Jump Bag
- Ambubag - Adult (A) - complete set
- Ambubag - Paeds (P) - complete set
- Baumanometer
- Cuffs - A
- Cuffs - P
- ET Tubes adult - Size 7
- ET Tubes adult - Size 8
- ET Tubes adult - Size 9 cuffed
- ET Tubes paediatric - Size 5
- ET Tubes paediatric - Size 6
- Glucometer
- Glucometer Test Strips
- Introducer - A
- Introducer - P
- K Y Jelly tube 100ml
- Laryngoscope blade set - A
- Laryngoscope blade set - P
- Stethoscope
- Magills forceps - A
- Magills forceps - P
- Oropharyngeal airways sets - A/P
- Oxygen masks - A
- Oxygen masks - P
- Oxygen cylinder (with regulator)
- Pocket Masks
- Pulse Oximeter
- Scissor - Plain/Unsterile
- Suction Machine/Aspirator
- Suction tubes
- Yankauer suction tips
- Torch - Pencil
- Tourniquet

INTRAVENOUS INFUSION

- Ringer Lactate 1L
- Dextrose 5% 200ml
- Sodium Chloride 1L
- Sodium Chloride 200ml

EMERGENCY DRUGS

- Adrenalin 1mg/ml ampoule
- Atropine 0.6mg/1ml ampoule
- Dextrose 50% 20ml
- Lasix 10mg injection
- Lorazepam 4mg/ml amps
- Solucortef 100mg

DISPOSABLE COMMODITIES

- Unsterile Gloves (Size - large)
- Gauzes Sterile
- IV administration set - A
- IV administration set - P
- Jelco needle (Blue) - 22G
- Jelco needle (Green) - 18G
- Jelco needle (Grey) - 16G
- Jelco needle (Pink) - 20G
- Micropore
- Needles (Black)
- Needles (Blue)
- Needles (Green)
- Syringes 20ml
- Syringes 10ml
- Syringes 5ml
- Transparent drip plaster /Tergaderm
- Webcol/Alcohol swab.

Please note: The supplies, equipment and consumables listed above are basic minimum requirements for a GP to perform safe MMC. Some consumables that are



health

Department:
Health
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not listed above but required for various functionalities shall, within reasonable capacity, fall under the GP's contractual obligation.

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REFERENCES

1. South African National Medical Male Circumcision Guidelines 2016 (or as amended)
2. NDOH VMMC Adverse Event Management and Reporting Standard Operating Procedure
3. National HIV Testing Services (HTS) Policy 2016