

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

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CONTENTS

ABBREVIATIONS	iii
PURPOSE/OBJECTIVES OF THESE GUIDELINES	1
CONSIDERATIONS FOR SELECTING GPS.....	1
OBLIGATIONS OF THE GP	1
NATIONAL VMMC PROGRAM POLICY VIOLATIONS	3
CONSEQUENCES FOR POLICY VIOLATIONS.....	4
OPERATIONAL READINESS REQUIREMENTS	6
Admin requirements.....	6
Process requirements.....	6
Approvals and structural requirements	7
SOPs, guidelines, policies and job aids	7
Infrastructure	8
Supplies, equipment and consumables	8
EMERGENCY SUPPLIES.....	10
Equipment and instruments	10
Intravenous infusion.....	11
Emergency drugs.....	11
Disposable commodities.....	11
CONTACT PERSON:.....	13
REFERENCES.....	14

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 prevention and control
M&E	Monitoring and evaluation
OTH	Online Training Hub
QA	Quality Assurance
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 District, 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 accredited 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)** according to the National HTS testing guidelines and algorithm.

OBLIGATIONS OF THE GP

Regulations and compliance

1. 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.



2. 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.
3. To **ensure that quality Monitoring and Evaluation (M&E) records and systems are maintained** in compliance with DoH reporting standards.
4. To **comply with occupational and environmental health and safety processes** that meet legislative requirements.
5. To **adhere to DoH VMMC infection control and waste management protocols**.

Data and information

6. 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.
7. To **demonstrate accountability** in terms of maintaining private medical records of patients including HIV status.

Services to clients

8. 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.
9. To **provide VMMC services to eligible males** who are 10 years of age and older, and **ensuring that the required informed consent processes are in place** and obtained according to the quality standards set out in the WHO and DoH VMMC implementation and clinical guidelines.
10. 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.
11. 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 condoms, having one sexual partner and other safe sex strategies.
12. To **provide pre- and post- VMMC counselling**, including informed consent for VMMC, abstinence counselling during the healing period including risk reduction counselling.

Quality control

13. 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.
14. 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.
15. 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.

Staffing

16. To **provide appropriate and adequate staffing as well as on-going training, mentoring and supervision of staff** to ensure high quality delivery of the minimum package of VMMC services.
17. To **ensure that all staff have enrolled and completed training** with the Online Training Hub (OTH) system.
18. To **ensure that all staff working in the practice have legally binding written contract of employment** that include reference to normal working hours, total remuneration, leave policy, and all other terms and conditions of employment.
19. 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.

NATIONAL VMMC PROGRAM POLICY VIOLATIONS

The following constitute National VMMC policy violations:

Data and reporting

1. No written informed consent retained for clients or parental/guardian consent for minor clients
2. No immediate reporting of any death or severe adverse event as per protocol in Appendix A
3. Double counting VMMC reported to different stakeholders or falsifying records (e.g. reporting ghost VMMCs)
4. Removing MMC source documents from DoH facilities or any other VMMC site where they were performed at

Services to clients

5. HIV testing not conducted as recommended (HIV testing is not compulsory)
6. VMMC performed in clients aged <10 years
7. 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
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

Quality control

9. The use of sedation or general anaesthesia during a VMMC surgical procedure
10. Absence of evidence of any client post circumcision follow-up conducted
11. Absence of emergency supplies, equipment and no evidence of VMMC Emergency preparedness training for staff on site
12. 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)
13. Not adhering to infection prevention and control (IPC) practices illustrated by poor scoring on the IPC Quality Standard of <60%. Scoring between 60 - 85% will require In-service training by IPC Coordinators.
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 be identified by District CQI team members the appointed Service Provider will be notified and an action plan summary should be shared with the District CQI teams and the service provider will 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 and the District CQI team members to ensure high quality service.

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 using approved NDoH guidelines and SOPs.

The appointed service provider shall agree to take part in CQI activities and ensure that all recommendations to address identified gaps are addressed within the agreed timeline. Failure of which shall constitute a breach of this Contract.

If there is no reporting of any severe notifiable AEs, 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

Can you tick off each of the following operational readiness requirements?

1. Admin
2. Process
3. Approvals & Structural
4. SOPs, Guidelines, Policies, and Job Aids
5. Infrastructure
6. Supplies, Equipment, and Consumables

ADMIN REQUIREMENTS

	Medical degree (MBChB or equivalent)
	Valid registration with the Health Professional Council of South Africa (HPCSA)
	Valid and adequate medical indemnity insurance
	Valid dispensing license as issued by DoH as the practice will be participating in dispensing activities
	Valid and adequate business or property insurance that cover medicine stock losses due to fire, storms, theft and other events
	Valid tax clearance certificate issued by the South Africa Revenue Service (SARS)
	VMMC OTH certificate with evidence of MMC surgical mentorship
	Competency Training certificate in VMMC surgical procedure (not older than 2 years)
	Facility readiness assessment report
	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
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SOPS, GUIDELINES, POLICIES AND JOB AIDS

	National VMMC Guidelines
	Informed Consent Process
	VMMC Surgical Manual (WHO or National)
	VMMC Register
	Client Record Forms
	Guidelines and Protocols for Medical Emergencies
	Anaesthetics Dosing Guidelines
	Immediate Post-Operative Care
	Post-Operative Follow-up Protocol
	Post-Operative Wound Care Written Instructions
	Adverse Event (AE) Prevention and Management Guidelines
	Adverse Event (AE) Reporting Flow
	Adverse Event (AE) Register
	HIV/AIDS Risk Reduction Counselling guidelines
	HIV Testing Services Guidelines
	HIV Testing Services Register
	STI Diagnosis and Treatment
	TB Screening Guidelines
	Infection Prevention and Control Guidelines
	Blood-borne Pathogen Exposure, including Post-exposure Prophylaxis (PEP) Guidelines
	Waste Management Guidelines
	Patient Rights Charter

	Staff Job Descriptions
	Minutes from Quality Improvement Team Meetings
	Inventory (Stock) cards



INFRASTRUCTURE

	Reception area
	Doctors consulting rooms
	Private counselling rooms
	Pre-op examination room
	Operating room with scrubbing area
	Recovery room/space
	Storage space for supplies
	Fit-for-purpose dispensary that meets temperature, access, fire safety, receiving of medicines, delivery and refrigeration requirements (for dispensing doctors)
	Waste management area
	Adequate water supply
	Adequate lighting
	Internet access
	Security for staff and patients
	Clean environment
	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
Alternative to Betadine in case of allergies to Betadine (savlon)
Chlorine/sodium hypochlorite (Jik)
Soap (plain/medicated/detergent)
Hand towels/disposable paper towels
Wall thermometer at all appropriate service areas
Daily updated Temperature control charts
HIV testing kits
HIV testing quality control samples
Fridge for HTS Quality Control serums
Freezer for the temporary storage of foreskins prior to disposal by accredited service providers
Air conditioners
Surgical beds
Diathermy machine
Anaesthetic (“bedside”) trolley with a drawer
Mayo trolley or surgical instruments trolley

EMERGENCY SUPPLIES

Can you tick off each of the following emergency supplies?

1. Equipment & Instruments
2. Intravenous Infusion
3. Emergency Drugs
4. Disposable Commodities

EQUIPMENT AND INSTRUMENTS

Emergency Trolley or emergency jump bag with the following contents:

Ambubag - Adult (A) - complete set
Ambubag - Paeds (P) - complete set
Baumanometer
Cuffs - Adult
Cuffs - Paediatric or smaller cuff
ET Tubes adult - Size 7
ET Tubes adult - Size 8
ET Tubes adult - Size 9
ET Tubes paediatric - Size 5
ET Tubes paediatric - Size 6
Glucometer
Glucometer Test Strips
Introducer - Adult
Introducer - Paediatric
K Y Jelly tube 100ml
Laryngoscope blade set - Adult
Laryngoscope blade set - Paediatric
Stethoscope
Magills forceps - Adult
Magills forceps - Paediatric
Oropharyngeal airways sets - A/P



Oxygen masks - Adult
Oxygen masks - Paediatric
Oxygen cylinder (with regulator)
Pocket Masks
Pulse Oximeter
Scissor - Plain/Unsterile
Suction Machine
Suction tubes
Yankauer suction tips
Torch - Pencil
Tourniquet
Different sizes urinary catheters

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
Lorazepam 4mg/ml amps
Promethazine
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 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