Guideline on the use of devices for adult male circumcision for HIV prevention

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Contents:

- Introduction and background
- Scope
- Process
- Evidence
- Recommendation
- Programmatic considerations
Introduction

• 3 conventional surgical male circumcision methods recommended

• Challenges of conventional surgical method
  – Supply
    • Limited number of health care workers
    • Time and resources required
  – Demand: inconsistent uptake, acceptability

• Innovative method solutions
  – Devices?
Many devices: should they be used?
Assessing device clinical efficacy and safety

- Technical Advisory Group on Innovation in Male Circumcision
  - advises WHO on technological innovations and reviews clinical data

- *Framework for clinical evaluation of devices for male circumcision*
  - describes clinical evaluation pathways required to assess device efficacy, safety
  - defines key device characteristics to evaluate clinically
In situ devices: categories based on mechanism of action

1. **Clamp:** a. **Collar clamp** and b. **Vice clamp**
   
   Rapid, tight compression of foreskin between hard surfaces

2. **Elastic collar compression**
   
   Slow compression of the foreskin between an elastic ring and a hard surface that is sufficient to occlude circulation and produce tissue ischaemia and necrosis

3. **Ligature**
   
   Rapid compression of foreskin between a ring and a non-rigid ligature tied around outside of the foreskin
# Prequalification of Male Circumcision Devices Programme, 2011

<table>
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<tr>
<th>Specific devices</th>
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<td>- Evaluated against international standards</td>
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<th><strong>Clinical</strong> efficacy and safety</th>
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| **Product performance**                      |
| Design, changes, version for PQ               |
| Tests to demonstrate performance             |
| Instructions for use                          |

| Biocompatibility                              |
| Sterilization                                 |
| Labelling                                     |

| **Quality manufacturing system**             |
| Technologies used                            |
| All components and suppliers verified/validated for quality |

| Inspection                                   |

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<th><strong>NOT WHO approval or endorsement of the specific product</strong></th>
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A **recommendation** provides information about what policy-makers, health-care providers or patients should do. It implies a choice between different interventions that have an impact on health and that have consequences for the use of resources.
WHO Guidance on devices as a method of MC for HIV prevention

Guideline on use of devices for adult MC recommendation and programme considerations

List of prequalified devices assurance of safety and quality of a specific device
WHO process of guideline and recommendation development

1. Scoping the document
2. Setting up Guideline Development Group and External Review Group
3. Disclosure and management of secondary interests
4. Formulation of the questions (PICO) and choice of the relevant outcomes
5. Evidence retrieval, assessment and synthesis (systematic review(s))
   - GRADE - evidence profile(s)
6. Formulation of the recommendations (GRADE)
   - Including explicit consideration of:
     - Benefits and harms
     - Values and preferences
     - Resource use
7. Dissemination, implementation (adaptation)
8. Evaluation of impact
9. Plan for updating
Scope of the guideline

Objectives:
- Provide an evidence-based recommendation on use of adult MC devices
- Present key programmatic considerations for introduction and use

Audience
- Policy and decision makers
- Programme managers
- Providers of MMC services
- Donors and implementing agencies
Process:

**guideline development groups**

1. **WHO Steering Group**
   - HIV, Adolescent, Reproductive Health, Essential medicines

2. **Guideline development group**
   - Content experts, programme managers, economist, researchers, civil society, implementers, methodologist

3. **External Review Group**
   - Other experts and those interested in MC for HIV prevention

WHO Technical Advisory Group representatives
Among adolescent and adult men seeking circumcision for HIV prevention in high HIV prevalence, resource-limited settings, are male circumcision devices a safe, efficacious and acceptable method for circumcision compared with conventional surgical male circumcision?
Priority outcomes to answer the key question

• Critical (7-9):
  – Eligibility
  – Successful circumcision
  – Moderate and serious adverse events
  – Healing time

• Important (4-6):
  – Pain at different points in time
  – Cosmetic results
  – Procedure time
Evidence

- Review of published literature
- Unpublished reports from investigators
- Studies on devices that met the criteria of the *Framework*
  - Initial safety studies
  - Comparative studies
  - Field studies
- Data used only from studies on the PrePex and ShangRing from 5 African countries
### Grading of Recommendation Assessment, Development and Evaluation

#### Quality of the Evidence

By outcome and overall:
- High quality
- Moderate
- Low
- Very low

#### Strength of the Recommendation

Strong or Conditional depends on:
- Quality of evidence
- Balance of benefits and harms
- Values and preferences
- Resource use
WHO prequalified male circumcision devices are efficacious, safe and acceptable as additional methods of male circumcision for HIV prevention among healthy men 18 years and older in high HIV prevalence, resource-limited settings (conditional, moderate quality evidence).

This recommendation applies in settings where:

• the devices are used by health-care providers, including physicians and mid-level providers, who are appropriately trained and competent in the use of the specific device; and

• surgical backup facilities and skills are available as appropriate to the specific device.

Quality of the evidence: Moderate

Strength of the recommendation: Conditional in favour of the intervention
Programme considerations

- Planning for scale up
- Health system readiness
- Policies and regulations
- Service delivery
- Communication programming
- Procurement, supply chain, waste management
- Monitoring
- Resource requirements and cost considerations
- Information gaps and needs
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External review group
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Technical Advisory Group on Innovations in Male Circumcision
Thank you!