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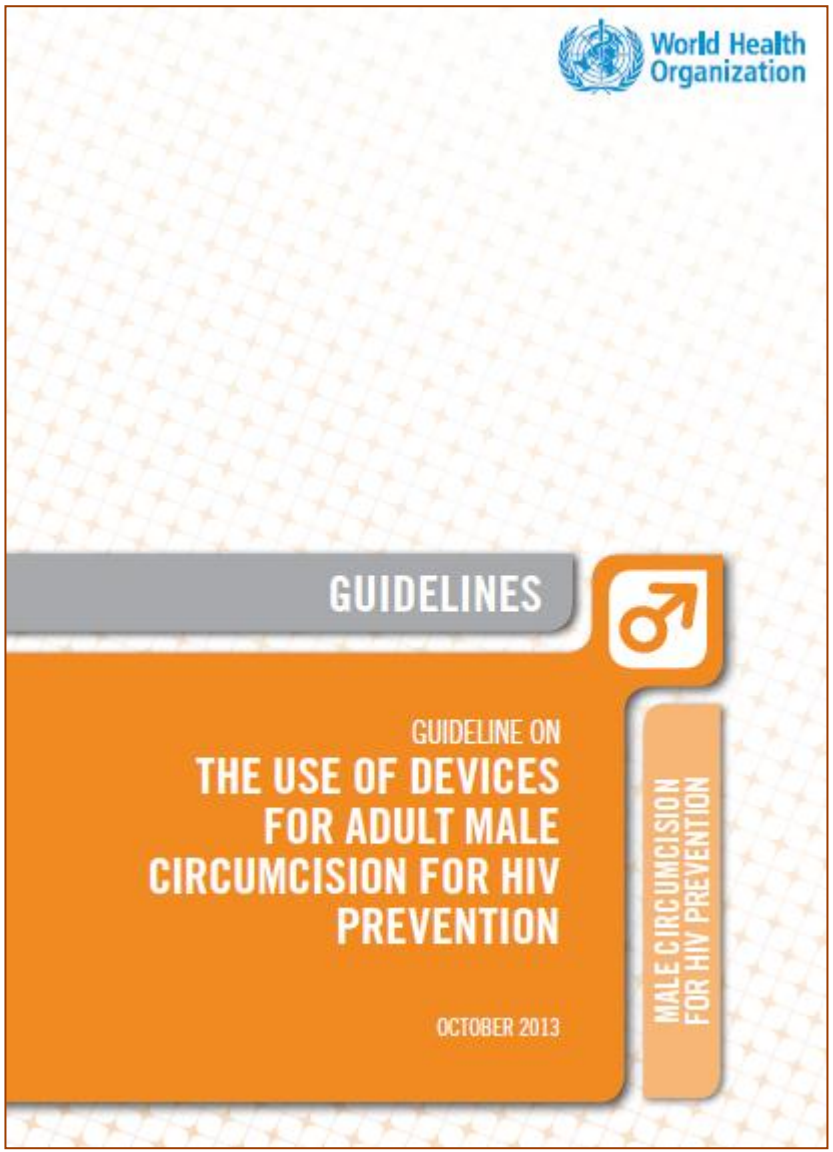
Guideline on the use of devices for adult male circumcision for HIV prevention

13 – 14 November 2013

World Health Organization

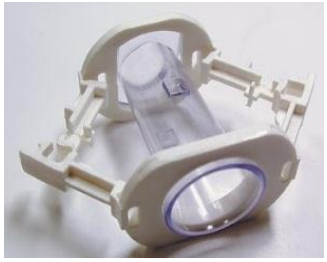


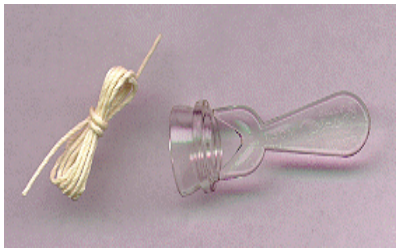
Contents

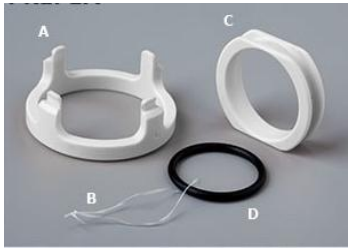
Introduction

- 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?



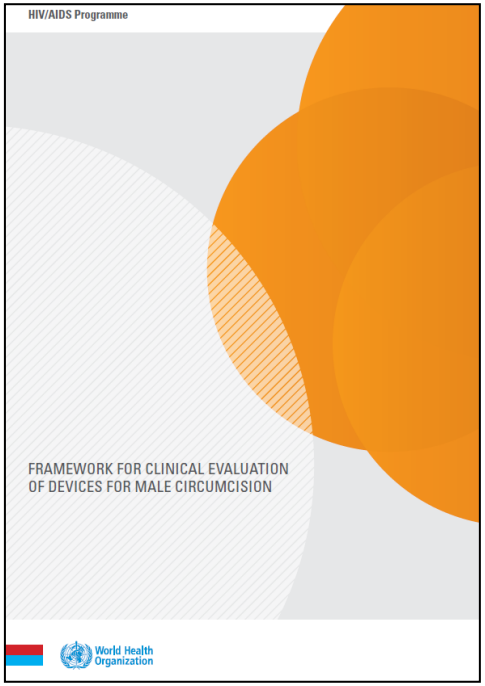




others?

Background: 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

Specific devices
-Evaluated against international standards

Clinical efficacy and safety

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

NOT WHO approval or endorsement of the specific product

WHO guidelines and recommendation

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

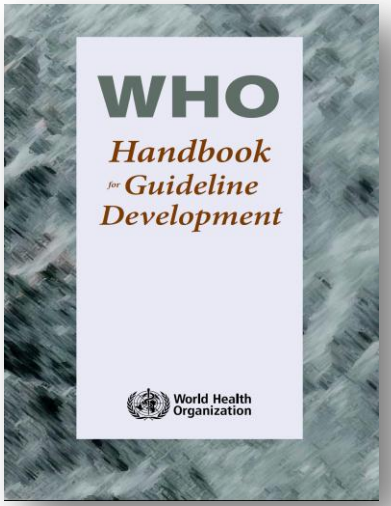
List of prequalified devices

assurance of safety and quality of a specific device

MALE CIRCUMCISION FOR HIV PREVENTION

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

WHO process of guideline and recommendation development



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

Key question

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

GRADE

Rating the evidence

Grading of **R**ecommendation **A**ssessment, **D**evelopment and **E**valuation

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

Recommendation

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

Acknowledgements

Guideline Development Group

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External review group

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Technical Advisory Group on Innovations in Male Circumcision

Thank you!