WHO information products on devices for adolescent and adult male circumcision

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Outline

- Background
- Devices
- Current WHO information products
- WHO information products in development
- Next steps

Background

- Currently only conventional surgical methods for MC for HIV prevention are recommended by WHO
- Initial devices consultation, 2009
- Technical Advisory Group formed Dec 2010
  - met July 2011 and January 2012
- Formal prequalification programme established, September 2011


Consultation to Review Manufacturing, Clinical and Regulatory Requirements for Male Circumcision Devices to Support Programme Expansion in High HIV Incidence Settings in Africa

11-12 March 2009, Nairobi, Kenya

Meeting Report

World Health Organization, Geneva

Report prepared by Ariane van der Straten and Tim Farley

World Health Organization

Department of Reproductive Health and Research (RHR)

World Health Organization

Seek to identify devices that:

- make adult male circumcision procedure safer, easier and quicker than current methods;
- facilitate more rapid healing and/or entail less risk of HIV transmission in the immediate post-operative period;
- may be used safely by health-care providers with a shorter period of training (mid-level providers);
- are more cost-effective for male circumcision scale-up than standard surgical methods.

Some of the devices marketed for adolescent and adult male circumcision

Elastic ring compression

PrePex

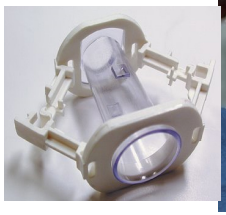
Collar Clamp & Latch

Kirve clamp

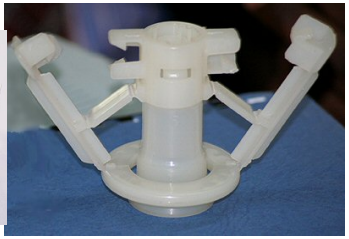
Sunathrone

Shang ring

Vice Clamp & Latch



Smart clamp



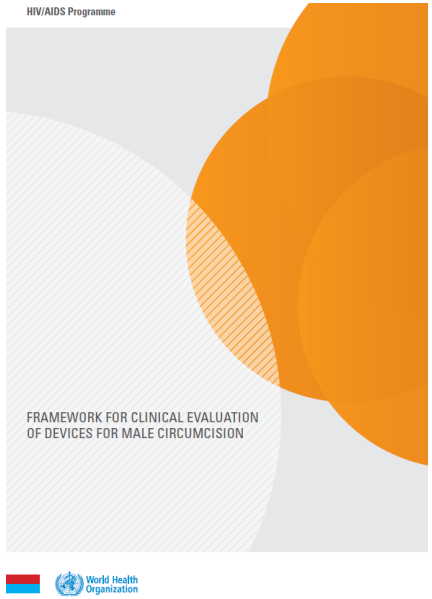
TaraKlamp

Ismail Clamp

Alisklamp

Current WHO information products

- *Framework for Clinical Evaluation of Devices for Male Circumcision, 2012*



- *Use of devices for adult male circumcision in public health HIV prevention programmes: conclusions of the TAG*, March 2012

World Health Organization

Framework: purpose

- Primary: provide a framework for assessing the suitability of a device for male circumcision in public health HIV prevention programmes
  - defines the type and minimum extent of clinical data required for an assessment of the safety of devices
  - series of steps and clinical studies are described
  - forms the basis for WHO clinical evaluation of a device
- Secondly: addresses regulatory issues and aspects of the WHO prequalification programme

Key characteristics of device for evaluation

Device characteristics	Specifics
Safety of device	Safe to use, Reduces the chance of injury to the glans, Consistent removal of an adequate amount of foreskin, protects the urethra, Rapid and uncomplicated post-operative recovery period.
Client acceptability	to the client, to sexual partners, to caregivers of male adolescents, to parents of baby
Provider acceptability	
Ease of use	device used easily by the provider, short procedure time, training completed effectively and easily easy and practical removal suitable for use by mid-level providers.
Low cost/affordable price	cost advantage over conventional surgical methods
Regulatory and marketing	approved in country of origin marketed in country of origin

Study types and requirements

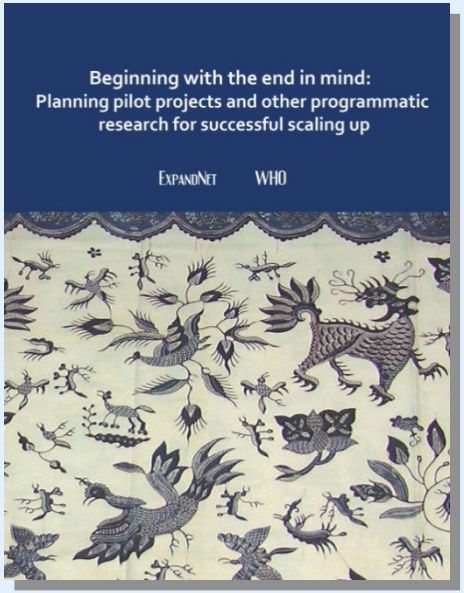
- Initial safety and efficacy clinical studies involving skilled surgeons in the country of origin or manufacture and the country of intended use
- Comparative clinical studies involving skilled surgeons in the country of intended use
- Acceptability studies in the country of intended final use
- Field studies involving trained clinical personnel in a low-resource setting, reflecting anticipated conditions of intended use

Minimum for WHO global consideration: at least 2 comparative and 2 field studies in 2 different settings /countries

Informing programme implementation

- Once safety and efficacy of a device has been established
  - not necessary to repeat the same series of randomized controlled trials and field studies described above.
- Prepare in a stepwise manner for introduction and implementation using a participatory planning process
  - ExpandNet scaling up health innovations network: www.ExpandNet.net
  - '*Beginning with the end in mind: planning pilot projects and other programmatic research for successful scaling up* (WHO 2011)

12 Recommendations on designing pilot projects



Participatory process.

Ensure the **relevance**

Reach consensus for scale-up.

Tailor innovation to sociocultural and institutional settings.

Keep as **simple** as possible.

Test in variety settings **where it will be scaled up.**

Test **under routine operating conditions** / existing resources constraints

Develop plans to assess and **document the process** of implementation.

Advocate for **financial support beyond pilot stage.**

Prepare to **advocate changes in policies,** regulations, health systems components

Develop plans on **how to promote learning and disseminate i**nformation.

Be **cautious a**bout initiating scale-up before the required evidence is available.

Pilot implementation studies

- Main objective
  - establish the feasibility and the acceptability of the new device for the programme, providers and clients, their families and partners.
- Aspects of feasibility:
  - training requirements
  - policy and regulatory issues
  - service delivery configurations that provide the minimum package of services
  - service settings for various male circumcision methods, programme logistics
  - costs

Potential pilot implementation studies

Type of study	Number of clients (range)	Objectives / end-points
Preparatory		Key stakeholder consultations and agreement on conditions for use in pilot study (providers, settings), regulatory issues
Phase 1	Typically 100 (50–200)	Training for providers, evaluation of training Acceptability for providers and for clients, potential advantages/ disadvantages Safety in specific country context and setting Feasibility in various settings where service delivery is expected to occur
Phase 2	Typically 500 (250–1000)	Acceptability, safety, feasibility; cost, training, logistics in settings where service will be routinely provided

Regulatory issues

- Regulations are developed and enforced to ensure the safety and effectiveness of a medical device designed for a specific procedure or purpose
  - All devices carry some risk; regulations alone cannot eliminate risk
- Regulation of medical devices:
  - varies greatly among countries
  - obtaining regulatory approval is generally less stringent for devices than drugs
  - in some countries there is no specific mechanism for approval of medical devices and devices can be imported without any regulatory review.

Use of devices for adult MC: conclusions of TAG, 2012

Review of limited data: one series of studies from only one country, Rwanda

Further data from at least one more country required before generalize recommendation

Other information gaps identified: eg, use for males <18 years, HIV positive men

For Rwanda:

- subject to approval by the national programme, Rwanda progress to phased implementation among men 18 years and older, with rigorous monitoring for AEs
- as not all men will be eligible for the use of this device, there must be access to standard surgical methods
- appropriate counselling on sexual abstinence /condom use after MC is always important but particularly crucial with this device as healing time is about 1 week longer than standard surgery
- can be used by trained doctors and nurses deemed competent in its use.

WHO planned information products / 'guidance' on device use for adolescent and adult MC

WHICH DEVICES **CAN** be used	**SHOULD** prequalified devices be considered for use and **HOW** to use a prequalified device	
List of prequalified devices Summary report on specific device and manufacturer	Recommendation(s) on use of prequalified devices for adolescent and adult MC	Programmatic, technical and introductory considerations

Next steps 2012 - 2013

- Review research data on PrePex and Shang Ring, Q4 2012
  - dependent on data availability from studies
- TAG meeting: review of data, Q1 2013
- Guidance development
  - continuing through Q2 – 3 2013

Summary

- Sequence of documents developed or are underway to guide the use and introduction of devices for adolescents and adult MC
- WHO balances the importance of establishing safety, efficacy and acceptability of devices with the urgent need to deploy them within a HIV public health prevention intervention.

Thank you

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