WHO information products on devices for adolescent and adult male circumcision

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Key Populations and Innovative Prevention
Outline

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


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

<table>
<thead>
<tr>
<th>Device characteristics</th>
<th>Specifics</th>
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<tbody>
<tr>
<td>Safety of device</td>
<td>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.</td>
</tr>
<tr>
<td>Client acceptability</td>
<td>to the client, to sexual partners, to caregivers of male adolescents, to parents of baby</td>
</tr>
<tr>
<td>Provider acceptability</td>
<td></td>
</tr>
<tr>
<td>Ease of use</td>
<td>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.</td>
</tr>
<tr>
<td>Low cost/affordable price</td>
<td>cost advantage over conventional surgical methods</td>
</tr>
<tr>
<td>Regulatory and marketing</td>
<td>approved in country of origin marketed in country of origin</td>
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</table>
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 information.
- Be cautious about 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

<table>
<thead>
<tr>
<th>Type of study</th>
<th>Number of clients (range)</th>
<th>Objectives / end-points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparatory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td>Typically 100 (50–200)</td>
<td>Key stakeholder consultations and agreement on conditions for use in pilot study (providers, settings), regulatory issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training for providers, evaluation of training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acceptability for providers and for clients, potential advantages/ disadvantages</td>
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<tr>
<td></td>
<td></td>
<td>Safety in specific country context and setting</td>
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<tr>
<td></td>
<td></td>
<td>Feasibility in various settings where service delivery is expected to occur</td>
</tr>
<tr>
<td>Phase 2</td>
<td>Typically 500 (250–1000)</td>
<td>Acceptability, safety, feasibility; cost, training, logistics in settings where service will be routinely provided</td>
</tr>
</tbody>
</table>
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.
<table>
<thead>
<tr>
<th>WHICH DEVICES CAN be used</th>
<th>SHOULD prequalified devices be considered for use and HOW to use a prequalified device</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of prequalified devices</td>
<td>Recommendation(s) on use of prequalified devices for adolescent and adult MC</td>
</tr>
<tr>
<td>Summary report on specific device and manufacturer</td>
<td>Programmatic, technical and introductory considerations</td>
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</table>
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