SAFE MALE CIRCUMCISION: Scale up of new devices.

David Serwadda
Makerere University School of Public Health
Rakai Health Science Program
Outline

- Background
- Rationale for surgical device
- Surgical device
  - Shang ring
  - Prepex
Studies in South Africa, Kenya and Uganda showed 50-60% prevention of acquisition of HIV among circumcised men. WHO/UNAIDS recommends scale up of circumcision services in populations with high HIV rates and low circumcision rates. Safe male circumcision devices have potential of scaling up circumcision activities.
Impact of Modelling

What ever your views on Mathematical modeling........

The enthusiasm/ excitement generated by these models illustrating the possible impact, circumcision can have on the HIV epidemic, has been huge in generating interest in the possibilities......
Modeling the Impact of MC on HIV Prevalence/Incidence

*Williams et al., 2006*

- 100% uptake of MC could avert 2.0 million new infections and 0.3 million deaths new infections over 20 years
- Could avert 5.7 million new infections over 20 years

*Mesesan et al., 2006*

- 50% uptake of MC could avert 32,000 – 53,000 new infections in Soweto, SA over 20 yrs. Prevalence would decline from 23% to 14%

*Nagelrke et al., 2007*

- Prevalence in Nyanza Province, Kenya would decline from 18% to 8% with 50% uptake of circumcision over 10Years.

*Gray et al., 2007*

- Assuming 50% uptake in Rakai, incidence would decline from 1.4% to 0.81 and $R_o$ would decline to 0.89
Circumcision needed to reach 80% coverage in 5 Years: Age (15 – 49) Years

<table>
<thead>
<tr>
<th>Country</th>
<th>Population aged 15-49 years (Millions)</th>
<th>Coverage of MMC (Percent)</th>
<th>Adult HIV prevalence (Percent)</th>
<th>Number of MC to be performed (Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>1.077</td>
<td>10</td>
<td>23</td>
<td>0.345</td>
</tr>
<tr>
<td>Lesotho</td>
<td>1.055</td>
<td>0</td>
<td>24</td>
<td>0.377</td>
</tr>
<tr>
<td>Malawi</td>
<td>6.841</td>
<td>21</td>
<td>13</td>
<td>2.102</td>
</tr>
<tr>
<td>Mozambique</td>
<td>10.319</td>
<td>60</td>
<td>13</td>
<td>1.530</td>
</tr>
<tr>
<td>Namibia</td>
<td>1.086</td>
<td>21</td>
<td>14</td>
<td>0.478</td>
</tr>
<tr>
<td>Nyanza, Kenya</td>
<td>1.512</td>
<td>45</td>
<td>13</td>
<td>0.230</td>
</tr>
<tr>
<td>Rwanda</td>
<td>4.492</td>
<td>10</td>
<td>3</td>
<td>1.746</td>
</tr>
<tr>
<td>South Africa</td>
<td>26.837</td>
<td>45</td>
<td>17</td>
<td>4.333</td>
</tr>
<tr>
<td>Swaziland</td>
<td>0.590</td>
<td>8</td>
<td>26</td>
<td>0.183</td>
</tr>
<tr>
<td>Tanzania</td>
<td>19.630</td>
<td>67</td>
<td>7</td>
<td>1.373</td>
</tr>
<tr>
<td><strong>Uganda</strong></td>
<td><strong>14.159</strong></td>
<td><strong>25</strong></td>
<td><strong>6</strong></td>
<td><strong>4.245</strong></td>
</tr>
<tr>
<td>Zambia</td>
<td>6.845</td>
<td>11</td>
<td>15</td>
<td>2.372</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>6.187</td>
<td>10</td>
<td>18</td>
<td>1.913</td>
</tr>
</tbody>
</table>

Baseline population characteristics by country

Provides the size of the population aged 15-49 years in 2008 [Ref spectrum],
The coverage of MMC before scale-up [31] and estimated HIV prevalence [31].
1. 4.2 million adult/adolescent men need to be circumcised in 5 years to avert 340,000 new HIV infections by 2025 (25% of new HIV infections that would have occurred otherwise).

2. Spending US$1-2 billion to achieve this impact will also save US$20.3 billion.

3. In Uganda, US$310 million is needed to achieve this impact in 5 years with a cost savings estimated at US$1.5 billion.
The demand for SMC is on the increase

Many implementing units are active, key challenges include;
- Insufficient human resource to offer service
- Insufficient supplies and equipment
- Inadequate skills capacity to offer safe services.
## Institutions, graduates and workforce by region (2008)

<table>
<thead>
<tr>
<th>Region</th>
<th>Population (millions)</th>
<th>Estimated number of schools</th>
<th>Estimated graduates per year (thousands)</th>
<th>Workforce (thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Medical</td>
<td>Public Health</td>
<td>Doctors</td>
</tr>
<tr>
<td>Asia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>1371</td>
<td>188</td>
<td>72</td>
<td>175</td>
</tr>
<tr>
<td>India</td>
<td>1230</td>
<td>300</td>
<td>4</td>
<td>30</td>
</tr>
<tr>
<td>Other</td>
<td>1075</td>
<td>241</td>
<td>33</td>
<td>18</td>
</tr>
<tr>
<td>Central</td>
<td>82</td>
<td>51</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>High Income Asia Pacific</td>
<td>227</td>
<td>168</td>
<td>26</td>
<td>10</td>
</tr>
<tr>
<td>Europe</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>122</td>
<td>64</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>Eastern</td>
<td>212</td>
<td>100</td>
<td>15</td>
<td>22</td>
</tr>
<tr>
<td>Western</td>
<td>435</td>
<td>282</td>
<td>52</td>
<td>42</td>
</tr>
<tr>
<td>Americas</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>North America</td>
<td>361</td>
<td>173</td>
<td>65</td>
<td>19</td>
</tr>
<tr>
<td>Latin America/Caribbean</td>
<td>602</td>
<td>513</td>
<td>82</td>
<td>35</td>
</tr>
<tr>
<td>Africa</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>North Africa/Middle East</td>
<td>450</td>
<td>206</td>
<td>46</td>
<td>17</td>
</tr>
<tr>
<td>Sub - Saharan Africa</td>
<td>868</td>
<td>134</td>
<td>51</td>
<td>6</td>
</tr>
<tr>
<td>World</td>
<td>7036</td>
<td>2420</td>
<td>467</td>
<td>389</td>
</tr>
</tbody>
</table>
Rationale for circumcision devices

- Potentially simpler and faster procedures.
- Require less trained health workers (task shifting).
- May be safer and more acceptable to the population.
- May be cost effective.
- Better cosmetic satisfaction.
- Easier to train.
- No devices for adult male circumcision have gained widespread acceptance yet.
Circumcision Device?

- Infant devices
  - Well studied in neonates
  - E.g.: Gomco quick & easy
  - Injuries very rare
- Adult devices?
  - Different physiology/ little data
  - Sutures needed for adult Gomco
  - Tara: poor results in one trial
The Shang ring method

- Invented in China
- Been tested in China, Kenya, Zambia and Uganda
- Device comprises of 2 concentric plastic rings:
  - an inner ring lined by soft silicone
  - an outer ring
- Applied under local anesthesia and aseptic conditions.
- Compresses foreskin to control bleeding
- Ring removed after 1 week
Pilot study, Kenya, Kisumu 2009

- 40 men with intensive follow-up
  - EngenderHealth: Mark Barone, Fred Ndede;
  - Cornell: Philip Li, Marc Goldstein
  - MOH: Homa Bay District Hospital

Results:

  - 100% would recommend Shang Ring to others
  - Post-study visit anecdotal reports:
    - Highly acceptable & preferred: shorter surgery / less pain
    - Excellent cosmetic results
Advantages of the Shang ring

- less time to complete a circumcision (~4.7 minutes)
- No stitches involved
- The wound appears better cosmetically
- It is easier to train service providers
- Minimal instruments are required
## MOVE Times: Forceps-Guided & Shang Ring

<table>
<thead>
<tr>
<th></th>
<th>Forceps Guided w/ w'out Diathermy</th>
<th>Shang Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>with Minutes w'out Minutes</td>
<td>Minutes</td>
</tr>
<tr>
<td>1. Injection of anaesthesia</td>
<td>1.00 1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2. Surgical preparation</td>
<td>3.00 3.00</td>
<td>3.00</td>
</tr>
<tr>
<td>3. Marking</td>
<td>0.25 0.25</td>
<td>0.50 3. Choosing Shang Ring size</td>
</tr>
<tr>
<td>4. Palpation of glans</td>
<td>0.25 0.25</td>
<td>0.25 4. Applying inner ring</td>
</tr>
<tr>
<td>5. Forceps placement</td>
<td>0.25 0.25</td>
<td>1.50 5. Everting foreskin</td>
</tr>
<tr>
<td>6. Cut</td>
<td>0.08 0.08</td>
<td>0.50 6. Adjusting fit</td>
</tr>
<tr>
<td>7. Haemostasis</td>
<td>2.00 8.50</td>
<td>0.5 7. Applying outer ring</td>
</tr>
<tr>
<td>8. Mattress sutures (4)</td>
<td>3.50 3.50</td>
<td>1.00 8. Cutting</td>
</tr>
<tr>
<td>9. Sutures – other</td>
<td>5.50 5.50</td>
<td>0.50 9. Dressing</td>
</tr>
<tr>
<td>10. Dressing</td>
<td>3.50 3.50</td>
<td></td>
</tr>
<tr>
<td><strong>Surgeon time:</strong></td>
<td>6.33 12.83</td>
<td>4.25</td>
</tr>
<tr>
<td><strong>Procedure time:</strong></td>
<td>19.33 25.83</td>
<td>8.75</td>
</tr>
</tbody>
</table>

* “…cautery can reduce AMC time by 5–8 minutes…” MOVE, WHO, p. 33.*
Rakai experience of the Shang ring.

- Acceptability is good so far (76.4%)
- Easily trainable to providers (nurses, clinical assistants)
- Easy and fast to apply
- Complication rates are at 0.5 per 100 surgeries
  These are mainly mild to moderate.
- A skilled staff in conventional methods needs to be in easy reach
Invented in the United States
Tested in Rwanda (*J Acquir Immune Defic Syndr.* 2011 Dec 15;58(5):e127-34) and Zimbabwe
No anesthesia, no blood, no sutures and no sterile settings
Consists of an inner firm plastic ring and an outer elastic band
The inner ring is placed under the foreskin and the elastic band is placed on the outer surface of the foreskin using the placement tool
The foreskin tissue dies due to lack of blood and
Foreskin and device are removed 7-9 days after application.
The foreskin tissue then dies due to lack of blood and is removed together with the PrePex device 7-9 days after it is applied. Pain control is achieved by using oral analgesics before and after the procedure. Local anaesthetic spray is used at removal of the device. This method is yet to be investigated at RHSP.
The Prepex procedure

preview of the procedure

Selecting Size

Marking, based on WHO guidelines (not device related)

Preparing for placement and inserting Inner Ring
Aligning Elastic Ring with Inner Ring, which keeps the foreskin from retracting, facilitating easy adjustment of the inner and outer foreskin. Release ElasticRing, which compresses the foreskin and stops the flow of blood. There is no crushing - the release of the Elastic Ring is painless – hence no injected anesthesia. Verify proper placement, cut Verification Thread and discard Placement Ring after use.
Removal procedure

- After 7-9 days

- Remove dead foreskin (like fingernails) with blunt, safe scissors (cannot harm glans)
- Pierce Elastic Ring to pop out
- Extract Inner Ring with fingers or spatula
Other devices

- Other devices have been employed for adult male circumcision.
- These include the Tara Klamp, Plastibell and Mogen Clamp.
- Most of these do not provide protection for the glans penis and hence fall short for safety concerns.
Limitations of the method

- May not apply where there are anatomical abnormalities such as phimosis
- Always requires a second visit for ring removal by a trained health worker.
- A specific diameter of ring must be used for a particular individual.
Conclusion

- The Shang ring / Prepex devices may potentially hasten the roll out process of SMC
- There is likely to be satisfaction for both provider and clients
- Can be suitable for camp settings.
- Large scale evaluation are needed