PEPFAR VMMC 3rd WEBINAR

Devices for Adult Medical Male Circumcision for HIV Prevention:

What’s the current situation? What’s next?
Moderator: Jason Reed, OGAC

Presenters:
- Godfrey Kigozi, Rakai Health Sciences Program
- Tim Farley, Sigma3 Services
- Julia Samuelson, WHO
- Peter Cherutich, National AIDS/STI Control Programme, Kenya Ministry of Health
- Mia Malan, Mail & Guardian
- Emmanuel Njeuhmeli, USAID

Welcome! We will begin in a few moments.

If you are participating in a satellite viewing party, please enter the number of guests at your party in the chat window to your right.
Introduction to MC medical devices
(“Devices 101”)

Godfrey Kigozi
### Surgical circumcision, Shang Ring and Prepex devices

<table>
<thead>
<tr>
<th>Surgical circumcision</th>
<th>Shang Ring device</th>
<th>Prepex device</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.jpg" alt="Surgical circumcision image" /></td>
<td><img src="image2.jpg" alt="Shang Ring device image" /></td>
<td><img src="image3.jpg" alt="Prepex device image" /></td>
</tr>
</tbody>
</table>

**Surgical circumcision**
- Foreskin is removed on day or surgery with a scalpel
- Stitches used to control bleeding
- Stitches dissolve and fall out in 7-9 days

**Shang Ring device**
- Foreskin is removed on day of placement with a scalpel
- Rings compress blood vessels to control bleeding
- Client returns 5-9 days after placement for removal of the rings

**Prepex device**
- Foreskin is not removed until approx 1 week after device placement
- Blood supply is interrupted by pressure between rings leading to foreskin necrosis
- Client returns 5-9 days after placement for removal of dried foreskin and rings
- No bleeding normally
Shang Ring Procedure

Measuring

Inner ring insertion

Skin eversion

Outer ring placement and then foreskin cut away

Device worn for approx 1 week

Cutting the ring at removal approx 1 week later
Prepex Placement Procedure

Selecting Size

Marking, based on WHO guidelines (not device related)

Preparing for placement and inserting Inner Ring
Removal Procedure

• After approx 1 week of wearing device

- 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
A Comparison of the Surgical Method and the Shang Ring and PrePex devices.

<table>
<thead>
<tr>
<th></th>
<th>Surgical circumcision</th>
<th>Shang Ring device</th>
<th>Prepex device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical skill level</strong></td>
<td>High (MO, CO, Nurse)</td>
<td>Moderate (MO, CO, Nurse)</td>
<td>Low (MO, CO, Nurse)</td>
</tr>
<tr>
<td><strong>Anaesthesia</strong></td>
<td>Injectable</td>
<td>Injectable</td>
<td>Topical cream</td>
</tr>
<tr>
<td><strong>Control of bleeding</strong></td>
<td>Suture or cautery</td>
<td>Compression</td>
<td>NA – no bleeding</td>
</tr>
<tr>
<td><strong>Suturing</strong></td>
<td>Yes</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Placement time</strong></td>
<td>~20 minutes*</td>
<td>~5 minutes*</td>
<td>~5 minutes</td>
</tr>
<tr>
<td><strong>Removal time</strong></td>
<td>NA</td>
<td>~3 minutes</td>
<td>~4 minutes</td>
</tr>
<tr>
<td><strong>Possibility for Displacement</strong></td>
<td>NA</td>
<td>Self removal, detachment</td>
<td>Self removal, detachment</td>
</tr>
<tr>
<td><strong>Adverse events</strong></td>
<td>&lt;2%</td>
<td>&lt;2%</td>
<td>&lt;2%</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>NA</td>
<td>Skilled surgical back-up required for rare AEs</td>
<td>Odor Skilled surgical back-up required for rare AEs</td>
</tr>
<tr>
<td><strong>Abstinence</strong></td>
<td>6 weeks after surgery or until wound healing</td>
<td>6 weeks after removal or until wound healing</td>
<td>7 weeks after removal or until wound healing</td>
</tr>
</tbody>
</table>

*Measurements do not include time required for injection and onset of local anesthesia
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Devices for Adult Medical Male Circumcision for HIV Prevention:

What’s the current situation? What’s next?
Clinical performance of ShangRing and PrePex devices

21 August 2013
WHO Technical Advisory Group (TAG)

- Advisory panel to WHO on technological innovations in male circumcision
- Reviews clinical data on safety and efficacy of circumcision devices considered for potential pre-qualification
- One of several key elements of WHO’s pre-qualification and guidelines development processes
- TAG’s summary of data on Shang Ring and PrePex devices presented here
**Adverse Event Classification adopted by TAG**

**Adverse Event (AE)**
Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs, excluding those definitely not related to the procedure or device

**Serious Adverse Event (SAE)**
An AE that resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function, *even if no permanent impairment occurred*

**Moderate AE**
Any AE not classified as an SAE but that required an intervention by a health care provider or medication (parenteral, oral or topical)

**Mild AE**
All other AEs
Shang Ring Device

• Developed in China; Studied in China and Africa
# Shang Ring Studies Reviewed

<table>
<thead>
<tr>
<th>Study (type)</th>
<th>Location</th>
<th>Clients</th>
<th>Type of providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Study</td>
<td>Kenya</td>
<td>40 healthy HIV-negative men</td>
<td>Physicians and nurses experienced in conventional surgical circumcision</td>
</tr>
<tr>
<td>Spontaneous Detachment</td>
<td>Kenya</td>
<td>50 healthy HIV-negative men</td>
<td>Physicians and nurses experienced in conventional surgical circumcision</td>
</tr>
<tr>
<td>Randomized Comparison with Surgery</td>
<td>Kenya and Zambia</td>
<td>200 Shang Ring, 200 surgery, healthy HIV-negative men</td>
<td>Physicians and non-physicians, all with extensive experience with surgical male circumcision</td>
</tr>
<tr>
<td>Field Studies</td>
<td>Kenya and Zambia</td>
<td>1256 healthy HIV-negative men</td>
<td>Physicians and non-physicians, all with extensive experience with surgical male circumcision</td>
</tr>
<tr>
<td>Acceptability and Safety</td>
<td>Uganda</td>
<td>621 healthy HIV-negative men, 508 of whom chose Shang Ring</td>
<td>Clinical officers in sterile conditions in outpatient operating rooms</td>
</tr>
</tbody>
</table>
Shang Ring Outcomes (1,983 placements)

• High proportion of successful device placements
  – 98.8% of men eligible for device circumcision and device successfully placed
  – Small number of men considered unsuitable for Shang Ring circumcision due to minor foreskin abnormalities
  – Device could not be placed in 15 men (0.8%)
    • Correct ring size not available (8)
    • Foreskin slipped from outer ring (3), damaged (2), too short (1)
    • Outer ring could not be closed (1)

• High proportion with successful circumcision by device alone
  – 1,980 (99.8%) foreskin successfully removed by device alone
  – 3 (0.2%) had insufficient skin removed
## Shang Ring Adverse Events (TAG Classification)

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>Number</th>
<th>Per cent [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total placements</td>
<td>1,983</td>
<td></td>
</tr>
<tr>
<td>Serious AEs</td>
<td>0</td>
<td>0.0% [0.0%, 0.2%]</td>
</tr>
<tr>
<td>Moderate AEs</td>
<td>20</td>
<td>1.0% [0.6%, 1.6%]</td>
</tr>
<tr>
<td>Pain placement (8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insufficient skin removed (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain leading to early removal (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound disruption (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild AEs</td>
<td>43</td>
<td>2.2% [1.6%, 2.9%]</td>
</tr>
</tbody>
</table>
Shang Ring Outcomes

• Procedure times (shorter than surgery)
  – Placement time 6.4 (SD 3.8) mins
    • Excludes time for injection and induction of local anaesthesia
  – Removal time 3.1 (SD 1.8) mins
  – Total time 10.3 mins (placement and removal)
    • Comparison: mean time for surgical circumcision 20.3 minutes (Kenya and Zambia studies)
    • Excludes time for injection and induction of local anaesthesia

• Healing times (longer than surgery)
  – Comparative study, mean time to complete healing
    • Shang Ring: 44.1 (SD 12.6) days from date of placement
    • Surgery: 38.9 (SD 12.6) days from date of surgery
    • Average 5.2 (2.7–7.7) days longer
  – Healing by secondary intention with ring circumcision
PrePex Device

Developed in Israel; Studied in Africa
## PrePex Studies Reviewed

<table>
<thead>
<tr>
<th>Study (type)</th>
<th>Location</th>
<th>Clients</th>
<th>Type of providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Study</td>
<td>Rwanda</td>
<td>50 healthy HIV-negative men</td>
<td>Physicians and nurses</td>
</tr>
<tr>
<td>Randomized Comparison with Surgery</td>
<td>Rwanda</td>
<td>144 PrePex, 73 surgery</td>
<td>Physicians and nurses</td>
</tr>
<tr>
<td>Pilot Study</td>
<td>Rwanda</td>
<td>49 healthy HIV-negative men age 21–54 years</td>
<td>Nurses</td>
</tr>
<tr>
<td>Field Study</td>
<td>Rwanda</td>
<td>666 generally healthy men [5 HIV-positive]</td>
<td>Lower cadre nurses</td>
</tr>
<tr>
<td>Safety Study</td>
<td>Zimbabwe</td>
<td>53 HIV-negative men</td>
<td>Physicians and nurse assistants</td>
</tr>
<tr>
<td>Randomized Comparison with Surgery</td>
<td>Zimbabwe</td>
<td>240 HIV-negative men</td>
<td>As above</td>
</tr>
<tr>
<td>Field Study</td>
<td>Zimbabwe</td>
<td>641 HIV-negative men</td>
<td>Nurses with physician back-up support</td>
</tr>
<tr>
<td>Field Study</td>
<td>Uganda (IHK)</td>
<td>634 healthy men</td>
<td>Surgeons, medical officers, clinical officers and nurses</td>
</tr>
<tr>
<td>Field Study</td>
<td>Uganda (Rakai)</td>
<td>187 HIV-negative men</td>
<td>Not stated</td>
</tr>
</tbody>
</table>
PrePex Outcomes (2,417 placements)

• High proportion of successful device placements
  – 92.6% of men eligible for device circumcision and device successfully placed
  – 5.9% of men considered unsuitable for PrePex circumcision due to phimosis, narrow foreskin opening, tight frenulum, other penile abnormalities
  – Device could not be placed in 38 men (1.3%)
    • Narrow, tight or short foreskin (31)
    • Adhesions (4)
    • Penis circumference outside the range of available ring sizes (3)

• High proportion with successful circumcision
  – 2,405 (99.5%) foreskin successfully removed by device alone
    • Surgery after: self-removal (4), requested early removal (2), displacement (5), device and foreskin removed surgically under local anaesthesia (1)
### PrePex Adverse Events (TAG Classification)

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>Number</th>
<th>Per cent [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total placements</td>
<td>2,417</td>
<td></td>
</tr>
<tr>
<td>Serious AEs</td>
<td>9</td>
<td>0.4% [0.2%, 0.7%]</td>
</tr>
<tr>
<td>See details on next slide</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>All required prompt surgical intervention to prevent permanent injury or damage</td>
</tr>
<tr>
<td>Moderate AEs</td>
<td>18</td>
<td>0.7% [0.4%, 1.2%]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Premature removal (8), Bleeding (5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Displacement (2), Infection (2), Difficult removal (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All required medical intervention to manage</td>
</tr>
<tr>
<td>Mild AEs</td>
<td>15</td>
<td>0.6% [0.3%, 1.0%]</td>
</tr>
</tbody>
</table>
PrePex Serious Adverse Events (Total 9)

- Device displacements following sexual activity, masturbation, erection, possible placement error, or accidental dislodging by another person (4)
- Premature self-removal secondary to pain (1);
- Meatal injury at removal (1)
- Difficult removal due to necrotic tissue everted over elastic ring requiring surgical intervention (1)
- Wound disruption or dehiscence (2)

• Displacements associated with pain, oedema and blistering required prompt surgical intervention to avoid serious infection or permanent injury to penis
PrePex Outcomes

• Procedure times (faster than conventional surgery)
  – Placement preparation 2.0 (SD 0.8) min
  – Placement procedure 1.5 (SD 1.0) min
  – Removal preparation 0.4 (SD 0.2) min
  – Removal procedure 2.0 (SD 1.1) min
  – In comparative study total placement and removal times 5.7 (SD 1.4) min, compared with 19.2 (SD 3.9) min for surgery

• Healing (longer than conventional surgery)
  – Comparative study, mean time to complete healing
    • PrePex: 38.0 (SD 12.1) days from placement
    • Surgery: 23.0 (SD 7.5) days from date of surgery
    • Average 15 (12 - 18) days longer
  – Healing by secondary intention following ring circumcision
PrePex Outcomes

• Pain
  – Greatest pain and discomfort 3-6 hours after placement
  – 5% lidocaine topical anaesthetic cream applied immediately before placement, oral analgesics given to take as required
  – Appears to be somewhat less pain while device worn than at comparable times following surgery
  – Transient (short duration but quite severe) pain during device removal

• Odour
  – Complaints of bad odour after 3-4 days
WHO guidance on devices for medical male circumcision for HIV prevention

21 August 2013

Julia Samuelson
Key Populations and Innovative Prevention Team
Many devices marketed for adolescent and adult male circumcision

1a. Collar Clamp
- ShangRing
- Kirve clamp
- Sunathrone

1b. Vice Clamp
- Alis Klamp
- Tara Klamp
- Ismail Clamp
- Smart Clamp

2. Elastic collar compression
- PrePex

3. Ligature
- Zhenxi Ring

WHO guidance on device use as a method for male circumcision:
- Prequalification programme information
- Guideline on use of devices
Objectives:

- Facilitate access to safe, appropriate, good quality male circumcision devices

Assessed according to international standards:

- Technical characteristics of device and its performance
- Manufacturer's quality management system
- Evidence on clinical efficacy and safety
Key information when a device is 'prequalified'

Information:

• List of 'prequalified' devices for male circumcision for HIV prevention
• 'Public Report' with technical information on each prequalified device

Used for procurement decisions by:

• Member States, UN, and other purchasers including Global Fund, PEPFAR

Not WHO 'approval' as approval is the sole prerogative of each national government
<table>
<thead>
<tr>
<th>Product name</th>
<th>Manufacturer name</th>
<th>Application</th>
<th>Letter of Agreement</th>
<th>Product dossier including clinical data</th>
<th>Manufacturer site inspections</th>
<th>Prequalification Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrePex</td>
<td>Circ Med Tech Limited</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prequalified : 31 May 2013</td>
</tr>
<tr>
<td>ShangRing</td>
<td>Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alisklamp Disposable Circumcision Device</td>
<td>ABAGROUP Healthcare Services Co. Ltd.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tara KLamp</td>
<td>Taramedic Corp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
WHO guideline on use of devices

Purpose:

to provide recommendations and considerations on introduction and use of devices as a method for adolescent and adult male circumcision in HIV prevention programmes

Process for development

– obtain inputs from diverse individuals
– review of clinical evidence and literature
– consider balance of benefits and harms, acceptability, resource use
– consider implications for programmes and services
Guideline (1): DRAFT key points

- prequalified devices: efficacious and safe method of MC
- among healthy males 18 years and older
- WHEN
  - used by health care providers who are adequately trained and competent with use of the specific device
  - in settings where urgent or immediate surgical back-up facilities and skills, appropriate to the specific device, are available
Guideline (2): DRAFT programmatic considerations

• Phased approach to introduction
  – with broad stakeholder engagement
  – pilot projects in routine settings

• Policies & regulations:
  • pre-market approvals in country
  • health care providers authorized to use device

• Monitoring, evaluation and reporting
  • safety monitoring
    • active follow up of the first 1000 clients in routine settings with ongoing monitoring after safety demonstrated
  • uptake and rates of return at removal visit
Guideline (3): DRAFT considerations

• Service delivery: many considerations
  • uniqueness of settings and each device
  • training includes observation to assess competence
  • 2 visits required - placement and removal

• Communications
  – accurate client and partner information; informed providers

• Procurement, supply management
  • good forecasting for a sufficient stock of full range of device sizes and appropriate accessories for placement and removal

Continue to offer minimum package of HIV prevention services and assure service quality
WHO

– Framework for clinical evaluation of male circumcision devices

http://www.who.int/hiv/topics/malecircumcision/en/


– Beginning with the end in mind

www.who.int/reproductive-health/publications

– Prequalification: list of products and public reports

http://www.who.int/diagnostics_laboratory/evaluations/prequalification_male_circumcision_devices

Clearinghouse on Male Circumcision

http://www.malecircumcision.org
Questions Countries Should Start Asking Now About MC Devices

What are the considerations for national VMMC programs introducing device(s)?

Dr Peter Cherutich, MD, MPH
Head, HIV Prevention, Kenya MoH
Strategic decisions!!

- Has the national MC ‘Task Force’ been engaged/discussed MC devices?
- What should the roll out strategy be?
  - What’s the appropriate mix of surgical vs devices?
    - Incorporate device(s) as an option to surgical VMMC everywhere all at once?
    - Gradually? If gradually, where first, second, and last?
  - What type of settings? Static only at first or include outreach from the beginning? Private sector? Traditional settings?
Stakeholder Engagement

- Who are the stakeholders that need to be engaged about device introduction (technical and non-technical stakeholders)? How are the various stakeholders identified?
- How should different stakeholders be engaged? When? By whom? Do they all require the same or different information?
Regulatory Questions

- What regulatory approvals are required to import and use the device(s) into the country?
- Is there a safety monitoring body or policy for medicines (and devices) that gives approval/oversight?
- Do current scopes of practice for health care workers, including nurses, cover the procedures for device placement and removal?
Service Delivery Considerations I

- When are device methods incorporated into existing VMMC SOPs, training curricula, national strategy documents?
- What is the process for revising data collection forms so that device-specific data elements, including adverse events, are collected and reported?
Service Delivery Considerations II

- Is there a (written) plan for training larger numbers of providers to use the device(s)? How will training be rolled out? Who will fund the trainings?
- What level of skill and experience should providers selected for device training have?
  - Focus on providers with previous surgical training
- What constitutes adequate training?
- Is retraining needed?
- Should providers be trained on one device or multiple devices as they are pre-qualified by WHO?
Eligibility, Choice, Referral

Access to surgical MC is required to handle AEs and provide MC for those ineligible for device or prefer surgery. How will the need for surgery be approached:

- for clients ineligible for device(s)?
- for clients who prefer surgery?
- for clients with adverse events that require surgical management?
AE Surveillance Considerations

- Once active adverse event (AE) surveillance of 1,000 routine cases is successfully completed, what is the longer-term plan for passive surveillance for device-related AEs?
- Will device-based safety monitoring be different than the passive follow-up and M&E for the surgical MC program?
- Who/what group in the national VMMC programme is responsible for monitoring safety of the surgical MC services?
- With which entities outside of the country will AE surveillance information need to be shared?
  - Donors
  - WHO
  - Manufacturers
Communication Considerations

- How should information on PrePex and Shang Ring (and any future pre-qualified MC devices) be communicated
  - with the public?
  - with press/media?
  - with communications partners already working on VMMC demand creation?
Vulnerabilities

- What are key vulnerabilities in VMMC programmes as a result of introducing new devices?
- Are there plans for addressing vulnerabilities and managing issues as they arise?
Thanks...
PEPFAR VMMC 3rd WEBINAR

Devices for Adult Medical Male Circumcision for HIV Prevention:

What’s the current situation? What’s next?
TELLING THE STORY OF MMC DEVICES: MEDIA CHALLENGES

Mia Malan,
Director: Mail & Guardian Health Journalism Centre,
Bhekisisa/ M&G Health Editor
Johannesburg, South Africa
NEGATIVE OR INACCURATE REPORTING ON MC

- Botswana: 27% of articles
- Uganda 26% of articles
- Zimbabwe 20% of articles
- Tanzania 14% of articles
- South Africa 5% of articles
- Kenya 0% of articles

- AVAC/USAID media content analysis (December 1, 2011 – August 31, 2012)

- Most common mistake: Confusion over the science around the 60% efficacy
LESSONS FROM KENYA

- Strong partnerships between the media, government and NGOs
- Significant amount of media training and mentoring (Internews plays a significant role) – a strong cadre of health journalists have been developed over a ten year period
- Several incentives for journalists to report on VMMC: travel grants, awards, access to equipment
- Regular media monitoring of VMMC reporting
REPORTING ON VMMC DEVICES: WHAT DO JOURNALISTS GET CONFUSED ABOUT?

- **IT’S TECHNICAL: What does prequalification mean?**

  - **Kenya:** Journalists perceive “pre”qualification as something that precedes another process. They asked: “Is there another level of approval that PrePex would need to attain before wide scale use? (AVAC/Internews science café, July 2013)

- **IT’S TECHNICAL: It’s hard to understand pain levels**

  A new medical male circumcision device, which could be a pain-free alternative to surgical circumcision, is about to be piloted in South Africa. (Specialist Health Reporter, SA national newspaper)

* **IT’S TECHNICAL: Who can administer PrePex? Few journalists have read the actual studies and, as a result, quote doctors out of context**

  The device “can be used by any person as long as they have been properly trained to use it”, said Dr Ntlotleng Mabena. (Specialist Health Reporter, SA national newspaper)
WHAT DO JOURNALISTS GET CONFUSED ABOUT?

IT’S TECHNICAL: Confusion about which devices have been prequalified
- Doctors are now hoping a new instrument called the PrePex circumcision device will make the practice easier and less painful. It is one of only two non-surgical circumcision devices pre-approved by the World Health Organisation. (SA TV national station)

IT’S TECHNICAL: Confusion about the difference between surgical and non-surgical circumcisions
- Surgical circumcisions using the TaraKlamp may be replaced by a new device which does not require a doctor’s expertise for circumcision (SA national newspaper)
WHAT CAN YOU DO TO HELP?

- Give journalists access to accurate information, but first you need to get them to read your press releases and media invitations. **YOU NEED A NEWS ANGLE – SOMETHING THAT EXPLAINS WHY AN ISSUE IS IMPORTANT**
  - Example:
    - Bhekisisa/AVAC/CAPRISA Media briefing at SA Aids Conference in Durban, April 2013
    - 35 people attended of which 22 were journalists
    - 19 media articles
Will non-surgical circumcision devices help SA to speed up medical circumcisions? And will they make traditional circumcisions safer?

The SA government has medically circumcised almost 1-million men. This reduces their chances of contracting HIV by more than half. But it’s far away from the target of 4.3-million circumcised men by 2016. We need to drastically speed up this process.

Two weeks ago, the World Health Organisation (WHO) approved a non-surgical circumcision device, the Prepex, with which medical circumcisions can be performed cheaper and quicker. Nurses can administer it, so doctors aren’t necessary.

Is this the answer to SA’s botched traditional circumcisions? And what about the controversial TaraKlamp that has not been endorsed by the WHO?
LESSONS LEARNED FROM PREPEX MEDIA BRIEFING

A media invitation with a strong news hook attracts journalists – without it, no one will turn up.

How do you do it?

1. A question(s) you will attempt to answer during a media briefing is an excellent way to start an invitation.
   “Will non-surgical circumcision devices help SA to speed up medical male circumcisions? And will they make traditional circumcisions safer?”

2. Give background in an invitation, but not too much
3. Do NOT use acronyms such as VMMC or MC
4. Conflict is a strong news value: use it in your invitation, e.g. we need to circumcise x amount, but we’ve only done x amount.

“The SA government has medically circumcised almost 1-million men. This has reduced their chances of contracting HIV by more than half. But it’s far away from the state’s target of 4.3-million circumcised men by 2016. We need to drastically speed up the process.

Two weeks ago, the World Health Organisation (WHO) approved a non-surgical device, the Prepex, with which medical circumcisions can be performed cheaper and faster. Nurses can administer it, so doctors aren’t necessary.

Is this the answer to SA’s botched traditional circumcisions? And what about the controversial TaraKlamp that has not been endorsed by the WHO?”
5. Tell journalists what they’re going to get from the briefing rather than merely providing names of speakers that they may not be familiar with.

“Come and hear how our government plans to use the Prepex. The head of the health department’s HIV directorate, Dr Thobile Mbengashe, will talk about pilot sites to be launched within the next two months. Learn from a medical doctor how the Prepex works, and from a community worker how traditional communities are expected to react to this device.”
Media Briefing:
Non-Surgical Devices for VMMC

SA AIDS 2013
Tuesday, 18 June
11am-1pm
Official Media Room
International Convention Ctr

The World Health Organisation (WHO) recently endorsed a non-surgical device that has the potential to make medical circumcision easier to implement and will likely approve the device in coming months. These devices don’t have to be administered by doctors and surgical theatres aren’t needed.

These devices may make it possible to circumcise more of them to reduce their chance of getting infected with HIV. Research has shown that medical male circumcision can reduce men’s risk of HIV infection by at least 60%.

The PrePex (from Israel) and Shang Ring (from China) from KZN’s controversial Tara Klamp: they’ve gone through WHO approved trials and have been proven to be safe.

Will our government be using these devices? And could
LESSONS LEARNED

2. Providing access to accurate information is NOT ENOUGH. Journalists need mentoring.

- Many stories appeared in the media as a result of our media briefing, but there were several with inaccurate information ("painless" device, "replacing" the TaraKlamp, one of two devices pre-approved by the WHO)

- What we would have done differently:
  • Ask the doctors to stay behind for longer
  • Provide journalists with mentors (e.g. Internews in Kenya does this), e.g. doctors who can be consulted re accuracy or experienced health journalists/trainers who could assist them with writing/producing stories
WHAT DO YOU DO WHEN JOURNALISTS GET IT WRONG?

- What if you were quoted inaccurately or if a reporter interpreted medical information inaccurately?
  - Phone the journalist first
  - Letter to the editor/journalist
  - Request for corrections in online stories
  - Comment online
  - Right of reply

- If you don’t know the answer to a question: don’t guess.
- Journalists have DEADLINES. If you don’t respect them, you won’t be quoted and journalists will stop contacting you.
HOW ELSE CAN YOU GET REGULAR, ACCURATE COVERAGE OF MC DEVICES?

- Give journalists access to case studies: human angles/news angles
- Build trust between yourself and journalists: they will then be open to send your quotes to you to check for accuracy
- Op-eds (news angle – there’s a huge difference between a news angle and the way the first paragraph of a research article is written, drop the acronyms and bullet points, stick to the word count)
- Use social media – “reporting” and the “distribution of information” are no longer trades that belong to journalists only
- Travel grants
- Awards
PEPFAR VMMC 3rd WEBINAR

Devices for Adult Medical Male Circumcision for HIV Prevention:

What’s the current situation? What’s next?
Voluntary Medical Male Circumcision

Summary of Devices Costing and Modeling Studies

Emmanuel Njeuhmeli, MD, MPH, MBA
Sr. Biomedical Prevention Advisor
Office of HIV/AIDS
USAID Washington
6 studies published and unpublished so far


3. V Mutabazi et al. Prepex costing study in Rwanda


5. E Njeuhmeli, K.Kripke, K Hatzold, J Reed, D Edgil, J Jaramillo, D Castor, S Forsythe, S Xaba, O Mugurungi, *Cost Analysis of Integrating The PrePexTM Medical Device Into a Voluntary Medical Male Circumcision Program in Zimbabwe*. Submitted for Peer Review Publication.


- Did not include device cost, supply chain, waste disposal
- Concluded that the PrePex device is unlikely to result in significant cost-savings in comparison to the forceps-guided method and personnel is largest proportion of costs for both methods

<table>
<thead>
<tr>
<th></th>
<th>Forceps-guided</th>
<th>PrePex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device cost</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>Consumables</td>
<td>$9.35</td>
<td>$5.32</td>
</tr>
<tr>
<td>Non-consumable supplies</td>
<td>$6.71</td>
<td>$5.45</td>
</tr>
<tr>
<td>Clinical personnel</td>
<td>$10.72</td>
<td>$8.03</td>
</tr>
<tr>
<td>Training</td>
<td>$0.97</td>
<td>$0.65</td>
</tr>
<tr>
<td>Capital</td>
<td>$2.57</td>
<td>$2.52</td>
</tr>
<tr>
<td>Maintenance and utilities</td>
<td>$3.47</td>
<td>$3.47</td>
</tr>
<tr>
<td>Support personnel</td>
<td>$10.78</td>
<td>$9.64</td>
</tr>
<tr>
<td>Management and supervision</td>
<td>$10.72</td>
<td>$10.72</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$55.29</strong></td>
<td><strong>$45.79</strong></td>
</tr>
</tbody>
</table>
### Rwanda PrePex - Mutabazi

- Did not included supply chain costs
- Staff costs based on time per circumcision
- Concluded that PrePex offers cost savings

<table>
<thead>
<tr>
<th></th>
<th>Dorsal slit</th>
<th>PrePex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>$0.00</td>
<td>$20.00</td>
</tr>
<tr>
<td>Consumables</td>
<td>$29.00</td>
<td>$02.75</td>
</tr>
<tr>
<td>Staff</td>
<td>$4.37</td>
<td>$0.35</td>
</tr>
<tr>
<td>Room &amp; equipment</td>
<td>$2.80</td>
<td>$0.80</td>
</tr>
<tr>
<td>Training</td>
<td>$1.30</td>
<td>$0.25</td>
</tr>
<tr>
<td>AEs</td>
<td>$1.78</td>
<td>$0.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$39.25</strong></td>
<td><strong>$24.15</strong></td>
</tr>
</tbody>
</table>

- Assumed full site utilization
- 15 surgical MC/day; 24 PrePex MC/day
- Concluded that PrePex has a higher unit cost than surgery
- Concluded that PrePex output (# MCs) 60% higher than surgery

<table>
<thead>
<tr>
<th></th>
<th>Sleeve resection</th>
<th>PrePex</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Devices</strong></td>
<td>$0.00</td>
<td>$20.00</td>
</tr>
<tr>
<td>Operator staff</td>
<td>$7.93</td>
<td>$4.95</td>
</tr>
<tr>
<td>Support staff</td>
<td>$1.86</td>
<td>$0.84</td>
</tr>
<tr>
<td>Consumables</td>
<td>$9.15</td>
<td>$3.06</td>
</tr>
<tr>
<td>Reusable sets</td>
<td>$0.59</td>
<td>$0.07</td>
</tr>
<tr>
<td>Sterilisation</td>
<td>$1.09</td>
<td>$0.27</td>
</tr>
<tr>
<td>Non staff costs</td>
<td>$0.82</td>
<td>$0.59</td>
</tr>
<tr>
<td>Overheads and shared costs</td>
<td>$1.22</td>
<td>$0.76</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$22.65</strong></td>
<td><strong>$30.55</strong></td>
</tr>
</tbody>
</table>

- Staff costs based on time per circumcision
- Concluded that in a static location and similar operational environment the unit cost of PrePex circumcisions is estimated to be lower than forceps-guided circumcisions
- Consumables and staff >90% of unit cost
- Should surgical circumcisions be carried out without disposable kits, the difference in unit costs would reduce significantly

<table>
<thead>
<tr>
<th>Phase II</th>
<th>Forceps guided</th>
<th>PrePex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>$0.00</td>
<td>$15.00</td>
</tr>
<tr>
<td>Consumable</td>
<td>$29.66</td>
<td>$12.92</td>
</tr>
<tr>
<td>Non-consumable</td>
<td>$0.37</td>
<td>$0.41</td>
</tr>
<tr>
<td>Personnel costs</td>
<td>$22.69</td>
<td>$16.38</td>
</tr>
<tr>
<td>Support personnel</td>
<td>$0.80</td>
<td>$.80</td>
</tr>
<tr>
<td>Training costs</td>
<td>$0.27</td>
<td>$0.18</td>
</tr>
<tr>
<td>Capital costs</td>
<td>$0.48</td>
<td>$0.30</td>
</tr>
<tr>
<td><strong>Total component cost</strong></td>
<td><strong>$54.26</strong></td>
<td><strong>$45.99</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase III</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>$15.00</td>
</tr>
<tr>
<td>Consumable supplies costs</td>
<td>$12.11</td>
</tr>
<tr>
<td>Non-consumable supplies costs</td>
<td>$1.01</td>
</tr>
<tr>
<td>Personnel costs</td>
<td>$17.26</td>
</tr>
<tr>
<td>Training costs</td>
<td>$0.11</td>
</tr>
<tr>
<td>Indirect costs</td>
<td></td>
</tr>
<tr>
<td>Capital costs</td>
<td>$0.27</td>
</tr>
<tr>
<td>Maintenance and utility costs</td>
<td>$6.24</td>
</tr>
<tr>
<td>Support personnel costs</td>
<td>$3.41</td>
</tr>
<tr>
<td>Management and supervision costs</td>
<td>$2.19</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$57.60</strong></td>
</tr>
</tbody>
</table>
E Njeuhmeli, K. Kripke, et al., Cost Analysis of Integrating The PrePexTM Medical Device Into a Voluntary Medical Male Circumcision Program in Zimbabwe. Submitted for Peer Review Publication.

- Costs for site rather than allocated to PrePex or surgery
- Staff costs based on actual (not theoretical) circumcisions per day
- Concluded that VMMC costs for routine surgery and mixed study sites were similar
- Consumables and staff contributed 80% to the unit cost
- Low service utilization was projected to result in the greatest increases in unit cost

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Routine Surgery Only Site</th>
<th>Surgery &amp; PrePex Research Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>$14.90</td>
<td>$17.83</td>
</tr>
<tr>
<td>Training</td>
<td>$0.30</td>
<td>$0.58</td>
</tr>
<tr>
<td>Consumables</td>
<td>$30.36</td>
<td>$27.62</td>
</tr>
<tr>
<td><strong>Device</strong></td>
<td><strong>$0.00</strong></td>
<td><strong>$3.25</strong></td>
</tr>
<tr>
<td>Durable equipment</td>
<td>$0.55</td>
<td>$1.42</td>
</tr>
<tr>
<td>Supply chain management</td>
<td>$9.53</td>
<td>$9.69</td>
</tr>
<tr>
<td>Waste management</td>
<td>$0.19</td>
<td>$0.19</td>
</tr>
<tr>
<td><strong>Total unit cost/circumcision</strong></td>
<td><strong>$55.83</strong></td>
<td><strong>$60.58</strong></td>
</tr>
</tbody>
</table>

- Variable costs only
- Used salary of 2 clinical officers/MC procedure based on average recorded time for each type of procedure
- Concluded that costs similar for 2 types of procedures
- Cost of clinician time higher for dorsal slit; cost for disposable supplies higher for Shang Ring

<table>
<thead>
<tr>
<th></th>
<th>Dorsal slit</th>
<th>Shang Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician time (2 clinicians)</td>
<td>$4.30</td>
<td>$2.37</td>
</tr>
<tr>
<td>Device</td>
<td>$0.00</td>
<td>$9.00</td>
</tr>
<tr>
<td>Disposable medical supplies</td>
<td>$12.36</td>
<td>$5.93</td>
</tr>
<tr>
<td>Reusable instruments</td>
<td>$1.01</td>
<td>$0.91</td>
</tr>
<tr>
<td><strong>Total Direct Cost</strong></td>
<td><strong>$17.67</strong></td>
<td><strong>$18.21</strong></td>
</tr>
</tbody>
</table>
Research questions

- Incremental cost of introducing new device into existing program
  - No study has looked into this question
  - Being address as part of the Prepex Pilot Introductory Studies in Lesotho, Tanzania, South Africa and Swaziland

- Comparison of device vs. existing conventional methods
  - Costing of Phase II study in Zimbabwe (Schutte et al.)
  - Shang Ring study in Zambia (Bratt et al.)

- Cost of VMMC Program before and after introduction of device
  - Prepex modeling in Zimbabwe (Njeuhmeli et al.)
  - Prepex Pilot Introductory Studies are looking into this question in Lesotho, Tanzania, South Africa and Swaziland

- Whether introduction of device will change demand creation (upward or downward)
  - Prepex modeling in Zimbabwe (Njeuhmeli et al.) did a sensitivity analysis to see if the unit cost was sensitive to site utilization
• Not possible to generalize any unit costs because:
  – In 5/6 studies, costs only collected in large facilities in urban centers; fixed sites
  – Unit cost significantly underestimated and cannot be used for budget purposes
  – No study included demand creation costs except Obiero et al, in Kenya
  – Commodities cost likely to change with volume
  – Staffs and commodities costs are varies by countries
  – Costs of overhead, program management, capital items, and training are based on # of circumcisions and could change with scale
Conclusions

• In 4/6 studies, MC using devices did not result in lower unit costs
• In all studies, staff cost is less with device
• In 5/6 studies, consumables (including device) costs higher with device (if use same device price for all studies)
• Cost is only one component of programmatic decision-making
• MC Unit cost is sensitive to the device price
• The MC Unit cost is highly sensitive to site utilization -- maximize utilization of resources
• Cost analyses can help identify opportunities for cost savings
  – Logistics including both commodities and supply chain
  – Demand creation
Acknowledgements

• The costing data compilation was done by Futures Institute under USAID funded Health Policy Project (HPP)

• Walter Obiero, Robert Bailey, Vincent Mutabazi, Carl Schutte, Karin Hatzold, Emmanuel Njeuhmeli, Katharine Kripke for providing data from various studies presented for this summary

• This summary was developed by Katharine Kripke of Futures Institute and Emmanuel Njeuhmeli of USAID

• Jason Reed of OGAC, Renee Ridzon, Anne Thomas of DoD provided key comments for this summary
Thank You!
Q&A

Jason Reed
OGAC
(Moderator)
PEPFAR VMMC 3rd WEBINAR

Devices for Adult Medical Male Circumcision for HIV Prevention:

What’s the current situation? What’s next?
Acknowledgments

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• The VMMC webinars are being implemented under the technical leadership of the PEPFAR VMMC Technical Working Group
  – Co-Chairs: Jason Reed, Emmanuel Njeuhmeli, Anne Thomas, Naomi Bock
For more information about the PEPFAR VMMC webinar series, contact:
  Tigi Adamu (Tigi.Adamu@jhpiego.org)
  Emmanuel Njeuhmeli (enjeuhmeli@usaid.gov)

Webinar Resources:
www.malecircumcision.org (Resources Page)
Webinar evaluation: surveymonkey.com/s/VMMC-webinar-3

Next PEPFAR VMMC webinar: 9 October 2013