Project IQ Webinar Series

Virtual Roundtable on ShangRing for VMMC: *Country Perspectives*

September 09, 2019
Today’s objectives

• Orient participants to ShangRing and WHO recommended process for device introduction

• Share country perspectives on ShangRing acceptability, safety, and operational considerations

• Discuss best practices and technical resource needs
Male Circumcision Devices

- Potential to simplify procedure and serve as highly acceptable alternative to conventional surgery
- WHO pre-qualified devices
  - PrePex
    - Elastic collar device
    - Scale-up stalled after recognition of increased tetanus risk
      - Likely related to necrotic foreskin being left in situ for 7 days
      - Men are largely inadequately vaccinated against tetanus in Africa
    - Manufacturing recently discontinued
  - ShangRing
    - Collar clamp device
    - Pre-qualified for ≥10 year olds
    - Update to IFU for topical anesthetic and easier “no-flip” technique
ShangRing

• Foreskin removed at time of placement
  – No sutures. Rigid rings used to achieve hemostasis
• RCTs from Kenya/Zambia and Uganda
  – Equivalent safety compared to conventional surgical circumcision
  – Faster procedure time, more acceptable
  – Longer healing time (7 weeks vs. 6 with surgery)
• Potential candidate method for sustaining future MC coverage
• Recent expanded PQ of simpler method ("no flip") and topical anesthetic
Multi-Phase Process

Assessment

Implementation Pilot Study

Active AE Follow-up
('Active Surveillance')

Passive AE Follow-up
(Routine Services)

Clinical, acceptability, and field studies, and other data, inform WHO’s decision about prequalification (PQ)

Evaluation in any country considering device use to inform national decisions
Key framework details

**WHO PQ + country stakeholder engagement / agreement**

**Assessment**

- Answers the Questions:
  - Is the device effective compared to surgery?
  - Is the device safe compared to surgery?
  - Is the device acceptable compared to surgery?
  - Is the manufacturing of consistent high quality?

**Implementation Pilot Study**

- Answers the Questions:
  - Is the device as effective and safe in a **country-specific research study** compared to results from the WHO PQ studies?
  - Is the device as acceptable as surgery in *X country*?

**Active AE Follow-up (‘Active Surveillance’)**

- Answers the Questions:
  - Is the device as effective and safe when provided at scale with **active follow-up** in *X country* compared to results of *X country’s* implementation pilot?

**Passive AE Follow-up (Routine Services)**

- Answers the Questions:
  - Is the device as effective and safe when provided at scale with **routine/passive follow-up** in *X country* compared to results of *X country’s* active AE surveillance?
Country progress toward ShangRing implementation

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First to use revised IFU--topical anesthetic and easier “no-flip” technique
Agenda

Introduction  
Carlos Toledo, CDC

Topic 1: Acceptability  
Elijah Odoyo-June, CDC Kenya  
Geoffrey Menego, Jhpiego Malawi  
Omega Chituwo, CDC Zambia

Q&A

Topic 2: Safety  
Abubakari Mwinyi, Jhpiego Namibia  
Kija Nyalali, IntraHealth Tanzania

Q&A

Topic 3: Start up/operations  
Elijah Odoyo-June, CDC Kenya  
Abubakari Mwinyi, Jhpiego Namibia

Q&A/Discussion/Closure
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