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
Virtual Roundtable

- Safety
- Acceptability
- Start up/Operations

Flags of different countries are shown.
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

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

Assessment

Implementation Pilot Study

Active AE Follow-up
(‘Active Surveillance’)

Passive AE Follow-up
(Routine Services)

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

Assessment

WHO PQ + country stakeholder engagement / agreement

Implementation

Pilot Study

Active AE Follow-up ('Active Surveillance')

Country stakeholder engagement / agreement

Passive AE Follow-up (Routine Services)

Country stakeholder engagement / policy decision

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?

Answers the Questions:
• Is the device as effective and safe compared to results from the WHO PQ studies?

Answers the Questions:
• Is the device as acceptable as surgery in X country?

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?

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

in progress
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
Project IQ Resources Web Page:
https://project-iq-resources.jhpiego.org/

Project IQ Webinar Series

In Pursuit of the Pivot
Reaching and Serving Clients Aged 15-29 Years
August 24, 2016

Provider Verbal Pre-Screening Questions for Voluntary Medical Male Circumcision

INSTRUCTIONS TO PROVIDERS:

These questions are intended to identify conditions that may not be apparent through physical screening but could still compromise the safety of VMMC.

1. Do you have any current or past conditions, or a chronic illness that we should be aware of?
2. Are you currently taking any medications or vitamins? Yes, please list them. (Consider further screening if client cites medications other than over-the-counter analgesics)
3. Are you allergic to any medicines?

A Healthy Obsession with Safety:
Improving Programs through Management and Reporting of Adverse Events

3 Questions for Safe Injections

Did you wash your hands?
Are you using a new needle and syringe EVERY TIME you access a vial?
is there any possibility that the vial is contaminated, spoiled, or expired?

Managing Adverse Events of Voluntary Medical Male Circumcision (VMMC)

An orientation for non-VMMC providers

Injection Safety For VMMC Service Delivery
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