



Improving Quality VMMC

Project IQ Webinar Series

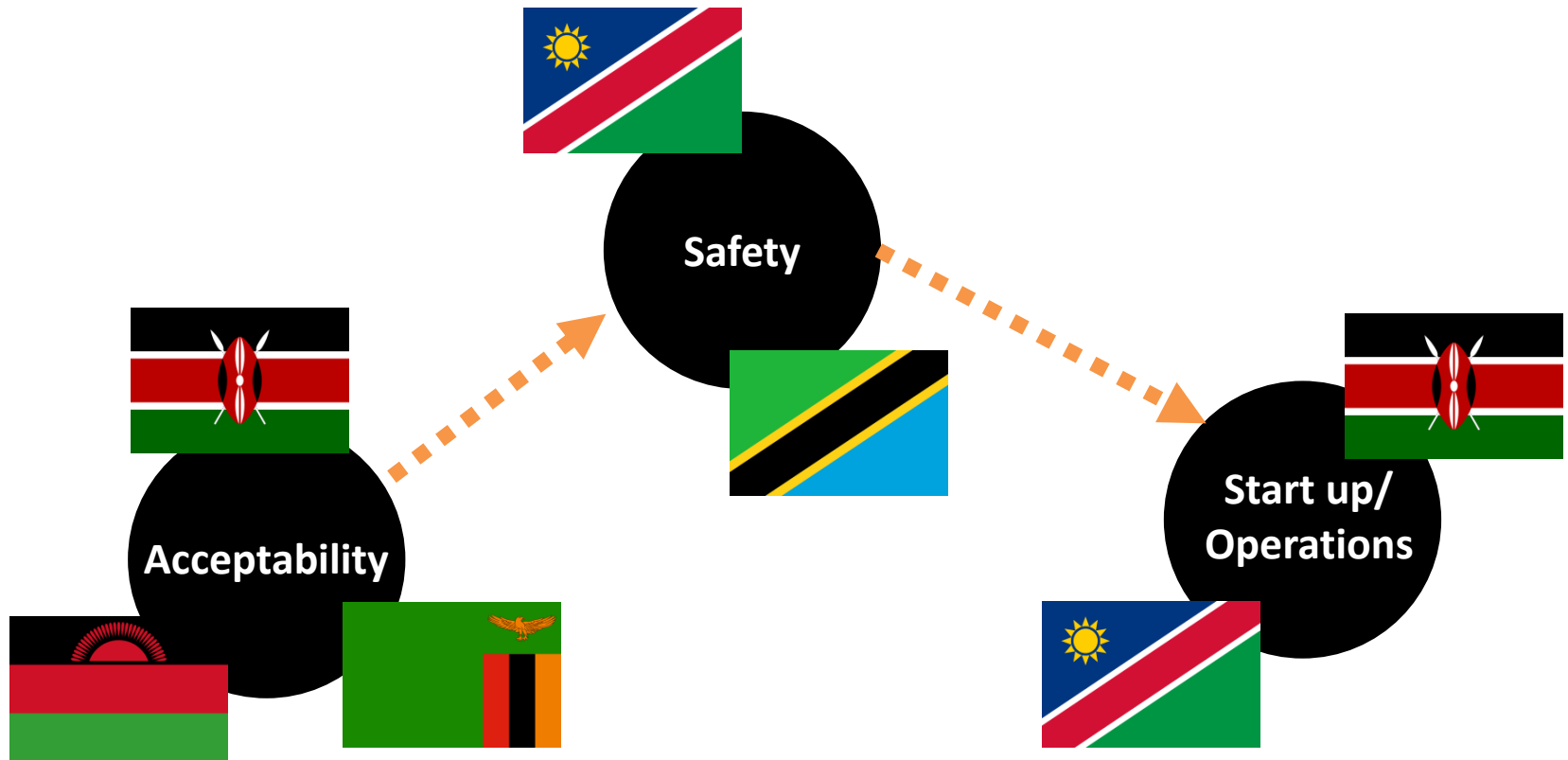
**Virtual Roundtable on ShangRing for VMMC:
*Country Perspectives***

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

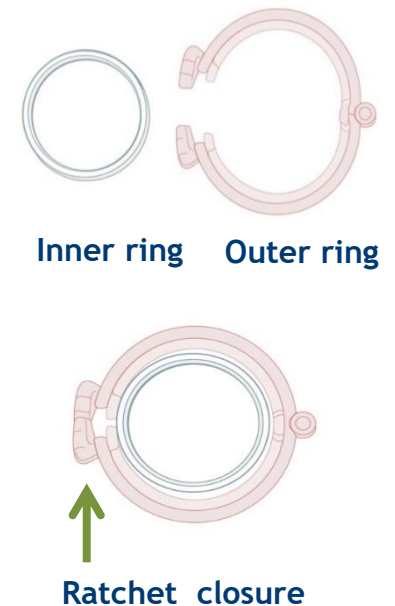


Male Circumcision Devices

- 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



FRAMEWORK FOR CLINICAL EVALUATION
OF DEVICES FOR MALE CIRCUMCISION

Multi-Phase Process

Assessment

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

WHO PQ

Implementation
Pilot Study

Active AE Follow-up
(‘Active Surveillance’)

Evaluation in **any country** considering device use to inform national decisions

Passive AE Follow-up
(Routine Services)

Key framework details

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?

WHO PQ

+ *country stakeholder engagement / agreement*

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*?

Country stakeholder engagement / agreement

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?

Country stakeholder engagement / policy decision

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

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

	Kenya	Malawi	Namibia	Tanzania	Uganda	Zambia
Implementation Pilot Study	✓	✓	<i>in progress</i>	✓	✓	✓
Active AE Follow-up ('Active Surveillance')	✓	✓			✓	✓
Passive AE Follow-up (Routine Services)						

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

Project IQ Resources Web Page: <https://project-iq-resources.jhpiego.org/>



Improving Quality VMMC

Project IQ Webinar Series

In Pursuit of the Pivot
 Reaching and Serving Clients Aged
 15-29 Years

August 24, 2016



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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.
- Please verbally ask the following questions **in addition** to performing physical screening of **all** voluntary medical male circumcision (VMMC) clients prior to performing circumcision, regardless of the circumcision method to be used.
- Questions should be asked even if a client or their guardian already completed a written form with similar information.
- If a client answers "Yes" to any of the full questions below, please follow site policies or consult the senior on-site clinician to determine whether any further testing or referral to a specialized provider is needed before circumcision.

*Check if answer is YES –
 Consider further screening*

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? If yes, please list them. *(Consider further screening if client cites medications other than over-the-counter analgesics)*
3. Are you allergic to any medicines?



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



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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?



Improving Quality VMMC

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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Announcements

Project IQ Discussions
Published by Cole Bingham (?) · September 17 at 2:44 PM

Project IQ supports the implementation of voluntary male medical circumcision (VMMC) by standardizing quality approaches and building capacity for improved timeliness, accessibility, actionability, and quality of VMMC data, and hosts periodic webinars convening VMMC field staff and implementing partners to discuss essential topics for maintaining and improving the quality of services.

This is a private Facebook group to continue discussions and share experiences. Please keep a business-appropriate tone and direct questions or concerns to a group administrator.

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