Improving Quality VMMC

Project IQ Webinar Series

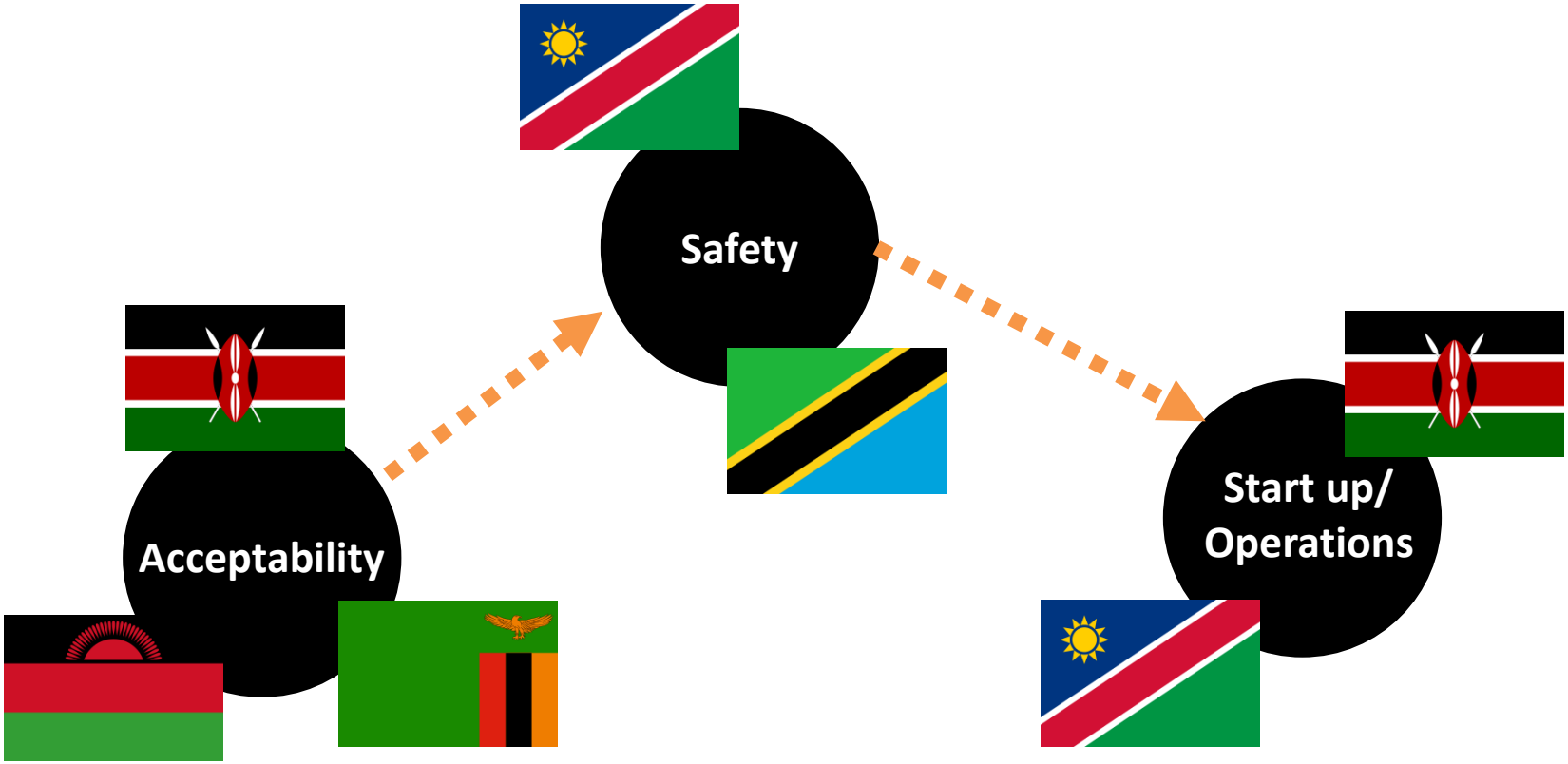
Virtual Roundtable on ShangRing for VMMC: *Country Perspectives*

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



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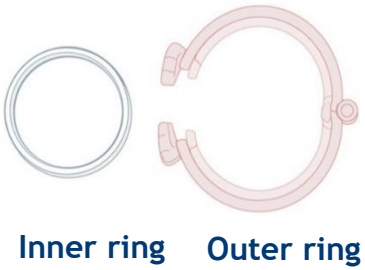
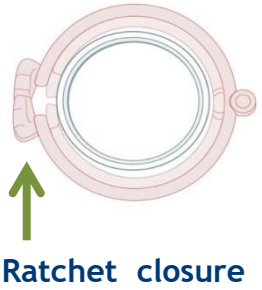
Male Circumcision Devices

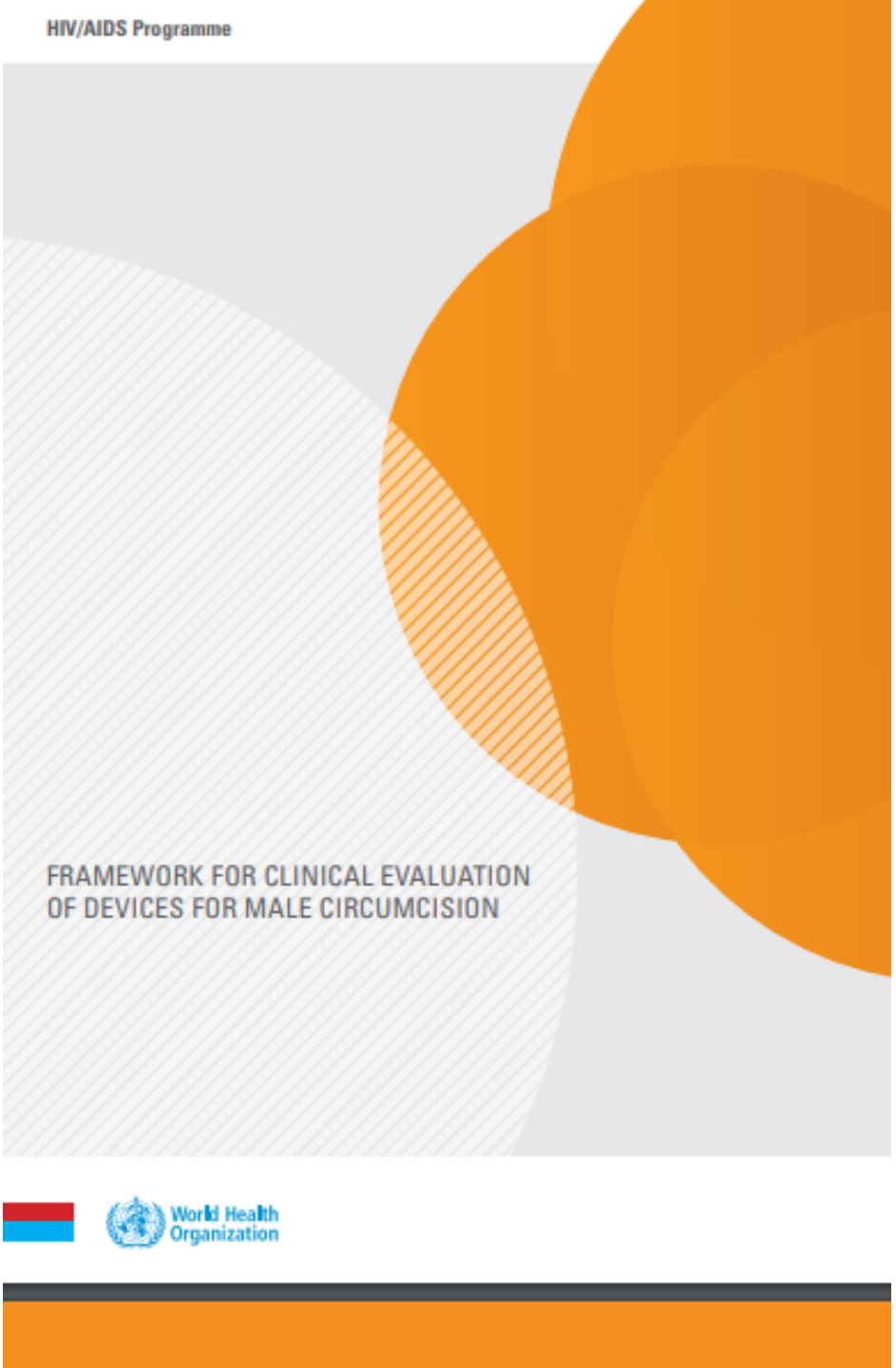
- Potential to simplify procedure and serve as highly acceptable alternative to conventional surgery
- WHO pre-qualified devices
  - PrePex
    - Elastic collar device
    - Scale-up stalled after recognition of increased tetanus risk
      - Likely related to necrotic foreskin being left in situ for 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

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

WHO PQ

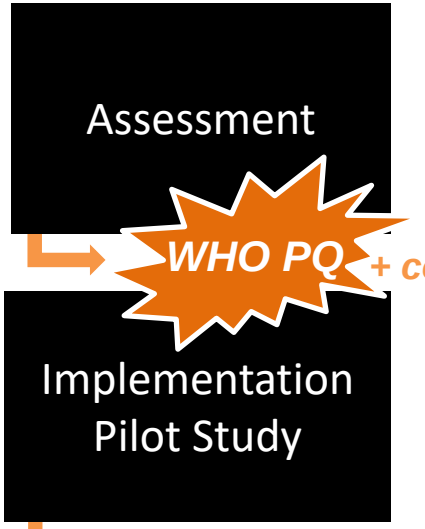
Implementation Pilot Study

Active AE Follow-up ('Active Surveillance')

Passive AE Follow-up (Routine Services)

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

Key framework details



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?

+ country stakeholder engagement / agreement

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?

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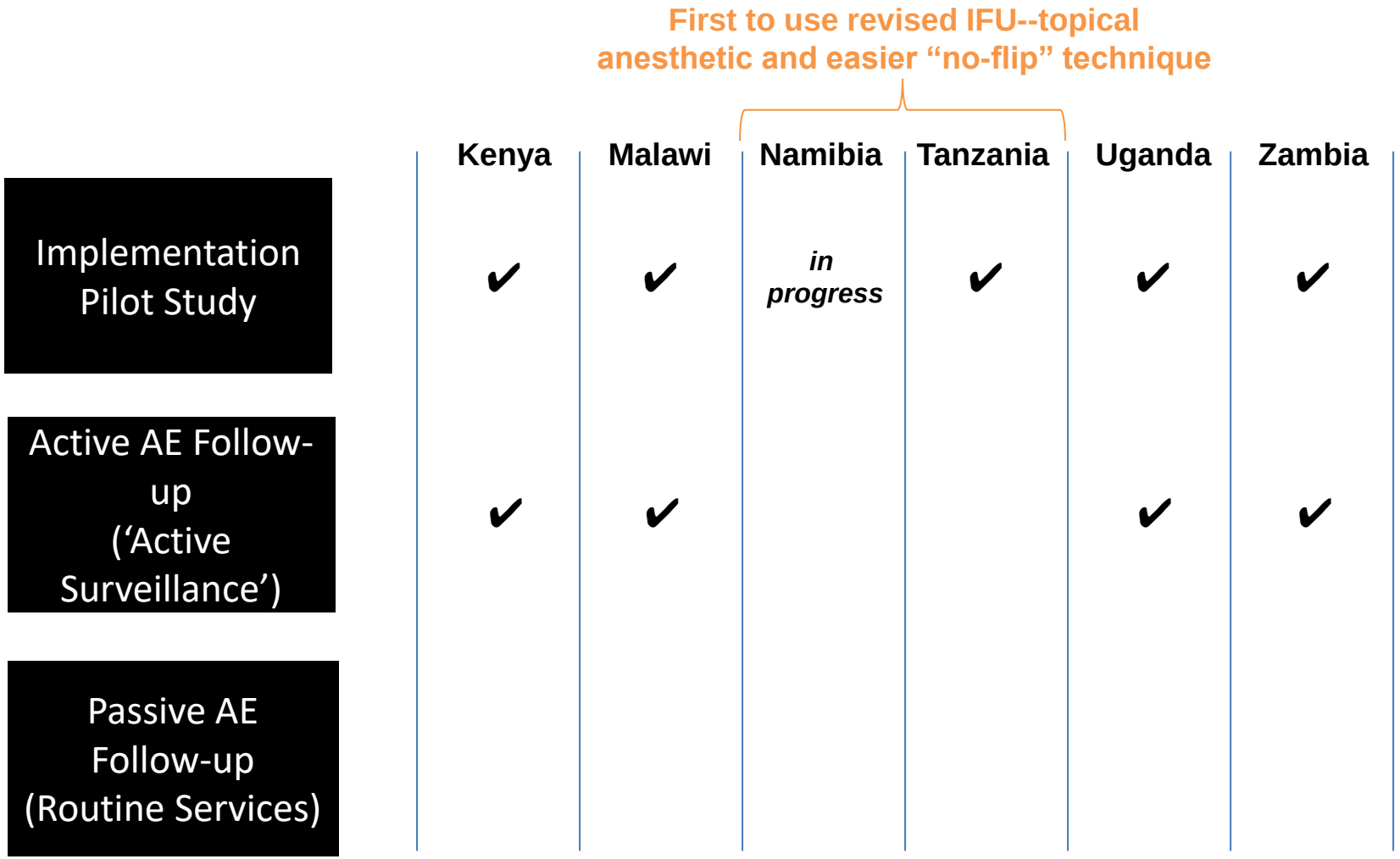
Country progress toward ShangRing implemenation



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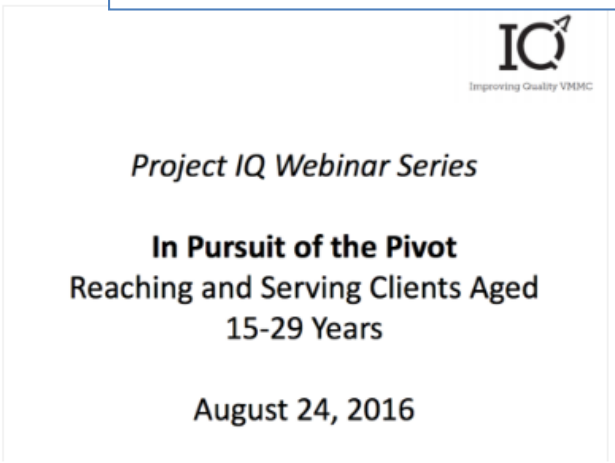
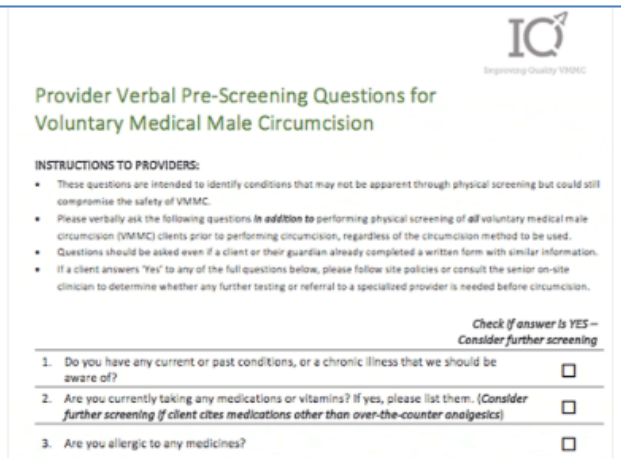
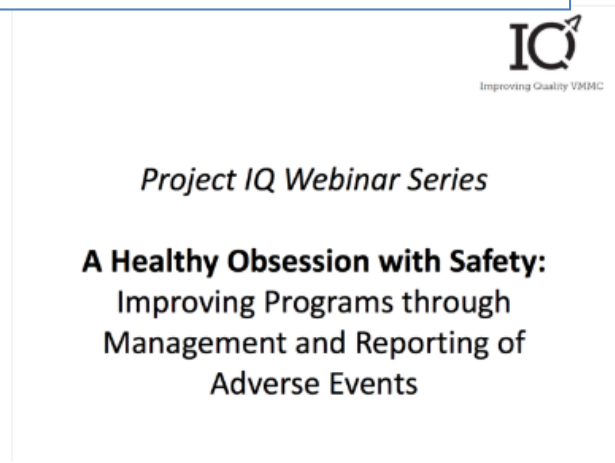
Agenda

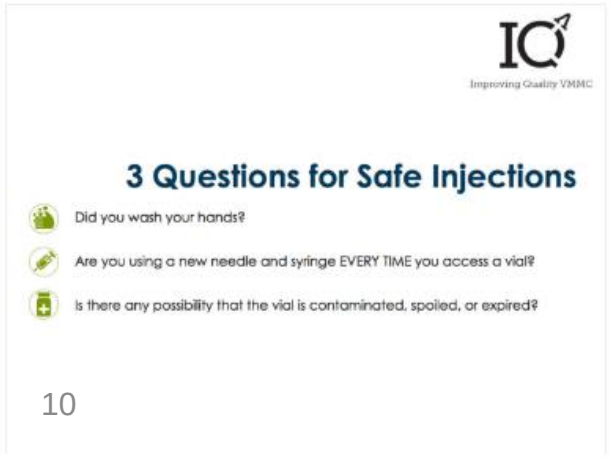
Introduction	Carlos Toledo, CDC
Topic 1: Acceptability 	Elijah Odoyo-June, CDC Kenya Geoffrey Menego, Jhpiego Malawi Omega Chituwo, CDC Zambia
Q&A	
Topic 2: Safety 	Abubakari Mwinyi, Jhpiego Namibia Kija Nyalali, IntraHealth Tanzania
Q&A	
Topic 3: Start up/operations 	Elijah Odoyo-June, CDC Kenya Abubakari Mwinyi, Jhpiego Namibia
Q&A/Discussion/Closure	

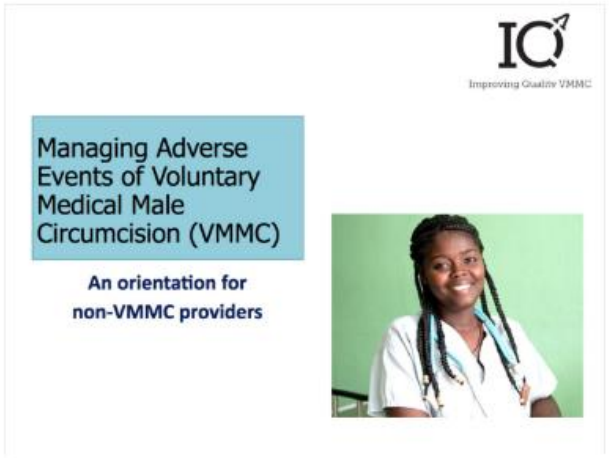
Project IQ Resources Web Page:
https://project-iq-resources.jhpiego.org/











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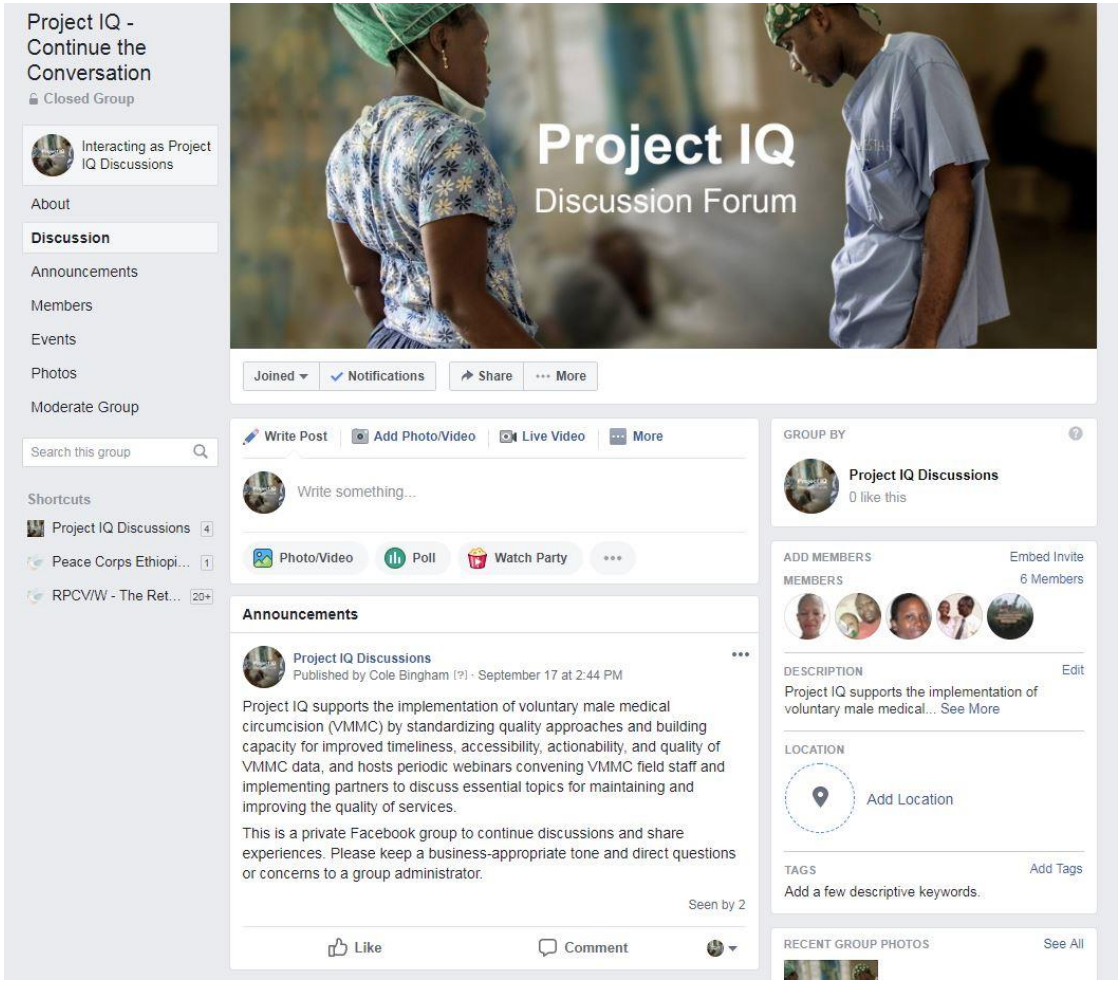

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