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PEPFAR VMMC 3rd WEBINAR

Devices for Adult Medical Male Circumcision for HIV Prevention:

What's the current situation? What's next?

USAID
FROM THE AMERICAN PEOPLE

MCHIP | Maternal and Child Health Integrated Program

CDC

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.

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Welcome and Introduction

Jason Reed

OGAC

(Moderator)

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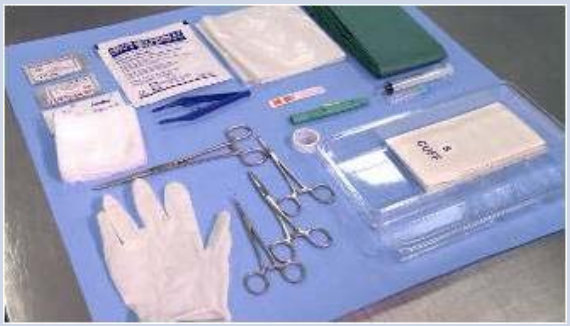
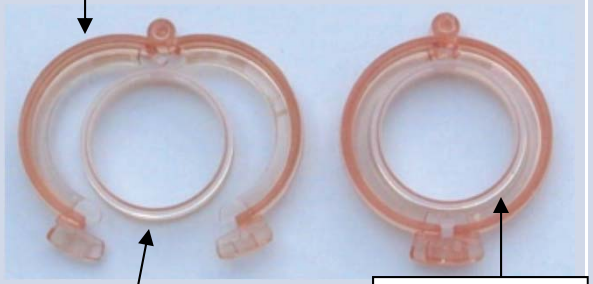
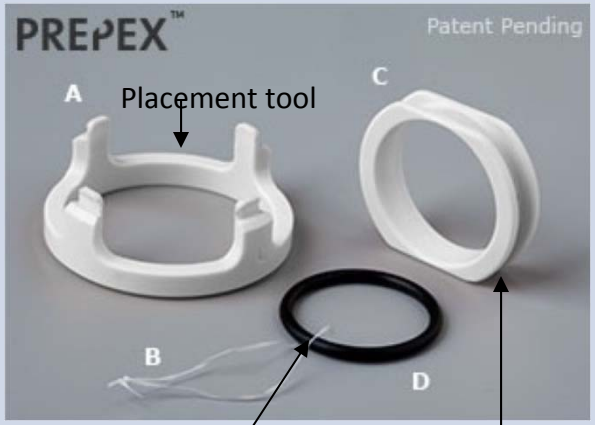
Introduction to MC medical devices ("Devices 101")

Godfrey Kigozi

Surgical circumcision, Shang Ring and Prepex devices

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

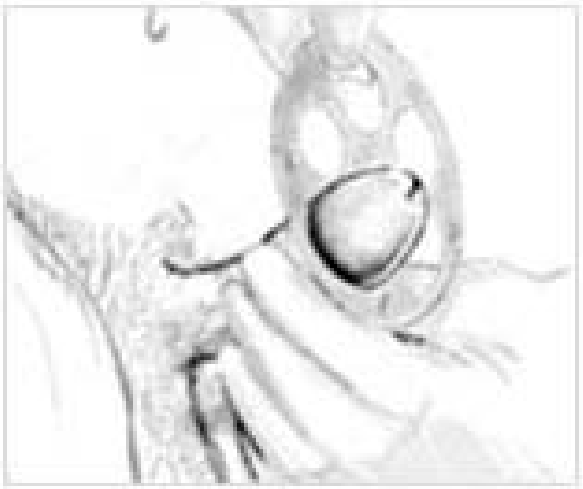
Skin eversion

Outer ring placement and then foreskin cut away

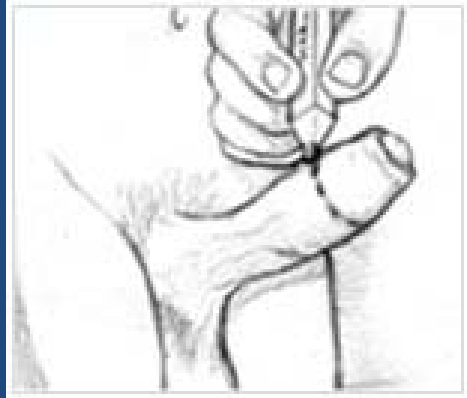
Device worn for approx 1 week

Cutting the ring at removal approx 1 week later

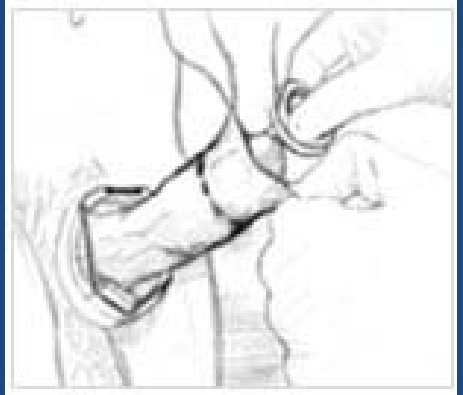
Prepex Placement Procedure



Selecting Size



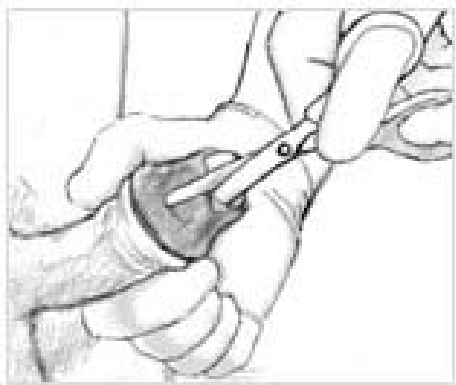
Marking, based on WHO guidelines (not device related)



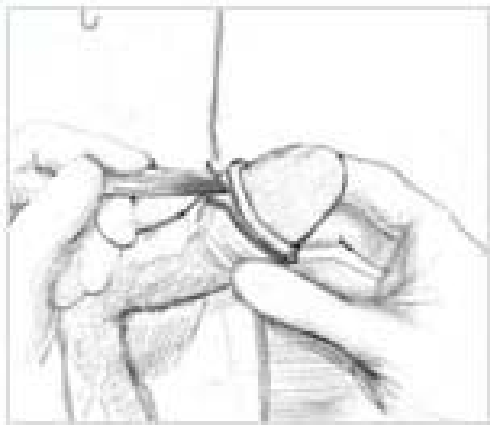
Preparing for placement and inserting Inner Ring

Removal Procedure

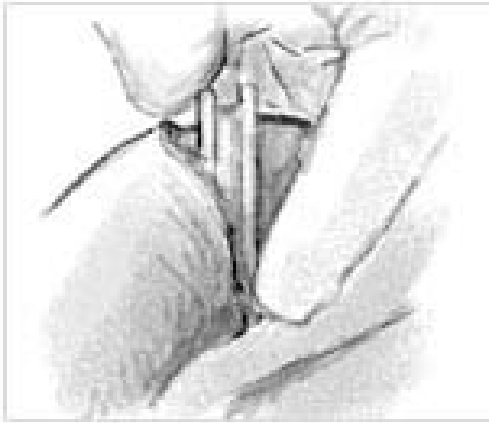
- After approx 1 week of wearing device



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.

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

*Measurements do not include time required for injection and onset of local anesthesia

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Tim Farley, Sigma3 Services, Nyon
Consultant to WHO HIV Department

Clinical performance of ShangRing and PrePex devices

21 August 2013

World Health Organization

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

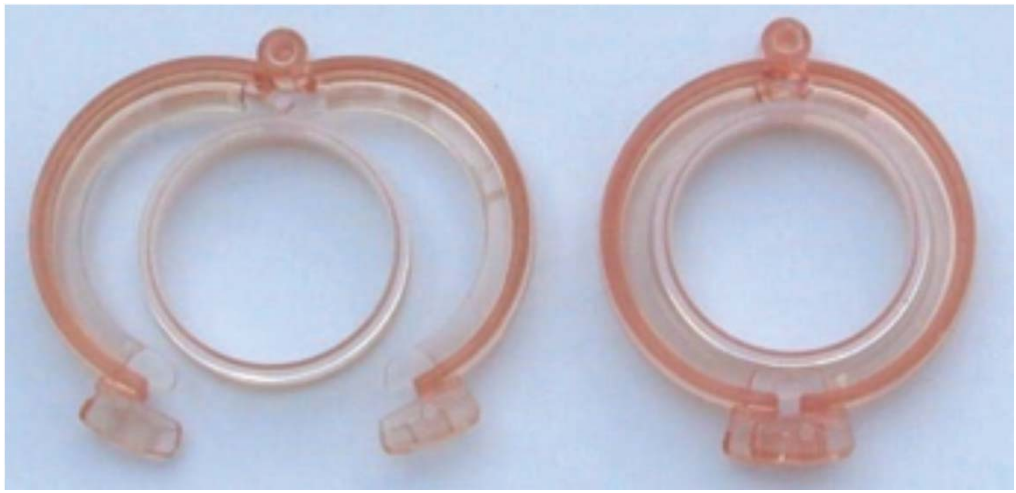
Any AE not classified as an SAE but that required an intervention by a health care provider or medication (parenteral, oral or topical)

Mild AE

All other AEs

Shang Ring Device

- Developed in China; Studied in China and Africa



Shang Ring Studies Reviewed

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

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)

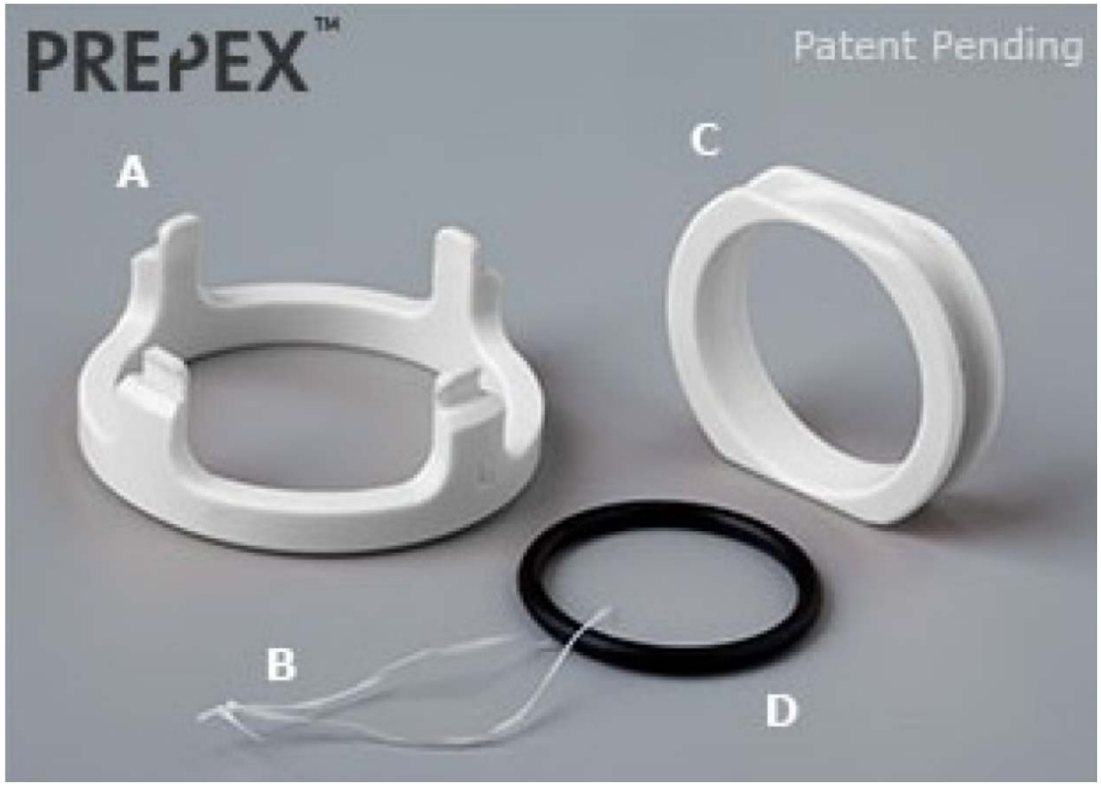
Type of Event	Number	Per cent [95% CI]
Total placements	1,983	
Serious AEs	**0**	**0.0% [0.0%, 0.2%]**
Moderate AEs	**20**	**1.0% [0.6%, 1.6%]**
Pain placement (8) Infection (4) Insufficient skin removed (3) Pain leading to early removal (2) Wound disruption (2) Bleeding (1)		
Mild AEs	**43**	**2.2% [1.6%, 2.9%]**

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

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

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)

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

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

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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

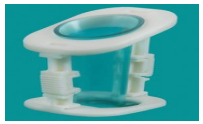
1a. Collar Clamp

ShangRing

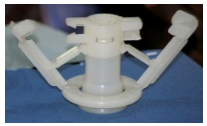
Kirve clamp

Sunathrone

1b. Vice Clamp



Alis Klamp

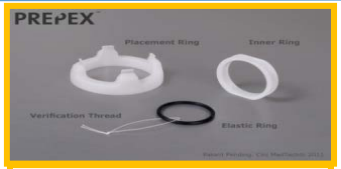


Tara Klamp

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

WHO Prequalification of Male Circumcision Devices Programme, established 2011

Objective:

- 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

Status of devices in WHO Prequalification Programme

Product name	Manufacturer name	Application	Letter of Agreement	Product dossier including clinical data	Manufacturer site inspections	Prequalification Status
PrePex	Circ Med Tech Limited					Prequalified : 31 May 2013
ShangRing	Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd.					
Alisklamp Disposable Circumcision Device	ABAGROUP Healthcare Services Co. Ltd.					
Tara KLamp	Taramedic Corp.					

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*
- *Technical Advisory Group Report on evaluation of two devices*

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

- *Beginning with the end in mind*

www.who.int/reprodutive 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

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Q&A

Jason Reed

OGAC

(Moderator)

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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?

Service Delivery Considerations III

- 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...

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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

Media briefing

HIV CONFERENCE WEBSITE

Will non-surgical circumcision devices help SA to speed up me circumcisions? And will they make traditional circumcisions sa

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

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

Is this the answer to SA's botched traditional circumcisions? And what al controversial TaraKlamp that has not been endorsed by the WHO?

Come and hear how our government plans to use the Prepex. The head of the heal

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?"

LESSONS LEARNED FROM PREPEX MEDIA BRIEFING

- **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 VMM

SA AIDS 2013

Tuesday, 18 June

11am-1pm

Official Media Room

International Convention Ct

RSVP: Amy Green

AmyG@mg.co.za:

The World Health Organisation (WHO) recently endorse non-surgical device that has the potential to make medic circumcision easier to implement and will likely approve device in coming months. These devices don't have to b administered by doctors and surgical theatres aren't nee

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

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

Will our government be using these devices? And, coul

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

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Voluntary Medical Male Circumcision

Summary of Devices Costing and Modeling Studies

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Office of HIV/AIDS

USAID Washington

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6 studies published and unpublished so far

1. Obiero W, Young MR, Bailey RC. The PrePex Device Is Unlikely to Achieve Cost-Savings Compared to the Forceps-Guided Method in Male Circumcision Programs in Sub-Saharan Africa. *PloS one.* 2013;8(1):e53380.
2. Duffy K, Galukande M, Wooding N, Dea M, Coutinho A. Reach and Cost-Effectiveness of the PrePex Device for Safe Male Circumcision in Uganda. *PloS one.* 2013;8(5):e63134.
3. V Mutabazi et al. Prepex costing study in Rwanda
4. Schütte, C, 2012. *Cost-efficiency analysis in the context of the Zimbabwe PrePex male circumcision device study.* **Unpublished**, UNFPA and Ministry of Health and Child Welfare, Zimbabwe.
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**.
6. Bratt JH, Zyambo Z. Comparing Direct Costs of Facility-Based Shang Ring Provision Versus a Standard Surgical Technique for Voluntary Medical Male Circumcision in Zambia. *JAIDS Journal of Acquired Immune Deficiency Syndromes.* 2013;63(3):e109-e112 110.1097/QAI.1090b1013e31828e39526.

Obiero W, Young MR, Bailey RC. The PrePex Device Is Unlikely to Achieve Cost-Savings Compared to the Forceps-Guided Method in Male Circumcision Programs in Sub-Saharan Africa. PloS one. 2013;8(1):e53380.

- 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

	Forceps-guided	PrePex
Device cost	**$0.00**	**$0.00**
Consumables	$9.35	$5.32
Non-consumable supplies	$6.71	$5.45
Clinical personnel	$10.72	$8.03
Training	$0.97	$0.65
Capital	$2.57	$2.52
Maintenance and utilities	$3.47	$3.47
Support personnel	$10.78	$9.64
Management and supervision	$10.72	$10.72
Total	**$55.29**	**$45.79**

Rwanda PrePex - Mutabazi

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

	Dorsal slit	PrePex
Device	**$0.00**	**$20.00**
Consumables	$29.00	$02.75
Staff	$4.37	$0.35
Room & equipment	$2.80	$0.80
Training	$1.30	$0.25
AEs	$1.78	$0.00
Total	**$39.25**	**$24.15**

Duffy K, Galukande M, Wooding N, Dea M, Coutinho A. Reach and Cost-Effectiveness of the PrePex Device for Safe Male Circumcision in Uganda. PloS one. 2013;8(5):e63134.

- 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

	Sleeve resection	PrePex
Devices	$0.00	$20.00
Operator staff	$7.93	$4.95
Support staff	$1.86	$0.84
Consumables	$9.15	$3.06
Reusable sets	$0.59	$0.07
Sterilisation	$1.09	$0.27
Non staff costs	$0.82	$0.59
Overheads and shared costs	$1.22	$0.76
Total	**$22.65**	**$30.55**

Schütte, C, 2012. Cost-efficiency analysis in the context of the Zimbabwe PrePex male circumcision device study. Unpublished, UNFPA and Ministry of Health and Child Welfare, Zimbabwe.

- 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

Phase II	Forceps guided	PrePex
Device	**$0.00**	**$15.00**
Consumable	$29.66	$12.92
Non-consumable	$0.37	$0.41
Personnel costs	$22.69	$16.38
Support personnel	$0.80	$.80
Training costs	$0.27	$0.18
Capital costs	$0.48	$0.30
Total component cost	**$54.26**	**$45.99**

Phase III	Average
Device	$15.00
Consumable supplies costs	$12.11
Non-consumable supplies costs	$1.01
Personnel costs	$17.26
Training costs	$0.11
Indirect costs	
Capital costs	$0.27
Maintenance and utility costs	$6.24
Support personnel costs	$3.41
Management and supervision costs	$2.19
TOTAL	**$57.60**

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

Cost category	Routine Surgery Only Site	Surgery & PrePex Research Site
Staff	$14.90	$17.83
Training	$0.30	$0.58
Consumables	$30.36	$27.62
Device	**$0.00**	**$3.25**
Durable equipment	$0.55	$1.42
Supply chain management	$9.53	$9.69
Waste management	$0.19	$0.19
Total unit cost/circumcision	**$55.83**	**$60.58**

Bratt JH, Zyambo Z. Comparing Direct Costs of Facility-Based Shang Ring Provision Versus a Standard Surgical Technique for Voluntary Medical Male Circumcision in Zambia. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2013;63(3):e109-e112 110.1097/QAI.1090b1013e31828e39526.

- 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

	Dorsal slit	Shang Ring
Clinician time (2 clinicians)	$4.30	$2.37
Device	$0.00	$9.00
Disposable medical supplies	$12.36	$5.93
Reusable instruments	$1.01	$0.91
Total Direct Cost	**$17.67**	**$18.21**

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*

Generalizations/Limitations

- 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**

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Q&A

Jason Reed

OGAC

(Moderator)

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Next PEPFAR VMMC webinar: **9 October 2013**

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