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...