



WHO TeleECHO™ Sessions

Preventing HIV through Safe Voluntary Medical Male Circumcision
for Adolescent Boys and Men in Generalized HIV Epidemics:
recommendations and considerations

21, 24, 25 August 2020



WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR AFRICA SUPPORTS THE COVID-19 RESPONSE




24 August 2020 Session 2

**Part 1. VMMC and younger adolescents
10 – 14 years**

**Part 2. Use of device-based methods for
male circumcision in the context of HIV
prevention**



Agenda – Part 1

Moderator Frank Lule	
Time	Topic and presenter
14.35 – 14.40	Opening remarks – Fabian Ndenzako
14.40 – 14.50	Overview of key considerations for younger adolescents - Afua Hesse
14.50 – 14.55	Evolution and characteristics of adolescent development - Wole Ameyan
14.55 – 15.05	Safety younger adolescents – Todd Lucas
15.05 – 15.15	Human rights and ethical issues, informed consent and assent for younger adolescents – Jerome Singh
15.15 – 15.25	Other factors to consider: public health impact, values and preferences, acceptability – Mable Mweemba
15.25 – 15.30	Other services for adolescents 10 – 14 years - Venkatraman Chandra-Mouli
15.30 – 15.40	Questions and Answers
15.40 – 15.45	Away from the screen break 

ISSUES AND CONSIDERATIONS REGARDING VMMC FOR YOUNGER ADOLESCENT BOYS

- 3.1 Adolescent development
- 3.2 Rationale and background for review of VMMC for HIV prevention among younger adolescents
- 3.3 Evidence to inform policy on the offer of VMMC for HIV prevention to adolescent ages 10–14 years compared with older adolescents: safety, acceptability and maintaining effective coverage
- 3.4 Other factors to inform decision-making

Opening remarks

Fabian Ndenzako
Medical Officer HIV Prevention and Treatment
WHO AFRO

Overview of key considerations regarding VMMC for younger adolescents

Afua Hesse

Professor Paediatric Surgery and Anatomy

President Accra College of Medicine

Accra College of Medicine, Ghana

Key consideration on offering VMMC to younger adolescents ages 10 through 14 years (1)

Based on new safety evidence, updated international human rights, national and local context

Public health burden of HIV and prevention effectiveness

- Circumcising adolescents 10–14 years will avert HIV and STI infection in future, but not immediately

Key consideration on offering VMMC to younger adolescents ages 10 through 14 years (2)

Informed consent

- Capacity to consent, and make independent decisions about their own health, evolves at varying rates across adolescence.
- Health care providers should seek to defer non-emergency invasive and irreversible interventions for adolescents until child is sufficiently mature to provide consent
- Laws or regulations should stipulate a minimum permissible age for consent to VMMC or refer to assessment of evolving capacity of child.
- Programmes should have supportive policies to ensure that children, parents and health workers have adequate rights-based guidance on consent, assent and confidentiality.

Key considerations to offer VMMC to adolescents ages 10 through 14 years (3)

- **Safety:** affected by their evolving physical development
 - With conventional surgical methods, rare serious adverse events (glans injuries and urethral fistula) occur at higher rate among adolescents 10–14 years than 15–19 years.
 - Attributed to the less mature genitalia of younger adolescent boys.
 - Defer until more developed physically.
- **Feasibility**
 - Unknown regarding offering some aspects of VMMC package and other services to younger adolescents while deferring surgical procedure to later.
- Adolescents', parents' and communities' **preferences should be considered**

Evolution and characteristics of adolescent development

Wole Ameyan

Technical Officer, Adolescent HIV

WHO Global Programme on HIV Hepatitis, and STIs

Key points on adolescence



- One of the most rapid phases of human development
- WHO defines adolescence, as ages 10–19:
 - early adolescence 10–14 years
 - late adolescence 15–19 years
- Maturity occurs at different rates
 - Physical maturity usually precedes psychosocial maturity—implications for policy and programme responses
- Younger adolescents may be particularly vulnerable when their capacities are still developing
- Unique nature and importance of adolescence requires explicit and specific attention in health policy and programmes.

Physical development and measurement

- Tanner stages are a common classification scale of sexual maturity
- Ideally, Tanner staging would be used in assessing VMMC safety among adolescents.
 - such information is not routinely collected
 - staging is subjective assessment
- Age is used as a proxy
- Male puberty onset ranges from 9–14 years and maturity is reached at 13–17 years
- Development of genitalia to an adult stage occurs on average 3 years after puberty begins

Table 3.2. Male sexual maturity scale, also known as Tanner stages of adolescent development

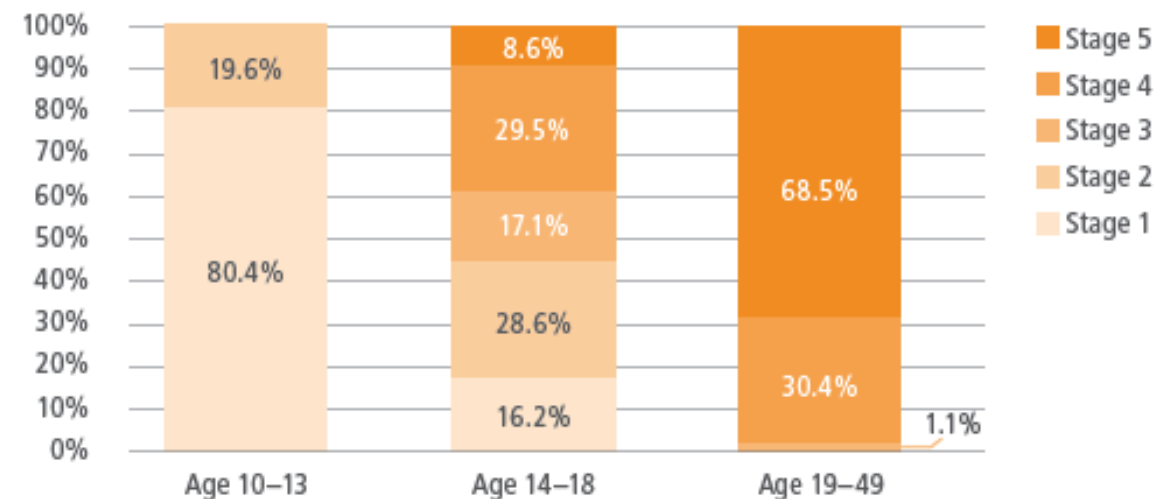
Stage	Age range (years)	Testes growth	Penis growth	Pubic hair growth	Other changes
I	0–15	Pre-adolescent testes (≤ 2.5 cm)	Pre-adolescent	None	Pre-adolescent
II	10–15	Enlargement of testes; pigmentation of scrotal sac	Minimal or no enlargement	Long downy hair, often appearing several months after testicular growth; variable pattern noted with pubarche	Not applicable
III	10.5–16.5	Further enlargement	Significant enlargement, especially in diameter	Increase in amount; curling	Not applicable
IV	12–17	Further enlargement	Further enlargement, especially in diameter	Adult in type but not in distribution	Development of axillary hair and some facial hair
V	13–18	Adult in size	Adult in size	Adult in distribution (medial aspects of thighs; linea alba)	Body hair continues to grow and muscles continue to increase in size for several months to years; 20% of boys reach peak growth velocity during this period.

Source: Adapted from: Antiretroviral therapy for HIV infection in infants and children: towards universal access. Recommendations for a public health approach: 2010 Revision. Annex H. Sexual maturity rating (Tanner staging) in adolescents. Geneva: World Health Organization; 2010 (2023).

Maintaining effective coverage: eligibility

- Eligibility for VMMC may be affected by the presence of normal physiological phimosis and adhesions - more common among younger, prepubescent adolescents.
- Evidence not available on outcomes of resolving these conditions before VMMC
- Penile measurement study in Tanzania:
 - 80% of adolescents 10–13 years were Tanner stage 1; great variability among those 14–18 years
- Provision of services for a large proportion of younger adolescents may need to be delayed until boys are more fully developed.

Fig. 3.3. Distribution of Tanner stages of sexual maturity by age group of adolescent and adult men assessed in Tanzanian study on measurements to inform circumcision device sizes and supply forecasting



Chrouser et al 2013 (Ref 217 in Guideline)

Safety of VMMC in younger adolescents

Todd Lucas
Medical Officer
U.S. Centers for Disease Control and Prevention

Evidence on the safety of VMMC by age

- Although extensive programmatic VMMC safety data exists, age disaggregated evidence on adolescents is limited
- Unpublished systematic review: six publications with safety information (adverse events) age-disaggregated to adolescents
 - age groupings were diverse
- Surveillance reports on serious AEs provide additional details
 - PEPFAR's Notifiable Adverse Events Reporting (NAER) surveillance system
 - ad hoc adverse event reports to WHO



Systematic review of moderate and severe AEs among adolescents

- **Six studies** in systematic review: **very low quality**, great variability
- **Only two** specifically **included age group 10–14 years** with sufficient detail:
 1. Cohort study, Zimbabwe, 2014–2015
 - **similar overall AE rates** among ages 10–14 years, 15–19 years and 20 years of age and older
 - 10–14 years with **a 2-3 fold higher risk of infections** than 15 years+
 - most procedures: forceps-guided or dorsal slit method; small proportion of elastic collar compression procedures
 2. Cohort study, Kenya
 - **lower risk of severe and moderate AEs among 13–17 years than 18 years+**
 - adjusted OR: 0.27, 95% CI: 0.14–0.52
 - no data were available for adolescents age 10–12 years

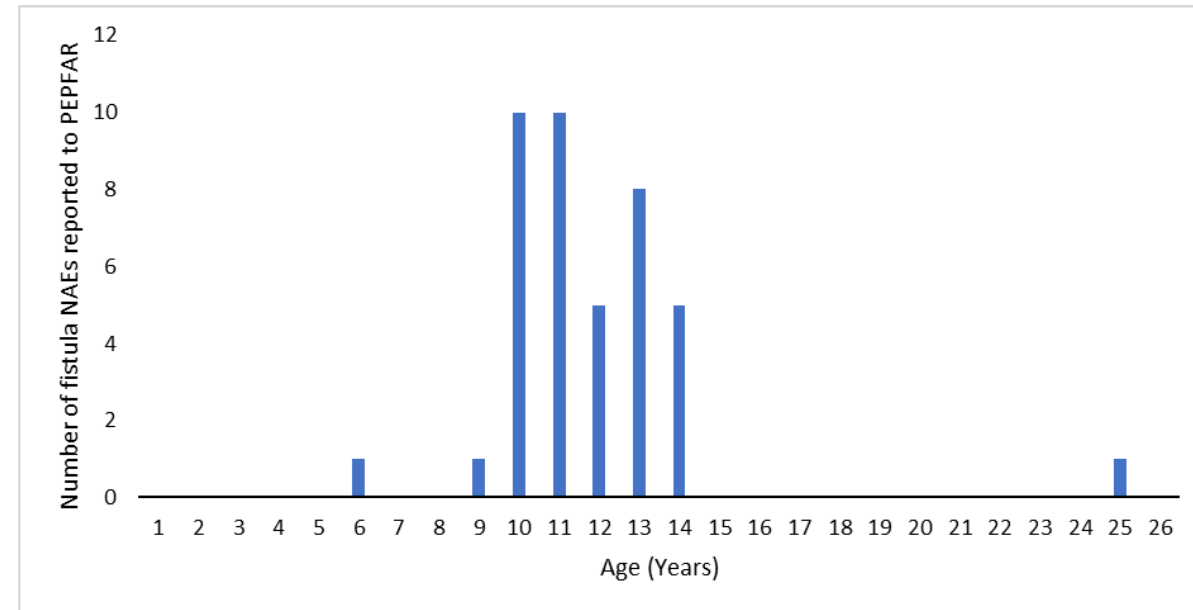
PEPFAR VMMC notifiable adverse event reporting system: glans injuries

- **All NAEs, 2015 - June 2018**
 - **prevalence greater among males 10–14 years than among those ≥15 years**
 - 2.1 versus 1.3 per 100 000 procedures, PR=1.6 [95% CI: 1.2–2.1]
 - infections were most common NAE in both age groups
- **Glans Injury NAEs, 2015 - 2018**
 - Background:
 - 2010-2014: large proportion of glans injuries occurred with use of forceps-guided method
 - WHO and PEPFAR advised against use of forceps-guided method with boys under age 15 years or with those older than 15 with immature genitalia
 - most priority countries implemented this policy
 - Analysis:
 - 36 glans injuries
 - most (64%) were partial or complete amputations
 - all patients under 15 years (~0.6 per 100 000 VMMCs in this age group), with decreasing annual rate
 - all amputations among 10–14 year-olds using the forceps-guided method

Evidence on serious AEs: urethral fistula

- PEPFAR NAERS, 2015 - 2019
 - Among 41 cases of urethral fistula, 98% among males under age 15
 - (median: 11 years)
 - Incidence rate:
 - 0.61 per 100 000: under 15 years
 - 0.01 per 100 000: 15 or older
 - OR 51 (95% CI: 8.6–2060)
- Cases reported to WHO, 2015-2019
 - 37 cases from 9 countries
 - 35 cases between 6–15 years

Number of urethral fistula notifiable adverse events reported to PEPFAR, by age, 2015–2019 (N=41)



Source: Lucas T, et al. Case series of urethrocutaneous fistulas after VMMC for HIV prevention: 15 African countries, 2015–2019

Data indicate younger adolescents' risk of selected serious AEs is greater than those over 15 years of age. Due to likely underreporting, it is not possible to provide precise estimates of risk. More age-disaggregated data are needed.

Evidence on serious AEs: tetanus

- Among all cases of tetanus reported to WHO since 2012
 - a minority (21%) occurred in the 10–14 year age group
 - which constituted 46% of procedures during that time period
- In the 2017 updated WHO tetanus vaccine position paper, statements were strengthened on need for boosters, particularly among adolescent boys
 - TTCV should be routinely available to adolescent boys whether or not they undergo VMMC.

Human rights and ethical issues, informed consent and equity for younger adolescents

Jerome Singh
Head of Ethics and Law
Centre for the AIDS Programme of Research in
South Africa (CAPRISA)

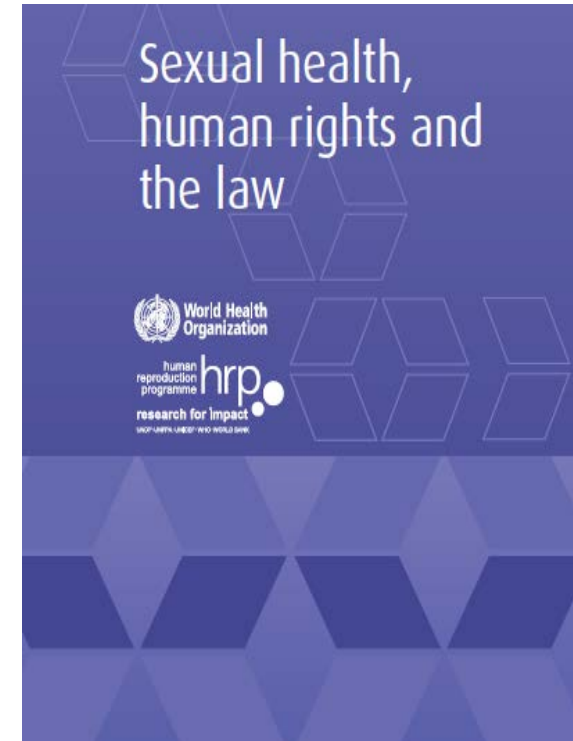


Ethics and human rights

- Human rights-based approach requires measures for safe procedure, with informed consent, without coercion or discrimination
- Protection and promotion of ethics and human rights is central to VMMC for adolescents.
- Adolescents' (particularly younger) evolving capacities have a bearing on their independent decision-making on their health issues (General comment No. 15 [2013] on the right of the child to the enjoyment of the highest attainable standard of health [Art. 24])
- Adolescents should have access to essential information for their health and development, and participate in decisions affecting their health (UN Convention on the Rights of the Child)
- Health care providers should strive to postpone non-emergency invasive and irreversible interventions until child sufficiently mature to provide informed consent. (Special rapporteur on the right to health, report to the General Assembly 2009 [Statement 49])

Informed consent and decision-making in the context of sexual and reproductive health

- WHO has developed guidance on informed consent and decision-making specific to sexual and reproductive health interventions, in line with international human rights statements.
- Many decisions relating to sexual health have an impact on people's ability to have a safe and satisfying sexual life and to have or not have children, so
 - Informed decision-making—which can include informed refusal of certain interventions—is particularly important.
- In the area of sexual health, informed decision-making includes fully understanding and accepting (or declining) a particular service or intervention.
- Individuals have the right to be fully informed about any treatment, intervention or other health services that they may seek or undergo.
 - Services should provide information in a clear and understandable way, including the likely benefits and potential adverse effects of proposed procedures and available alternatives.



Informed consent and decision-making

- Decision making capacity and autonomy of adolescents should be taken into account through processes such as informed consent and assent.
- Adolescents who are not able to provide autonomous informed consent may possess the ability to assent or dissent.
- As a general guide, informed consent should be sought from the child when the child is deemed mature enough to make an informed decision
- Usually, adolescents ages 15 years and older are able to give informed consent, while younger adolescents' ability to consent should be assessed case-by-case.

Four elements of informed consent

- 1. Disclosure.** The subject must be provided relevant information about the intervention, including its potential risks and benefits. Such disclosure should include informing the subject of his or her privacy rights and limitations thereto, and the health worker's disclosure obligations.
- 2. Understanding.** The subject must appreciate and understand the information provided. Understanding may be compromised when the subject is of a young age, lacks education or literacy, lacks the capacity to understand, or has a severe physical or mental illness affecting comprehension.
- 3. Voluntariness.** The subject's permission and actual participation should be free of coercion and be voluntary in nature.
- 4. Capacity.** The subject must possess the decision-making ability to give permission for the intervention. Decisional capacity or competence is determined by the "ability to understand material information, appreciate the situation and its consequences, consider the options, and communicate a choice".

Equity

- All adolescent boys should have a fair opportunity to access VMMC services, and none should be denied or discouraged from exercising this right to access, including vulnerable boys such as street children and those in child-headed households
- WHO recommendations on adolescent sexual and reproductive health and rights, states have obligations under human rights law to provide HIV prevention and care to adolescents.

Programme and implementation considerations

Mable Mweemba
Chief Adolescent Health Officer
Ministry of Health, Zambia

Community and parental engagement and communication



- Provide communities and parents accurate and balanced information on VMMC and its risks and benefits, address concerns.
- Provide adolescent clients, parents and guardians with information appropriate to the boy's age.
- Parents have a role to play in helping adolescents access other interventions provided in communities.
- Improve knowledge, address misconceptions of parents or guardians and provide meaningful guidance on puberty, sexuality and reproduction.
- Support parents in their roles in adolescent development, such as preparing girls and boys for puberty and building equitable gender norms.

Programme management responsibilities

- Monitor AEs among adolescents to further clarify and reduce risks.
- Implement data-driven quality improvement approaches and plans at all levels.
- Provide appropriate services to all adolescents and ensure meaningful engagement and participation.
- Provide health care workers and adolescent clients with enabling environment for effective solicitation, receipt and verification of consent and assent.



Needs of health care workers serving adolescent boys

- Technical competence to provide effective services and protect adolescents' rights to information, privacy, confidentiality, non-discrimination, non-judgmental attitudes and respect.
- Receive training on:
 - assessing adolescents' capacity to consent and how to engage parents in the informed consent process;
 - age-specific developmental considerations including
 - deferring the procedure to an older age and referral to a health care worker trained to perform MC on adolescents;
 - age-appropriate approaches to accurate and comprehensive HIV and sexuality education for adolescents;
 - refreshers to keep abreast of age-appropriate approaches to HIV health education and counselling;
- Understanding stages of adolescent development
- Determining maturity for informed consent.

**What other health services would be useful for
younger adolescents who cannot access
VMMC?**

**Venkatraman Chandra-Mouli
Scientist, WHO HQ, Department of Sexual and
Reproductive Health**

Essential package of interventions for school-age children and adolescents (ages 5–14 years)

Intervention	In primary health centres	In schools
Physical health		
Deworming	✓	✓
Insecticide-treated bed net promotion	✓	✓
Tetanus toxoid and HPV vaccination	✓	✓
Oral health promotion	Also treatment	✓
Correcting refractive error	Vision screening and provision of eye glasses	Vision screening and provision of eye glasses
Diet		
Micronutrient supplementation	–	✓
Multi-fortified foods	–	✓
Food provision	–	School feeding

Source: Bundy APD et al. Investment in child and adolescent health and development: key messages from Disease Control Priorities, 3rd Edition. *Lancet* 2017.

Essential package of interventions for adolescents 10–19 years

	Population	Community	Primary health	School
Physical health	Healthy lifestyle messages: tobacco, alcohol, injury, accident avoidance and safety	Adolescent-friendly health services	Adolescent-friendly health services: provision of condoms to prevent STIs; provision of reversible contraception; treatment of injury and abuse; screening and treatment of STIs	Healthy lifestyle education including accident avoidance and safety
	Sexual health messages	–	–	Sexual health education
	–	–	–	Adolescent-friendly health services
Nutrition	Nutrition education messages	–	–	Nutrition education
Mental health	Mental health messages	–	Mental health treatment	Mental health education and counselling

Source: Bundy APD et al. Investment in child and adolescent health and development: key messages from Disease Control Priorities, 3rd Edition. *Lancet* 2017.

Implications for policies & programmes

1. Engage with adolescents in open discussions about gender norms & attitudes that take into account their evolving cognitive capacities.



Commentary

Implications of the Global Early Adolescent Study's Formative Research Findings for Action and for Research

Venkatraman Chandra-Mouli, M.B.B.S., M.Sc.^{a,*}, Marina Plesons, M.P.H.^a, Emmanuel Adebayo, Ph.D., M.P.H.^a, Avni Amin, Ph.D., M.Sc.^a, Michal Avni, M.P.H.^b, Joan Marie Kraft, Ph.D.^b, Catherine Lane, M.P.H.^b, Clarissa Lord Brundage, M.P.H.^c, Tamara Kreinin, M.H.S.A.^d, Emily Bosworth, M.P.H.^d, Claudia Garcia-Moreno, M.Sc.^a, and Shawn Malarcher, M.P.H.^b

^aDepartment of Reproductive Health and Research, World Health Organization, Geneva, Switzerland

^bUnited States Agency for International Development, Washington, D.C.

^cBill and Melinda Gates Foundation, Seattle, Washington

^dDavid and Lucile Packard Foundation, Los Altos, California



The 5 C's of positive youth development

Asset	Definition	How to Foster It
COMPETENCE	Perception that one has abilities and skills	Provide training and practice in specific skills, either academic or hands-on
CONFIDENCE	Internal sense of self efficacy and positive self-worth	Provide opportunities for young people to experience success when trying something new
CONNECTION	Positive bonds with people and institutions	Build relationships between youth and peers, teachers and parents
CHARACTER	A sense of right and wrong (morality), integrity, and respect for standards of correct behavior	Provide opportunities to practice increasing self-control and development of spirituality
CARING	A sense of sympathy and empathy for others	Care for young people

THE TEEN YEARS EXPLAINED: A GUIDE TO HEALTHY ADOLESCENT DEVELOPMENT

By Clea McNeely, MA, DrPH and Jayne Blanchard

Implications for policies & programmes

2. Stimulate critical reflection to change attitudes and norms within peer groups

3. Tap into the reach and influence of media & technology

Peers can have strong positive or negative influences on adolescent health.

Social media use further extends the influence of peers on health. Online spaces have changed adolescent developmental tasks such as relationship & identity building which were mainly negotiated in face-to-face communication with peers.



Commentary

Implications of the Global Early Adolescent Study's Formative Research Findings for Action and for Research

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^d David and Lucile Packard Foundation, Los Altos, California

Our future: a *Lancet* commission on adolescent health and wellbeing



Research needs

Box 3.3. Research needs for age considerations

- Identify approaches to engage communities and parents for effective and acceptable delivery of male- and age-friendly health services.
- Assess service delivery approaches designed to maintain a high level of VMMC coverage.
- Assess the feasibility, effectiveness and cost of:
 - providing additional services to adolescents beyond the minimum VMMC service package and the contribution of these additional services to universal health coverage;
 - approaches that provide VMMC within a package of adolescent health services and the contribution of these approaches to sustainable development goals and universal health coverage;
 - uptake of other health services among boys ages 10–14 years, including those asked to defer circumcision until older.
- Identify effective training approaches to enhance adolescent health services.

Questions or comments?



*Away from the
screen break*

Agenda – Part 2

Moderator: Frank Lule	
Time	Topic and presenter
15.45 – 15.50	Introduction and overview of recommendations and WHO prequalification – Julia Samuelson
15.50 – 16.05	Evidence to inform recommendations on use of device-based methods: in situ and surgical assist – Tim Farley
16.05 – 16.15	Other factors: acceptability, values and preferences – Odoyo June Elijah
16.15 – 16.25	Questions and Answers
16.25 – 16.30	Wrap up - Moderator
End of Session 2	

Introduction and overview of recommendations and WHO prequalification

Julia Samuelson
Nurse epidemiologist
Global HIV, Hepatitis, and STIs Programmes
and
WHO Taskforce on Nursing and Midwifery

What are male circumcision devices?

- Devices used in a procedure that is alternative to conventional surgical methods (such as dorsal slit).
- Many devices on the market
- **In situ** devices: part of all of the device may remain on body for >24 hours. Include several types: clamp, elastic collar compression and ligature compression.
- **Surgical assist device**: removed from the body at the end of procedure. Includes clamps to crush and 'all-in-one guns'



Why and which device-based methods?

Device-based methods introduced, and additional evaluation done, to:

- **Simplify** procedure and/or reduce procedure time
- Potential use by **lower-skilled cadres**
- **Further improve safety**
- Increase **acceptability as alternatives to conventional surgery**
 - important for men who see aspects of surgery as a barrier to VMMC uptake (such as injected anesthesia, sutures—which are not necessary with some devices)

WHO recommendation in 2013:

WHO-prequalified male circumcision devices are efficacious, safe and acceptable as additional methods of male circumcision for HIV prevention among healthy men 18 years and older in high HIV prevalence, resource-limited settings

conditional recommendation

Review in 5 years

Prequalification

www.who.int/diagnostics_laboratory

- Promotes and facilitates equitable access to **safe, appropriate and affordable devices of good quality**
- Prequalified means a specific device has met relevant international standards on product performance, the manufacturer's quality management system, clinical safety and efficacy.
- **Not approval or endorsement** of a particular device; that is the prerogative of national programmes



Evidence for 2020 recommendation:

- data from all required studies described in the *Framework for clinical evaluation of devices for male circumcision*
- 2 in situ devices – 1 collar clamp (2 technique) and 1 elastic collar compression
- 1 surgical assist device with studies but not yet in PQ process

Updated recommendation

The use of WHO prequalified male circumcision devices is recommended as additional methods of male circumcision in the context of HIV prevention for males ages 15 years and older.

conditional recommendation, moderate quality evidence

- Evidence is limited on use at large scale

WHO prequalified male circumcision devices may be used as additional methods of male circumcision in the context of HIV prevention and in keeping with decisions whether to offer VMMC to adolescents ages 10 through 14 years

conditional recommendation, low quality evidence

- Evidence on use with a large number of younger adolescents is limited

Recommendations apply in settings where:

- a) the devices are used by health care workers, including physicians and mid-level clinicians, who are appropriately trained and competent in the use of the specific device; and
- b) surgical backup facilities and skills are available as appropriate to the specific device.

**Evidence to inform recommendations
on use of device-based methods:
in situ and surgical assist**

**Tim Farley, Statistician
Sigma3 Services**

Critical and important outcomes and evidence

- Priority outcomes
 - Critical
 - Eligibility (contraindications to method in addition to 'usual' VMMC exclusions)
 - Efficacy (successful circumcision by device method alone)
 - Safety (serious, severe and moderate adverse events)
 - Cosmetic result
 - Important
 - Procedure times
 - Acceptability – cosmetic result and time to return to normal daily living
 - Pain (before, during and after circumcision procedure)
 - Healing time
 - Odour
- Only concerned with circumcision devices with sufficient clinical data to be considered for the WHO Circumcision Device Prequalification process
- Published data, supplemented with information on clinical performance submitted by manufacturer to WHO

P: population
I: intervention
C: comparator
O: outcomes

Summary of studies: collar clamp device

Study type	Studies	Clients (age)		African countries	China	
					# studies	# clients
Conventional device placement technique						
RCT vs. surgical circumcision	3	263	(all ≥ 18 y)	KEN, UGA, ZMB	1	314
Concurrent cohort vs. surgical circumcision	2	845	(337 < 18 y) (508 ≥ 18 y)	UGA (2)		
Observational (single) cohort	7	2,427	(all ≥ 18 y)	KEN (4), MWI, ZMB (2)	5	2,355
Total	12	3,535			6	2,669
'No-flip' device placement technique						
Observational (single) cohort	3	654	(449 < 18 y) (200 ≥ 18 y)	KEN (3)	RCT 1 Obs 2	408 574

Followed WHO *Framework for clinical evaluation of devices for male circumcision* and minimum clinical evidence before considering prequalification:

- At least 2 RCTs each with at least 100 clients
- At least 2 field studies each with at least 500 clients
- Plus bridging studies for adolescents, comparison of scheduled ring removal at 7, 14 or 21 days, and no-flip placement technique

Age: participant under 18 years: conventional 10%; no-flip 69%
(under age 16 years: conventional 6%; no flip 56%)

Main outcomes: collar clamp device

- **Eligibility** 98.4% - 55 of 3,377 eligible men could not be circumcised with the collar clamp device, all due to lack of correct ring size in the clinic.
- **Efficacy**
 - Standard technique: Low failure rate of 3 per 1000 placements
 - No flip technique: One failure in 664 placements (most failures attributed to operator inexperience)
- **Safety: severe and moderate AEs**
 - Standard technique: 2.4%
 - No flip technique: 2.6% (similar patterns and proportions of AEs in adolescents and adults)
- **Acceptability**
 - Cosmetic result: 97% of clients reported satisfaction with penile appearance after the circumcision with the collar clamp device
 - Healing time: about one week longer than conventional surgery

Summary of studies: elastic collar compression

Study type	# studies	# clients	Countries
Standard placement and removal procedure			
Case series	2	152 (all ≥ 18 y)	RWA (2)
RCT	2	304 (all ≥ 18 y)	RWA, ZWE
Concurrent cohort	1	350 (all ≥ 18 y)	UGA
Observational (single) cohort	3	903 (402 < 18 y) (501 ≥ 18 y)	RWA, ZWE (2)
Pilot implementation	9	5,053 (83 < 18 y) (4970 ≥ 18 y)	BWA, IDN, KEN, MOZ, MWI, RWA, UGA, ZAF,ZMB
Active surveillance	3	2,641 (618 < 18 y) (2023 ≥ 18 y)	ZAF, ZBE, ZMB
VMMC Programme	1	3,452 (all ≥ 18 y)	ZBE
Day 0 foreskin removal procedure			
Research studies	5	1,254 (~5% < 18 y)	KEN (3), RWA, ZMB

- Followed WHO *Framework for clinical evaluation of devices for male circumcision*
 - Case series, RCTs, field studies, bridging studies (adolescents, HIV +ve men), pilot implementation, active surveillance
- **Age: participants under 18 years: 1,103 / 12,855 (9%)**

Main outcomes: elastic collar compression device

- **Eligibility**

- Many clients (8% overall) not eligible for device due to phimosis and/or adhesions preventing easy foreskin retraction – 6% ages \geq 18 yrs compared to 26% ages $<$ 18 yrs

- **Safety**

- Generally low AE rates (overall 2.8%, higher in pilot implementation studies, lower in VMMC programmes)
- Most serious AE type: device displacements and/or self-removals requiring prompt intervention by experienced surgeon, occurred in \sim 1 in 150 clients

- **Tetanus** (intensive surveillance 2014-2016)

- Device: 6 cases in 114 k procedures Incidence 5.3 (1.9 - 12) per 100 k
- Surgery: 6 cases in 3.72 million procs Incidence 0.16 (0.06-0.35) per 100 k
Incidence ratio 33 (8.7 – 120)

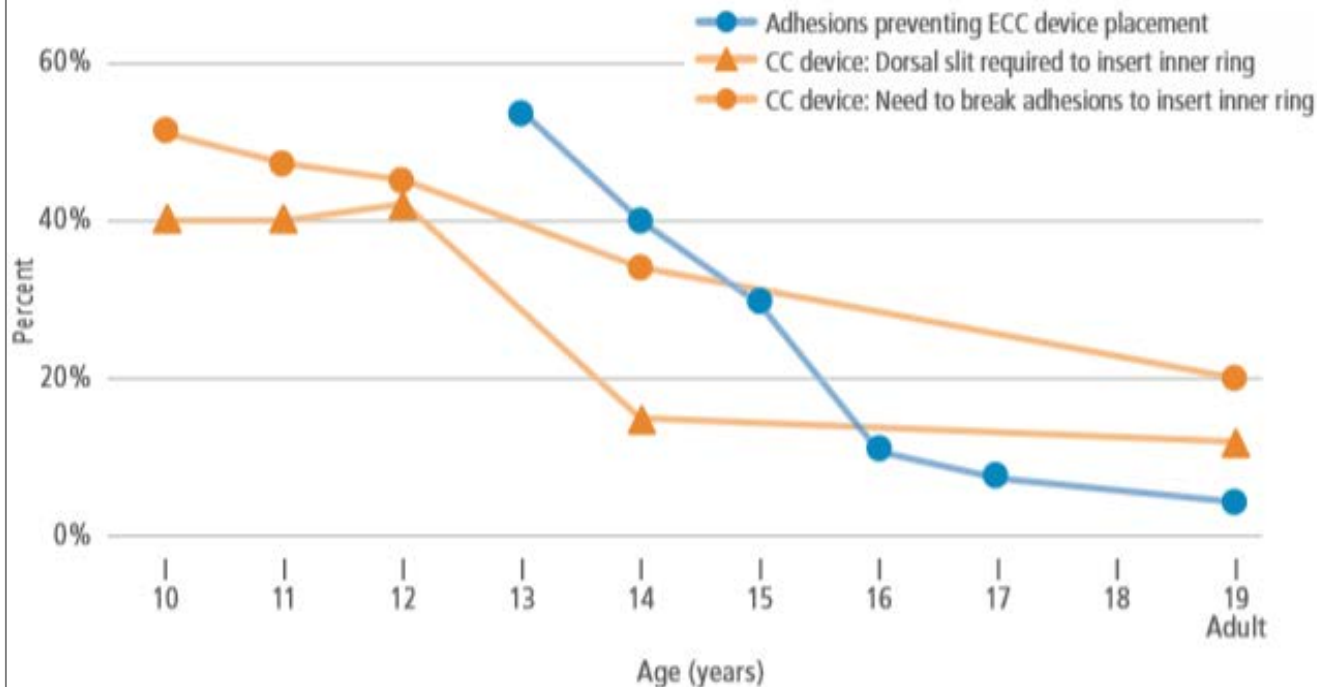
- Risk mitigation through tetanus toxoid vaccination 6 w and 2 w before placement
- Major impact on device uptake and programme costs
- Day 0 foreskin removal procedure developed to obviate need for vaccination
- High slippage and bleeding rates in first studies, procedure for foreskin cutting 30 mins after placement not standardized, tetanus risk unclear

- **Other outcomes**

- Some pain on device removal, healing times about 1 week longer than surgical circumcision, good final cosmetic result

Foreskin conditions by age

Fig. 3.2. Proportion of foreskin conditions affecting eligibility for some male circumcision methods, based on three studies on device-based methods



ECC = elastic collar compression device; CC= collar clamp device.

Source: Awori, 2019 (216); Barone, 2019 (211); Tshimanga, 2016 (212).

Adhesions or narrow foreskin

- Prevent placement of elastic collar compression device
- Require intervention before placing collar clamp device
- Breaking adhesions before device placement of collar clamp device associated with more pain and oedema
- Need to supplement routine topical anaesthesia with injectable anaesthesia before procedure in clients with adhesions

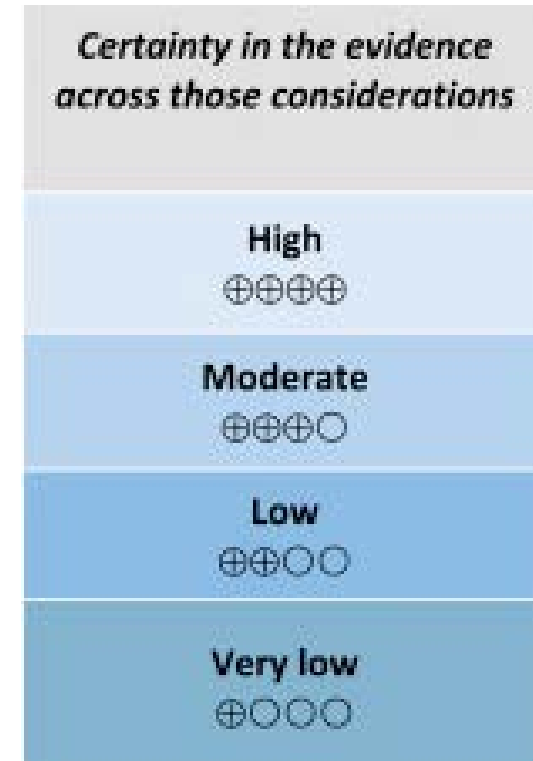
Summary of studies and outcomes: surgical assist device

Study type	# studies	# clients	Countries
RCT	2	150 (all ≥ 18 y)	ZAF (2)
Observational (single) cohort	3	214 (54 < 18 y) (160 ≥ 18 y)	ZAF (3)

- Limited clinical evidence on safety, efficacy and acceptability of device
- First RCT demonstrated device concept but 17 of 100 clients required sutures to control bleeding, attributed to poor design and manufacturing processes
- Revised device with stronger and more uniform crushing force, packed as single unit ready to use
- Topical anaesthesia sufficient to manage pain while crushing force applied
- Outcomes (with revised device)
 - No device-specific exclusions
 - 99.5% men successfully circumcised with device alone
 - Moderate AEs 14 / 264 - 9 (3%) required suture to control post-op bleeding
 - Neat uniform circumferential wound, 90-95% fully healed by 4 weeks
- Additional data required on clinical performance when used under field conditions by greater diversity of providers

Evidence quality

- In-situ devices:
 - moderate quality for device use among males ages 15 years and older
 - low quality for those 10 through 14 years
- Surgical assist devices
 - low quality



Collar clamp device – country implementation

Implementation phase	KEN	MOZ	MWI	NAM	RWA	TNZ	UGA	ZWE	ZMB
Training	✓	✓	✓	✓	✓	✓	✓	(✓)	✓
Implementation pilot study	✓	(✓)	✓	✓	-	✓	✓		✓
Active AE follow-up ('active surveillance')	✓		✓	✓	✓	✓	✓		✓
Passive AE follow-up (routine services)	✓		✓	(✓)		(✓)	✓		✓
Legend	✓ : ongoing			✓ : completed			(✓) : Planned		

Implementation pilot study (~500 clients)

- Is device as safe, effective and acceptable as in studies submitted for PQ?
- Pilot testing logistics

Active AE follow-up ('active surveillance') (first ~1,000 clients)

- Is device as safe, effective and acceptable when provided at scale?

Passive AE follow-up (routine services)

- Is device as safe, effective and acceptable when provided at scale with routine/passive follow-up?
- Monitoring for adverse events, identifying issues that need correction and/or (re)training

**Other factors:
acceptability, values and preferences,
costs, feasibility**

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U.S. Centers for Disease Control and
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Acceptability of device-based methods



Evidence/information

- Generally high rates of satisfaction with the cosmetic result reported among adult men and adolescent boys
- Studies consistently found that circumcision using devices interfered minimally with clients' work or daily activities; however, evidence was limited.
- Acceptability may vary by type of device and procedure e.g. bad odour while wearing elastic collar compression but not collar clamp device

Key Message

The existing evidence suggests that device-based VMMC is acceptable among adult men and adolescent boys.

Values and preferences regarding devices



Evidence/information

- Studies provided in indirect evidence of factors that influence men's decision to go for device based circumcision
- Time to healing from in situ placement takes 1-2 weeks longer, Counselling on longer period of abstinence from sex than after a surgical MC is a priority. While wearing the device, abstinence is essential.
- Procedure times were less than the times required for conventional surgery. This includes times at both the visit to place and the visit to remove the device.
- Providers: ease of procedure is a key facilitator to acceptability; better results.
- Views from female sexual partners, the wider communities, policy-makers and funders are not currently unknown.
- Programme managers expressed the importance of prequalification status to guide use of devices.

Key Message

Evidence is limited on how the commonly stated barriers or facilitators influenced clients' decision to undergo device-based VMMC.

Cost implications of using device-based methods



Resource use and cost

Evidence/information:

- Costs for device-based VMMC varied according to type of device used.
- Consumables and staffing costs are substantial contributors to total cost.
- Shorter duration of the procedure than with surgical methods, thus associated with lower cost of clinician time. However, costs of the device and associated medical supplies, as well as costs of device removal should be noted.
- Existing evidence focused on the use of elastic compression and collar clamp in situ devices. The costs of other VMMC devices remain unclear.

Key Message

Limited data on cost of device based methods.

Effect of device-based methods on equity and feasibility



Equity and ethics

Evidence/information:

- Evidence lacking on the impact of device-based VMMC on health equity.

Key Message

No evidence the effect of devices equity

Feasibility to deliver

Evidence/information:

- Evidence lacking on constraints/barriers to implementing device-based methods.
- To date, limited VMMCs performed using devices, but feasibility has been high where they have been used, including permitting less surgically skilled providers to perform MC. VMMC scale-up has been achieved largely with surgical VMMC

Key Message

Mixed. No evidence of barriers to the use of in-situ devices; requirement of TT for ECC device limits its use.

Key points

- Each circumcision device is unique. WHO prequalification is provided only for specific device products.
- Differences in eligibility exist among device types and with conventional surgical methods.¹ A small proportion of adult men are not eligible for device-based methods; for younger adolescents a large proportion are not eligible.
- When device-based procedures are performed by appropriately trained health care workers, their safety (based on rates of mild, moderate and severe AEs with various devices) has been similar to that of conventional surgery. However, the elastic collar compression device type has been associated with tetanus, which is rare but has a high case fatality rate. Tetanus is preventable, but offering 2 doses of TTCV prior to VMMC resulted in low VMMC uptake.
- Healing times after in situ type device-based procedures are one to two weeks longer than after surgical circumcision since healing is by secondary intention. For surgical assist methods, healing may be shorter or similar to that for conventional surgery.
- Device-based methods may have some benefits over surgical VMMC, although these advantages are not yet clearly established:
 - Procedure time is shorter; however, a second visit is required for device removal.
 - Most men and adolescent boys consider device-based methods acceptable. These methods may reduce loss of work or school time, and they provided a more regular cosmetic result.
 - Health care providers find device options simpler and easier to use.
- Costs of device-based methods are similar to those of surgical methods. Scale-up may yield efficiencies.
- Implementation and scale-up require post-market surveillance (23, 230).

Questions or comments

YOUR FEEDBACK REQUESTED

TYPE IN CHAT WINDOW NOW

- 1. Would you like more information on any of the topics covered today? Please specify.**
- 2. Would additional technical resources or tools assist you in implementing VMMC to reflect these updates? Please specify.**



Wrap up

<https://www.who.int/publications/i/item/preventing-hiv-through-safe-voluntary-medical-male-circumcision-for-adolescent-boys-and-men-in-generalized-hiv-epidemics-guidelines>