



PEPFAR

U.S. President's Emergency Plan for AIDS Relief

VMMC COP20 Technical Priorities

What Does PEPFAR COP20 Guidance Mean for VMMC Programs and Demand Creation?

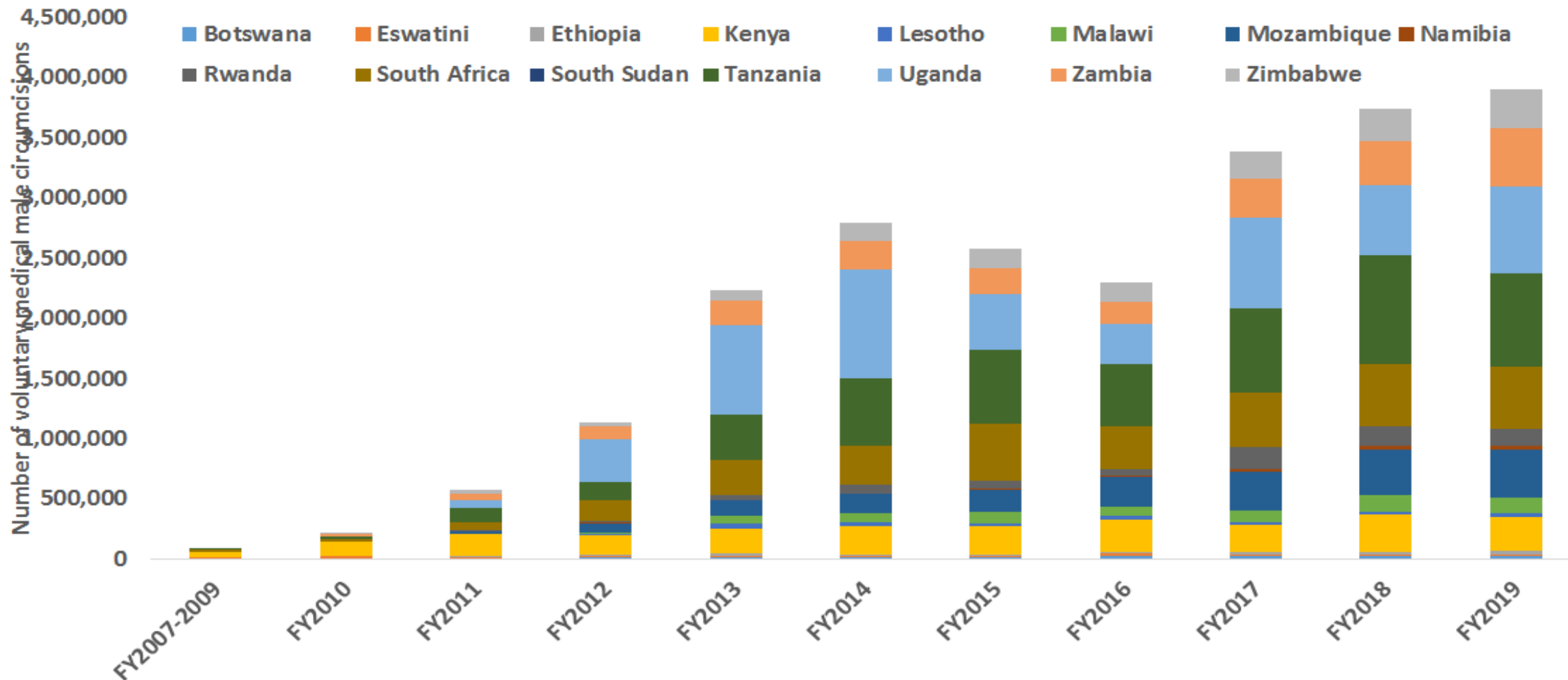
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17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

PEPFAR has supported nearly 23 Million men for VMMC through FY19



VMMC Progress Report, 2019, Total MCs =22, 901,129

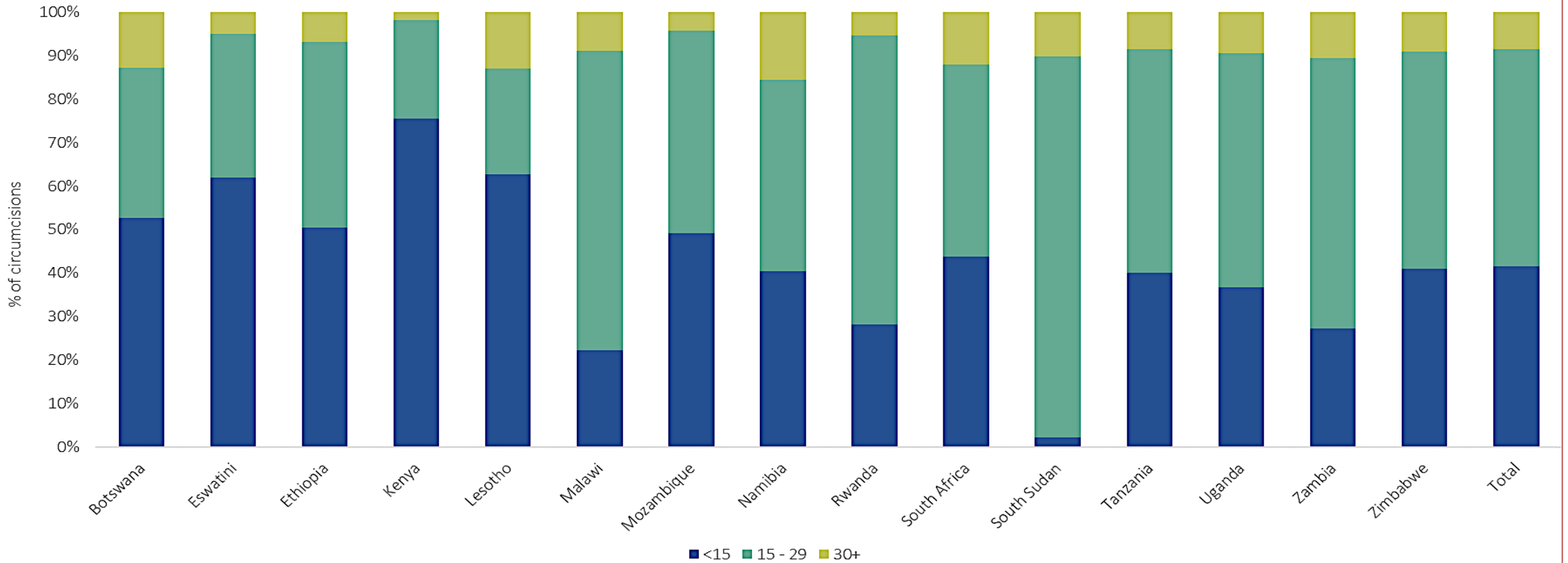
Source: WHO/UNAIDS



17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

Young adolescents 10-14, have been making up a large proportion of the program

Proportion of circumcisions by priority age bands, All OUs, PEPFAR FY19, Q3 All Agencies



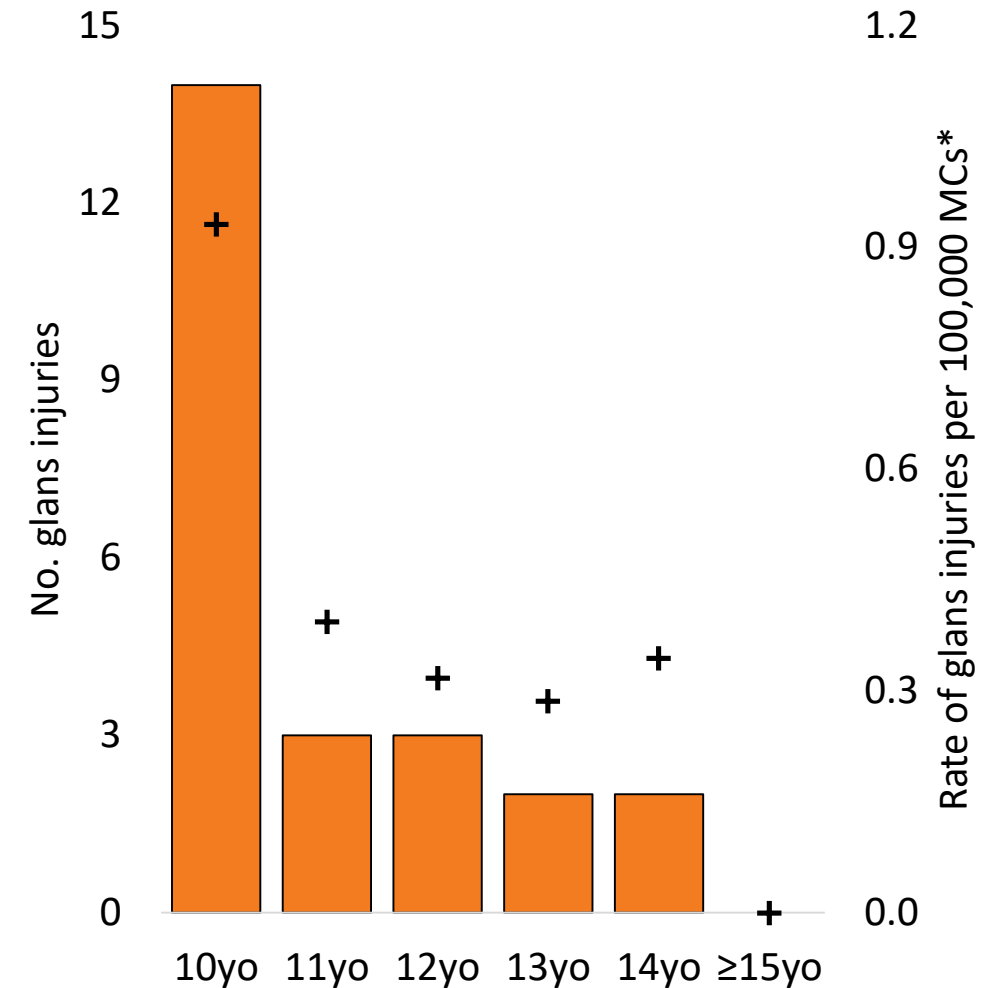
Source: Panorama

Minimum Age for VMMC

- VMMC is an elective procedure, so safety must be the primary focus when implementing it
- A review of NAEs by age group showed that 100% of Glans injuries and 90% of urethro-cutaneous fistulae occurred in clients <15 years. NAEs doubled in clients <15 years and were almost 10-fold in infants (EIMC).
- Glans injuries have persisted despite changes implemented to prevent them.
- Methods to prevent fistula less clear; most are related to small size of penis.
- Given elective and significant nature of procedure, need to ensure that informed consent is obtained from client; and parental/guardian consent documented for minors.

Glans Injuries during VMMC are exclusively in clients <15

- 27 glans injuries reported from 2015-2018 (9 countries)
- 100% of cases in patients aged <15 years
- Forceps-guided inappropriately used in vast majority
- All cadres involved (i.e., physicians, clinical officers, nurses). Physicians most common
- Tissue handling often inadequate
- Overall, difficult to repair;
 - Time-to-repair often too long (>6 hours in 50% cases where known)
 - A minority of attempted repairs were viable in the short-term (3 of 15 with known value)



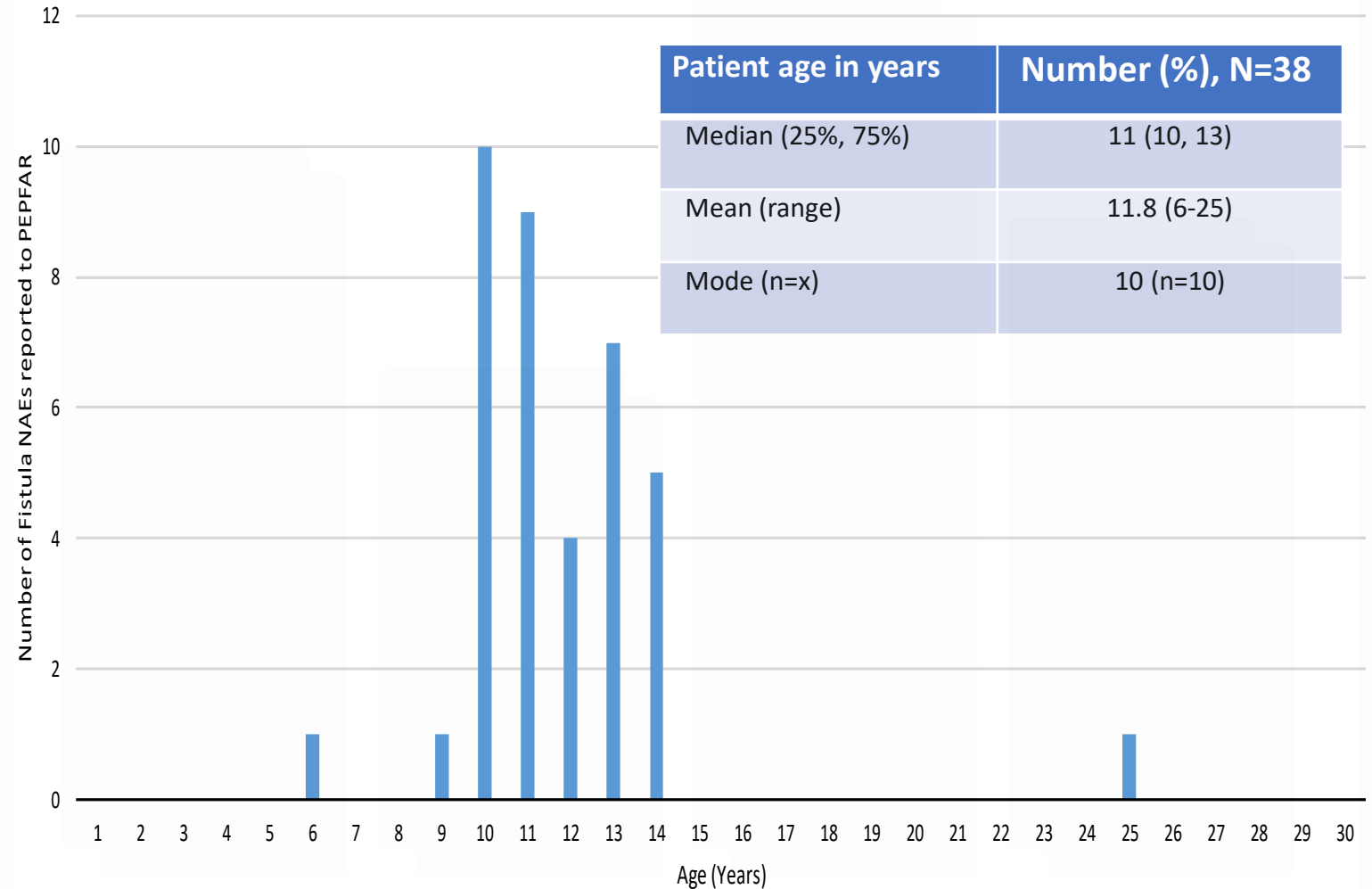
*Rates calculated through convenience sample of age-disaggregations shared by partners, representing 29% of all MCs in 10-14yo during 2015-2018

Source: CDC

Urethro-cutaneous fistula

- 38 cases of fistulas reported to PEPFAR 2015-2019
 - Reported across 10 countries
- Can happen to all cadre types and at any level of experience.
- Prevalence of dorsal slit method likely due to policy against forceps-guided in young clients.
- Hemostatic and skin sutures in frenular region still possible etiology although risky variations in surgical technique unlikely to be documented in the clinical record

Number of Fistula NAEs Reported to PEPFAR by Age, 2015-2019, N=38



Source: CDC

VMMC Change in Age

- Age Band Change

The lower age for VMMCs is now 15 years

- Below 15 for only those who have reached Tanner stage 3 of sexual development: presence of coarse pubic hair and significant growth in external genitalia
- Client must be able to understand options and give informed consent
- Shang ring may be considered < 15 with HQ approval and same informed consent requirement
- WHO will be releasing similar guidance with more details on informed consent issue

No infant circumcisions will be supported in COP20

While the change officially occurs in COP20, programs must immediately assure that those < 15 undergoing VMMC and their parent/guardian are aware of the increased risk of complications with VMMC at this age and of the option to postpone surgery until full sexual maturation

Boys presenting below age 15 can be offered age appropriate comprehensive risk reduction education and information on returning for VMMC. For countries where tetanus immunization is < 70% in this birth cohort, tetanus immunization can be provided if vaccine funded by host government.

Source: COP20

Tanner staging in young adolescents

Sexual Maturation Rating Male Genitalia (Tanner Stage)

- Stage 1
 - Preadolescent- testes, scrotum, and penis are similar in size to early childhood
- Stage 2
 - Testes and scrotum are enlarged, scrotum skin shows change in texture
- Stage 3
 - Penis has enlarged, mainly in length, testes and scrotum continue to enlarge
- Stage 4
 - Penis is further enlarged in length and breadth with development of glans, scrotal skin becomes darker
- Stage 5
 - Penis is adult in size, no further growth occurs



Additional VMMC guidance I

- **Suture change**

To further reduce risk of fistula formation, all programs should immediately begin using a 4.0 suture on a 19mm 3/8 circle reverse-cutting needle for VMMC in younger clients.

- In the future, VMMC supply kits will be changed to include this suture/needle combination as standard. In the meantime, teams should assure that this suture/needle option is available as an add on for VMMC in clients under age 15 to reduce the risk of fistula formation.
- This suture/needle combination is appropriate for VMMC in all age groups.

- **Lot numbers**

The lot number and batch of local anesthetic should be recorded on the VMMC record so that in case of adverse events the lots can be tracked

Source: COP20 Guidance

Additional VMMC guidance II

- **Other safety considerations**
 - Ensure adequate lighting for procedures
 - Limit caseloads/day for providers
 - Diathermy should not be used in frenular area or on clients with small penises
- If a fistula is diagnosed, the client must be referred to a specialist with experience in their management.
 - Each country team should identify experts for fistula management, potentially in another country
 - IP's should provide support for referral and follow up care
- Use data such as PHIA to target high risk men
 - Link to FCI and other initiatives reaching men to offer VMMC to those testing negative
 - Consider linking to STI and other clinics identifying high risk

Partners should discuss this guidance with all staff, especially, Providers and counsellors.

Key take away messages I

- **Minimum Age:** 15+; lower targets; age targeting; high risk men; no primary (but tertiary or higher) school campaigns; scale up what works for bringing in the hard to reach; high risk men
- **AEs prevention and management:** safety first; must continue monitoring AEs, even among older clients; AE management protocols in place, understood and followed.
- **Alternative safer methods:** explore, document safety, and costs of shang ring. Use in lower age groups must be approved. Safety improves demand.
- **Country Policies:** policies on eligible or target population for MC are variable across countries and may include EIMC or MCs for 10-14 year-old clients. Country programs supported by other funders may circumcise clients 10-14, or conduct EIMC. These are not bound by PEPFAR. We encourage country programs to ensure safety and follow WHO guidelines.

Key take away messages II

- **Suture and needle size changes:**
 - ✓ 4.0 sutures and 19mm 3/8 circle reverse-cutting needle are appropriate for all age groups
 - ✓ Providers need to be more cautious with smaller boys.
 - ✓ All providers must be competent or re-train in VMMC.
- **CQI:** be scaled up at all facilities, including in campaigns. Safety improves demand
- **Messages for 10-14, who continue seeking services:** provide appropriate messages to our future clients, and their parents. Messages should be discussed with all staff and clients who are eligible.
- **Informed consent (IC) documentation:** IC needs to be understood and AE information updated in the Informed consent document, for clients and parents of minor clients

Thank you