POLICY BRIEF

PREVENTING HIV THROUGH SAFE VOLUNTARY MEDICAL MALE CIRCUMCISION FOR ADOLESCENT BOYS AND MEN IN GENERALIZED EPIDEMICS: RECOMMENDATIONS AND KEY CONSIDERATIONS

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SUMMARY OF UPDATED RECOMMENDATIONS AND KEY CONSIDERATIONS

Reaching the 2030 HIV incidence goals in East and Southern Africa and then keeping HIV incidence at low levels will require the right combination of effective prevention interventions at high coverage levels. Voluntary medical male circumcision (VMMC) should be one of these interventions.

Updated recommendations on VMMC

1. VMMC should continue to be promoted as an additional efficacious HIV prevention option within combination prevention for adolescents age 15 years and older and adult men in settings with generalized epidemics to reduce the risk of heterosexually acquired HIV infection.
2. 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; this recommendation may apply for younger adolescents, ages 10 through 14 years, depending on the decision whether to serve that age group.

Key considerations

1. Decisions on offering VMMC to younger adolescents, 10–14 years, must consider several factors based on new safety evidence, human rights guidance, public health burden and the delayed impact on HIV incidence, and the capacity of health care providers.
2. A range of service delivery approaches has been studied across diverse settings, such as health facilities, communities, homes and schools, to enhance uptake of VMMC, with some evidence of effectiveness. Countries and implementers can consider which evidence-based approaches are most suitable for their population and context.
3. The use of economic compensation to enhance uptake of VMMC may address access barriers by reducing transport costs and reducing opportunity costs from wages lost during and after the procedure; decisions on its use require community engagement and consideration of context.
4. To sustain high VMMC coverage levels and the resulting benefits in HIV prevention, VMMC services should focus on older adolescents and be embedded within routine health services that are high quality, people-centred and widely accessible.

[1] Male circumcision is the complete surgical removal of the penile foreskin. "Medical" male circumcision is used to differentiate male circumcision delivered by the formal health sector from male circumcision by traditional providers.

WHY VOLUNTARY MEDICAL MALE CIRCUMCISION

In 2007 the United Nations Joint Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) recommended VMMC to reduce the risk of men heterosexually acquiring HIV infection. The recommendation was based on strong evidence of a 59% (44%–70%) reduced risk (efficacy) in ideal research settings.

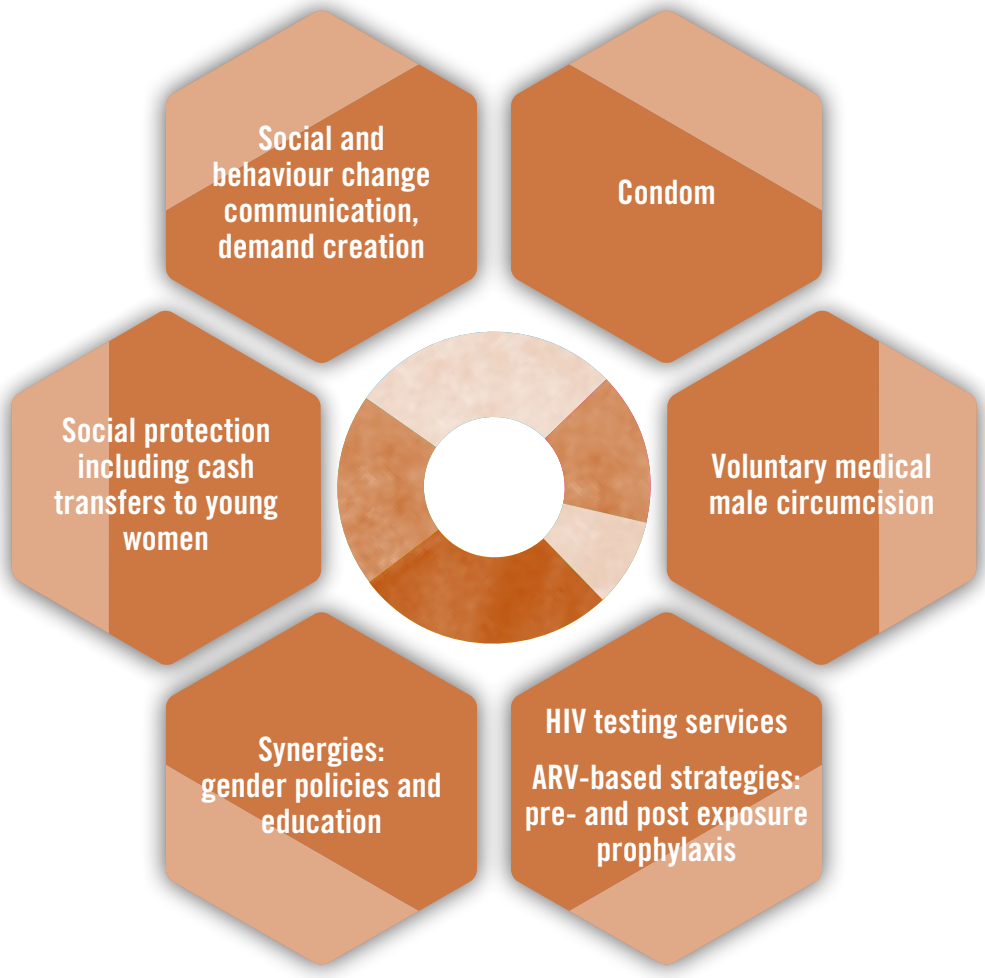
Since 2007, more than 23 million VMMC procedures have been performed in the 15 priority countries of East and Southern Africa, where in 2019 about half of all new HIV infections occurred. Through 2018 these procedures averted an estimated 250 000 HIV infections. Future benefits will be even larger, given VMMC's lifelong partial protection. The number of HIV infections averted by circumcisions through 2018 is projected to grow to 1.1 million by 2030.

In recent years other evidence-based HIV prevention options have been scaling up, including oral pre-exposure prophylaxis (PrEP) and HIV antiretroviral therapy (ART), with its secondary HIV prevention effect, along with already known interventions such as condom use and post-exposure prophylaxis. In the ongoing effort to end the AIDS epidemic, a re-examination of the role of VMMC in HIV prevention shows that the intervention remains important alongside other effective behavioural and biomedical HIV prevention interventions, as shown in Fig 1.

Evidence that medical male circumcision reduces a man's risk of heterosexual acquisition of HIV by 59% from three "gold standard" efficacy trials is supported by strong and consistent evidence of an overall 50% reduction in risk from 17 observational studies in diverse settings, including when implemented alongside ART, with its secondary prevention effect.

VMMC should remain an additional HIV prevention option within combination prevention for adolescents 15 years and older and for adult men in settings with generalized epidemics.

Fig. 1. Combination HIV prevention package in high HIV burden settings



VMMC remains an effective intervention in the combination HIV prevention package in high HIV burden settings and services offer men other interventions in the package.

EVIDENCE UPDATE ON VMMC FOR HIV PREVENTION

The high-quality evidence that medical male circumcision reduces men's risk of heterosexual acquisition of HIV by 59% (44%–70%) from three randomized controlled trials (RCTs) is supported by strong, consistent evidence of an overall 50% (44%–56%) reduction in risk from 17 observational studies conducted between 1986 and 2017. These studies included settings where VMMC services have been implemented in communities alongside other HIV prevention interventions and ART scale-up. Among men at higher HIV risk (for example, truck drivers, STI clinic patients, men with serodiscordant partners), combined results from five studies demonstrated a 71% reduction in the risk of heterosexually acquired HIV.

Other key points and programme considerations

- VMMC is a one-time, lifelong, partially protective intervention and, therefore, not affected by the realities of daily life that contribute to suboptimal adherence to ARV-based prevention or ART. However, VMMC should always be considered as part of combination HIV prevention.
- A minimum package of services, including safer sex education, condom promotion, the offer of HIV testing services and management of STIs, must be delivered along with the male circumcision procedure. Additional services, such as hypertension and/or tuberculosis screening, malaria management and tetanus toxoid-containing boosters, could be added to take full advantage of a man's contact with health services.
- Quality and safety remain top priorities for the provision of VMMC services and can be enhanced through consistent quality management, monitoring and reporting of adverse events (AEs) and promotion of a culture of learning for client safety.
- VMMC programmes are cost-effective and cost-saving in many countries of East and Southern Africa, when compared with lifetime costs of ART. In fact, the total cost of a VMMC procedure is similar to ART costs for a single year. Circumcising 15–29 year olds maximizes the cost-effectiveness of VMMC, requiring the fewest circumcisions to prevent one HIV infection of any age range. Focusing on men who have more than one sexual partner would further minimize the number of VMMCs—and, therefore, the cost—per HIV infection averted.
- As VMMC programmes expand and fewer men acquire HIV, women are benefitting indirectly from the lower risk of HIV infection in circumcised men. Women may also be less likely to acquire HIV infection from an HIV-positive man (who is not virally suppressed on ART but) who is circumcised than from one who is not, except when the man is recently circumcised and healing.
- Circumcised men and their female partners experience lower rates of several sexually transmitted infections, including human papillomavirus, herpes simplex virus-2, bacterial vaginosis and Trichomonas vaginalis, than uncircumcised men and their female partners.
- VMMC should be offered through the formal health sector, performed by competent trained health professionals. Evidence showed that procedures have been performed safely by several different cadres of health care workers (mostly clinical officers, nurses and physicians).
- Adverse events can occur during or after VMMC. Low rates of severe and moderate AEs were reported from diverse service delivery settings. Severe AEs were rare, including tetanus, urethral fistula and other penile injuries, and complications from unrecognized bleeding disorders.
- VMMC has proved feasible. However, challenges remain to achieving greater coverage, especially for men who are at greatest immediate risk.

USE OF DEVICE-BASED METHODS FOR MALE CIRCUMCISION

In 2013 WHO issued a conditional recommendation for the use of devices as efficacious and safe methods of surgical male circumcision; this recommendation was to be reviewed in five years. Although through 2018 the use of devices was limited, moderate quality evidence shows that device-based surgical methods offer a safe and acceptable alternative to conventional surgery. Also, they have the potential to make the procedure simpler and less resource-intensive, as they can be used by non-physician health care workers. Thus, these methods offer additional options to clients and health care workers and have the potential to expand coverage and increase programme impact.

Circumcision with WHO-prequalified devices offers a safe and acceptable alternative to conventional surgery. Device-based methods have the potential to make VMMC simpler and less resource-intensive and can be used by non-physician health care workers.

The evidence that informs the updated recommendation on male circumcision devices was restricted to data on devices that meet the full set of required studies described in WHO's *Framework for clinical evaluation of devices for male circumcision*[1] (Table 1). The evidence covered two types of in situ devices – one collar clamp device and one elastic collar compression device – and one surgical assist device.

Further evidence is needed to assess the safety and advantages of in-situ devices at scale in routine health care settings. Decisions on device-based methods for younger adolescents must take into account the general issues concerning the offer of VMMC to younger adolescents (see next section). There is also uncertainty about some aspects of patient acceptability and programme costs. Given the potential advantages of male circumcision with in-situ device methods, further assessment will better inform their use.

New evidence was available on the circumcision procedure with the use of a surgical assist device, which can be completed in a single visit, whereas in-situ device methods require that all or part of the device remains on the penis for up to one week. Wound healing with the surgical assist device is comparable to healing after conventional surgical circumcision. The cosmetic result is a uniform wound with no signs of recent suturing. More information needs to be collected on the safety of the surgical assist device when used by mid-level clinicians. As well, programme considerations such as training and supply requirements need to be explored.

Table 1. Benefits and disadvantages of in situ devices compared with conventional surgical methods

Issue	Benefit	Disadvantage
Eligibility	Device-based methods offer men a choice regarding the type of procedure. Devices were acceptable to many clients. No evidence exists, however, whether this has a positive effect on uptake of VMMC.	Slightly more men are ineligible for a device method than for surgery, especially younger adolescents. Conventional surgical male circumcision needs to be available as a back-up method for these men.
Procedure time	Device-based procedures take less than half as long as surgery. This includes times for both device placement and removal.	Services must be organized to accommodate two visits at an interval of one week.
Adverse events	The great majority of AEs associated with the use of devices were considered mild or moderate. [More evidence is needed on the safety advantages for adolescents of the no-flip collar clamp method as well as on use of topical anaesthesia.]	The greater risk of tetanus with the elastic collar compression method requires actions (vaccination) to mitigate that risk, requiring additional visits prior to male circumcision procedure. With the device-based methods, a few events, including device displacements and slippage, require immediate or urgent surgical intervention to prevent potentially serious long-term outcomes; therefore, such skills must be available.
Ease of use	Health care workers see device-based methods as simpler for them than conventional surgery and requiring less time.	—
Healing time	—	Healing times for in situ devices are one to two weeks longer (given secondary intention healing) than for conventional surgical circumcision. The longer healing period requires a longer period of sexual abstinence or conscientious condom use before wound healing.
Follow-up	—	[Potentially a disadvantage, but evidence is lacking as to whether the mandatory second visit with a device method limits acceptability.]

[1] https://www.who.int/hiv/pub/malecircumcision/framework/en/.

ISSUES AND KEY CONSIDERATIONS REGARDING VMMC FOR YOUNGER ADOLESCENT BOYS

In many settings VMMC for HIV prevention has been provided to younger adolescents. To maintain effective HIV prevention coverage levels, programmes need to determine which age range to focus on. The Guideline Development Group concluded, based on limited evidence and other factors, that, in deciding whether to offer VMMC to younger adolescents, ages 10–14 years, several factors should be considered and balanced within a national and local context.

- **Burden and effectiveness.** The public health burden of HIV and the prevention effectiveness of VMMC should be assessed. Circumcising boys in the 10–14 age group in high HIV prevalence settings will avert HIV and STI infections in the future but not immediately if the individual is not yet engaging in heterosexual activity. The reduction in HIV risk is expected to be the same for all circumcised men regardless of the age at which the procedure is performed.
- **Consent.** Adolescents' capacity to give informed consent varies. Like physical, emotional and intellectual capacity, children's capacity to make independent decisions that affect their own health evolves at varying rates. Some boys 10–14 years may have the capacity to give consent for VMMC, while others may not. Usually, adolescents ages 15 years and older are able to give informed consent. For younger adolescents, assessments as to whether a boy can give informed consent should be made on a case-by-case basis.

  Several factors should be considered in deciding whether to offer VMMC to younger adolescent boys, including their capacity to give informed consent, thus respecting their human rights, and safety, thus reducing risk of rare serious adverse events.

  As a general principle, health care providers should seek to postpone non-emergency invasive and irreversible interventions until the child is sufficiently mature to provide informed consent.

  Laws or regulations should stipulate a minimum permissible age for consent to VMMC or refer to assessment of the evolving capacity of the individual child. Programmes should have supportive policies in place, and boys, parents and health workers should have adequate rights-based guidance on consent, assent and confidentiality.
- **Safety.** VMMC services must assure the lowest possible risk of adverse events. Limited evidence has shown differences in the type of serious adverse events among adolescent age groups with use of conventional surgical methods and a higher rate of certain rare serious adverse events (particularly glans injury and urethral fistula) in the 10–14-year age group than in older adolescents. The precise magnitude of risk of these serious adverse events among younger adolescents is unknown but appears to be low.

  VMMC for adolescents with immature genitalia should be deferred until they are more developed physically. Male genital growth to nearly adult size is most often complete by 15 years. While most adolescents age 15 and older are physically mature, preventing serious adverse events among that age group when not yet physically mature means that some older adolescents may need to be deferred until more developed.
- **Feasibility.** VMMC presents an opportunity to offer other interventions. The feasibility of offering some aspects of the VMMC package and other services, such as comprehensive sexuality education and internationally recommended vaccinations (for example, tetanus toxoid-containing vaccination, recommended between ages 9 and 15 years), at specific adolescent ages, followed by the surgical procedure at a later age, is unknown.
- **Adolescents', parents' and communities' preferences** should be considered, including preferences concerning VMMC provided by the formal health sector rather than seeking male circumcision by traditional practitioners.
- **Health care workers serving adolescent boys** should:
  - have the technical competence to provide adolescent-friendly health services and to protect and fulfil 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 and physical conditions, including those that require deferral or referral; and age-appropriate approaches to accurate and comprehensive HIV and sexuality education and counselling;
  - be able to assure a meaningful, age-appropriate, comprehensible informed consent process for every client capable of giving consent and how to advise and assist those who cannot yet give consent.

Further research is needed on services and service delivery approaches that are friendly to adolescent males and more integrated within routine health services and other sectors; on costs; on effective training approaches to assure health care providers' competence; on the consequences of delaying medical male circumcision for younger adolescents, such as loss to follow-up or turning to procure circumcision from traditional or unqualified circumcisers.

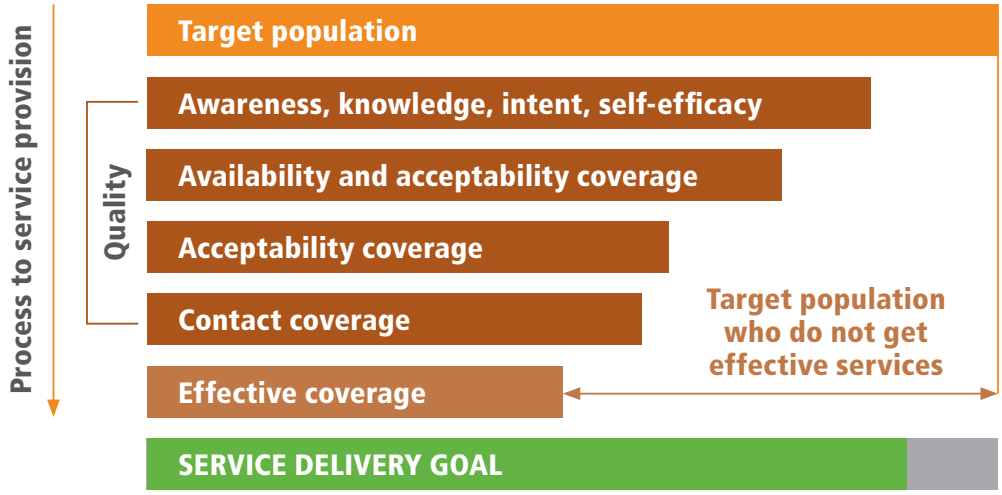
ENHANCING UPTAKE AMONG ADULT MEN AND ADOLESCENT BOYS

There is now a need to reorient and expand services to increase uptake among men at higher risk of HIV infection.

To reach HIV prevention targets, HIV prevention interventions must be focused on, accessible to and taken up by the people most at risk of acquiring infection. There is a need to increase uptake specifically among adult men and particularly those who may be at higher risk of HIV infection, such those with multiple sexual partners, partners of sex workers and men attending STI clinics. The lessons learnt from VMMC programmes about successfully reaching men can support the United Nations and WHO Member States' agreement to achieve universal health coverage by 2030. Universal health coverage requires ensuring that all people have access to needed health services of sufficient quality and must not expose the users to financial hardship.

Achieving effective service coverage means that all health services, goods and facilities must be available, accessible, of good quality and acceptable to those intended to use them. When these criteria are not met, service coverage is limited, as shown in Fig. 2. During the next few years, evidence-based interventions that overcome barriers and build on facilitators along the process to services are needed to enhance men's uptake of VMMC and other services.

Fig. 2. The process to achieve effective service coverage for a target population



Source: Adapted from Tanahashi, 1978.

Systematic reviews of published evidence covered the effect of service delivery approaches and economic compensation, both showing increased uptake of VMMC. No recommendations were made, given the limited evidence, a heterogeneity of interventions studied and the importance of context-specific considerations. However, important points for decision-makers emerged:

- Reorient services to a more people-centred approach that is context-, age- and gender-appropriate, which means tailoring interventions by engaging with communities, adolescents and men. To this end, the interpersonal communication skills of programme managers and service providers must be enhanced.
- Both supply and demand side barriers must be explored and monitored in specific contexts and addressed simultaneously with multi-component interventions. This requires good coordination among stakeholders.
- Multi-component interventions are needed to address diverse barriers and facilitators.

Service delivery changes

Moderate to high quality evidence suggests that overall changes to service delivery or to the services offered were effective in increasing VMMC uptake. These changes include the following:

- home-based HIV testing and education on HIV prevention and VMMC, followed up with supportive messages encouraging men to seek services;
- intensified promotional and mobile and/or outreach campaigns for short time periods, undertaken along with quality improvements such as providing greater privacy;
- a wider range of services offered by health care workers with competencies enhanced through training;
- engaging men's female partners for sexual and reproductive health education;
- use of geographic information system data to identify low coverage areas, where interventions then were made.

Considerations for service delivery include the following:

- Use approaches best suited to the (sub)populations and their contexts, including barriers and facilitators
- Improve access to services by reorienting models of service delivery, including reaching men in community settings.
- Strive for quality improvement and safety.
- Enhance the competence of health care providers.
- Integrate and expand VMMC into a package of services relevant to the life course and health needs of men, including sexual and reproductive health education, tuberculosis testing and treatment, and engaging partners as relevant.

Economic compensation

Low to moderate quality evidence suggests that economic compensation, in the form of food, transportation or subsidized vouchers for male circumcision at the health facility, was effective in increasing uptake among adult men. In contrast, a lottery-approach or variable amounts of compensation did not lead to more uptake.

Economic compensation may address access barriers that some adult men face, by reducing their costs, particularly costs of transport to health care facilities. However, such barriers may exist for other health care needs, too. Singling out VMMC for economic compensation may not be considered appropriate or sustainable as countries strive for universal health coverage. Decisions on the use, type and amount of compensation require community engagement, input of local stakeholders and consideration of the specific context.

Considerations for economic compensation interventions include the following:

- First address the availability and quality of services (supply side). Compensation or other demand-side interventions will not overcome problems of supply and quality.
- Identify what barrier(s) compensation would address for specific populations and whether compensation will be the most effective and equitable way to facilitate men's access.
- Multi-faceted interventions are likely to have a synergistic effect greater than compensation alone.
- Consider the potential expectations generated by compensation for one specific health intervention. However, given that VMMC is a one-time procedure that has lifelong benefits, compensation might be considered justifiable in some settings.
- Stakeholders' and communities' engagement is critical for deciding on use of compensation and, if introduced, its nature and amount. Ethical decision-making frameworks could be developed to support such discussions.
- Policies on financial compensation should be explicit and clear. The criteria and process for deciding who should benefit from the compensation should be transparent to clients and the community and subject to review over time.
- The effects of compensation for a prevention service for adolescents is not known.
- The medium- and long-term considerations of national programmes will differ from those of short-term, externally funded projects. Even in the short term, however, delivery mechanisms should be harmonized with country systems and strategies.

Closing gaps in men's health and services

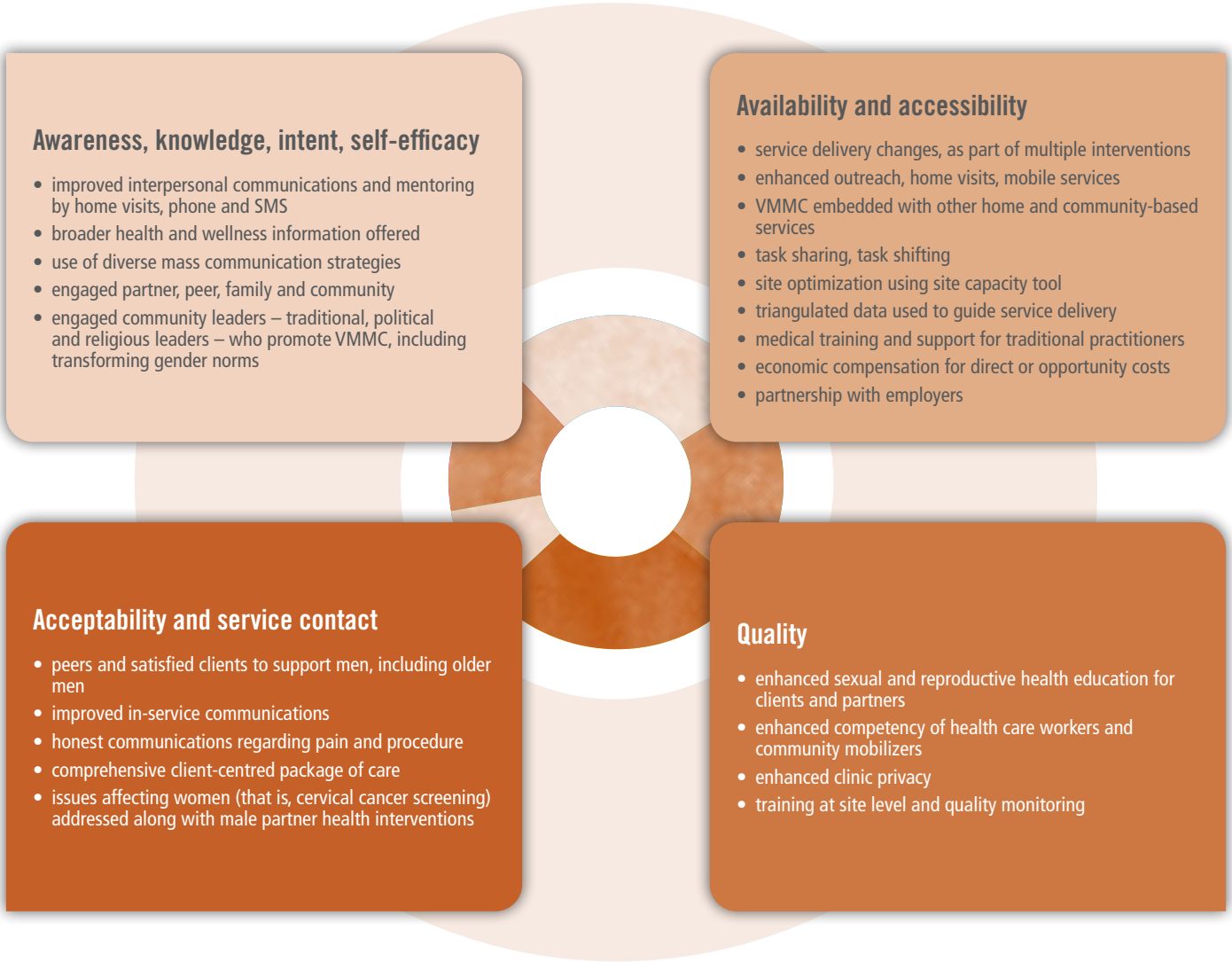
Most national strategic plans in East and Southern Africa acknowledge the importance of gender mainstreaming in HIV-related interventions, but very few refer to the need to engage men. Across HIV services there is a marked gender gap in access. The low level of use of health services, including HIV services, among men likely reflects the combined effects of prevailing gender norms, structural drivers, poor access to health services, lack of policies and weak political will. It is necessary to develop and implement policies and programmes that consider gender norms, improve men's access to services and address structural drivers of men's ill health.

Case studies

From 16 case studies submitted to WHO, 11 with an evidence base were selected. Fig. 3 shows types of interventions, from both systematic reviews and the case studies, organized by the domains to effective service coverage. Most interventions involved multiple components that address several barriers. Full details of case studies may be found in Web Annex 5.2.

Fig. 3. Evidence-based interventions* to enhance effective coverage of VMMC services: organized by domains to service provision

* A combination of the interventions listed below may have been used in one study or case.



SUSTAINING SERVICES WITH A FOCUS ON ADOLESCENT BOYS

As countries scale up to reach coverage targets among men, the focus of national VMMC programmes is shifting to the sustainability of services over the long term. VMMC uptake among adolescents has already been high; reorienting services to focus on adolescents is a next step in the progressive transition to sustaining high VMCC coverage.

Services with a focus on adolescents are a next step in the progressive transition to sustained VMMC coverage.

Embedding VMMC services within the overall health system is key to achieving sustainability and aligns with global efforts to strengthen health systems and achieve universal health coverage. The WHO health systems building blocks can serve as a framework to consider issues and opportunities for sustaining VMMC services (Table 2). Country priorities for sustainability may be identified by assessing needs in each health systems building block, which must be followed by implementing actions towards maintaining VMMC services.

Table 2. Framework for sustainable VMMC services: six health systems building blocks, components and critical enablers

Building block	Component
Finance 	Sustainable financing approaches for health interventions such as VMMC should aim to achieve universal coverage and also encourage the provision and use of an integrated mix of services in an effective and efficient manner. Components of sustainable financing include resource allocation and mobilization, purchasing and financial risk protection.
Health workforce 	For the health workforce, the overall goal is a readily available, competent, responsive and productive health workforce to provide VMMC services. Components of a sustainable health workforce include workforce planning, pre-service and continuing education, and management, support and supervision.
Strategic information 	Country VMMC programmes will need to move to more integrated, country-owned, less donor-dependent systems for data collection and use. Routine data collection and monitoring from the facility level through the national level are essential. Key components include data collection and management; data quality; data analysis and use; and safety monitoring.
Supplies and equipment 	Implementation of sustainable VMMC services requires a durable logistics system, involving commodity procurement, supply chain management, human resources, waste management and proper storage. Accurate forecasts of demand and timely ordering are crucial. Key components include norms and standards; procurement, supply and distribution; and quality of VMMC supplies and equipment.
Leadership and governance 	Strong leadership by government ministries and at higher levels of the government should foster implementation of sustainable, adolescent-responsive policies and programmes. Key components include: coordination; accountability, oversight and regulation; inter-sectoral coordination; and health sector plans and policies.
Service delivery 	Delivering adolescent-friendly VMMC services is important to meet different expectations and preferences of adolescents. The WHO working definition of quality adolescent-friendly health services calls for health services that are accessible, acceptable, equitable, appropriate and effective. Key components for service delivery include: access (strategic planning of health services); reorienting service delivery models; empowering and engaging people; safety and quality.
Critical enablers	
Critical enablers include community engagement, multisectoral partnership (that is, with education, family and social affairs, agriculture and nutrition) and enabling laws and policies to uphold adolescents' rights to health choices and well-being.	

Building on existing WHO models and frameworks, VMMC programming should reflect the following five overarching principles:

1. Adolescent focus. Adolescents will be an important group to reach so that high coverage levels will be maintained and the 2030 HIV incidence reduction goals are achieved. Taking into account the considerations for adolescents discussed in the previous section, sustaining VMMC services should focus on adolescents ages 15 years and above, who usually are capable of giving oral or written informed consent. Prioritizing adolescents in health services builds also on global commitments and strategies. Investment in all aspects of adolescent health, education and engagement yields social, demographic and economic benefits for the whole of society, including adolescents now, later in their lives and for the generations to come.

2. Integration within routine health services. VMMC integration has the potential to generate efficiencies and spur relationships with other adolescent-focused health programmes, including mental health, sexual and reproductive health, non-communicable diseases and vaccinations.

3. High quality and people-centred care. Services should put people and communities, not diseases, at the centre of health systems, empowering people to take charge of their health.

4. Widely accessible, inclusive services. In alignment with the principles of universal health coverage, all people should have access to needed, affordable and effective health services (including prevention).

5. Co-production. As the direct beneficiaries of VMMC services, adolescent boys should be involved in the design, implementation, monitoring and evaluation of VMMC programmes. A key consideration for adolescent leadership is meaningful involvement and engagement as direct stakeholders in VMMC at national, district and community levels.

More evidence is needed on how to integrate and/or link VMMC into existing health and other relevant services (such as youth services, sexual and reproductive health) so as to meet other health needs; how to maintain safe VMMC service delivery approaches for older adolescents, their effectiveness and cost; and the unintended consequences of deferring VMMC for younger adolescents.

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