



World Health  
Organization

GUIDELINES



**PREVENTING HIV THROUGH  
SAFE VOLUNTARY MEDICAL  
MALE CIRCUMCISION FOR  
ADOLESCENT BOYS AND MEN IN  
GENERALIZED HIV EPIDEMICS**

RECOMMENDATIONS AND KEY CONSIDERATIONS

AUGUST 2020



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## **Preventing HIV through safe voluntary medical male circumcision for adolescent boys and men in generalized HIV epidemics: recommendations and key considerations**

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# ACRONYMS AND ABBREVIATIONS

<b>AE</b>	adverse event
<b>ART</b>	antiretroviral therapy
<b>GIS</b>	geographic information system
<b>GRADE</b>	Grading of Recommendations, Assessment, Development and Evaluation
<b>HIV</b>	human immunodeficiency virus
<b>HPV</b>	human papillomavirus
<b>ILO</b>	International Labour Organization
<b>MC</b>	male circumcision
<b>MMC</b>	medical male circumcision
<b>MOH</b>	ministry of health
<b>NAER</b>	Notifiable Adverse Events Reporting
<b>PEPFAR</b>	United States President's Emergency Plan for AIDS Relief
<b>PrEP</b>	pre-exposure prophylaxis
<b>RCT</b>	randomized controlled trial
<b>SD</b>	standard deviation
<b>SRH</b>	sexual and reproductive health
<b>STI</b>	sexually transmitted infection
<b>TAG</b>	Technical Advisory Group on Innovations in Male Circumcision
<b>TTCV</b>	tetanus toxoid-containing vaccination
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNFPA</b>	United Nations Population Fund
<b>USAID</b>	United States Agency for International Development
<b>VMMC</b>	voluntary medical male circumcision
<b>WHO</b>	World Health Organization

## GLOSSARY

**Adolescence:** Adolescence is one of the most rapid and formative phases of human development, and the distinctive physical, cognitive, social, emotional and sexual development that takes place during adolescence demands special attention in national development policies, programmes and plans. An adolescent is a person 10–19 years of age. Younger adolescents refers to 10–14 year olds, while older adolescent refers to 15–19 year olds.

**Effective service coverage:** Effective service coverage is defined as follows: People who need health services obtain them in a timely manner and at a level of quality necessary to obtain the desired effect and potential health gains.

**Male circumcision:** Male circumcision is the complete surgical removal of the male penile foreskin.

**Medical male circumcision (MMC):** This term is used to differentiate male circumcision performed by a medical professional from that delivered by traditional practitioners.

**People-centred health care:** an approach to care that consciously adopts individuals', carers', families' and communities' perspectives as participants in, and beneficiaries of, trusted health systems that are organized around the comprehensive needs of people rather than individual diseases, and that respects social preferences. People-centred care also requires that patients have the education and support they need to make decisions and participate in their own care, and that carers are able to attain maximal function within a supportive working environment. People-centred care is broader than patient- and person-centred care, encompassing not only clinical encounters but also including attention to the health of people in their communities and their crucial role in shaping health policy and health services.

**Person-centred health care:** care approaches and practices that see the person as a whole with many levels of needs and goals, with these needs coming from their own personal social determinants of health.

**Voluntary medical male circumcision (VMMC):** This term refers to MMC undertaken with informed consent and without undue influence.

# EXECUTIVE SUMMARY

## Background

Since 2007 the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have recommended voluntary medical male circumcision (VMMC) as an important strategy for the prevention of heterosexually acquired HIV in men in settings where the prevalence of heterosexually transmitted HIV is high (1). The prevalence of male circumcision was particularly low in East and Southern Africa. This region is home to only 6.2% of the world's population, but it accounted for 47% of the 1.7 million people newly infected with HIV in 2018, and a significant proportion of incident infections are attributable to heterosexual transmission (2). Accordingly, VMMC has been a priority intervention in 15 countries in East and Southern Africa. Since the 2007 recommendation, other interventions have been shown to be effective in reducing HIV incidence as well as the secondary prevention effect of antiretroviral therapy (ART). Thus, it is timely to review the recommendation on VMMC for HIV prevention in the current environment of prevention options.

In the decade following the 2007 recommendation, the feasibility of implementing VMMC services has been demonstrated, with more than 23 million males circumcised through VMMC programmes in East and Southern Africa (3). A large proportion of those circumcised were adolescents, including those ages 10–14 years, a group not included in the trials that informed the 2007 recommendation. Younger adolescents are unique, given their dynamic physical and cognitive development. Since 2007 more information has become available on age-specific considerations for VMMC programmes. In order to sustain high circumcision coverage, many countries are increasing their focus on reaching uncircumcised adolescents, and so specific consideration of the adolescent age group is needed, as well as guidance on transitioning services so as to maintain coverage and sustain delivery.

Reaching adult men remains important, too, as they are at more immediate risk of HIV infection than many adolescents. However, uptake of VMMC among adult men has been limited in some settings, and Member States have asked WHO for guidance on enhancing uptake of VMMC to support them in achieving higher coverage among adult men.

Since 2007 innovative methods of male circumcision have been tested and their use expanded in an effort to enhance safety, to expand the range of health care workers able to perform VMMC, to increase the choice of methods available and, potentially, to increase uptake. More evidence is now available on the safety of conventional and device-based surgical circumcision methods, motivating this update to the 2013 WHO guidance on device-based methods.

## Purpose

These guidelines aim to update WHO recommendations to maximize the HIV prevention impact of safe VMMC services and to guide the transition to sustained provision of interventions with a focus on the health and well-being of both adolescent boys and men.

Informed by reviews of the evidence, this guidance addresses:

- male circumcision for HIV prevention
- considerations on VMMC for adolescent males ages 10–14 years
- use of devices as methods of male circumcision
- interventions to enhance uptake of VMMC for HIV prevention among adult men
- the transition to adolescent-focused, sustainable VMMC services.

## Intended audience

These guidelines are intended primarily for policy- and decision-makers; programme managers in ministries of health in high burden HIV settings, particularly in East and Southern Africa; health care providers in VMMC services; donors; and implementing agencies supporting interventions on HIV and for the health of adolescent boys and men.

## Guideline development process

The WHO Department of Global HIV, Hepatitis and HIV Programmes led the development of these guidelines, which was undertaken in accordance with the *WHO handbook for guidelines development* (4). The process involved internal and external consultations with technical experts, national programme managers, consumer advocates, institutions working in HIV prevention and VMMC, evidence reviewers and an evidence review methodologist.

## Recommendations

Table 1 summarizes the recommendations and important considerations presented in these guidelines.

**Table 1. Summary of WHO recommendations and important considerations on voluntary medical male circumcision**

Intervention and the new evidence	Recommendations and key considerations
<b>UPDATED</b>	
<b>Chapter 2</b>	
<p><b>VMMC for HIV prevention</b></p> <p>10 years of additional evidence on impact of VMMC, including in the context of combination HIV prevention</p>	<p><b>Recommendation</b></p> <p>Voluntary medical male circumcision (VMMC) should continue to be promoted as an additional efficacious HIV prevention option within combination prevention for adolescents 15 years and older and adult men in settings with generalized epidemics to reduce the risk of heterosexually acquired HIV infection (<i>strong recommendation, high quality evidence</i>).</p>
<b>NEW</b>	
<b>Chapter 3</b>	
<p><b>VMMC for younger adolescent boys</b></p> <p>New programme data on safety among younger adolescents (&lt;15 years); updated international human rights statements</p>	<p><b>Key considerations</b></p> <p>Decisions on offering VMMC to younger adolescents 10–14 years must consider several factors based on new evidence, human rights and national and local context, including:</p> <ul style="list-style-type: none"> <li>• the public health burden of HIV and the impact on HIV incidence of deferring circumcisions among those ages 10–14 years;</li> <li>• human rights guidance to postpone non-emergency invasive and irreversible interventions until the child is sufficiently mature to provide informed consent;</li> <li>• capacity of health workers to facilitate informed consent and the existence of supportive policies to ensure that children, parents and health workers have adequate rights-based guidance on consent, assent and confidentiality;</li> <li>• safety of procedure: increased risk of serious adverse events among adolescents with immature genitalia (usually under 15 years); therefore, encourage deferral until they are more physically developed;</li> <li>• preferences of adolescent, parents, community on providing VMMC as a safer alternative to traditional male circumcision.</li> </ul>
<b>UPDATED</b>	
<b>Chapter 4</b>	
<p><b>Use of device-based methods for male circumcision</b></p> <p>New evidence since 2013 on elastic collar compression, collar clamp and surgical assist devices</p>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>• 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 (<i>conditional recommendation, moderate quality evidence</i>).</li> <li>• 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 (<i>conditional recommendation, low quality evidence</i>).</li> </ul>

Table 1. (continued)

Intervention and the new evidence	Recommendations and key considerations
<b>NEW</b>	
<b>Chapter 5</b>	
<p><b>Enhancing uptake of VMMC among male adults and adolescents</b></p> <p>New comparative and non-comparative evidence on interventions to enhance uptake; case studies with programme data</p>	<p><b>Key considerations</b></p> <p>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 approaches are most suitable for their population and context.</p> <p>The use of economic compensation to enhance uptake of VMMC may address barriers to access that some adult men face, by reducing costs such as transport to health care facilities. Such compensation also may reduce opportunity costs from wages lost during and after the procedure.</p> <p>However, singling out VMMC for compensation may not be considered appropriate as countries shift to universal health coverage. Decisions on its use require community engagement and consideration of context.</p>
<b>NEW</b>	
<b>Chapter 6</b>	
<p><b>Sustaining VMMC with a focus on adolescent boys</b></p> <p>Based on WHO health systems building blocks</p>	<p><b>Key considerations</b></p> <p>To sustain high VMMC coverage and the benefits achieved 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.</p>

## VMMC for HIV prevention

In the ongoing effort to end the AIDS epidemic, VMMC remains important alongside other effective behavioural and biomedical HIV prevention interventions, including prevention of HIV transmission and reduction of community viral load due to ART. High-quality evidence from three randomized controlled trials (RCTs) is supported by observational studies conducted between 1986 and 2017, all of which showed that medical male circumcision reduced the risk of heterosexual acquisition of HIV by 50% or more. These studies included settings where VMMC services have been implemented in communities alongside other HIV prevention interventions and ART scale-up. Further, the cost of implementing VMMC programmes is more than offset by the HIV infections prevented and savings on future costs of lifelong ART.

Evidence that medical male circumcision reduces a man's risk of heterosexual acquisition of HIV by about 60% from three 'gold standard' efficacy trials is supported by strong and consistent evidence of a reduction in risk of about 50% from 17 observational studies in diverse settings, including when implemented alongside ART, with its secondary prevention effect.



Other benefits of medical male circumcision include the reduced risk of some other STIs in women as well as men, including human papillomavirus, the cause of cervical cancer.

The feasibility of implementing VMMC service packages has been demonstrated. By the end of 2018 over 23 million adolescents and men had been reached. For adolescents over 15 years and adults, male circumcision by several surgical methods, when performed within the formal health sector by competent health care workers, has been shown to be safe. Rates of moderate and serious adverse events have been low. One rare serious adverse event, tetanus, has drawn attention to gaps in immunity among adolescent boys and men and the limited routine service provision of tetanus toxoid-containing boosters to them, as well as gaps in safe wound care practices in communities.

### VMMC for younger adolescent boys

In deciding whether to offer VMMC to younger adolescents, ages 10–14 years, **safety, which is affected by their evolving physical development, and capacity to provide informed consent should be considered** along with other factors such as public health impact, the acceptability and feasibility of delivering VMMC along with other services, and maintaining the benefits of high VMMC coverage. Consideration should be given to deferring the circumcision of younger adolescent boys for several

Consideration should be given to deferring the circumcision procedure among younger adolescent boys (ages 10–14 years) until they are older and more physically developed.

years until their capacity to give informed consent is sufficient, thus respecting their human rights. The reduction in HIV risk is expected to be the same for all circumcised men regardless of their age when the procedure is performed.

The limited available evidence indicates that, although rare, serious adverse events, particularly glans injuries and urethral fistulas, occur with the commonly used conventional surgical methods at a higher rate among adolescents 10–14 years than among those 15–19 years old. The additional risk is attributed to the less mature genitalia of younger adolescent boys. The precise magnitude of risk is unknown, although it is likely to be small. It is critical that all VMMC programmes maintain patient safety as a priority and strive to have the lowest risk of adverse events possible for this preventive intervention.

### 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 use through 2018 has been limited, device-based surgical methods

Device-based methods have the potential to make VMMC simpler, less resource-intensive and usable by non-physician health care workers. However, to date use has been limited.

have shown potential to make the procedure simpler and less resource-intensive and can be used by non-physician health care workers. Thus, these methods offer additional acceptable options to clients and health care workers and have the potential to expand coverage and increase programme impact.

Studies and surveillance since 2013 have provided information on the safety and use of device-based methods. The evidence covers two types of in situ devices and one surgical assist device. Given the availability of multiple device products on the market and the unique characteristics of each device, the WHO prequalification process<sup>1</sup> has been applied to ensure that specific device methods are evaluated in a systematic and rigorous manner.

The evidence reviewed led to two age-specific recommendations, as shown in Table 1. In general, device methods have had low rates of moderate and serious adverse events (AEs) compared with conventional surgical methods. However, for one specific method (elastic collar compression), the risk mitigation measures required for tetanus prevention (involving two doses of tetanus toxoid-containing vaccine) make its use less feasible. Given the limited use of any device method on a large scale to date, the recommendations are conditional. Use among younger adolescents, ages 10–14 years, has been even more limited. Given the potential advantages of male circumcision with device methods, further assessment is encouraged.

### Enhancing uptake of VMMC among male adults and adolescents

To achieve HIV incidence goals, a combination of interventions with a people-centred<sup>2</sup> focus will be required. While over 23 million men and adolescent boys have been circumcised in VMMC programmes since 2007, uptake needs to increase further, particularly among adult men and men at higher risk of HIV infection.

During the next few years, interventions are needed that address barriers and build on facilitators to enhance men's uptake of VMMC and other services as well as to overcome the lower rate of uptake of HIV testing and treatment among men than women. WHO reviewed the published evidence on the effect of service delivery approaches and economic compensation to increase men's uptake of VMMC. No recommendations were made, given the limited evidence, the heterogeneity of interventions studied and the importance of context-specific considerations. However, the evidence reviewed does provide decision-makers with information on interventions to consider. The diverse needs and preferences of different subpopulations must be addressed, also recognizing that these may change over time. A more people-centred approach that is context, age- and gender-appropriate means tailoring interventions by engaging with communities,

Evidence-based interventions are needed that address barriers and build on facilitators to enhance men's uptake of VMMC.

adolescents and men. To this end, 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

<sup>1</sup> Listing of a specific device as "prequalified" by the WHO Prequalification for Male Circumcision Devices Programme provides assurance that the specific device meets global standards of quality, safety and efficacy. "Prequalified" does not imply WHO approval or endorsement of a particular device; that is the exclusive prerogative of national programmes. The list of specific prequalified devices is available on the WHO website ([www.who.int/diagnostics\\_laboratory](http://www.who.int/diagnostics_laboratory)).

<sup>2</sup> People-centred health care is an approach to care that consciously adopts individuals', carers', families' and communities' perspectives as participants in, and beneficiaries of, trusted health systems that are organized around the comprehensive needs of people rather than individual diseases, and that respect social preferences. People-centred care also requires that patients have the education and support they need to make decisions and participate in their own care, and that carers are able to attain maximal function within a supportive working environment. People-centred care is broader than patient- and person-centred care, encompassing not only clinical encounters but also including attention to the health of people in their communities and their crucial role in shaping health policy and health services. (WHO 69th World Health Assembly agenda item 16.1, A69/39, 15 April 2016)

simultaneously with multi-component interventions. This requires good coordination among stakeholders.

Other health services often do not reach adult men and adolescent boys. The lessons learnt from VMMC 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 to be effective and must not expose the user to financial hardship.

**Overall changes to service delivery or to the services offered** were identified as effective in increasing uptake. Most approaches included multiple components. Home-based HIV testing and education on HIV prevention and VMMC were followed up with supportive messages encouraging men to seek services. Intensified promotional and mobile and/or outreach campaigns for short time periods were undertaken along with quality improvements, such as providing greater privacy. A wider range of services was offered by health care workers whose competencies were enhanced through training. Men's female partners were engaged for sexual and reproductive health (SRH) education. Geographic information system (GIS) data were used to identify low coverage areas, where such interventions then were made. These studies took place in diverse settings, such as health care facilities, community and home settings as well as school settings, with the focus on adolescents.

**Economic compensation.** Interventions studied offered economic compensation either for undergoing VMMC or for seeking counselling on VMMC at a health facility. Compensation was either a fixed amount for each client or a prize in a lottery. Compensation included food, transportation or subsidized vouchers for male circumcision at the health facility. Offers of compensation were delivered either at an initial home visit by health workers or in writing via post. The findings indicate that fixed compensation to cover transport or opportunity costs was associated with higher uptake of VMMC among adult men. Use of a lottery-approach or variable amounts of compensation did not lead to higher 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 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.

A policy review on men's health and services found that, although most national strategic plans acknowledge the importance of gender mainstreaming in HIV-related interventions, very few refer to the need to engage men. Across HIV services – from prevention to testing and treatment – there is a marked gender gap in access. There are many potential reasons for men's limited use of health services, likely reflecting prevailing gender norms, structural drivers, poor access to health services, opportunity costs and limited focus on men's health issues in policies.

## Sustaining VMMC with a focus on adolescent boys

Lastly, programmatic guidance provided here supports the transition to sustainable services with an adolescent focus. The WHO health systems building blocks have been used as a framework for detailed considerations. This transition is a new phase, and

Partnering with adolescents, local community organizations and other sectors can increase access for adolescents.

lessons will be learned as programmes evolve. Cross-cutting interventions will be needed that provide an enabling environment, including adolescents' and young people's leadership, local ownership and participation, community engagement and multisectoral partnerships.

# INTRODUCTION

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# 1 INTRODUCTION

Globally, about 1.7 million people became infected with HIV in 2018. Sixty percent of these people resided in sub-Saharan Africa. Nearly half of new infections occurred in

Half of new HIV infections in 2018 occurred in East and Southern Africa.

East and Southern Africa. In this region about 800 000 new HIV infections occurred, there were 20.6 million people living with HIV, and 310 000 people died of AIDS-related causes (2). Yet, East and Southern Africa is home to only 6.2% of the world's population.

Sustainable Development Goal 3.3 emphasizes the urgency and importance of ending the spread of HIV by reducing incidence, particularly in high-burden priority areas: *“By 2030 end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases”* (5). The 2016–2021 strategy of the United Nations Joint Programme on HIV/AIDS (UNAIDS) for ending the AIDS epidemic as a public health threat by 2030 aims for 90% of people to know their HIV status, 90% of those infected to be on antiretroviral treatment (ART) and 90% of those on treatment to be virally suppressed (“90–90–90”) by 2020. Coverage of each element is to increase to 95% by 2030 (“95–95–95”) (6). Prevention goals are to reduce the number of annual new HIV infections to fewer than 500 000 globally by 2020 and fewer than 200 000 by 2030 (6).

A combination of interventions will be required to achieve these goals. The UNAIDS HIV Fast Track strategy identifies five HIV prevention “pillars” – three with biomedical focus: condom use, pre-exposure prophylaxis (PrEP) and voluntary medical male circumcision (VMMC); and two with a population focus: combination prevention for key populations and for adolescent girls and young women. The Fast Track strategy also calls for a clearer focus on a people-centred health approach. For adolescent boys and young men, multiple factors related to gender and sociocultural context have an impact on health and HIV risk (6–8).

This new guidance on VMMC updates WHO's recommendations and addresses sustaining and expanding VMMC services in alignment with global efforts to achieve universal health coverage.

## 1.1 Background

In 2007, based on compelling evidence, WHO and UNAIDS recommended that medical male circumcision be recognized as an additional important intervention for prevention of heterosexually acquired HIV infection in men in settings where the prevalence of heterosexually transmitted HIV is high and the prevalence of male circumcision is low (1) and, thus, the impact and cost-effectiveness of such an intervention would be greatest (9, 10). This recommendation was based on evidence from three randomized controlled trials (RCTs) among males ages 15 years or older (11–13) and supported by a wealth of observational data (14).

At that time, the main interventions recommended for prevention of heterosexual transmission were education on safer sex, including condom use and delayed onset of sexual relations, reduced number of partners, abstinence and management of other STIs. These interventions were part of the VMMC minimum services package to be delivered while scaling up VMMC (1). Since the issuance of the 2007 recommendations, other efficacious HIV prevention interventions have been recommended, including PrEP and, for people who inject drugs, harm reduction. The effectiveness of ART in preventing HIV transmission at the individual level has been established (15). However, at the population level ART has been found to be less effective in reducing HIV incidence than initially

After a decade of experience and a changing context of HIV prevention interventions and epidemiology, it is timely to review the 2007 VMMC recommendations.

hoped (16). Thus, it is timely to review the 2007 VMMC recommendation, updating and revising as necessary in light of new evidence on safety, HIV impact, programme experience and the contribution of VMMC given the changed profile of combination prevention interventions and the likely future trajectory of HIV incidence.

During the decade after the 2007 VMMC recommendation, nearly 23 million males in 15 countries of East and Southern Africa were circumcised (17). In pursuit of the 2020 targets, about half of these circumcisions (11 million) were performed in the three years between 2016 and the end of 2018. Although the majority of VMMC clients have been 15 years or older, a large proportion were ages 10–14 years, a group not included in the three RCTs that initially demonstrated the effectiveness of male circumcision in preventing heterosexual HIV acquisition. Thus, issues unique to this group were not

Many countries are turning to activities to sustain VMMC coverage, with a focus on reaching uncircumcised adolescent boys.

considered in detail for the 2007 VMMC recommendations. Additionally, given the success in reaching a high level of coverage among men in high burden countries, many countries are now turning to sustaining coverage, with a focus on reaching uncircumcised adolescents.

Despite the good progress on coverage overall, uptake of VMMC among adult men has often lagged behind uptake among adolescents. Member States have asked WHO for guidance on enhancing uptake of VMMC to support them in achieving higher coverage among adult men over the next five to 10 years, since this group is at current risk of HIV and, thus, key to epidemic control. In parallel, the need for other health services to address men's health needs such as tuberculosis and hypertension management will continue. Thus, lessons on underlying health care-seeking behaviour and enhancing uptake of VMMC among men may inform programming for other health interventions as well as HIV testing and other HIV and STI prevention, treatment and care interventions that have also had limited uptake to date among adult men.

Since 2007 innovative methods of male circumcision have been tested and their use expanded in an effort to simplify the procedure, expand the range of health care workers who are authorized to perform VMMC and broaden the choice of methods available, thus potentially increasing uptake. In 2013 WHO made an initial recommendation on use of prequalified devices. There is now further evidence on and experience with the safety of surgical circumcision methods, including age-specific evidence. Thus, it is timely to review the use of device-based methods VMMC.



While the protective effect of VMMC against men's heterosexual acquisition of HIV is well established, the evidence is less clear whether VMMC reduces HIV infection among men who have sex with men. The WHO 2016 recommendation, issued initially in 2011, remains:

VMMC is not recommended to prevent HIV transmission in sex between men, as evidence is lacking that VMMC is protective during receptive anal intercourse. Men who have sex with men ... may still benefit from VMMC if they also engage in vaginal sex [with women]. Men who have sex with men should not be excluded from VMMC services in countries in East and Southern Africa where VMMC is offered for HIV prevention (18).

Research since then has not supported a change in this recommendation. In 2011 and 2019 systematic reviews of the evidence found studies on the topic to be of low quality (19, 20). One 2019 study reported potential risk reduction among men who engage primarily in insertive anal intercourse, but its authors considered the evidence on the effect of male circumcision to be preliminary, with further data required, given limitations regarding stratification by subcategories of sexual position and differentiating bisexual men from men who have sex exclusively with men (19). Therefore, the 2016 recommendation on VMMC among men who have sex with men was not revised and so is not considered further in this guideline.

As higher levels of adult coverage of VMMC are reached in the next few years, programmes will shift to offering VMMC to each new cohort of adolescents. Reorienting the delivery of VMMC for adolescents and addressing its impact and safety will respond to ministries' requests for guidance on the transition to sustainable adolescent services. Countries must consider this transitional phase in the context of delivering other adolescent services, aligning with broader efforts to strengthen adolescent health services in keeping with goals of universal health coverage and as called for in the Global Strategy for Women's, Children's and Adolescents' Health (21) and the global Accelerated Action for the Health of Adolescents (AA-HA!) guidance (22). Cross-cutting interventions will be needed that provide an enabling environment, including adolescents' and young people's leadership, local ownership and participation, community engagement and multisectoral partnerships.

## 1.2 Goal and objectives

Overall goals: To maximize HIV prevention impact with safe VMMC services and to guide provision of interventions for the health and well-being of adult men and adolescent boys.

Specific objectives include updates to the following WHO recommendations:

- 2007 recommendation on male circumcision for HIV prevention (1)
- 2013 conditional recommendation on use of devices as efficacious and safe methods of surgical male circumcision (23)

and a review of current evidence on:

- efficacy and safety of male circumcision methods for males ages 10–14-years



- enhancing uptake of VMMC for HIV prevention among adult men
- providing programmatic guidance to promote the transition to adolescent-focused, sustainable VMMC services.

### 1.3 Intended audiences

This guidance is intended for use by:

- policy- and decision-makers
- national programme managers in ministries of health in high burden HIV settings, particularly in East and Southern Africa
- health care workers in VMMC services
- donors and implementing agencies supporting interventions on HIV and for the health of men and adolescent boys.

### 1.4 Guideline development process

The WHO Global HIV, Hepatitis and STI Programmes developed this guideline according to WHO standards and requirements for guideline development (4) and with the oversight of the WHO Guideline Review Committee. Annex 1.1 presents details of the guideline development process.

It is anticipated that sections of this guidance will be updated in two to five years, depending on progress in programmes and updated evidence.





# VOLUNTARY MEDICAL MALE CIRCUMCISION AS AN INTERVENTION FOR HIV PREVENTION

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## 2 VOLUNTARY MEDICAL MALE CIRCUMCISION AS AN INTERVENTION FOR HIV PREVENTION

### Summary of the recommendation and age-specific considerations

**UPDATED**

#### Recommendation on medical male circumcision as an intervention for HIV prevention

Voluntary medical male circumcision<sup>1</sup> (VMMC) should continue to be promoted as an additional efficacious HIV prevention option within combination prevention for adolescents 15 years and older and adult men in settings with generalized epidemics to reduce the risk of heterosexually acquired HIV infection.

Surveillance systems for STIs are weak in many countries and disconnected from HIV surveillance.

*(Strong recommendation, high quality evidence.)*

### Key points

- Combined results of three randomized controlled trials showed an estimated 60% lower incidence of heterosexually acquired HIV infection in circumcised men. This led to the 2007 WHO recommendation on VMMC as an additional HIV prevention intervention.
- Seventeen prospective observational studies between 1986 and 2017 showed an overall 50% lower risk of HIV infection in circumcised men, including when VMMC is implemented alongside combination prevention.
- Among men at higher HIV risk, combined results from five studies demonstrated a 71% reduction in the risk of heterosexually acquired HIV.
- Where VMMC services had been implemented in communities in parallel with increasing antiretroviral treatment (ART) coverage, the prevalence of HIV infection was 44% lower in circumcised men than in uncircumcised men.

<sup>1</sup> 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.

## Key points (continued)

### Other main points

- Effective combination prevention strategies, including high VMMC coverage combined with the HIV prevention benefits of ART, will be necessary to reach the 2030 United Nations HIV incidence goals in East and Southern Africa.
- A minimum package of services, including education on safer sex, condom promotion, offer of HIV testing services and management of STIs, must be delivered along with the surgical procedure.
- The 23 million VMMCs performed through 2018 are estimated to have averted 250 000 HIV infections in the 15 priority countries of East and Southern Africa,<sup>1</sup> with even larger future benefits, given VMMC's lifelong partial protection. The number of infections averted by these circumcisions is projected to grow to 1.1 million by 2030 even if no more VMMCs were performed.
- VMMC should be offered through the formal health sector and performed by competent trained health professionals.
- Circumcised men and their female partners experience lower rates of several sexually transmitted infections (STIs), including human papillomavirus, herpes simplex virus-2, bacterial vaginosis and *Trichomonas vaginalis*.
- Women benefit indirectly, from the lower risk of HIV infection in circumcised men as VMMC programmes expand and fewer men acquire HIV.
- Women may be less likely to acquire HIV infection from an HIV-positive man who is circumcised than from one who is not, except when the man is recently circumcised and healing.
- For adolescents ages 15 through 19 years, consent procedures must reflect the legal age for minor surgery in the country.
- VMMC is a cost-effective and cost-saving HIV prevention intervention in countries of East and Southern Africa when compared with lifetime costs of ART.

<sup>1</sup> The 15 priority countries are Botswana, eSwatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, South Sudan, Uganda, the United Republic of Tanzania, Zambia and Zimbabwe.

## 2.1 Evidence to inform updated recommendations: the impact of male circumcision on risk of HIV infection

The systematic review conducted to inform the recommendations examined the impact of male circumcision on HIV incidence in men (24) and in women (25) and changes in HIV incidence and prevalence in communities where interventions to increase VMMC coverage had been implemented. The findings of these studies are highlighted below.

### 2.1.1 Effect of medical male circumcision on HIV acquisition in men

The evidence that circumcision reduces the risk of HIV infection in men is strong (26). Results come from diverse settings, span 32 years (1986 to 2017) and are very consistent.

**Randomised controlled trials (RCTs) and follow-up.** Data from three RCTs conducted in different countries showed a 59% (44%–70%) reduction in HIV incidence (efficacy) among circumcised men ages 15–49 years (11–13). The protective effect was seen soon after circumcision. The protective effect was confirmed in extended post-trial follow-up to six years of men in two of the three RCTs (in Kenya and Uganda) (27, 28). The estimated impact over the six years was a 66% (51%–76%) reduction in risk, which is close to the result of the “as-treated” analysis of the three RCTs.

**High-risk cohorts.** Among high-risk cohorts in diverse settings (five studies), circumcised men had a 71% (57%–81%) reduced risk of HIV infection compared with uncircumcised men, although the effect was less uniform than in studies of the general male population. These studies involved STI clinic patients in Nairobi, Kenya (29); trucking company employees in Mombasa, Kenya (30); STI clinic patients in India (31); men in Uganda with HIV-infected wives at a time when few people knew their HIV status (32); and HIV-negative men in stable serodiscordant relationships with HIV-infected female partners prior to extensive ART coverage (33).

**Community-based cohorts** before VMMC scale-up showed an overall 52% (30%–67%) lower HIV risk among circumcised men compared with uncircumcised men. The lower risk was seen both where male circumcision was less commonly practiced (Uganda (32) and India (34)) and in Kenya, where it was common (35, 36).

In six communities with simultaneous increases in VMMC prevalence and expansion of ART due to programme efforts (Kenya (37), South Africa (38–40) and Uganda (41, 42)), the reduction in HIV incidence in circumcised men compared with uncircumcised men was 44% (36%–51%) and similar across studies.

**Combined results of all observational studies** showed the HIV risk (effectiveness) to be 50% (44%–56%) lower among circumcised men than among uncircumcised men. The estimated absolute reduction in risk of HIV infection was 13 (10–15) fewer infections per 1000 person-years in the post-RCT follow-up studies through six years; 9 (5–12) fewer infections per 1000 person-years in the community-based studies before VMMC scale-up; and 7 (6–8) fewer per 1000 person-years during VMMC scale-up. In the high-risk cohorts, the estimated absolute reduction in risk was 39 (31–44) fewer infections per 1000 person-years. This greater degree of risk reduction illustrates the greater impact of male circumcision in high HIV incidence settings.

The Guideline Development Group considered the evidence for the direct effect of VMMC on HIV risk among heterosexual men to be of high quality. Annex 2.1 presents the GRADE tables, forest plots and evidence-to-decision-making tables.

### 2.1.2 The effect in communities as coverage of both VMMC and ART were increasing

HIV prevalence was 35% (30%–40%) lower in circumcised men than in uncircumcised men in communities where there had been recent increases in VMMC coverage in parallel with more HIV testing and greater ART coverage – Orange Farm in South Africa (38) and Lake Victoria fishing communities in Uganda (42).

In the Rakai, Uganda, community cohort over the period 1999–2013,<sup>1</sup> each 10% increase in circumcision prevalence was estimated to be associated with a 13% (7%–18%) reduction in male HIV incidence, and, for each 10% increase in ART coverage in women, male incidence was on average 5% lower (from 19% lower to 13% higher). There was little relationship between HIV incidence in women and either a) coverage of ART in men or b) the proportion of men circumcised (43).

### 2.1.3 The effect of male circumcision on HIV acquisition in women

**Women benefit indirectly** from VMMC programmes due to the lower HIV incidence and prevalence among circumcised men and, thus, less chance for a woman to have sex with an HIV-infected man.

Women benefit indirectly from VMMC and perhaps directly as well.

Women who are HIV-negative may benefit directly, as well, from a reduced risk of transmission if an HIV-positive male partner is circumcised. This direct effect of male circumcision was assessed in two observational cohorts (32, 44) among serodiscordant couples (HIV-negative women with known HIV-positive male partners). A lower HIV incidence among women whose HIV-infected male partner was circumcised was found compared with women whose HIV-infected male partner was not circumcised (pooled incidence rate ratio 0.59 (0.35–0.99), or 41% lower risk of infection). Both studies were conducted prior to the availability of ART. Annex 2.1 presents the GRADE evidence profile on the effect of VMMC for women.

Among men with HIV but not on ART when circumcised and their female partners who were HIV-negative, an RCT found a higher risk of HIV transmission in the first six months after the procedure, particularly if the couple resumed sex more than five days before the circumcision wound had been certified as healed (45). This study was conducted before immediate ART was recommended for all people with HIV. As all men with HIV should be offered ART, this early increased HIV transmission risk is likely negligible if the male partner is on ART and virally suppressed.

<sup>1</sup> An analysis of HIV incidence in the 45 communities within the Rakai community cohort.

Among 4.8 million men seen at VMMC services in 12 countries during 2013–2016, nearly all were tested for HIV, and less than 1% were HIV-positive (46). Still, for the partners of HIV-positive men, the potential consequences of early resumption of sex following circumcision are serious. This underlines the importance of HIV testing before circumcision in VMMC programmes, so that men in high prevalence settings know their status. Those who test positive for HIV should start treatment for their own health. Those who test positive and wish to be circumcised should delay circumcision until ART has lowered their viral load. They should recognize that VMMC provides them no HIV benefit.

### 2.1.4 Modelling estimates of VMMC impact within combination prevention, including full ART coverage, and by sexual risk

VMMC has already averted a substantial number of HIV infections. Modelling exercises estimate that the nearly 23 million circumcisions performed by the end of 2018 in

Even as ART is scaled up, providing some prevention effect, VMMC remains a crucial prevention intervention.

15 priority countries in East and Southern Africa prevented 250 000 new HIV infections – roughly one infection averted for every 83 procedures. The number of infections averted by these procedures is projected to increase to 1.5 million by 2030 (3), given the lifelong partial protection offered by VMMC.

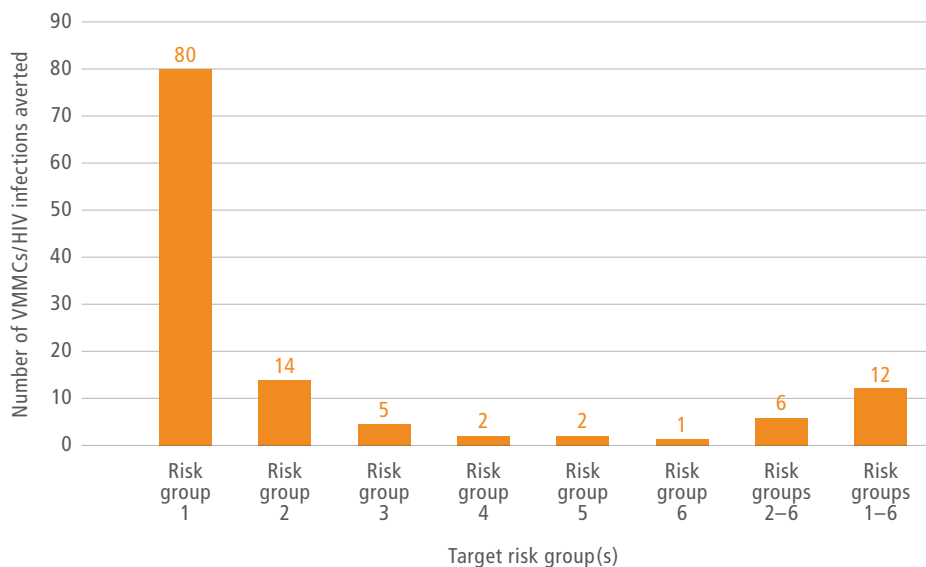
VMMC remains a crucial intervention to achieve HIV prevention and epidemic control, even as other prevention interventions are scaled up. Modelling also indicates that, when VMMC is scaled up as part of combination prevention including 90% ART coverage, VMMC still contributes to reducing HIV incidence. If no more VMMCs were to be conducted, the number of HIV infections averted by VMMC through 2018 would rise to about 1.5 million by 2030 and to 4.5 million by 2050, assuming that the coverage of other HIV interventions, including ART coverage, remains constant at current levels, or to 660 000 by 2030 and 1.0 million by 2050 if Fast Track targets are achieved for all interventions.

Scaling up VMMC was projected to add to the reductions in incidence attributable to the expansion of treatment to 90% – the more so if the level of treatment coverage were lower (47). Studies in four countries (48–51) – eSwatini, Malawi, South Africa and Uganda – have shown similar estimated impacts of VMMC programmes in the context of expanding ART to meet the 90% 2020 coverage goals. In Zimbabwe, if VMMC and ART 90% coverage targets are achieved by 2021 and maintained, the VMMC programme will avert 108 000–171 000 infections (10%–13% of all new infections averted) by 2030 (52). In Kenya 21 000–33 000 infections will be averted through 2030 by VMMCs conducted through 2015. The longer-term impact will be much greater (80 000–160 000 infections averted), as these men will be protected throughout their sexually active lives (53).

A modelling study for Zambia (54) estimated the effectiveness of VMMC for different levels of sexual risk behaviour (Fig. 2.1), assuming six levels of risk based on number of sexual partners. The groups range from the lowest risk with one sexual partner (Risk group 1) to the highest risk, for female sex workers and their male clients (Risk group 6). Reducing focus on the largest proportion (52%) of men in Risk group 1 and instead focusing on males in the higher risk groups (2–6) would be more effective.



**Fig. 2.1. Modelled VMMCs per HIV infection averted among men by sexual activity risk group**



Source: Awad et al., 2015 (55).

### 2.1.5 Additional realities of HIV programmes: quality gaps, viral suppression and HIV drug resistance

Beyond modelling results, experience with ART programmes and evidence suggest that the preventive effect of VMMC will continue to be important. Real-world situations that contribute to lower viral suppression via ART include suboptimal adherence at times over a lifetime of ART use, service delivery limitations and drug resistance. Despite significant advances in the prevention and treatment of HIV, countries continue to experience serious gaps in ART service delivery, including suboptimal retention in treatment and care services, drug stock-outs and inadequate support for adherence to ART. Sustained attention and support to close quality gaps in HIV treatment service delivery continue to be critical to reach the goals of 95–95–95.

### 2.1.6 Other non-HIV benefits: reduction of other STIs

To varying degrees, male circumcision protects women against a range of STIs. Systematic reviews have found that male circumcision reduces the risk in women of oncogenic genotypes of human papilloma virus (HPV), *Trichomonas vaginalis*, bacterial vaginosis and possibly genital ulcer disease (56, 57) (Table 2.1). The evidence on herpes simplex virus type 2, *Chlamydia trachomatis*, *Treponema pallidum* and candidiasis was mixed.

Specifically regarding bacterial vaginosis (BV), microbiome data are increasingly pointing to the role of the male foreskin, which “could facilitate survival of BV-associated organisms, such as gram-negative anaerobic bacteria, resulting in more efficient and

prolonged transmission of such bacteria to sexual partners” (58). A review that found gram-negative anaerobic bacteria to be common under the foreskins of men in a large RCT of VMMC concluded that, by reducing penile proinflammatory anaerobic bacteria, VMMC likely decreases BV risk in female partners (59).

**Table 2.1. Randomized controlled trial findings of protection from STIs for women with circumcised male partners**

STI	Circumcised partner versus uncircumcised partner
High-risk HPV	Incidence ratio: 0.72 (95% CI: 0.60–0.86; $P=0.001$ )
Genital ulcer disease	Adjusted prevalence ratio: 0.78 (95% CI: 0.63–0.97)
Trichomonas vaginalis	Adjusted prevalence ratio: 0.52 (95% CI: 0.05–0.98)
Bacterial vaginosis	Adjusted prevalence ratio: 0.60 (95% CI: 0.38–0.94)

Source: Adapted from Morris et al., 2019 (56).

The potential impact of VMMC on cervical cancer was modelled based on data from Uganda (60). The results showed that VMMC scale-up alone will prevent about 20% of cervical cancer cases in the current scenarios of limited scale-up of HPV vaccination and cervical cancer screening and management. If these interventions were scaled up to 90% coverage, the impact of VMMC would be less important.

### 2.1.7 Other non-HIV benefits: population and individual benefits through delivery of other services

As a unique health intervention exclusively for men and adolescent boys, VMMC on a large scale represents an opportunity to offer other interventions to many men and their families. VMMC is offered in conjunction with a standard minimum package of services, defined by WHO to include:

- offer of HIV testing services (HTS)
- education on safer sex, including male and female condom education and promotion, and
- STI management.

VMMC services also provide an opportunity to link men to other health services, such as HIV care and treatment for those who test HIV-positive.

VMMC service delivery has served as a gateway to ancillary services beyond the standard package of services for VMMC clients. Services offered have addressed not only men but also women, particularly counselling and screening for cervical cancer as a way to involve female partners (61, 62). Other additional services reported in the published literature have included screening for hypertension and other non-communicable diseases (63), tuberculosis screening (64) and female condom provision (65). Also, malaria

management and family planning services have been integrated with VMMC in outreach services to high-risk communities, with resultant good uptake of VMMC noted (66, 67).

Since 2016 tetanus toxoid-containing vaccination (TTCV) has been advocated as an additional service to deliver along with VMMC to enhance its safety and to address gaps in tetanus immunity (68). This aligns with the 2017 updated WHO tetanus vaccine position paper, which strengthened statements on the need for boosters, particularly among adolescent boys (69). However, in studies in Rwanda (70), Uganda (71) and Zambia (72), there was a significant drop in uptake of VMMC when policy *required* two doses of TTCV prior to VMMC. (Programmes instituted the policy in response to tetanus risk with a specific circumcision method.) In the Uganda study more men dropped out after TTCV1 when they were required to receive two doses of TTCV vaccines before being circumcised than when one TTCV dose was required, mostly on the same day as the circumcision (56% versus 99% circumcised).

### 2.1.8 Balance of benefits and harms of offering male circumcision as an HIV prevention intervention

In addition to the HIV prevention benefits for circumcised men who have sex with women, VMMC may have several other benefits, including a reduction in HIV risk in women and in the risk of certain STIs.

At the same time, medical male circumcision involves some chance of adverse events (AEs). Such events are uncommon and manageable, mainly bleeding, infection, wound disruption, device-based method displacements and self-removal.

### 2.1.9 Harms

#### Severe and moderate adverse events

**Evidence from published literature.** Rates of severe and moderate AEs reported from diverse service delivery settings and study designs ranged from 0.2 to 16.2 per 100 medical male circumcisions, with an average of 0.3 per 100 (0.3%) based on a 2019 systematic review that identified 31 relevant publications<sup>1</sup> (Table 2.2). Most circumcisions were performed using one of the three conventional surgical methods as described in the *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men* (73), the majority with the forceps-guided method,<sup>2</sup> although the method used was not always stated. A limitation of these data is that AE definitions and severity classifications were not well standardized and the intensity and completeness of follow up varied over different types of studies.

The three RCTs (11, 74, 75) considered the safety of surgical male circumcision when performed under well-resourced research conditions by experienced surgeons or recently trained health care workers with access to expert supervision. There was close follow-up of clients over the two-year study period. Such research settings do not reflect the routine conditions under which male circumcision would be provided in VMMC

<sup>1</sup> Jindai K, Awori Q, Farley T, Temu J, Samuelson J. Safety of male circumcision for HIV prevention by conventional surgical methods and age, unpublished systematic review, June 2019; available from WHO/Universal Health Coverage/Communicable and Noncommunicable Diseases (UCN)/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

<sup>2</sup> Since 2014 this method has not been recommended for younger adolescents.

**Table 2.2. VMMC-related adverse events reported from diverse study types and settings**

Type of study	Number of studies	Number of countries	AEs per 100 procedures
Randomized controlled trials	3	3 African	3.33 (2.89–3.83)
Device-based research with comparison with conventional surgical method	11	7 African	4.70 (3.43–6.29)
Small pilot implementation, with fewer than 1000 clients	5	4 African and Dominican Republic	6.65 (5.68–7.73)
Pilot implementation, surveillance or retrospective reviews in routine settings with 1000 to 10 000 clients	8	5 African	3.86 (3.63–4.11)
Larger programme, routine adverse event reporting with at least 10 000 clients	4	3 African	0.22 (0.22–0.23)
All studies	31		0.30 (0.29–0.31)

programmes for HIV prevention. However, the lowest AE rate of 1.8 per 100 found in these studies provides a baseline for the lowest likely rate of AEs under research conditions.

In 2011 many countries started to report large volumes of circumcisions (76). The two largest and most recent studies reported findings on the safety of medical circumcision performed in a variety of routine service delivery settings. In Mozambique 1868 AEs were reported among 737 894 clients, for a rate of 0.25 AEs per 100 circumcisions (77). In Zimbabwe from October 2011 to March 2014, 290 AEs were reported among 171 588 clients, or 0.17 per 100 (78).

With a passive surveillance system, AE rates are susceptible to misclassification and to underreporting. However, a quality improvement project in Malawi demonstrated the value of case discussions to improve/correct reporting of AEs (79). Overall, AE rates were reduced from 8.5 to 4.4 per 100 over six months mainly through reclassification of mild inflammations that had been incorrectly classified as infected wounds. However, reports of bleeding-related AEs increased, from 0.3 to 1.5 per 100. Other studies have compared routine to active surveillance and noted higher rates of AEs obtained from active surveillance, suggesting that those lost to routine follow-up may have had higher rates of AEs (80, 81).

The main types of AEs reported have been bleeding and infection. It is difficult, however, to generalize rates of specific AEs from the various studies. Reported rates of serious and moderate AEs vary according to setting and intensity of follow-up (82).<sup>1</sup> Comparisons are

<sup>1</sup> Most studies use definitions as per the *Adverse event action guide for voluntary medical male circumcision (VMMC) by surgery or device* (80).

difficult due to likely variations regarding definitions and classification of adverse events and the rates of loss to follow-up at various post-operative times as specified by different study designs.<sup>1</sup> Thus, monitoring of AEs needs to include more specific age groups and requires systematic approaches to address the quality of safety data.

Among the studies identified in the review, six were case series reports on serious AEs, which included tetanus, Fournier's gangrene (necrotizing fasciitis), bleeding disorders, urethral fistula and penile injuries (68, 77, 83–89). Some of these cases may have been reported in more than one publication.

**Data from country monitoring systems.** WHO requested case reports on severe adverse events from national HIV programmes for the period 2014–2017. Five countries – Botswana, Lesotho, Malawi, Mozambique and Zambia – reported adverse events that occurred during this time period, when about three million VMMCs were performed in these countries. The most frequently reported severe AEs were excessive bleeding, infections and rare cases of penile and glans injuries and urinary fistula.

From 2012 through 2018, countries have reported to WHO 18 tetanus cases post-VMMC. During post-market surveillance of a device-based method, a significant difference by circumcision method, particularly a higher risk with the elastic collar compression device method, was reported in 2016 (89) (see Chapter 5, on use of devices).

The tetanus cases focused attention on a gender gap in tetanus protection. In pursuit of the global goal of eliminating neonatal tetanus, more women of reproductive age, including adolescent girls, than men received tetanus toxoid-containing boosters (90). WHO's 2017 vaccine position paper has further emphasized providing the booster dose to adolescent boys as well as girls (91).

The Notifiable Adverse Events surveillance system<sup>2</sup> of the United States President's Emergency Plan for AIDS Relief (PEPFAR) provided data on serious AEs for the period 2015–2018 (92). The most common severe AEs reported to that system were bleeding (n=42) and infection (n=69). Also reported were glans injuries (n=24), urethral fistulae (n=20) and tetanus (n=14), as well as long-term complications, such as keloids (n=4). It is likely that many of these cases were reported to WHO as well as to PEPFAR.

In summary, reported rates of severe and moderate AEs in VMMC programmes have been at a level similar to those observed in the randomized controlled trials (pooled prevalence of 3.3%). Many of the main severe AEs, including infection and bleeding, are resolvable events. The rates of AEs may decline as programmes, quality assurance approaches and the competence of health care workers mature. Tetanus risk could be reduced through adequate tetanus toxoid vaccination among adolescent boys. The low risk of uncommon but serious adverse events may likely decline further as a better understanding of adverse events that occur across countries permits learning and changes in practice.

<sup>1</sup> Jindai K, Awori Q, Farley T, Temu J, Samuelson J. Safety of male circumcision for HIV prevention by conventional surgical methods and age, unpublished systematic review, June 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

<sup>2</sup> PEPFAR's Notifiable Adverse Events surveillance system is a passive surveillance system that collects information on a subset of rare serious AEs. The system includes a notification and investigation process to monitor serious AEs, identify relatedness to the procedure and make recommendations for programme improvement.

**Safety with various cadres of health care workers.** An unpublished literature review<sup>1</sup> synthesized the evidence comparing the safety of VMMC when performed by diverse cadres of health care workers. Eleven publications compared performance by different health care cadres in a total of 20 018 procedures. Of these studies, only two found higher AE rates among non-physicians. In Kenya the AE rate was higher for nurses than clinician officers when inexperienced health care workers (<100 circumcisions) were included; this difference was not seen with active surveillance or among experienced health care workers (93). In a Ugandan study the AE rate was 2.6% (8/309) for nurses, 1.4% (2/143) for clinical officers (difference  $P=0.25$ ) and nil for physicians (who performed 109 of the 625 procedures) (94). Six publications did not make

Most studies have found no difference in AE rates between physicians and non-physician clinicians trained to perform VMMC.

comparisons; they involved over 7700 clients and found AE rates in non-physician cadres ranging from 0.7% to 2.6%. Procedures were typically surgical but did include the elastic collar compression device. In addition, one publication found a significantly higher follow-up visit rate among clients of nurses than among clients of physicians (81).

### Psychological distress

Only one paper on psychological distress was identified in a review of published literature from 2008 through 2019 (95), but it had limited relevance to VMMC for HIV prevention. This was a case-control study in Turkey of a small number of adults. It assessed psychosocial and physical effects after circumcisions performed for unstated reasons, not specifically for HIV prevention.

### Risk compensation

There has been no evidence of significant risk compensatory behaviour post-circumcision – that is, more risky sexual behaviour following circumcision driven by perception of lower HIV risk.

The extended post-trial follow-up of men in the RCTs in Kenya and Uganda found little evidence of risk compensation (27, 28). One meta-analysis<sup>2</sup> (96), assessed differences in sexual risk behaviours between circumcised and uncircumcised men before and after scale-up of VMMC. There was no difference between circumcised and uncircumcised men in condom use (relative odds ratio 1.06 (95% CI: 0.95–1.18; interaction  $P = 0.310$ )) nor in the number of non-cohabiting sexual partners (relative odds ratio 0.95 (95% CI: 0.86–1.05)). Still, the authors urge continued attention to local context and communication of accurate messages about partial protection and safer sexual behaviours.

Other, small studies have indicated that women may not understand that the protection provided by VMMC is partial. Women need, and have expressed an interest to be, more involved in developing accurate messaging on partial protection (97–99). Some small studies have suggested that local context and beliefs may be related to riskier

<sup>1</sup> Davis S, Baker H, Gross J, Leslie S, Chasokela C, Samuelson J et al. The role of nurses and midwives in expanding and sustaining voluntary medical male circumcision services for HIV prevention: an integrative review, unpublished literature review, 2020; available from WHO/Universal Health Coverage/Communicable and Noncommunicable Diseases (UCN)/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

<sup>2</sup> Analysis of Demographic and Health Survey data from 10 countries in East and Southern Africa, with a sample of 67 590 men.

behaviours during healing (100, 101). One qualitative study indicated that some rural men considering VMMC anticipated engaging in high-risk behaviour after circumcision, and they believed, contrary to fact, that VMMC enhances sexual performance – a misperception that has been reported elsewhere (see Annex 2.3) (102).

## 2.2 Other factors to inform decision-making

WHO commissioned a review of the literature (2007 through September 2018) looking at values and preferences, acceptability, resource requirements and costs (including cost-effectiveness), ethics and equity, and feasibility.<sup>1</sup>

### 2.2.1 Values and preferences<sup>2</sup>

No publications were identified that addressed the relative importance that men, women or the community place on the outcomes of undergoing VMMC (such as reduced risk of HIV infection of circumcised males, reduced risk of HIV infection of female sexual partners, reduced HIV prevalence in the community, complications of the procedure). However, studies do provide indirect evidence on the key factors behind the decision to undergo VMMC (see next section). One qualitative process evaluation of a sports-based intervention noted that older men reported a lack of motivation for circumcision because HIV testing and VMMC would make little difference at their age (103). Due to lack of evidence, it is not possible to assess whether there are any important uncertainties and variabilities in the importance of VMMC for HIV prevention.

The Guideline Development Group considered the health burden of HIV, including its social implications, to be huge. It is important to implement effective interventions, including VMMC, that help people to avoid this burden.

### 2.2.2 Acceptability

The large number of adolescents and men – over 23 million by the end of 2018 – who have been circumcised through HIV prevention programmes indicates the acceptability of VMMC to men and parents, although the target of 90% coverage was not achieved. In surveys a large proportion of men have said that they find circumcision acceptable both for themselves and for their sons, and a high proportion of women and mothers said they find circumcision acceptable for their partners or sons. There was no major variation across these respondents.

A literature review identified 70 studies on the acceptability of VMMC, conducted in 18 countries (61, 93, 97, 101, 103-167).<sup>3</sup> The ages of the participants in these studies ranged from 10 to 86 years.

<sup>1</sup> Systematic Review Solutions. WHO guidance on voluntary medical male circumcision (VMMC) for HIV prevention amongst adolescent boys and men: literature reviews for PICOs 1, 2 & 3, full report, unpublished, 2018; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int). See Annex 2.2.

<sup>2</sup> Values and preferences, as defined by the WHO Handbook on guidelines development, pertain to the relative importance that people assign to the outcomes associated with the intervention or exposure, not the intervention itself.

<sup>3</sup> Botswana, China, Dominican Republic, Haiti, India, Jamaica, Kenya, Lesotho, Malawi, Papua New Guinea, Rwanda, South Africa, Swaziland, Thailand, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. Sample sizes ranged from 20 to 4874 participants; none of the studies was longitudinal.

The majority of these studies (62 of the 70) assessed the acceptability of VMMC among males, while 29 studies assessed the acceptability of VMMC among females; one study explored the acceptability of VMMC in communities (145). Two studies assessed the acceptability of VMMC among health care workers (105, 110), and one study explored the acceptability of VMMC among policy-makers (140).<sup>1</sup>

Acceptance rates and willingness of males to undergo VMMC and females' attitudes toward partners' and sons' circumcision were reported quantitatively in 13 studies in eight countries (97, 105-107, 116, 118, 121, 128, 134, 135, 148, 158, 164). These studies collected data between 2007, when WHO issued the recommendation of VMMC, and 2015. Respondents included men and women ages 15 to 50 years. Between 40% and

Across eight countries  
40%–85% of men and  
50%–93% of women found  
VMMC acceptable.

85% of uncircumcised men considered VMMC acceptable; as did 50%–93% of women. Where reported, acceptability for men and women was highest for circumcising sons as children and adolescents and lowest for adult men. (For information on adolescents, see section 4.2.)

### Facilitators and barriers to acceptability

A large number of small descriptive studies have identified a wide array of facilitators and barriers to the acceptability of VMMC (see Annex 2.3). The three most common facilitators reported in the studies were increased knowledge of HIV/STI prevention, improved penile hygiene and expectation of improved sexual activity/pleasure. (Although some men identified improved sexual pleasure as a motivation for circumcision, there is very limited evidence whether circumcision increases sexual pleasure. Thus, it should not be promoted as a benefit of VMMC.) The three most common barriers were fear of pain and injury, the possibility of complications/AEs and the need for time off from work. None of the studies reported legal or ethical constraints.

Key facilitators of the uptake of services among young people, as reported in a literature review (168), included targeted messaging, youth-focused services, a youth-friendly service environment and promoting additional benefits of VMMC. Parental engagement plays a vital role in helping adolescents understand the benefits of VMMC and encouraging service uptake and proper wound care after surgery. Schools are an essential partner as well.

Barriers to both accessing services and appropriate delivery of services include negative interactions with health care workers and violations of privacy. Additionally, specifically for adolescents, a desire of both boys and parents to include elements of traditional non-medical circumcision in medical circumcision may be a barrier (168).

In a qualitative study health care workers (VMMC counsellors, nurses, midwives) and facility managers in South Africa, United Republic of Tanzania and Zimbabwe agreed that, to be effective, VMMC training needs to incorporate thorough adolescent-specific guidance (169). Specifically, training should cover areas that health care workers consider their responsibility: HIV testing, family planning including provision of condoms, STI testing and treatment and other, general health services.

<sup>1</sup> Many of these studies were qualitative in nature and employed a cross-sectional design; one was a systematic review (158). Some studies used a convenience sample, thus limiting the extrapolation of results to the larger population.



### 2.2.3 Resource requirements including costs

**Cost per procedure.** Cost per VMMC performed varies across countries and settings. Personnel and consumables are key cost factors. Eleven studies reported on cost per VMMC procedure (170–180). The estimated cost ranged from US\$ 23 to US\$ 191 in various African countries. A few studies (174, 176, 178) reported cost data based on larger study sizes in several African countries and thus have better generalizability. Their range of costs was US\$ 66 to US\$ 160 per procedure.

In a study of four sub-Saharan countries, supply-side factors associated with lower VMMC unit costs included level of service provision (lower costs in primary health care facilities than in hospitals), provision of other services (including ART and PMTCT) along with VMMC, volume of VMMCs and delegation of tasks to less specialized staff (178). Higher costs were noted in facilities that conducted outreach and those that employed health care workers with more years of experience. Staff costs constituted the largest component of VMMC unit costs in all four countries, with consumables such as circumcision kits and HIV test kits contributing the second largest share. In Uganda use of reusable kits (US\$ 8.46 each) saved 46%–59% over disposable kits (US\$ 15.60 – US\$ 20.80) (181) and cost savings on personnel were attributable to shifting tasks from physicians to clinical officers at both mobile camps and fixed centres (180). Also, training for Ugandan surgeons who lacked experience performing adult circumcisions yielded efficiencies and cost savings. The authors of the four-country study suggest that quality

Personnel and consumables costs are the largest expenses in VMMC programmes.

VMMC services can be delivered at lower costs by, for example, ensuring access during the season when demand for VMMC is greatest, offering other HIV services and adjusting the staffing mix, including through task shifting (178).

**Cost-effectiveness.** VMMC is cost-effective. Evidence of this comes from nine studies across East and Southern Africa (124, 170–172, 176, 179, 181–183). Estimates of the cost per HIV infection averted in adults have ranged from US\$ 117, reported from Kenya (170), to US\$ 4949, reported from Rwanda (179), with costs from other countries falling within that range (154). Estimates of cost per HIV infection averted were lowest for the longest projected time periods post-circumcision, since more heterosexual acts are partially protected.

A 2016 UNAIDS and WHO consultation reviewed multiple modelling studies and concluded that VMMC in the age groups 15–19, 20–24 or 25–29 years maximize the cost-effectiveness of circumcision. At these ages the lowest number of circumcisions were required to prevent one HIV infection, the discounted cost per HIV infection averted was lowest, and net savings was greatest (184). This review included a costing study reporting that, in Malawi, South Africa, Swaziland, Uganda and the United Republic of Tanzania, the lowest cost per HIV infection averted could be achieved by circumcising males ages 15–34 years (185). A recent study in Zimbabwe modelled savings of US\$ 55–198 million in ART costs avoided from 2017 through 2030 thanks to the preventive effect of VMMC (52).

**Cost-benefit.** The third edition of the World Bank’s Disease Control Priorities (2015) lists VMMC as one of 44 essential surgical procedures because it addresses substantial needs, is cost-effective and can be widely implemented (186). The Copenhagen

Consensus undertook an extensive review of proposed interventions to support the Sustainable Development Goals and concluded:

VMMC is a highly cost-beneficial intervention to address the HIV epidemic in hyperendemic countries for the period 2015–2030 (187).

– *The Copenhagen Consensus*

## 2.2.4 Ethics and human rights

The field of health ethics seeks to understand the values underlying decisions and actions in health care and health policy and to provide guidance for action when these values conflict (188). In 2020 the ethical issues regarding VMMC remain similar to those addressed in 2007, although with additional attention to issues relevant to younger adolescents, as they do not yet have full autonomy (see section 4.2). For older adolescents and adults, the ethics statements made in the 2007 WHO/UNAIDS recommendations (1) remain relevant:

- A human-rights and ethics-based approach to the development or expansion of MMC services requires measures that ensure that the appropriate laws, regulations and policies are available so that the procedure can be provided safely, under conditions of informed consent and without coercion or discrimination.
- The promotion of MMC is justified when males voluntarily choose the procedure on the basis of accurate information and adequate understanding of risks (AEs), benefits (partial protection over lifetime from HIV and other STIs) and other implications for their lives and the lives of others (reduced risk of HIV in community).
- Promoting, and providing, safe male circumcision should not replace other interventions to prevent heterosexual transmission of HIV but provides an additional prevention strategy.
- Stakeholders and other decision-makers should be consulted to analyse and justify the reasons for promotion of VMMC.

**Informed consent** is a core component of human rights. As noted in UNESCO's *Universal declaration on bioethics and human rights* (2005) (189), any preventive, diagnostic or therapeutic medical intervention is to be carried out only with the prior, free and informed consent of the person concerned, based on adequate information. As VMMC is offered to healthy men and adolescent boys for HIV prevention, it is particularly important that they are informed and can consider the benefits and risks, including the risk of rare adverse events, to guide them in their decision-making. Consent should be explicit, and it may be withdrawn by the person concerned at any time before the procedure and for any reason without disadvantage or prejudice. In countries that lack explicit reference in law or policy to informed consent as a human right, the right may be inferred from the *right to privacy*, the *right to dignity* and in some instances the *right to bodily integrity*, which is centred on the importance of personal autonomy and the self-determination of human beings over their own bodies.

**Public health considerations.** The strength of the ethical justification for VMMC also depends on the reliability of the scientific data on VMMC and the effects of its implementation, as described above. However, a purely public health justification of VMMC initiatives, in which success was measured exclusively in terms of the numbers of infections averted, regardless of how those numbers were achieved, would be ethically

problematic. Rather, the overall ethical justification for VMMC as a public health initiative is dynamic and depends on a number of different factors that can change over time, including the emergence of new HIV prevention modalities, epidemiological changes, new data about safety and new approaches to voluntary informed consent. In any case, male circumcision should not replace other methods of HIV prevention and should always be considered part of a comprehensive HIV prevention package. Also, males who decline VMMC should not face stigma and discrimination.

VMMC should not replace other methods of HIV prevention and should always be considered part of a comprehensive combination HIV prevention package.

### 2.2.5 Equity

Equity speaks to fairness in the protection of rights, interests and welfare (190). All adolescent and adult males should have a fair opportunity to obtain VMMC services, and efforts should be made to reduce disadvantages in access (for example, because of onerous costs of the procedure, follow-up care or travel to facilities; see Chapter 6 on financial compensation).

A few studies were identified that address equity. Traditional community values and ethnic and social situations are factors directly affecting the acceptability of VMMC, thus indirectly affecting equity. Those who live in or near communities where VMMC is not supported or available have been adversely affected in terms of equity (148, 191). People in the United Republic of Tanzania who resided in remote locations, farther than 5 km and, even more so, farther than 10 km from a fixed VMMC facility, were likely to be disadvantaged for follow-up to VMMC (5–10 km versus 0–1 km: OR 1.71, 95% CI 1.08–2.7; >10 km: OR 2.8, 95% CI 1.26–6.21) (192).

### 2.2.6 Feasibility

Unanimously, the Guidelines Development Group considered VMMC a feasible intervention. As of the end of 2018, nearly 23 million men and adolescent boys had been circumcised through HIV prevention programmes (76), demonstrating its feasibility. However, challenges remain to achieving greater coverage, particularly among adult males who are at greatest immediate risk of HIV infection.

Human resources – that is, health care workers and their training and support – are essential to all health systems. As noted, staffing is one of the key costs of VMMC programmes. But these costs are a crucial investment in better trained personnel and, thus, better health outcomes (193).

Approaches to VMMC implementation may affect the sustainability of delivery. One process evaluation study qualitatively compared integration of VMMC into routine services in 21 districts in Zimbabwe with a vertical stand-alone service approach used in 43 other districts. While the integrated approach slowed initial scale-up, it strengthened local ownership and partnerships. Overall, the benefits were considerable, including improved capacity to overcome obstacles and to sustain services (194). This integrated and

While an integrated approach slowed initial scale-up, it offered considerable overall benefits over a separate, parallel service for VMMC.

blended model's reliance on existing facilities, staff, and commodity and supply infrastructure, supplemented by performance-based financing, appeared to help reduce donor costs and motivated health care workers to incorporate VMMC into their work. A reliable, integrated health information system has strengthened this approach.

## 2.2.7 Programme and implementation considerations

### Populations and services for HIV prevention

VMMC is an important HIV prevention intervention as well as a strategic point of contact with health services for men. Therefore, it should be included in combination HIV prevention, offered as part of a package of prevention services. Reaching men at higher risk of HIV infection, irrespective of age, should be a priority, as circumcision will most reduce absolute risk for these men, and they also could benefit from other HIV prevention, testing and treatment services. Examples include men attending STI clinics (both private- and public-sector) and men in certain occupational groups with historically high HIV infection rates, such as migrant workers, members of uniformed services, fisherfolk and truck drivers. For ongoing scale-up to higher coverage levels among adults, including those at higher risk, governments must continue to lead in advocacy, strategic planning and coordinating across relevant ministries and sectors and with other, nongovernmental partners.

HIV prevention services should always include education for safer sex (promoting delay in the onset of sexual relations, abstinence from penetrative sex and reduction in the number of sexual partners); provision and promotion of correct and consistent use of male and female condoms; providing HIV testing services; and services for the management of STIs. VMMC service provision should be used as an opportunity to address the sexual health needs of men and to offer locally relevant noncommunicable disease interventions.

VMMC should be considered an opportunity to deliver other needed health services for men and adolescent boys. Guidance is available elsewhere on service packages and how to operationalize services (195).

Policy-makers and programme managers also could consider ways that VMMC programming can address gender norms that are harmful for men and women and gender-based violence. Managers should monitor and minimize possible negative gender-related impacts of male circumcision programmes, such as risk compensation, as part of any VMMC programme.

VMMC should be offered through the formal health sector and performed by competent trained health professionals in settings with adequate resources. Where traditional circumcision is practiced, efforts should be made to engage with traditional practitioners to replace unsafe practices with VMMC.

Safety monitoring should be improved, including promoting learning and response systems on adverse events at all levels.

## Training and communication on VMMC

Health care workers need sufficient training to clearly convey key messages such as these:

- VMMC does not provide full protection from HIV infection, but it does contribute, along with other protective measures, to reducing the risk of HIV infection.
- Men who resume sexual activity before wound healing may be at higher risk of HIV infection.
- Men who have HIV and are not virally suppressed on ART are at higher risk of infecting their sexual partners if they resume sex before the circumcision wound is fully healed.

It is important that these messages are understood — in particular the message that circumcision does not provide complete protection against HIV infection; circumcised men can still become infected with HIV and, if infected, can infect their sexual partners. Because VMMC is not completely protective against HIV infection, clear and accurate information on the continuing need for other HIV prevention measures is crucial. This is necessary to prevent circumcised men from developing a false sense of security and engaging in high-risk sexual behaviours.

Because of HIV-positive men's higher risk of passing HIV infection if they have sex before their circumcision wound heals, HIV-positive men who want circumcision should be supported to be on ART and virally suppressed before undergoing circumcision. This support should include education on benefits for his own health (such as reduction in STIs) and how to reduce transmission risk during the healing period, such as condom use. Use of condoms for six months also will help to protect the wound until fully healed.

### Box 2.1. 2007 WHO recommendations and good practice statements on communication

- Global, regional and national level communication strategies need to ensure that clear and consistent messages are disseminated and that MC [male circumcision] is promoted within the context of comprehensive HIV prevention strategies. This is necessary to prevent a false sense of security and engaging in high risk sexual behaviours that could undermine the partial protection provided by MC.
- Messages need to be developed to ensure that men who opt-in for the procedure and, where possible, their partners are counselled that male circumcision is only partially protective and, therefore, they need to continue to use other effective measures of HIV prevention.
- Messages should be carefully tailored, culturally sensitive, draw on local language and be appropriate to the level of understanding of population groups, both for men and women.

Source: WHO and UNAIDS, 2007 (1).

In settings where female genital mutilation takes place, the message that medical male circumcision is very different from female genital mutilation needs emphasis. Female genital mutilation has serious adverse effects on the health of women and on obstetric outcomes. Unlike male circumcision, female genital mutilation has no demonstrated medical benefits, and it harms girls and women in many ways (196).

### Preventing harm

Programme managers and policy-makers have an ethical obligation to monitor and minimize the potential for harms resulting from misunderstanding or misrepresentation of VMMC for HIV prevention. Some of these harms may particularly affect women. Gender implications of male circumcision as an HIV prevention method include possible risk compensation, mischaracterization of the potential HIV risk-reduction effect of circumcision for men who have sex with men and transgender women, mischaracterization of the efficacy of circumcision in reducing sexual transmission of HIV from men to women, inadvertently appearing to promote unsafe sex and conflating male circumcision with female genital mutilation. On the positive side, managers and policy-makers should consider how VMMC programming might offer opportunities to address harmful gender norms and gender-based violence.

#### Box 2.2. Research needs on HIV prevention with VMMC

To inform programming, service design and service delivery, research is needed to:

- measure the impact and contribution to HIV prevention of VMMC within combination prevention services, taking account of ART's secondary prevention effect;
- assess the effect of VMMC in reducing other STIs and cervical cancer;
- assess and understand more broadly men's values and preferences concerning HIV prevention, including its importance, relative to their life situations;
- better understand policy-makers', communities' and individual's perspectives on VMMC for HIV and STI prevention.
- assess feasibility, cost, and effectiveness of expanding other services for men provided along with VMMC services.

# ISSUES AND CONSIDERATIONS REGARDING VMMC FOR YOUNGER ADOLESCENT BOYS

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### 3 ISSUES AND CONSIDERATIONS REGARDING VMMC FOR YOUNGER ADOLESCENT BOYS

#### Key considerations on offering VMMC services to younger adolescents

**NEW**

In many settings VMMC for HIV prevention has been provided to younger adolescents. Decisions on offering VMMC to younger adolescents, ages 10–14 years, must consider several factors within a national and local context. Regarding the offer of VMMC services for younger adolescents, the Guideline Development Group concluded, based on limited evidence and other factors, that the following should be considered:

- **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.
- **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.

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 AEs by adolescent age group with use of conventional surgical methods (forceps-guided and dorsal slit) and a higher rate of certain rare serious AEs (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 with the dorsal slit method is unknown but appears to be small (likely <1 per 100 000 VMMCs).



- 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. An adolescent boy who is not yet developed should be advised to return later, when further advanced in puberty. While most adolescents age 15 and older are physically mature, preventing serious AEs among adolescents 15 years and older who are not yet physically mature means that some may need to be deferred until more mature.
- **Feasibility.** The feasibility is unknown of offering some aspects of the VMMC package and other services and education needed at specific adolescent ages, such as comprehensive sexuality education and internationally recommended vaccinations such as tetanus toxoid-containing vaccination (recommended between ages 9 and 15 years).
- **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.

Note: Based on the scoping to determine the focus of these guidelines, infant male circumcision is not included here, given that the primary purpose of VMMC is the prevention of HIV to reduce the epidemic during the next decade.

### 3.1 Adolescent development

Adolescence, defined as ages 10–19, spans various developmental stages. Adolescence is often divided into two periods – early adolescence, ages 10–14 years, and late adolescence, ages 15–19 years, with the latter stage transitioning into adulthood. These periods correspond approximately, but not consistently, to phases of physical, social and psychological development in the transition from childhood to adulthood. Adolescents mature physically, socially and emotionally at different rates during these years (197). Physical maturity usually occurs before psychosocial maturity. Table 3.1 shows the different stages of adolescence. Age ranges are indicative, since there is significant variation among individuals, and physical, psychological and social development may proceed at different rates in different people.

Physical maturity is an important factor in the safety of VMMC in younger adolescents, and cognitive and psychosocial maturity are central to the capacity to give informed consent. Maturity in these different areas of development is not usually reached at the same time; physical maturity does not necessarily indicate cognitive maturity. Adolescents of the same age also may differ in terms of their sexual behaviour and their roles and responsibilities with family and community.

**Table 3.1. Developmental characteristics of adolescent boys**

	Early adolescence (~10–14 years)	Late adolescence (~15–19 years)
<b>Physical development</b>	Puberty: growth of body hair; increased perspiration and oil production in skin and hair; great physical growth (both height and weight); growth in testicles and penis; wet dreams; deepening of voice	Physical growth continues
<b>Cognitive development</b>	Growth in capacity for abstract thought; mostly interested in present with little thought about the future; expansion of and increased importance placed on intellectual interests; deepening of moral thinking	Continued growth in capacity for abstract thought; increased capacity for setting goals; interest in moral reasoning; thinking about the meaning of life
<b>Social and emotional development</b>	Struggle with sense of identity, feeling awkward about themselves and their bodies; worry about being normal; realizing that parents are not perfect; heightened conflict with parents; increasingly influenced by peer group; greater desire for independence; return to childish behaviour when stressed; prone to mood swings; testing rules and limits; becoming more private; growing interest in sex	Intense self-involvement, alternating between high expectations and poor self-identity; continued adjustment to changing body; worry about being normal; tendency to distance self from parents; continued drive for independence; driven to make friends and relying more on them (popularity can be an important issue); heightened capacity for emotional regulation; experiencing feelings of love and passion; increasing interest in sex

Source: Sawyer et al., 2012 (198).

### 3.2 Rationale and background for review of VMMC for HIV prevention among younger adolescents

The three RCTs that demonstrated, by the mid-2000s, the efficacy of VMMC for HIV prevention involved only males ages 15 years and older (11–13). No difference in the preventive effect is expected among younger adolescents, given the early observations of the association of lower HIV risk with male circumcision in countries where infant circumcision is routine (199, 200). No RCT evidence was available on the safety and acceptability of VMMC among younger adolescents. Nor have studies focused on how to maintain effective coverage of VMMC, including among younger adolescents. In addition, since 2007, informed consent standards regarding adolescents have been updated and need to be reconsidered. The 2007 recommendations (1) regarding age were:

Such countries (generalized epidemics) should consider scaling up access to male circumcision services as a priority for adolescents, young men and, as indicated by local epidemiology and other considerations, older men at particularly high risk of HIV.

Where male circumcision is provided for minors (young boys and adolescents), there should be involvement of the child in the decision-making, and the child should be given the opportunity

to provide assent or consent, according to his evolving capacity. Depending on the local laws, some mature minors may be able to give independent informed consent. Parents who are responsible for providing consent, including for the circumcision of male infants, should be given sufficient information regarding the benefits and risks of the procedure in order to determine what is in the best interests of the child.

While males ages 10–14 years were not an initial priority population group for VMMC, it has been estimated that annually, from 2015 through 2017, 42%–46% of uptake was among younger adolescents (10–14 years) and about 27% was among older adolescents (15–19 years) across 14 VMMC priority countries of East and Southern Africa (201). By comparison, in earlier years, 2010–2013, no more than one third of VMMC clients were in the younger age group. Thus, a shift has occurred, particularly as countries reach higher coverage levels among adults, who were the priority group in the initial, catch-up phase (201), and due also to population demographics. Currently, one quarter of the populations in these countries are young people, and that fraction will increase in the coming decade.

As countries reach higher coverage levels of adult medical male circumcision and seek to maintain VMMC coverage, they need to reorient to delivering services to new, uncircumcised cohorts of males. Deciding which age range to focus on requires considering several factors.

To sustain effective HIV prevention coverage levels, programmes need to reorient the delivery of services to uncircumcised cohorts of males. However, evidence on which age range to focus on has not been systematically considered, including information on safety for younger adolescents compared with older adolescents, on approaches to maintaining high coverage levels for the lifelong benefit of HIV prevention and on integration or linkage with delivery of other health interventions.

### 3.3 Evidence to inform policy on the offer of VMMC for HIV prevention to adolescents ages 10–14 years compared with older adolescents: safety, acceptability and maintaining effective coverage

As noted, adolescents develop at diverse ages. The Tanner stages (Table 3.2) are a common classification scale of sexual maturity, often used in paediatric and adolescent practice to counsel about puberty. Ideally, a classification such as the Tanner stages would be used in assessing VMMC safety among adolescents. However, such information is not routinely collected. Thus, age is used as a proxy. In males the onset of puberty ranges from 9 to 14 years and maturity is reached at 13 to 17 years. Development of genitalia to an adult stage occurs on average three years after puberty begins (202).

#### 3.3.1 Safety

Although there are extensive programmatic VMMC safety data, evidence that is systematically age disaggregated is limited, including information on boys ages 10–14 years, who are at diverse stages in puberty. An unpublished systematic review on the

safety of conventional surgical male circumcision methods<sup>1</sup> identified only six publications with safety information (adverse events) specific to adolescent males (10–19 years) and that were age-disaggregated in sufficient detail (77, 81, 204–207). Even in these studies, age groupings were diverse, and only two studies presented data specific to the younger age group of 10–14 years (77, 204). These studies report on severe and moderate AEs.

Surveillance reports on serious AEs provided additional details, including data from PEPFAR's Notifiable Adverse Events Reporting (NAER) surveillance system and ad hoc adverse event reports made to WHO.

**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 (203).

<sup>1</sup> Kazu J, Awori Q, Farley T, Temu A, Samuelson J. Safety of male circumcision for HIV prevention by conventional surgical methods and age, unpublished systematic review, 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

The six studies in the systematic review were of low quality, and, as noted, only two specifically included the age group 10–14 years and sufficient details. A cohort study (204) in Zimbabwe during 2014–2015 showed similar overall rates of severe and moderate AEs among males ages 10–14 years, 15–19 years and 20 years of age and older. However, adolescents ages 10–14 years had a twofold to threefold higher risk of infections than those 15 years and older (adjusted RR 3.07 (95% CI: 1.36–6.91)). Most procedures were forceps-guided or dorsal slit, with a small proportion of elastic collar compression procedures. A cohort study in Kenya showed a lower risk of severe and moderate AEs among those 13–17 years of age than among males 18 years and older (adjusted odds ratio 0.27, 95% CI: 0.14–0.52); no data were available for adolescents age 10–12 years (205). (See GRADE table, Annex 2.1.)

The PEPFAR NAER system provided evidence on AEs by age for the period 2015 through June 2018. Of VMMC-related AEs reported to this system, prevalence was greater among males 10–14 years than among those  $\geq 15$  years (2.1 versus 1.3 per 100 000 procedures, PR=1.6 (95% CI: 1.2–2.1)). Infections were the most common AE in both age groups: 0.6 per 100 000 procedures in both groups (92).

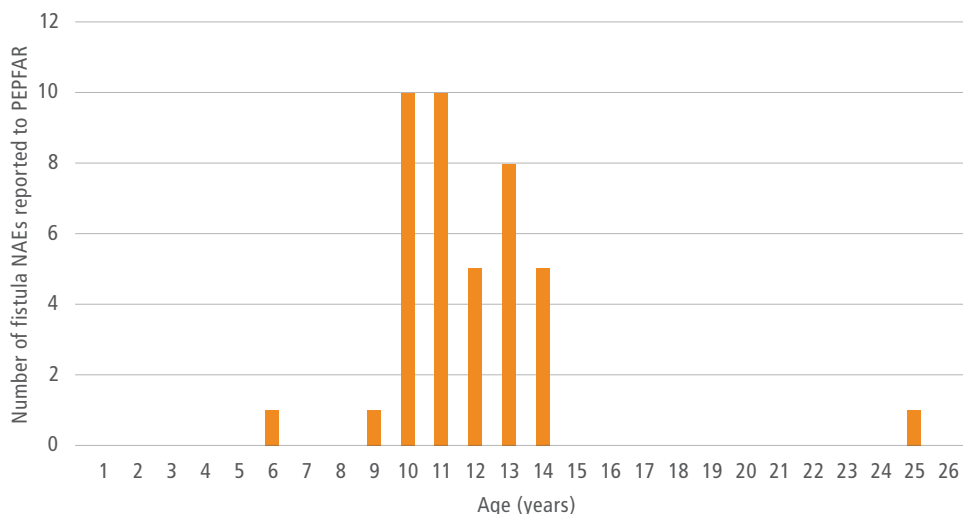
A large proportion of glans injuries occurred during procedures performed by the forceps-guided method between 2010 and 2014, resulting in WHO and PEPFAR advising against the use of the forceps-guided method with boys under age 15 years or with those older than 15 with immature genitalia. Most of the priority countries implemented this policy. However, 36 glans injuries were reported through NAER systems from 2015 to 2018. All patients were under 15 (~0.6 per 100 000 VMMCs in this age group), with a decreasing annual rate. Most glans injuries (64%) were partial or complete amputations. All amputations among 10–14 year-olds occurred using the forceps-guided method (206).

Among 41 cases of urethral fistula reported to PEPFAR from 2015 to 2019, 98% were reported among males ages 10 through 14 years. The median age was 11 years. The incidence was 0.61 per 100 000 among those under 15 years compared with 0.01 per 100 000 among those ages 15 or older (95% CI: 8.6–2060)<sup>1</sup> (Fig. 3.1). Similarly, cases reported to WHO (likely many the same as reported to PEPFAR) on rare serious AEs between 2015 and 2019 included 37 cases of urethral fistula from nine countries, with all but two clients between the ages of 6 and 15 years.

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<sup>1</sup> Lucas T, Hines J, Samuelson J, Hargreave T, Davis S, Prainito A et al. Case series of urethrocutaneous fistulas after VMMC for HIV prevention: 15 African countries, 2015–2019, unpublished report, 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

**Fig. 3.1. Number of urethral fistula notifiable adverse events reported to PEPFAR, by age, 2015–2019 (N=41)**



Source: Lucas T, Hines J, Samuelson J, Hargreave T, Davis S, Prainito A et al. Case series of urethrocutaneous fistulas after VMMC for HIV prevention: 15 African countries, 2015–2019, unpublished report, 2019.

These data indicate that younger adolescents' risk of selected serious AEs (a subset of severe AEs having the potential for lifelong consequences) is greater than that of those over 15 years of age. However, due to likely underreporting, these data do not provide precise estimates of risk. More age-disaggregated data are needed.

Among all cases of tetanus reported to WHO since 2012, a minority (21%) occurred in the 10–14 year age group, which constituted about 46% of procedures during that time period. In the 2017 updated WHO tetanus vaccine position paper (69), statements were strengthened on the need for boosters, particularly among adolescent boys – a service that should be routinely available to all adolescent boys globally whether they undergo VMMC or not.

### Box 3.1. Research needs for assuring safety for adolescents

- Collect surveillance information on moderate, severe and serious AEs so as to better inform actions that reduce risks among adolescents
  - Assess AEs by method and, among younger adolescents, disaggregate by individual year of age or 2-year age bands (that is, 10–11, 12–13, 14–15).
- Assess the capacities of health care providers to determine adolescents' physical size and capacity for informed consent.

### 3.3.2 Acceptability

VMMC acceptability for the adolescent age group is suggested by programmatic data showing the large proportion of adolescent clients – about 70% – in the scale-up to nearly 23 million men of all ages in the priority countries by the end of 2018. About 45% were adolescents ages 10–14 years and 25% were ages 15–19 years. This programmatic evidence suggests that, for adolescent boys and their parents, VMMC at ages 10–14 years may be acceptable. Studies are limited, however, particularly studies that differentiate between parental and peer influences on the young adolescent.

About 45% of the VMMCs since 2015 have been among adolescents ages 10–14 and 25% among those 15–19 years.

Only three small cross-sectional studies have reported measures of acceptability, in four African countries (Rwanda, South Africa, United Republic of Tanzania and Zimbabwe) (208–210), including assessment of parents' views on the acceptability of VMMC for their sons (208, 210). In the Tanzanian study, 95%–97% of both men and women supported VMMC for their sons. Of these, two thirds of women preferred prepubertal circumcision (12 years or younger), while one third preferred post-pubertal circumcision (above 12 years) in a medical setting. Reasons for preferring prepubertal circumcision were faster wound healing, less bleeding and pain and no lost time at work during wound healing (210).

Two studies assessed the acceptability of VMMC to younger and older adolescent boys (208, 209). These studies were larger and more nationally representative than the studies that assessed the acceptability of VMMC to parents. Both younger adolescents (10–14 years) and older adolescents (15–19 years) reported that key facilitators for undergoing VMMC were protection from HIV/STIs, improved hygiene and when VMMC was suggested or advised by parents or school. Among the younger adolescents, the main barrier to VMMC was pain, and the main facilitator was HIV protection. Pain was a common barrier to uptake of VMMC among all adolescents, either pain from the procedure or pain from the injection of anaesthetic (younger adolescents: 44.5%; older adolescents: 66.4%) (209). Recovery from the procedure was perceived as “hard” or “very hard” by 13.1% of younger adolescents and 8.4% of older adolescents ( $P = 0.004$ ) (209). Other, minor barriers to undergoing VMMC were duration of healing and concern about sexual abstinence during wound healing and potential damage to the penis (2%–4%).

Information was limited on such aspects of acceptability as healing time, cosmetic result and time to return to activities of daily living. Trials comparing conventional surgery and device-based methods have shown that younger adolescents heal more quickly in either case (68, 211, 212). Regarding cosmetic results, one potential longer-term complication identified was keloids, of which nine cases had been reported to WHO by mid-2018; the age range was 11–15 years. In a 2008 study in Kenya among 298 adolescents, keloids were identified as occurring after both traditional and clinical circumcision (213). A review of the literature on keloids suggests that multiple factors may be associated with their occurrence, including genetics, with the incidence of keloids higher in people of African descent than in other populations (214, 215). (Pre-existing keloids are a contraindication to VMMC.)

The Guideline Development Group noted that evidence is limited on the acceptability of VMMC for adolescents among adolescents themselves, their parents and policy-makers. However, the Guideline Development Group noted that programmatic experience suggests that VMMC for this age group is acceptable and factored this into the decision-making process. They considered that refusing medical male circumcision to this age group – a group already accessing VMMC services in many countries – could have unintended adverse consequences, such as loss to follow-up, movement out of the health sector to traditional or unqualified circumcisers and creating a negative perception of VMMC in the community.

### 3.3.3 Maintaining effective VMMC coverage

As countries shift to sustainable VMMC services in order to maintain high VMMC coverage for HIV prevention, several factors can inform programme decisions on which ages deserve focus. These include safety, capacity to consent, acceptability, eligibility for VMMC by specific method, and integration or linkage with other services that contribute to achieving universal health care (such as health education, deworming, family planning and hygiene education) and that provide lifelong benefits.

Many adolescents ages 10 through 14 years will not have the capacity to provide informed consent. For adolescents of any age who do have this capacity, the proportion who are ineligible due to physical conditions may depend on the circumcision method and the preventability of risks associated with specific methods. For some conditions identified as contraindications to VMMC, prevalence differs between younger and older adolescent age groups. Some conditions are absolute contraindications, while others may be resolved in order to proceed with the procedure – for example, treatment of an STI. Two resolvable

Eligibility may be affected by the presence of physiological phimosis and adhesions, which are more common among younger, prepubescent adolescents and which need resolution before circumcision.

physiological conditions that are more common among younger adolescents than older adolescents or adults are phimosis and adhesions. Physiological phimosis and adhesions are normal in pre-pubertal males (73). These conditions are contraindication to use of the forceps-guided method and certain device-based methods of circumcision.

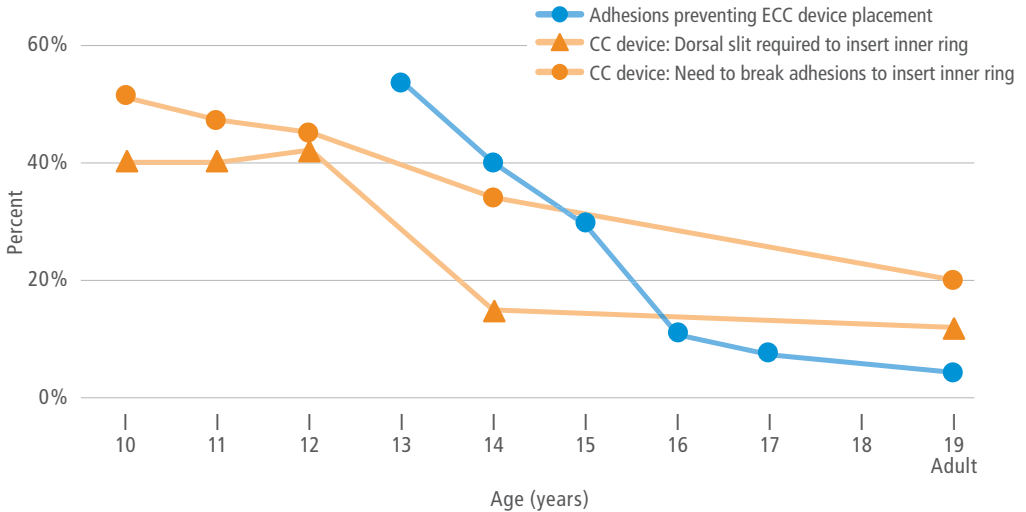
Some age-specific evidence exists on the proportion of adolescents who are ineligible for various circumcision methods due to phimosis or adhesions. Studies in three countries on the use of devices for VMMC have found that phimosis and adhesions are more common among younger adolescents (211, 212, 216). In two studies that assessed the collar clamp method, the prevalence of phimosis and adhesions among those ages 10–12 years was 40%–50% (211, 216). One study using the elastic collar compression device identified as ineligible 56% of 13-year-olds, 42% of 14-year-olds, 32% of 15-year-olds, 16% of 16-year-olds and 20% of 17-year-olds (212). Fig. 3.2 shows these proportions from these studies. Beyond these studies, evidence is not available on the outcomes of resolving these conditions medically before VMMC.

Additionally, as noted, the risk of injury to less developed genitalia may be greater than to more mature genitalia, particularly with such circumcision methods as the forceps-guided method and dorsal slit method (also see

For a large proportion of younger adolescents, provision of VMMC services may need to be delayed until these boys are more physically developed.



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

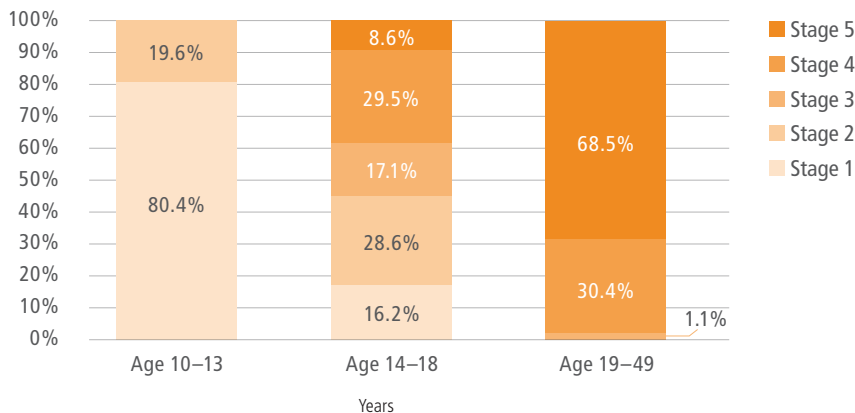


ECC = elastic collar compression device; CC= collar clamp device.

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

Chapter 4, on devices). The Tanner stages of development of adolescent secondary sexual characteristic recognize the variability in male (and female) physical development, including of the genitalia (202). In a penile measurement study in Tanzania to inform the choice of circumcision device sizes, 80% of adolescents ages 10–13 years were in Tanner stage 1; great variability occurred among those ages 14–18 years; by 19 years most were physically mature (Fig. 3.3) (217). Thus, the provision of services for a large proportion of younger adolescents may need to be delayed until these 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**



Source: WHO, 2015 (68) from Chrouser (217).

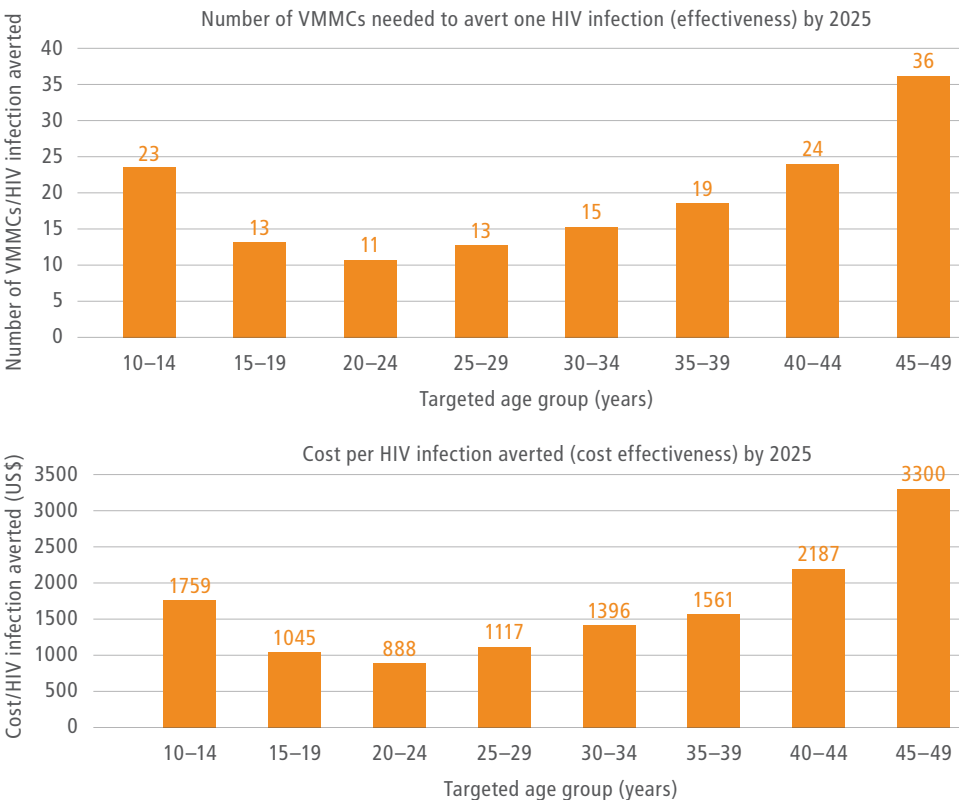
### 3.3.4 Modelling estimates of impact

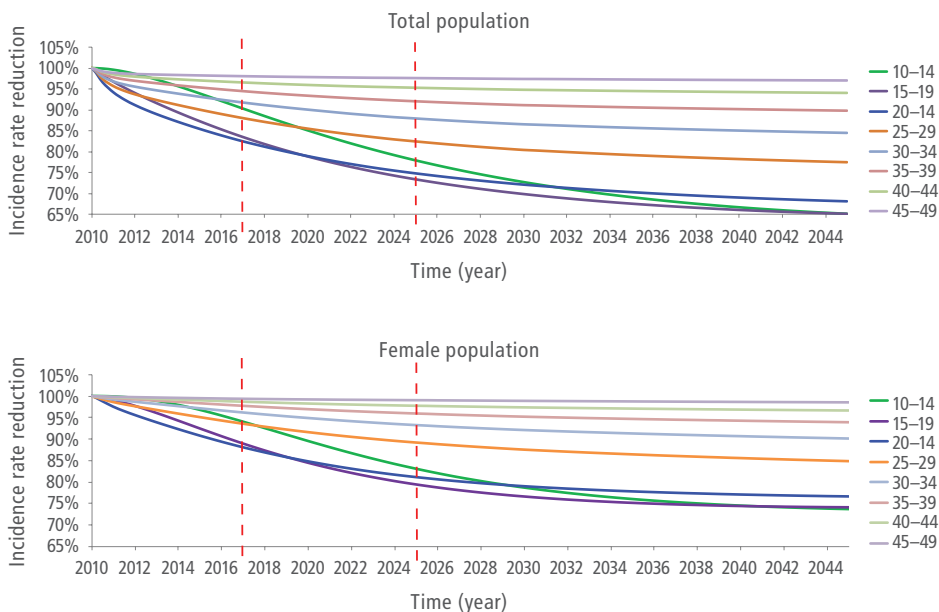
Important programme considerations are HIV incidence and the time horizons to the impact of VMMC. The population-level impact on HIV incidence of VMMC among younger adolescents will be delayed, but male circumcision prior to sexual debut avoids the small risk of HIV infection during wound healing.

The population-level impact on HIV incidence of VMMC among younger adolescents will be delayed.

A WHO and UNAIDS consultation in 2016 reviewed multiple modelling studies that looked at VMMC impact by age group. All studies were based on estimated HIV incidence from several years ago, and so the results do not necessarily reflect current HIV incidence rates overall or by age group. The consultation found that the greatest short-term impact on HIV incidence in the five years 2016–2020 would be obtained by expanding circumcision coverage in the 20–24, 25–29 and 30–34 year age groups, as this is the age range at which men are entering the highest risk of HIV infection. Thus, reaching younger adolescents is not urgent. However, circumcision services provided to the adolescent age group will still have a large public health benefit eventually, even though it will take more years to be realized – likely until 2030. Fig. 3.4 presents an example.

**Fig. 3.4. Impact of scaling up circumcision coverage to 80% in five-year age strata over seven years (2011–2017) and maintaining it through 2050, compared with baseline scenario of no VMMC programme (model applied to Zambia)**





Source: Awad et al., 2015 (54).

A summary of modelling studies with a time horizon of 15–45 years noted that male circumcisions would avert the most HIV infections by 2030 if performed on men ages 15–29 years. If programmes were to focus more narrowly, the greatest impact through 2025 would come from circumcisions in the 20–24 and 25–29 age groups (184).

### 3.3.5 Provision of other services to adolescent boys

Benefits of VMMC to adolescent boys include not only the benefits of the procedure (lifetime partial reduction in risk of HIV, reduced risk of certain STIs for them and their female partners) but also the provision of additional health education and services, including tetanus toxoid-containing vaccination, in association with VMMC. Medical male circumcision is offered in conjunction with a standard minimum package of services, defined by WHO to include offer of HIV testing services, education on safer sex, promotion of male and female condoms and STI management (1). The package of services also includes appropriate linkage to other services, such as care and treatment for adolescents who test positive for HIV or other STIs.

VMMC presents an opportunity to offer other interventions to adolescents, their partners and their families.

As a unique health intervention that is addressed exclusively to men and adolescent boys on a large scale, VMMC presents an opportunity to offer other health interventions to adolescents, their partners and their families and so to move towards universal health coverage. VMMC services may be the first instance that adolescent boys have contact with the health care system. Interventions should be locally determined but may include

psychosocial, sexual and reproductive and gender-related interventions. Tables 3.3 and 3.4 describes interventions suitable for younger adolescents and adolescents more broadly. These interventions should be considered for younger adolescents whether or not eligible for the circumcision procedure and adolescents in general as part of a comprehensive package of services. The WHO guidance *Global accelerated action for the health of adolescents* provides the evidence base for needed age-specific services (22). The *Global sexual and reproductive health service package for men and adolescent boys* (195) provides guidance on more detailed service packages and how to operationalize services. *International technical guidance on sexuality education: an evidence-informed approach* (2018) provides guidance on sex education across the phases of adolescence (218).

**Table 3.3. Essential package of interventions for school-age children (ages 5–14 years)**

Intervention	In primary health centres	In schools
<b>Physical health</b>		
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
<b>Diet</b>		
Micronutrient supplementation	—	✓
Multi-fortified foods	—	✓
Food provision	—	School feeding

HPV = human papillomavirus.

Source: Bundy et al., 2018 (219).

**Table 3.4. Essential package of interventions for adolescents (around 10–19 years)**

	Population	Community	Primary health centre	School
<b>Physical health</b>	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 for and treatment of STIs	Healthy lifestyle education including accident avoidance and safety
	Sexual health messages	—	—	Sexual health education
	—	—	—	Adolescent-friendly health services
<b>Nutrition</b>	Nutrition education messages	—	—	Nutrition education
<b>Mental health</b>	Mental health messages	—	Mental health treatment	Mental health education and counselling

Source: Bundy et al., 2018 (219).

### 3.3.6 Offering safe procedures in the context of traditional male circumcision rites

While VMMC is undertaken in the formal public health sector, some communities practice traditional male circumcision. The Guideline Development Group noted that traditional male circumcision may present public health safety issues, and poor outcomes from traditional male circumcision (which may not completely remove the foreskin) may have adverse impact on public attitudes toward the VMMC programme.

Very few studies have systematically reported on complication rates of traditional male circumcision among adolescents. The only study specifically designed for this purpose was conducted in Kenya in 2004, where complications of clinical and traditional male circumcision were compared. The findings were alarming: complication rates after traditional circumcision of 35% and after clinical circumcision performed by people without adequate training, materials or supervision of as high as 17% (compared with 1.7% in the Kisumu trial) (213). At that time the authors concluded:

Extensive training and resources will be necessary in sub-Saharan Africa before male circumcision can be aggressively promoted for HIV prevention. Two thirds of African men are circumcised, most by traditional or unqualified practitioners in informal settings. Safety of circumcision in communities where it is already widely practised must not be ignored.

A retrospective review of records from one South African general hospital reported 5035 hospital admissions after traditional circumcision, including 214 amputations and 453 deaths, from June 2006 to June 2013 (220). Causes of death included septicaemia,

dehydration, pneumonia, thromboembolism and gangrene. The authors noted that young initiates faced risk due to the limited capacity for wound management among young and inexperienced traditional attendants without basic health training (221). Recent evidence also indicates that some risky sexual behaviours, specifically less condom use and a higher numbers of sexual partners, were associated with traditional circumcision (222).

The Guideline Development Group noted that, although the data are limited, access to the formal medical sector for male circumcision may be reducing serious AEs and deaths associated with traditional circumcision and may play a greater role in the future by providing access to safer services.

Access to the formal medical sector for male circumcision may be reducing serious AEs and deaths associated with traditional circumcision.

### 3.3.7 Other harms (in addition to safety considerations)

Limited evidence was available regarding pain during male circumcision. In two studies on the collar clamp device method, pain scores (noted at 20 minutes after device placement and during device removal) were similar across the age group 10–15 years (211, 216). Data specific to pain and pain control in the presence of adhesions or phimosis were not available.

## 3.4 Other factors to inform decision-making

A WHO internal review of the literature on acceptability included evidence since 2007 (1 January 2007 through 2 September 2018, as noted in section 4.1).<sup>1</sup> This review looked at age-specific perspectives on values and preferences, resource requirements and costs, health equity, acceptability and feasibility.

### 3.4.1 Values and preferences

No articles were identified that addressed the values and preferences placed on male circumcision by young adolescent boys, their parents or guardians or the community. However, indirect evidence on the key factors behind decisions to undergo VMMC was available; see the subsection on acceptability in section 4.2.1. Some Guideline Development Group members conjectured that turning young adolescents away from VMMC services might lead them to seek circumcision outside the formal health sector, where quality and safety cannot be monitored.

### 3.4.2 Resources, including costs and cost-effectiveness

Information on costs, including costs for different adolescent age groups, was limited. Modelling using the DMPPT2.0 model projected the effects of age at circumcision on programme impact and cost-effectiveness over a 15-year period in Malawi, South Africa, Swaziland, Uganda and the United Republic of Tanzania (48–51, 185). Focusing VMMC on the age group 15–34 years was a cost-effective age group option in all five countries.

1 Systematic Review Solutions. WHO guidance on VMMC for HIV prevention amongst adolescent boys and men: literature reviews for PICO 1, 2 & 3, full report, unpublished, 2018; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int). See Annex 2.2.

Over a 15-year period, including males ages 10–14 years led to only a small increase in HIV infections averted and resulted in a higher cost per HIV infection averted. Information from another model, the Age Structured Mathematical (ASM) model<sup>1</sup> (54), projected the impact in Zambia of scaling up circumcision coverage to 80% in specific 5-year age groups over seven years (2011–2017) and maintaining it through 2050, compared with a scenario of no VMMC programme. The modelling showed that cost per HIV infection averted was higher for circumcision in the 10–14 age group than in the 15–19 age group (US\$ 1759 versus US\$ 1045). The model's analyses and results have uncertainties, as they do not take into account projected future changes in HIV incidence rates.

Similar to the results on HIV incidence impact noted above, cost-effectiveness is not a compelling argument for urgently reaching the 10–14 year age group. Males ages 10–14 years are not as sexually active as older adolescent males and, thus, there is a time lapse before the effect of VMMC on HIV incidence.

### 3.4.3 Ethics and human rights

The protection and promotion of ethics and human rights should be central to the provision of VMMC for adolescents as well as for adults. WHO and UNAIDS addressed ethical issues regarding VMMC in 2007. The resulting guidelines state (1):

The protection and promotion of ethics and human rights should be central to the provision of VMMC for adolescents as well as for adults.

A human rights-based approach to the development or expansion of male circumcision services requires measures that ensure that the procedure can be carried out safely, under conditions of informed consent, and without coercion or discrimination.

Since the 2007 recommendations, international agencies have advanced additional and more explicit considerations. Policies, programmes and services should reflect these key global human rights standards, including that:

- **Children's evolving capacities have a bearing on their independent decision-making on their health issues. Laws or regulations should stipulate an age for this process or refer to the evolving capacity of the child.** It is therefore essential that supportive policies are in place and that children, parents and health workers have adequate rights-based guidance on consent, assent and confidentiality. (General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (Art. 24) (223))
- **Adolescents should have access to the information that is essential for their health and development,** and they should have opportunities to participate in decisions affecting their health (notably through informed consent and the right of confidentiality), to acquire life skills, to obtain adequate and age-appropriate information and to make appropriate health behaviour choices. (United Nations Convention on the Rights of the Child) (223))

<sup>1</sup> The Age-Structured Mathematical model is described in *Models to inform fast tracking voluntary medical male circumcision in HIV combination prevention: meeting report*. Geneva: WHO; 2017 (<https://apps.who.int/iris/bitstream/handle/10665/259706/WHO-HIV-2017.39-eng.pdf;sequence=1>).

- Health care providers should **strive to postpone non-emergency invasive and irreversible interventions until the child is sufficiently mature to provide informed consent.** (Special rapporteur on the right to health, report to the General Assembly 2009 (Statement 49) (224))

### 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 (225); it is aligned with the international human rights statements.

- Because many of the decisions relating to sexual health may have an impact on people's ability to have a safe and satisfying sexual life and to have or not have children, informed decision-making – which can include informed refusal of certain interventions or medicines – is particularly important. Individuals have the right to be fully informed about any treatment, intervention or other health services that they may seek or undergo. In the area of sexual health, informed decision-making includes fully understanding and accepting (or declining) a particular service or intervention.
- Services should provide information in a clear and understandable way, including the likely benefits and potential adverse effects of proposed procedures and available alternatives.

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.

The decision-making capacity and autonomy of adolescents should be taken into account through processes such as informed consent and assent. Soliciting these can be particularly challenging. Adolescents who are not able to provide autonomous informed consent may possess the ability to assent or dissent. Assent is defined as the willingness to participate in a clinical procedure decision such as VMMC by persons who are too young to give informed consent but who are old enough to understand the procedure in general, its

expected risks and possible benefits and the activities expected of them (226). In addition, 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 above are able to give verbal or written informed consent. For younger adolescents, assessments as to whether a boy can give informed consent should be made on a case-by-case basis (22).



Box 3.2 summarizes the elements of informed consent.

### Box 3.2. 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".

Source: Adapted from World Health Organization, 2018 (226).

### 3.4.4 Equity

The Sustainable Development Goals and principles of universal health coverage recognize that a human rights-based approach to health for all adolescents is needed. 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.

As noted in *WHO recommendations on adolescent sexual and reproductive health and rights* (227), states have obligations under human rights law to provide HIV prevention and care to adolescents. States are obligated to ensure that adolescents have access to confidential HIV testing and counselling services and to evidence-based HIV prevention and treatment programmes provided by trained personnel who fully respect the rights of adolescents to privacy and non-discrimination.

### 3.4.5 Feasibility issues

Approximately 45% of clients accessing VMMC services in 2016 and 2017 were adolescents ages 10–14 years. This demonstrates that it is feasible to implement services, albeit predominantly stand-alone services rather than integrated with routine health services, for this age group (3, 17), given the relative ease of reaching adolescents through

community-based settings such as schools and outreach services (228). Services beyond the clinical procedure could be offered and might include comprehensive sexuality education, including information on harmful alcohol and drug use. Providing prevention education early and through complementary approaches in schools, communities and health facilities is effective (see also Table 3.4) (218).

As for the overall counselling approach for younger adolescents, in a Tanzanian study many health care workers felt it was appropriate to hold back some information perceived to be irrelevant for clients under age 15 years (for example, sexual health). They felt that these topics could be broached with older adolescents if the provider deemed it appropriate. Facility managers in all three countries indicated that their facilities generally conducted group counselling sessions according to age and engagement in sexual activity, often grouping adolescents under 15 years separately from those 15 and older. These health care workers and facility managers largely believed that very young boys (10–12 years) “don’t know much yet” and have few sexual experiences; therefore, their counselling does not have to address sexual issues in detail or at all. For older adolescents, over age 15 years, health care workers and facility managers generally felt that it was more appropriate to address sexual topics because these adolescents were more likely to have started experimenting with their sexuality. A few health care workers, however, thought sexuality content was appropriate only for those 18 years of age or older (169).

### 3.4.6 Balance of benefits, harms and other factors in deciding on offering adolescents’ male circumcision for HIV prevention

In summary, regarding the offer of VMMC services for younger adolescents, the Guideline Development Group concluded that multiple factors should be considered and balanced:

Decisions on offering VMMC to younger adolescents must consider several factors within a national and local context.

- The public health burden of HIV and the prevention effectiveness of VMMC: Circumcising this age group in high HIV prevalence settings will avert large numbers of HIV infection in the future, but not immediately.
- VMMC provides important benefits for the circumcised adolescent: reduced risk of HIV and other STIs.
- Informed consent:
  - ethical and human rights standards, especially capacity to provide informed consent: Are adolescents meaningfully involved in the informed decision to undergo this surgical procedure for HIV prevention?
  - the diverse physical and cognitive capacity of individuals within this age group: Some boys 10–14 years may have the capacity to consent.
  - the competence of health care workers to screen and to assess capacity to consent.
- Safety for adolescents with immature genitalia: Most younger adolescent boys are not yet physically mature. Some adolescents ages 15 and older also may not be physically mature. Preventing serious AEs among adolescents who are not yet physically mature may mean deferring VMMC for some until they are more mature.

- Feasibility to offer, at specific adolescent ages, VMMC and other needed services and education such as comprehensive sexuality education and internationally recommended vaccinations such as tetanus toxoid-containing vaccination (recommended at between ages 9 and 15 years).
- The adolescent's, parents' and communities' preferences, including provision of the surgical procedure by the formal health sector rather than seeking traditional male circumcision.

### 3.4.7 Programme and implementation considerations

In addition to the policy considerations noted above on offering VMMC for HIV prevention to younger adolescents, specific points for programme considerations are the following:

#### Community and parental engagement and communication

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

#### Management responsibilities

- Monitor the occurrence of AEs among adolescents to further clarify and reduce risks.
- Implement quality improvement approaches and plans at all levels that are data-driven.
- Provide appropriate services to all adolescents irrespective of their ability to pay, age, marital status, education level, ethnic origin, sexual orientation or other characteristics and in a manner that ensures their meaningful engagement and participation.
- Provide health care workers and adolescent clients with an enabling environment for the effective solicitation, receipt and verification of consent and assent (229). This includes:
  - Invest in human resources to maintain and enhance competence in handling informed consent, drawing on lessons from other services and research on obtaining informed consent.
  - Involve health care workers and see that they are fully trained and certified as competent to deliver person-centred adolescent services appropriate to each stage of physical development.

Health care workers serving adolescent boys should:

- have the technical competence to provide effective 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;
  - on age-specific developmental considerations and physical conditions, including those that require deferring VMMC to an older age and those that require referral to a health care worker specifically trained to perform male circumcision procedures on adolescents;
  - on age-appropriate approaches to accurate and comprehensive HIV and sexuality education for adolescents;
  - as refreshers to keep abreast of age-appropriate approaches to HIV health education and counselling;
  - on caring for adolescents generally.
- understand the stages of adolescent development and be able to determine maturity for informed consent;
- be able to assure a meaningful, age-appropriate, comprehensible informed consent process for every client.

### **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.

# USE OF DEVICE-BASED METHOD FOR MALE CIRCUMCISION IN CONTEXT OF HIV PREVENTION

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## 4 USE OF DEVICE-BASED METHOD FOR MALE CIRCUMCISION IN CONTEXT OF HIV PREVENTION

### Summary of the recommendations

**UPDATED**

#### Recommendation on use of device-based methods

The use of WHO-prequalified male circumcision devices<sup>1</sup> 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.)*

WHO prequalified male circumcision devices<sup>1</sup> 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.)*

These 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.

The recommendations were considered conditional because:

- evidence on use at a large scale is limited
- evidence on use with a large number of adolescents is limited.

<sup>1</sup> Information on a device that is WHO prequalified includes the specific instructions for use of the method that was clinically evaluated.

## 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.<sup>1</sup> 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).

<sup>1</sup> Three methods as described in the *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men* (216).

## 4.1 Rationale for review and background on use of device-based methods for male circumcision in the context of HIV prevention

### 4.1.1 Need for new male circumcision methods

WHO made an initial conditional recommendation on use of devices for VMMC 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, moderate quality evidence*). A recommendation on device use with younger male adolescents (less than 18 years of age) will be considered when additional data become available. (23)

At that time the use of devices for circumcision in the context of HIV prevention was seen as a potential way to address the shortage of surgically skilled health care workers (231–233), to simplify the procedure, to increase acceptance by health care workers and clients and to further improve the safety of the procedure (230).

Device-based methods of male circumcision were sought to simplify the procedure, increase acceptance and further improve safety.

Since the 2013 recommendation, two in situ devices of different types have been further used, particularly in pilot and early scale-up phases, and surgical assist devices have begun to be evaluated. Thus, additional evidence was available to review and update the recommendation. The key question to be answered was: Among adolescent boys and adult men, are select device-based male circumcision methods efficacious, safe and acceptable when compared with conventional surgical methods<sup>1</sup> or other device-based methods?

Critical outcomes assessed included: eligibility for use, efficacy of the method in removing foreskin, safety (moderate, severe and serious AEs) and acceptability, particularly cosmetic result and time to return to activities of daily living. Important outcomes were: pain, odour, healing time, procedure time, device/wound care and required facility visits. (Annex 4.1 provides details.)

### 4.1.2 Background and device categories

In 2010 WHO established the Technical Advisory Group (TAG) on Innovations in Male Circumcision to review WHO's work and advise on technological innovations in male circumcision, including devices. Based on inputs of the TAG, WHO developed the *Framework for clinical evaluation of devices for male circumcision* (230). It describes the clinical evaluation pathways that must be followed to provide sufficient evidence on the efficacy and safety of a new male circumcision device.

Information from such clinical evaluations is used by the WHO Prequalification of Male Circumcision Devices Programme, which seeks to promote and facilitate equitable access to safe, appropriate and affordable male circumcision devices of good quality. The

<sup>1</sup> Three methods as described in the *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men* (73).



Prequalification Programme ascertains whether a specific device has met relevant international standards in terms of product performance, the manufacturer's quality management system and clinical safety and efficacy. Once the assessment is complete and the overall findings demonstrate that the product meets the WHO prequalification requirements, the specific device manufactured at a specific site is listed as "prequalified". Prequalification provides assurance of quality and makes the device eligible for procurement by United Nations agencies, WHO Member States, donors and other purchasers such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. "Prequalified" does not imply WHO approval or endorsement of a particular device; that is the sole prerogative of national programmes. The list of specific prequalified devices is available on the WHO website at: [https://www.who.int/diagnostics\\_laboratory/evaluations/prequalification\\_male\\_circumcision\\_devices/en/](https://www.who.int/diagnostics_laboratory/evaluations/prequalification_male_circumcision_devices/en/).

The WHO TAG, in consultation with external device and regulatory experts, determined the initial categories of devices based on mechanism of action. Given the changes since the 2013 recommendation, these categories have been expanded and slightly revised with the inputs of medical device experts. The difference between in situ and surgical assist devices has been further specified. The categories are defined as follows:

**In situ devices:** Part or all of the device is in contact with the body for at least 24 hours. Several types of in situ devices exist. Within each type one or more brand-specific products are available.

**Clamp devices:** This category includes two subcategories: **collar clamp devices** and **vice clamp devices**. With both types, the mechanism of action is a rapid, tight compression of the foreskin between hard surfaces to achieve haemostasis. The compression is sufficient to prevent slippage of tissue so that the foreskin can be removed at the time of, or soon after, placement of the device. Part of or the entire device is left in situ for a period of time to prevent bleeding. Because the device crushes the foreskin upon placement, and live tissue is excised immediately after device placement, local anaesthesia is required for pain control.

**Elastic collar compression devices:** The mechanism of action is a slow compression of the foreskin between an elastic ring and a hard surface that is sufficient to occlude circulation and produce tissue ischaemia, devitalization and necrosis. Part or all of the device is left in position for at least 24 hours after device placement. The foreskin may be removed with scissors after seven days, when the foreskin is fully necrotised (termed "standard removal", or "Day 7 removal"), or excised within a few hours after device placement, leaving a short cuff to prevent slippage (termed "Day 0 removal"). Local anaesthesia requirements depend on when the foreskin is removed.

**Ligature compression devices:** The mechanism of action is a rapid compression of the foreskin held tightly between a ring placed under the foreskin and a flexible ligature tied around the outside of the foreskin. Compression is sufficient to achieve haemostasis and prevent slippage of tissue so that the foreskin can be removed at the time of, or soon after, device application. Part or all of the device is left in situ for a limited time. Because the device crushes the foreskin, and live tissue is excised immediately after placement, local anaesthesia is required. The compression force and security of the knot depend on the dexterity and skill of the clinician.

**Surgical assist devices:** These devices are used during surgical circumcision and are removed from the body at the end of the procedure. Thus, in contrast with in situ devices, they remain in contact with the body for a short time, usually less than one hour, but in any case less than 24 hours. They include clamp devices to crush and cause tissue adherence and “all-in-one guns”, which are complex mechanisms that perform foreskin excision, haemostasis and wound closure. These devices may be either reusable or single-use. Surgical assist devices are considered in this guideline for the first time; they were not included in the 2013 guidance.

## 4.2 Evidence to inform updated recommendations

The evidence used to inform the updated recommendation was restricted to data on devices that met the full set of required studies described in the *Framework for clinical evaluation of devices for male circumcision (230)*. The evidence covered two types of in situ devices – one collar clamp device (brand-name Shang Ring™) and one elastic collar compression device (brand-name PrePex™) – and one surgical assist device (brand-name Unicirc™).

The evidence for recommendation making covered two types of in situ devices – one collar clamp device and one elastic collar compression device – and one surgical assist device.

The strength of the recommendation was based on the quality of the evidence on critical outcomes (efficacy, safety and acceptability, particularly cosmetic result) and other factors such as the balance of anticipated benefits and harms, the values and preferences of clients and health care workers, and resource implications.

The recommendation was deemed conditional, rather than strong, primarily due to uncertainties about the benefits of device-based methods compared with the conventional surgical methods. Further evidence is needed that demonstrates the safety and advantages of devices at scale in routine health care settings.

Further evidence is needed that demonstrates the safety, including among adolescents, and advantages of devices at scale in routine health care settings.

Uncertainty about some aspects of patient acceptability and programme costs also warranted a conditional recommendation. For use of devices with younger adolescents (10 through 14 years), the recommendation was deemed conditional because evidence on use with this age group is limited. (The offer of VMMC by any clinical method to this age group is more broadly discussed in Chapter 3.)

### 4.2.1 Quality of the evidence

Annex 4.1 presents the GRADE tables, summary of studies and evidence profile tables. Given that each device has its unique characteristics, the annex includes a detailed quality assessment for each outcome by each type of device – for the collar clamp, the elastic collar compression device and the surgical assist vice clamp device.

The majority of the clinical studies of circumcision devices for potential use in VMMC programmes followed a common classification of AE severity. In particular, AEs that could be treated by mid-level clinicians within the VMMC programme were considered

moderate AEs, while those that required prompt surgical intervention by an experienced specialist surgeon or referral to a higher level of care were considered severe AEs.

In the findings below, references are indicated only when one or a selection of the studies, rather than all studies, were used for the estimates.

In the determination of overall quality of the evidence, only critical outcomes were considered (see section 4.1.1).

The quality of data on efficacy, safety and acceptability (assessed by cosmetic results) was considered low due to indirectness and the risk of bias, as neither patients nor observers were blinded.

## 4.3 Evaluation of collar clamp and elastic collar compression (in situ) devices

### 4.3.1 Overview of collar clamp device studies

A systematic review<sup>1</sup> identified publications or reports referring to the safety, efficacy and/or acceptability of the collar clamp male circumcision device. All these studies used the Shang Ring™ device, including 27 studies of this collar clamp device applied with the conventional placement technique of everting the foreskin over the inner ring before applying the second clamping ring and nine studies in which the device was applied by the “no-flip” device placement technique (summarized in Annex 4.1). Twelve studies on the conventional placement technique, involving a total of 3535 clients, were conducted in Africa, as well as three studies on the no-flip method<sup>2</sup> with limited numbers of participants (654 clients across three studies) (211, 216, 234). This evidence, directly relevant to the performance of the device in VMMC programmes for HIV prevention in East and Southern Africa, was supported by evidence from China published in English.

### 4.3.2 Priority outcomes for collar clamp device

#### Eligibility

Studies conducted in Africa (235–241) systematically reported reasons that men allocated to or requesting the collar clamp device could not be circumcised after having been screened and found eligible for circumcision. In a small proportion, 1.6%, (55 of 3377) eligible men could not be circumcised with the collar clamp device, all due to lack of the correct ring size in the clinic. There were no additional exclusions. No clients (N=636 in the studies that reported) were excluded from studies using the no-flip method (211, 216, 242).

<sup>1</sup> Farley T, Hargreave T, Galukande M, Hesse A, Musau P, Ridzon R et al. Safety and acceptability of male circumcision devices – a systematic review, unpublished report, 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

<sup>2</sup> The no-flip placement technique was developed in China as a simpler method of placing the device without foreskin eversion over the exterior of the ring.

### Successful circumcision (efficacy)

Circumcision was achieved in nearly all clients on whom device placement was attempted. The overall failure rate was low, 3 per 1000 placements (95% CI: 2 to 6 per 1000). These failures were attributable to device slippage after removal of the foreskin (n=4), health care workers' inexperience with the foreskin eversion procedure in adolescents (n=3), damage to the foreskin (n=2), insufficient foreskin for eversion (n=1) and a thick foreskin preventing closure of the outer ring (n=1). Most of the failures occurred when the device was first used at a new site (237) or in adolescents (238). With the no-flip technique, only one placement failure occurred (in the 664 procedures in Africa (211, 216, 234)), due to the outer ring slipping off immediately after the device had been applied and the foreskin removed. In all these cases the wound was closed using sutures.

### Safety: adverse events (harms)

Adverse events are considered first in terms of the number of clients with severe or moderate AEs, irrespective of type or cause, and then by main types (for example, bleeding, infection, wound disruption). In Africa 2.4% (79/3329) severe and moderate AEs were reported among clients circumcised with the collar clamp device and in China 6.7% (204/3045). Four AEs (1.4%) were classified as severe, and the remainder, as moderate. In the three randomized device trials conducted in Africa, there were more severe and moderate AEs among clients circumcised with the device than with conventional surgery, although this difference was not significant (12.5% compared with 7.3%) (235, 236). In the two concurrent cohort studies conducted in Africa (237, 238), the proportion of clients with severe or moderate AEs was lower (1.2% of device clients, 0.4% of conventional surgery clients) than in the two randomized trials. Pain is discussed below. Oedema and haematoma were less common with the collar clamp device than with conventional surgery (235–239). The available evidence on infections was limited.

Rates of severe and moderate AEs with use of the no-flip technique in the three African studies were low (2.6%, 17/654 clients). They included severe pain, bleeding after device placement and wound dehiscence (211, 216, 234).

### Acceptability

Critical outcomes to assess acceptability included cosmetic result and return to activities of daily living.

#### Cosmetic result

Clients' opinions of the final cosmetic result were assessed during the healing or at the final follow-up visit, usually four to six weeks after placement. One study followed men for longer-term outcomes to 32 months post-circumcision (243). Rates of satisfaction with the appearance of the penis were high in all studies in Africa (235–241, 243–245), including with the no flip technique, and substantially higher compared with the satisfaction of clients circumcised with conventional surgery in the randomized trials (91% versus 73%) (235, 236).

Some 97% of clients reported satisfaction with penile appearance after the circumcision with the collar clamp device.

### ***Return to activities of daily living***

No new evidence was identified beyond the limited information available for the initial recommendation in 2013. In one of the earlier Kenyan field studies (243), 76% reported ease of bathing and enhanced penile cleanliness, and, in a small sample of adult men, 94% reported that condom use was easier following circumcision. Time taken off from work, school or other activities for the clinic visits for device placement and removal has not been compared with the time taken for clinic visits for conventional surgery. Many of these client observations are likely following conventional surgical circumcision as well, but these reports provide evidence that circumcision with the collar clamp device is acceptable.

### **Other values and preferences**

Other values and preferences noted as important outcomes are healing time, odour, pain and procedure time.

#### ***Healing time***

Healing following male circumcision with the collar clamp device took approximately one week longer than after surgery. Healing is by secondary intention rather than primary intention (as is the case for surgical male circumcision, in which the wound edges are approximated with sutures). Mean healing duration was approximately 42 days (235, 244) (5.5 days longer than healing following conventional surgical circumcision in the randomized studies (235)), with approximately 86% healed at six weeks (235–241, 245). Mean healing time with the no-flip technique was slightly shorter (34 days), which may partly reflect the younger age of the clients in those studies (211, 234).

Healing with the collar clamp device took about one week longer than after conventional surgery.

A small number of wound disruptions (<1% of procedures (21/3329)) occurred several weeks after device removal. These were departures from the normal healing process.

#### ***Odour***

No evidence was identified concerning odour as an issue with the collar clamp methods.

#### ***Pain***

The level of pain reported during placement of the collar clamp device and in the post-procedure period was similar to that reported with conventional surgery. A collar clamp device is designed to avoid the need for sutures for haemostasis during surgery and to clamp the skin edges firmly together to fuse as part of the healing process. Because of the tight clamping mechanism and because the foreskin is cut away during the procedure, local anaesthesia is required before device placement, as it is for conventional surgery. In addition to pain during administration of the injectable anaesthetic, men reported some pain while wearing the device and a somewhat higher level of pain during erection than at comparable times after conventional surgery.

Evidence regarding pain with the no-flip method was of very low quality. Avoiding injections may reduce pain. Topical anaesthesia was compared with injectable local anaesthesia with the no-flip technique in adolescents (216). There was a longer wait time for the topical anaesthesia to prevent pain during the procedure, and 27% of clients with adhesions or phimosis required supplementary injectable anaesthesia, compared with

5% of those without adhesions or phimosis. The *WHO Technical Advisory Group on Innovations in Male Circumcision Report*<sup>1</sup> noted:

More than half the clients in the 10 through 15-year age group had phimosis and/or adhesions which needed to be resolved before the collar clamp could be placed. Available evidence showed that clients with phimosis and/or adhesions had longer circumcision time, longer removal time and more pain during removal than those client without either condition.

Some men reported a short, transient discomfort or pain as the device was removed. Pain scores on device removal were similar to those reported during placement (mean 2.3 on a scale of 1 to 10, SD 1.6, based on 565 clients). In contrast, in Kenya a comparison of removal strategies (seven, 14 or 21 days after device placement) resulted in considerable discomfort in the two later removal arms, as the devices had started to self-detach (245). Delayed removal and non-removal (leaving the device to fall off) appear to be safe but do not offer many advantages.

### **Procedure time**

Studies in Africa (235-238) showed that the mean device placement time, excluding the time for injection and induction of local anaesthesia, was 6.0 minutes (SD 2.3) compared with 17.3 minutes (SD 5.2) for the conventional surgical procedures. The pooled difference in placement times was 9.7 minutes shorter (from 9.4 to 10.0 minutes shorter) with the device than with conventional surgical circumcision. The mean duration of device placement in all the studies in Africa was 6.7 minutes (SD 2.7). Mean duration of device removal was reported to be 4.0 minutes (SD 2.0), based on 3236 removals (235–239, 241, 243–246). The mean duration of placement time during the no-flip technique was also about 6 minutes (211, 216, 234).

### **4.3.3 Overview of elastic collar compression device studies**

A systematic review<sup>2</sup> included 21 studies involving 12 855 clients circumcised with the elastic collar compression device (all with the PrePex™ device) with foreskin and device removal scheduled seven days after placement (“Day 7 removal” procedure) and five studies involving 1254 clients circumcised with the device applied and the foreskin excised on the same day, followed by device removal after seven days (“PrePex Day 0 foreskin removal procedure”).

### **4.3.4 Priority outcomes for elastic collar compression device**

#### **Eligibility**

In addition to clients with standard contraindications to surgical circumcision in VMMC programmes,<sup>3</sup> several clients were not eligible to be circumcised with the elastic collar compression procedure. Some 8.4% (868 of 10 335, from 19 studies) of clients who were interested in circumcision with the elastic collar compression device were not eligible.<sup>4</sup>

<sup>1</sup> Report available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

<sup>2</sup> Farley T, Hargreave T, Galukande M, Hesse A, Musau P, Ridzon R. Safety and acceptability of male circumcision devices – a systematic review; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

<sup>3</sup> Penile abnormalities (hypospadias, epispadias), active genital infection or genital warts, known bleeding or coagulation abnormalities.

<sup>4</sup> Reasons for non-eligibility included phimosis (n=177), narrow foreskin (n=131), adhesions (n=122), tight or short fraenum (n=19), multiple or unspecified combinations of penile conditions (n=418) or repeated erections while preparing for device placement (n=1).

The main reasons for ineligibility were phimosis (177), narrow foreskin (131) and adhesions (122).

In the two studies of adolescents ages 13–17 years (212, 247), 26% (360/1391 clients) were not eligible for elastic collar compression circumcision compared with 6% (508/8944 clients) in 17 studies in adults ( $P < 0.001$ ) (94, 246, 248–262). Physiological adhesions and phimosis that affect eligibility are common among younger adolescents, reducing with physical development during adolescence (see Fig. 3.2).

### Successful circumcision

Surgery was required to complete circumcision as a result of device self-removal, device displacement or requested early removal in 0.7% of clients (85/12 852 clients). Since these events occurred several hours or days after device placement and required prompt intervention by a skilled surgeon to prevent serious complications, they were classified as severe AEs and are discussed in the next section.

### Safety: AEs (harms)

Across 19 studies severe and moderate AEs were reportedly low at 2.8% (359/12 852) among those circumcised with the elastic collar compression device. About one third (30%,  $n=109$ ) of these AEs were classified as severe, and the remainder, as moderate.

The severe and moderate AE rate varied considerably among studies. The research studies, with and without comparison groups, reported low overall AE rates of 1%, with similar rates of severe and moderate AEs across studies.<sup>1</sup> In contrast, quite varying AE rates were noted in the practice-based settings of pilot implementation studies and active surveillance, with a median of about 2% and a range from 0.4% to 12%.

The most common severe AEs identified were self-removals, device displacements and requested removals in the first few days after device placement.<sup>2</sup> These rare events were usually associated with severe oedema that could not be managed by mid-level clinicians delivering conventional surgical circumcision within the VMMC programme and so required management by an experienced surgeon. All cases were successfully treated, with no long-term sequelae. Severe and moderate bleeding and infections were rare.<sup>3</sup>

Although rare, cases of tetanus, considered serious AEs, were reported with use of the elastic collar compression device (83). WHO technical reports (263–265) on the risk of tetanus by method indicated a greater tetanus risk with the elastic collar compression method than with conventional surgical methods. This evidence led WHO to advise countries to ensure protection through TTCV (demonstration of sufficient vaccination or provision of needed doses) before use of this method.

In 2017 several studies explored the safety and efficacy of a new procedure, whereby the foreskin was excised within a few hours after device placement (“Day 0 foreskin removal procedure”) to address odour and discomfort associated with the necrotizing foreskin before removal at seven days and to reduce the risk of tetanus infection (261, 266–269).

<sup>1</sup> Nine severe AEs in 652 clients, or 14 per 1000, and eight moderate AEs in 1054 clients, or eight per 1000.

<sup>2</sup> 40 self-removals, 27 displacements, four requests for early removal and 14 for which the type of AE was not specified in the study reports.

<sup>3</sup> Bleeding in 0.28% ( $n=32$  in 11 635 placements) and infection in 0.19% ( $n=22$ ).



However, as of 2020 the evidence was uncertain as to whether this modification reduced risk of tetanus (270).

## Acceptability

### *Cosmetic result and satisfaction*

Cosmetic result was assessed by asking clients about their satisfaction with the procedure or the appearance of the circumcised penis. Overall, most clients (92%, 3362/3655 in nine studies) were “satisfied” or “very satisfied” with appearance at various times after the procedure (247, 250–253, 257, 260, 271–273). Longer-term outcomes, including satisfaction, were assessed one and two years after the procedure in a pilot implementation study (94) that contacted a subset of 304 of the original 625 clients (274). Ninety percent of these men reported being “very satisfied or extremely satisfied with scar appearance (colour, texture and thickness)”.

As for adolescents, in a study in Zimbabwe, 96% of adolescent boys were very satisfied with the elastic collar compression procedure (212) at 14 and 60 days post device application.

### *Return to activities of daily living*

Among adults, a few studies identified interference with normal activities, including hygiene maintenance and urination (250, 275), and less time (260, 271) taken off work with use of elastic collar compression device (249, 275). Before they actually experienced the procedure, men in both the device and surgery groups perceived that circumcision would have a much larger impact on their daily activities, especially work-related activities, than they actually experienced. At seven days post-procedure, men in the device group reported that they had lost on average half a day (0.57 days) of work compared with more than a full day (1.15 days) in the surgery group (260).

In one study a small proportion of clients (about 8%) reported that an “unpleasant smell” while wearing the device affected their activities of daily living, and 14% reported that others had noticed the odour (252). Some adolescent boys cited disruption of daily routines and activities, saying that device-based VMMC affected their ability to sit, walk, sleep, do housework, participate in sports and attend school (212).

## Other values and preferences

Other values and preferences, reported as important outcomes, involved healing time, odour and pain.

### *Healing time*

Healing following male circumcision with the elastic collar compression device is by secondary intention. Healing took at least one week longer than after surgery. Thus, longer sexual abstinence (during healing) is needed than after standard surgical methods. Almost all men had healed by eight weeks.<sup>1</sup>

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<sup>1</sup> The one comparative study to assess healing at weekly intervals found that healing times were on average 14 days longer (from 11 to 17 days longer) following elastic collar compression device circumcision than after a conventional surgical method (264). A mean time to complete healing of 42.2 days (SD 8.6 days) was observed among 1423 clients (253, 255, 262, 264, 265, 279). The overall proportion of clients healed six weeks after elastic collar compression device circumcision was 69%, based on 3238 clients (92, 209, 210, 249, 252, 254–256, 276).



### **Odour**

Odour was commonly reported as a barrier to acceptability: 58% of clients (1844/3173) reported an unpleasant smell or odour while wearing the device, variously described as “bad odour” on removal or “bad odour while penis healing” (94, 251–253, 256, 257, 259). One study reported that few participants (2.2%) would not recommend device-based VMMC to others because of odour (253). Another study found that 10% of respondents who reported experiencing odour while wearing the device would have chosen surgical VMMC over device-based VMMC if they had known about the odour, including 1.4% who stated that they would have decided not to be circumcised at all (256).

### **Pain**

Comparing pain scores is difficult because the pain control protocols varied across studies, but they became more similar over time as further information on pain became available. The elastic collar compression device does not require injectable anaesthesia during placement. The comparative research studies showed higher pain scores for conventional surgical circumcision than for the elastic collar compression device, predominantly attributable to the (anticipated or actual) pain experienced with injectable anaesthesia used for surgical circumcision, in contrast to the topical anaesthesia used with this device in all except the initial two studies.

Details about pain during device placement, while wearing the device and during device removal were available from 15 studies (94, 212, 248–251, 253–258, 260, 261, 273), not all of which reported on all three time points. In all studies that reported, pain scores reported at device placement and during erections were low; reported pain scores at device removal were higher than at device placement or during erections. Across 11 studies the overall pain score with the device was 0.8 (SD 1.2) on a scale of 0 to 10.

All pain scores reported at placement of the elastic collar compression device were low. Greater pain was reported during device removal.

Pain during erection while wearing the device was somewhat greater than pain reported at placement (mean score 2.6) and less than pain reported at a similar time after surgical circumcision (mean score 1.3 lower).

Pain during device removal was more common than at other time points and quite variable across studies, perhaps reflecting different expectations of pain at removal as well as variability in the way clients interpreted the visual analogue scale scores and cartoon faces depicting different levels of pain. Overall, the mean pain score on removal was 4.2 (SD 2.2). During the period that the active surveillance study was collecting data at six sites in South Africa, some form of analgesia at removal was introduced, with each site choosing whichever methods it had available. The results showed that lidocaine spray had the least effect, while EMLA cream had the greatest (254).

### **Procedure time**

There was variation in placement and removal times over the different studies, with more experienced clinicians reporting shorter procedures. The mean placement duration was 3.5 minutes (SD 2.3), and the mean duration of device removal was 3.4 minutes (SD 1.7), based on about 3000 placements and removals (246, 248–252, 255, 260, 261, 273).

### 4.3.5 In situ devices in general: other factors influencing the recommendation-making

The following information pertains to in situ devices generally rather than to specific device types, unless specified otherwise.

#### Acceptability of in situ devices

This section combines information on acceptability from studies on three types of in situ device-based methods. However, it is important to note that each device type is different, which may affect acceptability. An unpublished review<sup>1</sup> included 21 studies reporting on the acceptability of device-based VMMC. Common types of devices used were a collar clamp (Shang Ring™) (seven studies) (235–237, 239, 240, 245, 271) and an elastic collar compression device (PrePex™) (13 studies) (94, 212, 250–253, 256, 257, 260, 271–273, 276). Alisklamp™, a disposable vice clamp device, was used in one study (277). Details are available in Annex 4.1, with some study description presented below.<sup>2</sup>

Overall, adult men and adolescent boys who were circumcised with one of the three studied device methods reported high rates of satisfaction and said that they would recommend device-based VMMC to others. In studies that compared satisfaction between device-based methods and conventional surgical methods, no significant difference was noted overall. The existing evidence suggests that device-based VMMC is acceptable among adolescent and adult males. However, considerations are specific to each device.

The views of female sexual partners, the wider communities, policy-makers and funders are currently unknown. Across the five studies reporting on health care providers' views on device-based methods, ease or simplicity of the procedure was the most common facilitator (235, 239, 245, 251, 253). A large proportion of providers preferred device-based VMMC over surgical VMMC (235, 239, 251).

#### Interference with work and daily activities

Studies consistently report that circumcision using devices had interfered minimally with clients' work or daily activities except for sexual activity. (Men were instructed not to engage in sexual activity for six weeks after the removal procedure.) Despite the consistency of findings, the overall quality of the evidence with respect to interference with daily activities was considered low (237, 244, 245).

#### Values and preferences

Several studies provided indirect information on key factors in the decision to undergo device-based VMMC as well as complaints post-procedure.<sup>1</sup>

Reported facilitators to undergoing an elastic collar compression or collar clamp method included: less pain than expected (235, 240, 251), overall cosmetic result/appearance

<sup>1</sup> Systematic Review Solutions. WHO guidance on voluntary medical male circumcision (VMMC) for HIV prevention amongst adolescent boys and men: literature reviews for PICOs 1, 2 & 3, full report, unpublished report, 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int). See Annex 2.3.

<sup>2</sup> The studies were conducted in different countries and regions, including Botswana, Kenya, Malawi, Mozambique, South Africa, Uganda, Zambia and Zimbabwe. Study designs varied from randomized controlled trials to observational and qualitative studies. Study sample size ranged from 50 to 2250. These studies collected data between the years 2011 and 2014, predominantly with participants ages 18 to 54 years.

(235, 240, 251, 260) and improved hygiene (235, 240, 251, 260). Also, stated specifically for one device but likely relevant to both types were: ease of procedure (239), maintaining routine daily activities (250, 253), quick procedure (235, 240), no stitches (235, 240), comfortable wearing a device for one week (250), greater safety than the surgical approach (272) and perceived faster healing process (260).

Complaints post-procedure for both categories of devices included discomfort or pain with erections (235, 240, 250, 277). For the elastic collar compression device, complaints included difficulties with hygiene (250) and with urinating (250), lengthy procedure time (272), concerns about safety (272), long healing time (271, 272), too much time off from work or school (271) and the inconvenience of returning for device removal (94) or follow-up visits (272).

### **Adolescent boys' perspectives**

Adolescents' preferred procedure types were explored in only two studies (271, 273), involving respondents in Zambia and Zimbabwe. In the age group 10–14 years (n=261), 26% chose surgical VMMC, 36% preferred PrePex™, 16% preferred Shang Ring™, and 23% preferred Unicirc™. Similar results were observed in the age group 15–19 years (n=200) – 23% preferred surgical VMMC, 37% preferred PrePex™, 19% preferred Shang Ring™, and 23% preferred Unicirc™ (271). Adolescents considered pain, healing time and time off from work or school to be barriers to uptake of device-based VMMC (273).

### **Health care workers' perspectives**

Overall, health care workers, both physicians and non-physicians (primarily nurses and clinical officers), reported that performing circumcision with a device was easy. A large proportion preferred device-based methods (both collar clamp and elastic collar compression) over surgical VMMC (235, 239, 251). Most commonly, health care workers commented that, compared with surgical methods, the device techniques were easier to perform and required less time, provided better cosmetic results, resulted in fewer complications, eliminated the need for suturing and caused less bleeding. Ease/simplicity of procedure was the most common facilitator (239, 260, 273, 278).

A large proportion of health care workers preferred device-based methods over surgical VMMC.

As for barriers to acceptability, one study reported health care workers' reluctance to recommend the collar clamp device because they perceived that "it was sometimes too painful" (245). Another study noted a slow healing process as a barrier to acceptability among health care workers (235).

### **Resource use**

Consumables and staffing costs are the two key cost drivers for VMMC. Compared with costs of a surgical method, the costs of device-based circumcision reflect the shorter duration of the procedure and, thus, less clinician's time. However, the additional costs of the device itself and associated medical supplies, as well as costs associated with subsequent device removal, increase the overall cost of device-based circumcision. The existing evidence focuses on the use of collar clamp and elastic collar compression devices. The costs of other VMMC devices remain unclear.

**Table 4.1. Benefits and disadvantages of in situ devices compared with conventional surgical methods**

Issue	Benefit	Disadvantage
<b>Eligibility</b>	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 (see Fig 3.2). Conventional surgical male circumcision needs to be available as a back-up method for these men.
<b>Procedure time</b>	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.
<b>Adverse events</b>	The 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.
<b>Ease of use</b>	Health care workers see device-based methods as simpler for them than surgery and requiring less time.	—
<b>Healing time</b>	—	Healing times for in situ devices are one to two weeks longer (given secondary intention healing) than for surgical circumcision. There is a higher risk of HIV acquisition with unprotected sex before the wound is healed, and the longer healing period requires a longer period of sexual abstinence or conscientious condom use before wound healing.
<b>Follow-up</b>	—	[Evidence is lacking as to whether the mandatory second visit with a device method limits acceptability.]

The direct unit costs of surgical and device-based VMMC were roughly equivalent across eight cost analysis studies (273, 279–285), of which seven were on the elastic collar compression method and one on the collar clamp. However, overall average cost-effectiveness is very sensitive to the rate of resource utilization. Overall unit cost per device-based VMMC ranged from US\$ 18.21 to US\$ 65. By comparison, more recent cost estimates for conventional surgery indicate US\$ 65 to be the lowest unit cost (see Chapter 2). Compared with conventional surgery, device-based circumcision may have

greater economies of scale; that is, cost per procedure drops more quickly as total resource utilization increases. However, the threshold of total resource utilization needed to obtain this savings in cost per procedure remains unclear.<sup>1</sup>

### Equity, ethics and human rights

No evidence was identified on the effect of use of devices on health equity or on ethical issues.

### Feasibility

No specific evidence was identified on constraints or barriers to implementing use of device-based methods. The Guideline Development Group noted that the tetanus toxoid-containing vaccination requirements with the use of the elastic collar compression device reduced uptake of VMMC.

## 4.4 Evaluation of surgical assist devices

Several types of surgical assist devices exist for male circumcision. The only device discussed here (trade-named Unicirc™) is one that nearly met the clinical evaluation study requirements described in the WHO *Framework for the clinical evaluation of devices* (230). The mechanism of action of this single-use, disposable surgical assist circumcision device is a vice clamp that consists of a polyacrylate bell placed over the glans under the foreskin and an external clamp that crushes the foreskin between two plates for at least five minutes to fuse the skin edges and prevent bleeding. Then, the residual foreskin is cut away and the clamp is removed, leaving the blood vessels and skin edges fused. Surgical-grade cyanoacrylate glue is applied to the circumcision site to reduce the likelihood of wound disruption, and the wound is dressed using a strong adhesive bandage. The systematic search identified three publications and one report in an on-line database (286–289) referring to five studies on the efficacy, safety and acceptability of this surgical assist device.

### 4.4.1 Priority outcomes for surgical assist devices

#### Eligibility

There were no device-specific exclusions in addition to the standard contraindications to surgical circumcision within VMMC programmes.<sup>2</sup>

#### Successful circumcision

Almost all men (99.5%, 362/364 clients) were successfully circumcised with the device alone. The two failures were due to operator error (neglecting to fully tighten the device, addressed by training and revised instructions for use) and mismatched parts (addressed by ensuring that all parts are presented in a single package).

<sup>1</sup> Systematic Review Solutions. WHO guidance on voluntary medical male circumcision (VMMC) for HIV prevention amongst adolescent boys and men: literature reviews for PICOs 1, 2 & 3, full report, unpublished report, 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int). See Annex 2.3.

<sup>2</sup> Penile abnormalities (hypospadias, epispadias), active genital infection or genital warts, known bleeding or coagulation abnormalities.

## Safety: AEs (harms)

In total 59 severe and moderate AEs were reported among 364 clients (15%) circumcised with the device. Forty-three were reported in the first comparative study using the prototype device, which was then modified to exert a stronger and more uniform crushing force. The remaining AEs, which occurred with use of the redesigned devices, included the two device failures described above that required immediate suturing to prevent bleeding (severe AEs) and 14 moderate AEs in 264 clients (5%). The AEs included post-operative bleeding requiring a small suture (9), infection (4) and haematoma (1). These were comparable to the eight AEs in 50 clients circumcised surgically in the RCTs (16%), which included two cases of post-operative bleeding requiring sutures and six infections treated with antibiotics. All bleeding cases with the device occurred before discharge from the clinic and were managed with sutures or pressure. No AEs occurred in the case series of 54 adolescents (286).

## Acceptability

### Cosmetic result

Cosmetic result was assessed after four weeks and classified as "regular", "irregular" or "scalloped". Overall, 92% of clients had a regular appearance, and the remainder had a scalloped or irregular appearance attributable to the need for suturing in some in the early client series. In contrast, only 31% of clients circumcised by conventional surgery had a regular appearance after four weeks, mainly due to the circumferential sutures. Longer-term results were not reported.

## Values and preferences

### Pain

Pain was systematically recorded using a visual analogue scale intra-operatively (286), immediately post-operatively (289) and in the first 24 and 48 hours after the procedure in the first comparative study (288). Pain scores were very similar to those reported in the surgical arms in the RCTs. The first study to use topical (as opposed to injectable)

### Box 4.1. Balance of benefits and harms

The circumcision procedure with the surgical assist device can be completed in a single visit. In contrast, other circumcision device methods require all or part of the device to remain on the penis for up to one week in order to achieve haemostasis, and then they must be removed. Wound healing is rapid after use of this surgical assist device, comparable to healing after conventional surgical circumcision. The cosmetic result is a neat, uniform wound with no signs of recent suturing.

To date, the device has been used by only a limited number of physicians, all experienced in performing conventional circumcision. More information needs to be collected on the safety of this device when used by mid-level clinicians. As well, programme considerations such as training and other requirements need to be explored.

local anaesthesia (287) reported that two of 118 clients experienced transient pain as the maximum crushing force was applied to the foreskin; the intensity of pain was not reported. Sufficient pain control was obtained with topical anaesthesia applied for at least 25 minutes before starting the procedure (topical pain control used in the three most recent studies involving a total of 214 procedures) (286, 287, 289).

### **Healing time**

Over all studies 93% of clients circumcised with the device were fully healed by four weeks. In the comparative studies nearly all – 90% – of clients circumcised with the device and 89% of clients circumcised with conventional surgery were healed by four weeks, as were 95% of clients in the observational cohorts.

### **Procedure time**

The mean duration of circumcision was 10.6 minutes (SD 2.4), based on 360 circumcision procedures with the device, including the five minutes' waiting time under the full crushing force.

## **4.5 Programme considerations on use of device-based methods for male circumcision**

### **Planning for device adoption and scale-up**

- National programmes need to lead and coordinate with key stakeholders throughout the process. Messages need to clearly convey evidence, advantages and disadvantages.
- A national focal person and strategy should be in place.
- A prequalified device should be implemented through a phased approach, starting with pilot or demonstration sites. (See *Framework for clinical evaluation of innovations in male circumcision devices* (230).) Introduction and phased scale-up is an iterative process carried out over an extended period of time.
  - Pilot or demonstration projects in routine operating conditions are a first step. These projects assess feasibility and refine use through an ongoing learning process. Country teams should lead pilots, which should be informed by strategic assessments and experiences in other countries and settings.
- Health systems need to be ready to ensure that the new method is provided safely and that supply is sufficient.

### **Regulation**

- Governments may use the WHO Prequalification of MC Devices Programme to inform decisions regarding premarket approval, licensing and importation. WHO prequalification is based on a transparent and scientifically sound assessment process that helps to ensure that male circumcision devices meet global standard of quality, safety and efficacy. UN and other procurement agencies rely on WHO prequalification to make purchasing decisions.
- Policies and regulations that might affect the adoption of a prequalified device method should be reviewed to expedite progress while assuring safety, such as pre-market approval, licensing of manufacturers, post market surveillance requirement, health care providers who are authorized to use the specific device method.

- Male circumcision device-based methods should be authorized for use only in eligible populations in which safety and efficacy have been established by independent evaluations.
- Manufacturers must demonstrate that they have a functioning system to collate information on incidents with their devices and to act on this information to ensure product safety. They must evaluate complaints as they are received and take corrective action as required. (New WHO guidance on post-market surveillance of medical device, with complementary guidance on male circumcision devices, will be issued in 2020.)
- Providers or managers experiencing any problems related to prequalified devices should complete the relevant user complaint form for reporting problems and submit it to: [diagnostics@who.int](mailto:diagnostics@who.int).
- Scope of practice, or other relevant health cadre practice documents, should be reviewed and revised as needed to allow appropriate cadres of health care providers to perform VMMC using specific devices.

### Service delivery

- Prequalified devices have been demonstrated to achieve circumcision safely when used by appropriately trained and competent staff in suitably equipped settings and worn by clients according to device use instructions. Manufacturer's instructions for use, however, are not a sufficient guide to competent performance with a device method. Device-specific clinical guidelines should be developed.
- Appropriate training is essential for all health care providers. All clinical staff expected to perform circumcision using a device, including those with training and experience in surgical circumcision, will need to go through standardized competency-based training on the specific device-based method. All training must include emergency management as appropriate to the device.
- The requirement for facilities, equipment and commodities for device placement and removal will depend largely on the type of device used.
- The use of device-based methods does not obviate the need for surgical services, whether for men ineligible for device-based methods, to resolve rare complications or to serve clients who prefer conventional methods.
- Use of a device-based method still requires that the client receives the minimum service package, proper education and counselling sufficient to inform his informed consent.
- When a device-based method is used (and it is required for in situ devices), a second visit may be required for device removal. Services must be organized to accommodate two visits one week apart.

### Communications

- Men, and their partners as relevant, should receive information on the risks and benefits of the specific method. They should commit to, for in situ devices, wearing the device for one week, abstaining from sexual activity while wearing the device and during the time to healing (6–7 weeks for in situ devices); not removing the device themselves and returning for follow-up visits as required.



- Procurement and supply chain management
- A reliable procurement and supply management system is needed to ensure consistent supply. Costs associated with the new device must be estimated, as well as logistics, commodities and waste management requirements.
- Some particular challenges with device procurement are:
  - Devices are available in multiple sizes, and, thus, a sufficient quantity of each size needs to be stocked. Small studies of penile size might be undertaken to inform procurement. As devices are used more extensively, programmatic data can inform the sizes needed.
  - Each device may require additional unique accessories and supplies. To undertake the procedure safely, these must be available.
  - Adding device-based methods increases the complexity of the supply chain and logistics. These will need to evolve to an assured system that ranges from warehousing through oversight of consumption to forecasting of needs.
  - Waste management should follow the relevant protocols for type of materials.

### Monitoring

- Since large-scale roll-out of devices has not taken place, assessing the current post-market surveillance system will be an important initial step in preparations.
- The introduction of a new method of male circumcision implies additional monitoring, reporting and evaluation activities to inform safety and decision-making. Early monitoring in routine service settings will provide more information on safety and use before expanding to wider use.
- The main responsibility for recording and reporting adverse events lies with national programmes. A mechanism must be in place for monitoring safety and sharing information about adverse events or device-related incidents with manufacturers and the WHO prequalification team.
- Post-market surveillance starts with problem identification by the client or the provider. Both must be alert to the importance of reporting such issues and be supported in doing so.
- Active surveillance should be conducted as devices are introduced in non-research settings, meaning a proactive effort to follow up clients. (See *Framework for clinical evaluation of devices for male circumcision (230)*.)
- Once the rate of adverse events is deemed low by an independent group, active surveillance may be changed to passive monitoring.
- Programme monitoring during service delivery can help inform decisions. Information routinely gathered can include numbers of each device used, the total number of clients and client age by method.

**Box 4.2. Research needs for device-based methods**

- Assess effectiveness and efficiency, including efficiencies resulting from reduced time required for procedures and throughput, costs and acceptability to providers and clients.
- Assess further the use of surgical assist devices, including their use by non-physician providers, and explore training and other implementation requirements.
- Conduct research on:
  - pain management, particularly with new or revised methods, including use of topical anaesthesia. A consistent method for pain control with topical anaesthesia needs to be clarified; this is needed for use of topical lidocaine alone, as to date only EMLA has been studied with the no-flip technique.
  - safety of use of alternative ring sizes with the collar clamp should be documented in programme monitoring.
- Explore the effectiveness of service delivery models with a specific circumcision method and a mix of methods available.

# ENHANCING UPTAKE OF VMMC AMONG ADULT MEN AND MALE ADOLESCENTS IN HIGH HIV PREVALENCE SETTINGS

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## 5 ENHANCING UPTAKE OF VMMC AMONG ADULT MEN AND MALE ADOLESCENTS IN HIGH HIV PREVALENCE SETTINGS

### 5.1 Rationale and background

To reach 2030 HIV prevention targets, HIV prevention programmes must be focused on, accessible to and taken up by the people most at risk of acquiring infection. Uptake of VMMC among adolescent boys and adult men has been impressive, with over 23 million circumcised in the VMMC programmes of 15 priority countries between 2008 and 2018. However, there is now a need to increase uptake among adult men and especially those who may be at higher risk of HIV infection, such as partners of sex workers, men in serodiscordant relationships and men attending STI clinics. Early programme efforts focused on generating demand for VMMC, primarily through communication strategies (1, 290, 291) and raising awareness, which may have tapped into a latent demand for the service.

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

Experience since has revealed the need for a more strategic and holistic approach, tailored to the different ways that potential VMMC clients make decisions and addressing both demand and supply factors (292).

This chapter describes a framework for the process of achieving service coverage for any health intervention. It then reviews VMMC-specific service delivery changes and economic compensation interventions, presenting the peer-reviewed evidence and other considerations on their use, case examples with evidence, and programme and policy considerations. Annex 5.1 presents the GRADE tables and the evidence-to-decision-making table. Annex 5.2 presents case studies received in response to a call for evidence-based examples of interventions.

Reaching more men for VMMC can support achieving universal health coverage by 2030. Universal health coverage requires ensuring that all people have access to needed health services, which must be of sufficient quality to be effective and must not expose the user to financial hardship. Thus, VMMC services must be reoriented and expanded to offer sexual and reproductive health and other life-course-relevant services to men, engaging with people and communities to reach effective service coverage and coordinating across health programmes and providers as needed. Many of the interventions presented here are people-centred approaches (293).

The language and frame of reference used here build on WHO's *Innov8* approach (294) for achieving effective service coverage (Box 5.1). **Effective service coverage** is described as follows: "People who need health services obtain them in a timely manner and at a level of quality necessary to obtain the desired effect and potential health gains". All health services, goods and facilities must be available, accessible, of good

### Box 5.1. A framework for achieving effective service coverage

WHO's *Innov8* – leaving no one behind (294) adapted a framework (296) for achieving effective VMMC service coverage.

**Fig. 5.1. The process to achieve effective service coverage for a target population**



Source: Adapted from Tanahashi, 1978 (296).

quality and acceptable to those intended to receive them (295). Some populations and subpopulations, including adolescent boys and adult men, may face particular barriers and facilitators both on the demand side (related to wider context, client knowledge, risk perception, interest and self-efficacy) and on the supply side (related to the availability and accessibility of VMMC services) (292). These barriers result in limited service uptake, which slows progress towards effective coverage and achieving the public health goals for HIV infections averted. To increase VMMC service uptake, evidence-based interventions must address both barriers and facilitators in the context of adolescent boys and men's realities.

A recent systematic review (297), a literature review<sup>1</sup> (see section 2.2 and Annex 2.3) and qualitative market research (298) examined barriers and facilitating factors influencing the uptake of VMMC.

Common factors facilitating uptake of VMMC included:

- support from family and peers
- knowledge of HIV and STI prevention
- an understanding of improved penile hygiene and reduction of health risks

<sup>1</sup> Systematic Review Solutions. WHO guidance on voluntary medical male circumcision (VMMC) for HIV prevention amongst adolescent boys and men: literature reviews for PICOs 1, 2 & 3, full report, unpublished report, 2019; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int). See Annex 2.3.

- satisfaction associated with male circumcision and belief in enhanced sexual performance (299). (Note: there is no evidence that VMMC improves sexual performance and should not be used as a reason promoting circumcision.)

Common barriers to uptake identified included:

- fear or uncertainty regarding pain, injury, complications and adverse events
- negative perceptions attributable to religious or cultural influences
- lost wages from time off work
- sexual abstinence required during the healing period
- shame
- benefits judged not relevant.

As this guidance focuses on evidence-based interventions, WHO commissioned a scoping review of peer-reviewed literature on enhancing adult men's uptake of VMMC, followed by systematic reviews on those interventions with more than three comparative studies. This included service delivery and economic compensation interventions.<sup>1</sup> Box 5.2 summarizes the key points from the systematic reviews on these two types of interventions and key points from the Guideline Development Group discussion. Tables 5.1 and 5.2 summarize all available interventions with comparative evidence.

### **Box 5.2. Key points from comparative evidence and Guideline Development Group discussions on interventions to enhance VMMC services uptake among men and adolescents**

- No recommendations were made on service delivery interventions or economic compensation, given limited evidence and the diversity of types of interventions. The quality of evidence was moderate to high for service delivery interventions; low to moderate for economic compensation.
- Both service delivery interventions and economic compensation interventions addressed access barriers. Service delivery interventions also addressed awareness, self-efficacy and acceptability barriers.

#### **Service delivery changes**

Overall, changes to the way VMMC services were delivered enhanced uptake. Studies of service delivery interventions took place in diverse settings such as health facilities, communities, homes and schools. Countries and implementers can consider which approaches would best suit their populations and context. The types of service delivery approaches examined in research studies included:

<sup>1</sup> Figueroa C. Report on a scoping review of interventions to increase men's uptake of voluntary medical male circumcision in East and Southern Africa, unpublished report, 2017; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).

**Box 5.2. (continued)**

- Community approaches, including home-based approaches
  - intensified campaigns for short time periods at fixed sites plus VMMC promotional activities;
  - community outreach at primary health facilities, workplaces and schools; and services provided at local dispensaries and non-health care facilities for less served areas identified by geographic information systems (GIS);
  - home-based services linked to facilities – HIV testing, broader HIV and VMMC information/education using various referral and reminder approaches, such as text messages or home visits, to prompt men to seek VMMC services.
- Facility-based approaches
  - community health centres offering to test for HIV and link to VMMC services that provide comprehensive group health education;
  - training to enhance the competence of health care workers to deliver the service package;
  - engaging men’s female partners and adolescent boys’ mothers;
  - improving service quality at outreach sites (enhanced privacy, greater engagement of female partners).
- School- and sports-based approaches, focused on adolescents, with several components
  - coach/mentor with secondary school students and transport to service sites;
  - through school contacts, a football-based coaching intervention;
  - in-school education, coordinators and on-site services with client-friendly appointment times.

**Use of economic compensation to enhance uptake of VMMC among adolescents and adults**

Interventions studied offered compensation either for undergoing VMMC or for obtaining counselling on VMMC at a health facility. Compensation was either a fixed amount for each client or a prize in a lottery. Compensation included food, transportation or subsidized vouchers for male circumcision at the health facility. Offers of compensation were delivered either at an initial home visit by health workers or by flyers.

Fixed compensation, particularly to cover transport or opportunity costs, was associated with higher uptake of VMMC among adult men. Use of a lottery approach and variable amounts of compensation did not lead to greater uptake. The Guideline Development Group decided against a recommendation due to considerations of feasibility, ethics, acceptability and human rights. Key points are:

- Evidence on compensation was limited both in general and particularly regarding adolescents.

**Box 5.2. (continued)**

- Decisions on the use, type and amount of compensation require community engagement, input of local stakeholders and consideration of the specific context and the broader health system including effect on universal health coverage.
- Compensation may be thought of as addressing one aspect of inequity – access to services.
- Economic compensation may address access barriers that some adult men face by reducing their costs, particularly costs of transport to health care facilities. Such compensation also may reduce opportunity costs from wages lost during and after the procedure.
- Clients considered economic compensation acceptable, and compensation increased uptake in most settings where studied. However, a few studies reported that community leaders had reservations about compensation.
- Common elements of the interventions were trained interpersonal agents and community engagement.

It should be recognized that financial constraints are only one type of barrier to be addressed to enhance uptake. To determine which barriers to address and how, it is essential to understand the constellation of barriers to uptake and to recognize that these change over time.

## 5.2 Evidence-based interventions: service delivery changes for enhanced uptake of VMMC for HIV prevention among adolescents and adults

**No recommendation was made on service delivery changes to enhance uptake of VMMC** due to limited evidence, the heterogeneity of interventions across diverse settings such as home, community and schools, and context-specific considerations. However, **service delivery options that are reoriented towards people-centred services and that reduce barriers to access and acceptability may enhance uptake.**

Service delivery interventions were defined as changes to the ways in which VMMC services are delivered. These could include:

- improved training of health care workers (facility- and/or community-based);
- changes to the physical space and/or site organization at VMMC sites (such as restructuring the flow of VMMC services and/or the flow of clients within a facility);
- changes to the structure of health services – for example, providing services at different hours, days or locations; including home- or community-based and outreach (fixed and mobile) services; using different health care workers, including private-sector providers;
- providing additional health education, either at the time of VMMC or during follow-up;



- co-location of VMMC with other health services, such as hypertension or diabetes screening or services;
- developing a people-centred approach.<sup>1</sup>

A systematic review examined the effectiveness of various service delivery interventions to increase uptake of VMMC (300). The nine comparative studies included took place in five countries of East and Southern Africa. The diverse interventions were grouped into three broad categories: (1) community-based, including home-based, interventions, (2) school-based interventions and (3) facility-based interventions. Multiple studies included adolescents and young men but did not stratify outcome data by age. Several studies of school-based interventions included a small number of adult men, but participants were predominantly younger than 20 years of age. (Table 5.1 summarizes these studies.)

### 5.2.1 Summary of evidence on service delivery changes

Nearly all of the included studies reported that the different service delivery interventions were associated with improved VMMC uptake. Four RCTs provided high to moderate quality evidence, while six observational studies provided low quality evidence. For details on all outcomes assessed, see GRADE tables in Annex 5.1.

Two **community-based** RCTs showed increased VMMC uptake among participants in service delivery interventions (301, 302) (RR: 1.67, 95% CI: 1.29–2.14).<sup>2</sup> After community-based HIV testing in rural South Africa and Uganda, referral enhanced by text messages and phone call reminders to HIV-uninfected men or lay counsellors' reminders increased VMMC uptake compared with standard referral (301). In the United Republic of Tanzania, increased uptake was found at sites supported by enhanced demand creation, which

Nearly all service delivery interventions were associated with improved uptake of VMMC services.

included public address messages and peer promotion by recently circumcised men, as well as increased privacy in facilities and greater engagement of female partners, compared with sites with standard VMMC outreach (302).

Data from the three observational studies examining community-based approaches, including VMMC campaigns, mobile services and targeting of services using GIS, were not pooled, but the studies similarly reported increased VMMC following implementation of service delivery interventions compared with routine pre-intervention facility-based services (303–305). In Zimbabwe VMMC uptake among eligible males was significantly higher during campaigns (64%) than during routine services (36%) ( $P < 0.001$ ) (303). Suggesting a contextual preference, a study in the United Republic of Tanzania found that mobile VMMC services, compared with outreach or routine facility-based services, reached more older clients (ages 20 years or older) than younger clients (304). Also in

<sup>1</sup> People-centred health care is an approach to care that consciously adopts individuals', carers', families' and communities' perspectives as participants in, and beneficiaries of, trusted health systems that are organized around the comprehensive needs of people rather than individual diseases, and that respects social preferences. People-centred care also requires that patients have the education and support they need to make decisions and participate in their own care, and that carers are able to attain maximal function within a supportive working environment. People-centred care is broader than patient- and person-centred care, encompassing not only clinical encounters but also including attention to the health of people in their communities and their crucial role in shaping health policy and health services. World Health Organization 69th World Health Assembly agenda item 16.1, A69/39, 15 April 2016.

<sup>2</sup> Absolute difference: 185 more per 1000, 95% CI: 80–316 more.

**Table 5.1. Service delivery interventions to increase VMMC uptake used in included studies**

Study	Location	Service delivery intervention examined
<b>Community-based</b>		
<b>Ashengo 2014</b> (303)	United Republic of Tanzania, Zimbabwe	<b>VMMC campaign:</b> short-term, high-volume VMMC services with task shifting and increased promotional activities at fixed sites and mobile VMMC units visiting lower-level facilities and clinics, workplaces, schools, etc.
<b>Barnabas 2016</b> (301)	South Africa, Uganda	Following home-based HIV testing services, different VMMC referral/reminder approaches: <b>Intervention 1: VMMC text message reminders</b> three weeks after testing and follow-up phone call one month after testing, if needed. Then, text message 6–7 weeks after testing and phone call two months after testing. <b>Intervention 2: Follow-up home visits</b> by lay counsellors to promote VMMC
<b>Hellar 2015</b> (304)	United Republic of Tanzania	<b>Intervention 1: VMMC outreach campaign</b> during which teams of health care workers move into new communities and do 1–3 week bursts of intense, high-volume mobile or facility VMMC services with increased promotion <b>Intervention 2: mobile VMMC services</b> address hard-to-reach areas
<b>Mahler 2015</b> (305)	United Republic of Tanzania	<b>GIS</b> technology used to target VMMC mobile outreach/campaigns to less-served areas; services at local dispensaries and non-health facilities
<b>Wambura 2017</b> (302)	United Republic of Tanzania	<b>Intensified demand-creation intervention package:</b> enhanced public address messages, peer promotion by recently circumcised men; outreach “parent” and satellite sites; facility changes to increase men’s privacy; engagement and education of female partners
<b>School-based</b>		
<b>Kaufman 2016</b> (124)	Zimbabwe	<b>Boys reached through schools:</b> trained “coaches” (circumcised men ages 18–30) facilitated interactive game (metaphor for HIV protection), coaches shared own stories, with group discussion; coaches followed up with students and facilitated transport to VMMC clinic
<b>Miiro 2017</b> (137)	Uganda	<b>Football-based promotion:</b> mentor/coach served as VMMC champion, accompanied students to VMMC clinic, followed up
<b>Montague 2014</b> (307)	South Africa	<b>Phased school-based VMMC promotion and service access:</b> includes community sensitization meetings, in-school VMMC awareness sessions, teacher liaison and VMMC coordinators. VMMC and HIV testing services offered in schools; schedule optimized to minimize school disruption. Peer recruitment to VMMC services (with incentives for recruiters). Post-operative services in-schools. Those testing HIV-positive linked to care.
<b>Facility-based</b>		
<b>Weiss 2015</b> (306)	Zambia	<b>Spear and Shield: comprehensive educational programme</b> about HIV/sexual risk reduction and VMMC promotion (Box 5.3)

GIS = geographic information systems; VMMC = voluntary medical male circumcision.

the United Republic of Tanzania, VMMC service delivery reached more clients through rural dispensaries and non-health care facilities after services were targeted for underserved areas through GIS (305).

A **facility-based** study (RCT) in Zambia found greater VMMC uptake among men receiving the expanded education sessions and support of the Spear and Shield intervention (see Box 5.3), for which health care workers were specially trained, than among those who participated in time-matched educational sessions on prevention of tuberculosis, malaria, cholera and water-borne diseases and who also received condoms (RR: 1.71, 95% CI: 1.38–2.11<sup>1</sup>) (306).

School-based interventions were assessed in one RCT and two observational studies that reported on VMMC uptake (124, 137, 307). The RCT, in Zimbabwe, reported that men and boys involved in a programme using a trained coach to spark discussion of VMMC, follow-up with students and facilitation of transport to the VMMC clinic were 2.66 times more likely to be circumcised than those who did not participate (95% CI: 1.53–4.62<sup>2</sup>) (124). Two observational studies found increased VMMC uptake among men and boys receiving school-based interventions. One intervention, in Uganda (137), was a football-based promotion by VMMC champions who accompanied participants to VMMC and followed up. Participants were 2.2 times more likely to be circumcised (95% CI: 0.94–5.36). The second intervention, in South Africa (306), included community sensitization and in-school awareness raising, with services offered in schools along with scheduling of appointments to meet clients' needs, peer recruitment and transportation coordination. The number of VMMC procedures per month increased from 58 pre-intervention to 308 post-intervention (137, 307).

There were no clear trends in VMMC uptake by location (rural or urban), except in one study in the United Republic of Tanzania comparing VMMC uptake before and after rollout of GIS-based prioritization of VMMC services. After GIS-based prioritization, the majority of VMMC procedures shifted from primarily urban settings (~60%) to almost all in rural settings (~90%) (305).

### Box 5.3. Spear and Shield: comprehensive educational programme

The Spear and Shield intervention consisted of four 90-minute group sessions of HIV/sexual risk reduction education (including on the influence of alcohol and drugs) and VMMC promotion. It involved specialized training for counsellors and nurses about HIV/sexual risk reduction and VMMC promotion, including male and female condom negotiation, use and supply; cognitive-behavioural skills-building; sexual negotiation and improving communication techniques in relationships; and a peer mentor/coach who had undergone VMMC and received VMMC education. Male participants were recruited after voluntary HIV counselling and testing. Female partners were invited to join educational sessions. All study participants were compensated US\$ 4 for each pre- and post-VMMC visit (306).

<sup>1</sup> RD: 172 per 1000, 95% CI: 92–269.

<sup>2</sup> Absolute difference of 76 more per 1000 (95% CI: 24–166 more).

## 5.2.2 Other factors considered in decision-making

### Values and preferences

No studies were identified on people's feelings regarding uptake of VMMC (300) nor on end users' or health care workers' values and preferences concerning uptake of testing services or safer sex and risk reduction counselling within VMMC services.

### Acceptability

Six studies, published between 2012 and 2018 (103, 137, 308–311), examined the acceptability of service delivery interventions from the perspectives of users or potential users of VMMC as well as those of health care workers and other stakeholders (such as partners, families and communities of potential VMMC clients). VMMC clients or potential clients considered discussions with VMMC advisers and coaches particularly helpful. One study surveyed South African men attending VMMC services; 83% said that they would not have been circumcised had they not had motivational interviews with a VMMC adviser (310). In these studies other interventions that clients particularly appreciated were: (1) information (including specific information about the procedure and pain that they might experience) and encouragement from community leaders and peers, including age- and peer-appropriate face-to-face interactions; and (2) mobile or male-friendly services that reduced logistical and access barriers to VMMC. In the Botswana study (308), clients did not consider mass media messages or mobile entertainment helpful. Despite the wide acceptability of these interventions, one study noted that concomitant HIV testing was a potential barrier to VMMC uptake (308).

### Ethics, equity and human rights

None of the included studies addressed ethical, equity or human rights issues of service delivery interventions. However, the basic ethical principle that health is a human right remains relevant and applicable to the provision of VMMC services. The right to health may be assessed across the domains of availability, accessibility, acceptability and quality (United Nations Convention on the Rights of the Child) (223).

### Costs review

Eleven studies presented cost data (55, 124, 170–173, 177, 180, 312–314). These studies took place in Kenya, South Africa, Uganda, United Republic of Tanzania and Zimbabwe. Seven studies focused on community-based interventions, two on schools and two on facility settings. These studies found that scaling up service delivery interventions may create economies of scale and efficiencies. Linkages to VMMC services that optimize the use of non-physician clinicians and existing HIV and sexual and reproductive health services may save costs. Findings were mixed regarding the costs of various service delivery modalities (mobile versus fixed, outreach versus fixed).

Scaling up service delivery interventions may create economies of scale and efficiencies.

## Feasibility review

Three studies examining community-based interventions were considered feasibility studies (233, 315, 316). These studies were published between 2011 and 2014, during early scale-up; thus, their relevance currently may be limited. Conducted in eSwatini, Kenya, South Africa, United Republic of Tanzania and Zimbabwe, some studies aggregated data from multiple countries. Service-delivery interventions were generally considered feasible. In particular:

- facility preparedness and service quality improved as the number of VMMC facilities increased;
- expanding the role of mid-level health care workers enabled more facilities to offer VMMC; and
- scale-up led to decreased surgical time and other efficiencies.

## 5.3 Evidence-based interventions: economic compensation

**No recommendation was issued on economic compensation to enhance VMMC uptake among adult men and adolescent boys** due to the heterogeneity of studies and interventions; limited evidence on feasibility, sustainability as a single health intervention, issues relating to equity and ethics that could lead to a disproportionate emphasis in communities on VMMC over other health needs; and the need for stakeholder deliberations to consider specific contexts and the broader health system.

Compensation is generally understood as the provision of something, often money, to someone in recognition of loss. Definitions of compensation, and the difference between compensation and incentives, are not always clear-cut.

The Guideline Development Group considered **compensation** to be something provided to ensure that a person does not incur economic loss when taking action to promote her or his health. In contrast, an **incentive or inducement** is meant to ensure that a person gains or profits when doing something to promote their health, and it is specifically intended to increase motivation. In recent tuberculosis guidance from WHO, incentives were defined as goods and services delivered free to patients that are deemed not essential for the patient to adhere to health recommendations (such as free tickets to a sports event) (190).

The systematic review on economic compensation (317) found several types of VMMC interventions studied in Kenya, Malawi and South Africa. These included either or both economic interventions to compensate for transportation costs and/or time/wages lost due to the procedure (economic compensation) and financial incentives (for example, lotteries open to those being circumcised). For this review “compensation” is defined as an intervention that provides money, goods or services to clients:

- for completing a component of the VMMC service (for example, counselling for VMMC) or for undergoing the VMMC procedure;
- to reimburse them for costs associated with the procedure, including travel to services, as well as wages lost due to time off work during and after the procedure;
- the opportunity to earn rewards equivalent to fixed compensation through lotteries.

Several outcomes were assessed.<sup>1</sup> Outcomes were stratified by age group, disaggregating the adolescent male population from adult men.

### 5.3.1 Summary of evidence on compensation

Low to moderate quality evidence showed increased uptake of services, but the absolute increases were small.

The review (317) found that economic compensation for men over 18 years (seven studies) (318–324) and adolescents (one study) (124) was effective in increasing VMMC uptake by reducing actual costs, such as transportation costs, as well as opportunity costs, such as lost wages. Fixed economic compensation interventions for adults seemed more effective than variable amounts determined by chance (such as a lottery). The evidence was too limited and the approaches too heterogeneous to allow generalization for a recommendation. Also, there was limited information from the review on broader community-level impacts, the feasibility of delivering compensation and sustainability.

Economic compensation increased VMMC uptake by reducing actual costs and opportunity costs.

Evidence on compensation among adolescents was limited to one study (320). There were no data on uptake of HIV testing in VMMC services or of safer sex/risk reduction counselling in VMMC services, changes in community expectations of economic compensation for other services or potential coercion. Annex 5.1 presents the GRADE evidence table.

All but one of these studies were undertaken between 2013 and 2016, when scale-up towards the 80% coverage target varied from about 45% to nearly complete coverage. The study in Malawi (320) was undertaken even earlier, in 2010, when VMMC coverage was low (325, 326).

Most studies were of economic compensation interventions only. Types of compensation included fixed or variable amounts of cash or subsidy vouchers for food or transport; amounts ranged from the equivalent of US\$ 2 to US\$ 15. Discussions with the community informed setting compensation amounts. Incentive-based interventions were included as an arm in one study that offered all participants a non-monetary gift (free t-shirt or football match ticket) (124) and in one study that offered the opportunity to win prizes/products, including smartphones, bicycles and gifts through a lottery open to clients who chose circumcision (318). Table 5.2 summarizes the included studies.

In one study compensation was offered to adults after pre-VMMC counselling (321), while in all others it was offered after the circumcision procedure. Men learned of the compensation from health workers during home visits or from written messages such as postcards. In a study involving adolescents (ages 14–20 years), transportation to the VMMC facility was provided after a sports-based activity that promoted VMMC. Participants in the first five of the 13 intervention schools also received a non-monetary incentive (gift of t-shirt) (124).

<sup>1</sup> Outcomes assessed: (1) uptake of circumcision, (2) uptake of HIV testing within VMMC services, (3) uptake of safer sex and risk reduction counselling within VMMC services, (4) changes in community expectations of economic compensation for participation in other services and (5) potential coercion (undue influence) on individuals or groups within the community.

## Study findings

Combining RCT data on the effect of different types of economic compensation interventions (from four studies that presented data in similar formats; one RCT was not combinable) showed that VMMC uptake significantly increased with economic compensation interventions compared with uptake among the controls (RR: 5.23, 95% CI: 3.13–8.76) (318–321). All these studies involved adults only. Table 5.2 details the studies on economic compensation.

An observational study found that, when pregnant women attending antenatal care received transport vouchers (valued at US\$ 8.50) for their male partners, the intervention might have increased VMMC uptake compared with the pre-intervention phase. The women also received an information brochure and other education on benefits of VMMC, procedure details, wound care, complications, how/when to get the procedure and communication skills to enable them to speak to their partners). The impact on VMMC uptake was uncertain, given wide confidence intervals (RR: 1.69, 95% CI: 0.50–5.74) (323).

Nearly all studies involved adult men.<sup>1</sup> The one study that focused on adolescents and young men (124) found a potentially increased uptake of VMMC when male secondary school students ages 14–20 years were offered a non-monetary gift. However, large confidence intervals make this uncertain (RR 1.62, 95% CI: 0.88–2.98).

Four studies took place in urban settings and four in rural areas. There were no clear patterns in uptake of VMMC by location.

**Table 5.2. Studies included in the systematic review on use of economic compensation to enhance VMMC uptake among adult men**

Study	Location	Service delivery intervention examined
<b>Lottery</b>		
Thirumurthy 2016 (318)	Kenya	<b>Lottery-based:</b> Opportunity to participate in a lottery with prizes valued from US\$ 2.50 to US\$ 120. All study participants received some prize.
<b>Food and/or transport vouchers</b>		
Thirumurthy 2016 (319)	Kenya	<b>Fixed compensation</b> conditional on VMMC uptake: Food vouchers (value US\$ 2.50 for transportation or US\$ 8.75 for transportation plus 1- or 2-days' lost wages or US\$ 15 for transportation plus 2- or 3-days' lost wages)
Thirumurthy 2016 (318)	Kenya	<b>Fixed compensation</b> conditional on VMMC uptake: Food voucher (value US\$ 12.50)
<b>Lower price of VMMC services</b>		
Thornton 2016 (320)	Malawi	<b>Vouchers</b> for subsidized VMMC at a private facility such that the final price after using voucher varied: free, 50 Malawi Kwacha (US\$ 0.33), 100 Kwacha, 200 Kwacha or 500 Kwacha
<b>Cash</b>		
Wilson 2016 (321)	South Africa	Postcard offering a <b>cash transfer</b> (South African Rand 100/US\$ 10) conditional on completing VMMC counselling session

<sup>1</sup> The minimum age in four studies was 20 years, in three other studies it was 18 years, and, in one study with very small numbers, the minimum age was not reported, but the median age was 29 years.



### 5.3.2 Other factors to inform decision-making

The Guideline Development Group also considered acceptability, equity, ethics and human rights. Although the evidence reviewed indicated that economic compensation can increase VMMC uptake, other factors were considered critical, and they did not favour making a recommendation for this intervention. In particular, providing financial compensation for a single health intervention was not thought to be sustainable and could lead to a disproportionate emphasis in communities on VMMC over other health needs (for example, maternal and child health, non-communicable diseases). Although financial compensation could increase equity, facilitating access for men in distant communities for whom transport cost may be a barrier, it also could be inadvertently coercive. This consideration applies to access to health services in general and should be addressed more broadly rather than singling out VMMC.

#### Acceptability

The review (317) examined studies that considered the perspectives of men and boys who have had or potentially would have VMMC, as well as the acceptability of the interventions among health care workers and other stakeholders, such as partners, families and communities. The literature on acceptability was summarized qualitatively. Six identified studies examined the acceptability of economic compensation and lottery-based interventions (103, 111, 310, 322, 324, 327). See Annex 5.1 for study descriptions.

These six studies suggest that perspectives on compensation and lottery-based approaches for adults are mixed. Compensation was generally acceptable, valued for addressing key barriers and motivating to men. However, some participants felt that the amount of compensation proposed was not sufficient to offset costs, while others thought it was unnecessary. Some community leaders also felt that men would not want their VMMC decisions to be public knowledge. One study (324) that involved a raffle for a mobile phone noted that the intervention raised community suspicions as to the reason for free services and also for offering a phone; it raised the question, "What's behind this?" No information was available on impressions of coercion or persuasion.

Stakeholders' views on compensation for VMMC clients were mixed.

Many other studies assessed interventions to enhance uptake but did not assess compensation as an intervention. In these, most study arms, including control arms, received a cash or food voucher compensation to cover estimated loss of wages or cost of transport.<sup>1</sup> The amount of compensation was decided through consultation with the community.

#### Ethics, equity and human rights

The Guideline Development Group affirmed the importance of considering ethical and human rights issues prior to the introduction of economic compensation to enhance uptake of VMMC.

While no studies specifically examining these issues were identified, the Guideline Development Group considered the principles of public health ethics, equity and human rights, which inform the guidance below.

<sup>1</sup> Figueroa C. Report on a scoping review of interventions to increase men's uptake of voluntary medical male circumcision in East and Southern Africa, unpublished report, 2017; available from WHO/UCN/Global HIV, Hepatitis and STIs Programmes (hiv-aids@who.int).



## Preserving autonomy and ensuring that VMMC is voluntary

It is important to make the distinction between financial benefit or other benefits that are intended as *compensation* for the costs incurred obtaining VMMC (including direct costs, such as transport, and opportunity costs, such as wages lost to attend the service), on one hand, and, on the other, payments or other rewards intended as *incentives* to encourage participation.

It is important to distinguish between *compensation* for costs incurred and *incentives* to participation.

People should be enabled to make decisions regarding VMMC of their own free will and without coercion. To make such decisions, people must have information that is comprehensive and factually accurate and that they can easily understand.

**Compensation.** What constitutes fair economic compensation depends upon the local context as well as the circumstances of the individual (188). Engagement with local stakeholders is essential to understanding the local context and determining what amount and form of compensation might be appropriate. For example, in some settings non-monetary compensation, perhaps in the form of vouchers for food or other goods or services, might be more appropriate than payments of cash.

To help assure that the choice of circumcision is voluntary, instead of offering compensation for undergoing VMMC, compensation can be offered for participation in a service linked to VMMC. For example, similar to the South Africa study that offered a cash transfer for completing a counselling session (321), a study in Zambia offered compensation for attending educational and counselling sessions on VMMC and being offered *the option* to undergo the procedure (306).

**Incentives.** In contrast to compensation, people should not be offered incentives that *induce* decisions that might not be in their interest or not aligned with their values. Above a certain amount, economic payments have the potential for coercive influence upon an individual's decision about VMMC. Thus, compensation should not be so high as to act as an inducement (188). People should not feel compelled to choose VMMC, when they might not truly want to, for the financial benefit offered. People in precarious financial positions may be particularly vulnerable to such pressure.

While it is important to avoid compensation so high that it becomes an inducement, at the same time, if too low, it may not remove financial barriers to access – that is, compensation – and not be an effective enabler of access to VMMC.

In decisions about payments, it is also important to recognize that an individual's decisions may be influenced or limited not just by financial pressures, but also by other vulnerabilities, imbalances of power and social or even structural pressures (328).

## Compensation to ensure equity of access

Everybody should have the right to health and access to services regardless of where they live or their social, economic or demographic characteristics. Reducing inequalities in access to health care requires addressing barriers and facilitating fair opportunity to obtain services.

Compensation is intended to minimize or neutralize the costs that might be associated with obtaining VMMC (320, 329). This might include the costs of transport or lost wages incurred as a result of attending the service. Removing costs that might act as a barrier ensures equity of access to VMMC irrespective of an individual's financial means.

Mitigating barriers to access through other means might also be feasible and should be considered when determining the most effective and ethical strategy to enhance VMMC uptake. For example, providing services through outreach or providing transport to attend a clinic may be other options (132).

As described above, compensation can be offered for participation in a service providing information on VMMC and offering *the option* to undergo the procedure (306). Offering compensation in this way aims to promote equity of access while reducing the risk of coercion.

Ongoing care after the procedure is important to improve VMMC outcomes. Compensation has been shown to increase rates of VMMC aftercare attendance (330). As costs associated with follow-up may also be a barrier, ensuring equity of access to these services is also important.

### **Is offering compensation appropriate?**

Compensation should be offered only where the VMMC services available are of high quality and safe.

In some cultural contexts, taking money from others may be considered disrespectful, and so compensation might be viewed suspiciously. Meaningful stakeholder engagement is crucial to determine whether this is the case.

Compensation to improve access to VMMC must be considered within the larger perspective of health interventions that a population needs. Introducing compensation for one type of intervention or service might establish the expectation of reward for uptake of other health services, including services not relevant to public health. The implications also should be considered of introducing a short-term offer of compensation that will be withdrawn at some point in the future. The efficient use of resources must be evaluated, taking into account the overall cost of compensation, the number of individuals that might need to be compensated and the level of compensation. Ethical doubts about the efficient use of resources come into play if the compensation is disproportionately high and the individuals to be compensated are great in number (331).

The impact of introducing compensation in different settings remains unclear (329). If introduced, compensation strategies should be monitored, and monitoring should involve local stakeholders.

### **Costs of economic compensation**

One study in the systematic review presented cost data from Soweto, South Africa (321). Costs (excluding clinical costs) were calculated at US\$ 10 for cash transfers, US\$ 2 for a postcard message and US\$ 1 for refreshments. The numbers of postcards to deliver the message, given the uptake suggested by the studies, implies potentially high costs. The total programme cost attributable to the intervention was US\$ 91 per additional circumcision. Another study in the literature review reported clients' out-of-pocket costs

(in the absence of compensation). It found that the average transport cost for respondents in South Africa was US\$ 9.20. Eight clients (4%) reported wages lost (175).

No evidence was available on the effects of financial compensation for VMMC on the unit cost of other demand creation activities to encourage VMMC.

### Feasibility of delivering compensation

Studies have not assessed the feasibility and unanticipated effects in the near or longer term of compensation for VMMC uptake. Some considerations may be drawn from the studies reviewed. Studies report that the initial offer of compensation was made to adult men either during home visits by workers trained in interpersonal communication or by a postcard. These means of informing men were feasible in the context of these studies, but no evidence was available on feasibility in routine programming contexts.

## 5.4 Programme and policy considerations from evidence and Guideline Development Group discussions

When making decisions on interventions, programmes need to recognize and consider that different subpopulations have unique needs and preferences and these may change over time (294). Programmes should establish monitoring and evaluation systems alongside interventions so as to assess impact and to inform ongoing programme decisions.

**Broad considerations for enhancing VMMC uptake** that emerged from the evidence, the Guideline Development Group discussions and external reviewers' inputs include the following:

Different subpopulations may have various needs, and these may change over time. Barriers also may change.

- Understanding and responding to the local context is key. This requires engaging communities and tailoring interventions to meet their needs, values and preferences.
- There should be a move towards more people-centred – and person-centred – approach that is age- and gender-appropriate. To this end, the interpersonal communication skills of health care workers must be enhanced.
- Supply and demand barriers must be holistically understood and explored in specific contexts. To address both supply and demand simultaneously, interventions need coordination between stakeholders, including ministries of health and partners.
- Multi-component interventions are needed to address awareness, availability, accessibility and acceptability of VMMC.

### 5.4.1 Considerations for service delivery

- Consider the approaches most suitable to the (sub)populations and their contexts, including barriers and facilitators to the process of men connecting with services and accepting VMMC.
- To improve access to services, reorient models of service delivery, including to reach 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 and tuberculosis testing and treatment, engaging partners as relevant.

#### 5.4.2 Considerations for economic compensation interventions

- First address 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. If the barrier is costs, such as transport or opportunity costs, then consider other solutions for getting services to people that reduce such costs.
- A combination of multi-faceted interventions (for example, the Spear and Shield intervention (306) (see Box 5.3)) is 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.
- If the amount of compensation is high and many receive compensation, the programme expenditure may not be an efficient use of funding for VMMC.
- Policies on financial compensation should be explicit and clear. The criteria and process for deciding who should benefit from the intervention, including the data on which such decisions are based, should be transparent to clients and the community and subject to review to ensure that they are being applied equitably.
- The effects of compensation for a prevention service for adolescents are 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 to the extent possible, including with the national benefits package.
- Participation considerations:
  - Stakeholders' and communities' engagement is critical for deciding on use of compensation and, if introduced, its nature and amount.<sup>1</sup> Ethical decision-making frameworks could be developed to support such discussions (188). The calculation should ensure that compensation is not so high as to create a risk of undue inducement in the local context.

Stakeholders' engagement is critical. Clients' views are the most important.

<sup>1</sup> Reasons to involve stakeholders include: (1) to improve the quality of decisions through diverse perspectives; (2) to provide input on values and inform policy decisions; and (3) to provide a mechanism for public accountability for decisions (188). Stakeholders can be engaged in a number of ways, such as interviews, focus group discussions, public meetings, citizens' councils and community advisory panels.

- Community leaders' and health care workers' sentiments on economic compensation often differ from those of end users. The clients' views are the most important.
- Human rights perspectives: A human rights framework developed for cash transfer programmes to reduce poverty and support vulnerable populations (332) proposes the following characteristics of a compensation intervention that respects human rights: (1) governance and accountability of those involved in providing compensation, with legal and regulatory oversight; (2) reaching the most vulnerable and most excluded; and (3) accountability, transparency and clients' access to information, including information on risks and harms.

## 5.5 Policy review on men's health and services

The information that follows comes from a policy review undertaken by Sonke Gender Justice for UNAIDS and WHO and inputs from key stakeholders.

Reviews of health policies in East and Southern Africa by the non-profit organization Sonke Gender Justice reveal great variation in policies on men's health (Box 5.4). Some countries explicitly recognize the need to expand services for men beyond the minimum services package for VMMC (333). Fig. 5.2 shows that,

Almost all the national strategic plans reviewed had a very limited conceptualization of gender.

although most national strategic plans acknowledge the importance of gender mainstreaming in HIV-related interventions, very few refer to the need to engage men. Almost all the national strategic plans reviewed had a very limited conceptualization of gender, seeing it as referring to women only. National strategic plans were more likely to mention men in relation to efforts to prevent mother-to-child transmission of HIV than to mention male-specific services such as VMMC. They rarely mentioned men in terms of policies to affect their attitudes towards condom use, to involve them in home-based care or to increase their uptake of HIV testing and treatment services.

### Box 5.4. Key points about men's health from Sonke Gender Justice

- Men's health requires urgent attention – for everybody's sake.
- Improving men's and boys' health should enhance – not detract from – women's health and Health for All.
- The low use of health services among men reflects prevailing gender norms, structural drivers, poor access to health services, lack of policies and weak political will.
- A growing number of policies and programmes are improving men's health – in the few countries where they exist.
- It is necessary to develop and implement policies and programmes that shift gender norms, improve men's access to services and address structural drivers of men's ill health.

Source: World Health Organization Regional Office for Africa, 2017 (334).

**Fig. 5.2. Results of a men's health policy scan by Sonke Gender Justice**

■ Adequate    ■ Room for improvement    ■ Inadequate

	HIV and gender	Attempts to challenge or transform gender norms	Engaging men for prevention of GBV	Men's support of PMTCT	Male circumcision	Condoms	Men's use of VCT	Marginalized men and boys	Treatment	Home-based care
Ethiopia	Room for improvement	Inadequate	Inadequate	Inadequate	Room for improvement	Inadequate	Inadequate	Room for improvement	Inadequate	Inadequate
Kenya	Adequate	Room for improvement	Inadequate	Adequate	Room for improvement	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate
Namibia	Room for improvement	Room for improvement	Inadequate	Room for improvement	Room for improvement	Inadequate	Inadequate	Room for improvement	Inadequate	Inadequate
Rwanda	Adequate	Room for improvement	Inadequate	Adequate	Room for improvement	Inadequate	Inadequate	Room for improvement	Inadequate	Inadequate
South Africa	Adequate	Room for improvement	Room for improvement	Adequate	Room for improvement	Room for improvement	Room for improvement	Room for improvement	Inadequate	Adequate
United Republic of Tanzania	Adequate	Adequate	Inadequate	Adequate	Room for improvement	Room for improvement	Room for improvement	Room for improvement	Room for improvement	Room for improvement
Uganda	Room for improvement	Inadequate	Inadequate	Adequate	Room for improvement	Inadequate	Inadequate	Room for improvement	Room for improvement	Inadequate
Zambia	Adequate	Room for improvement	Inadequate	Adequate	Room for improvement	Room for improvement	Adequate	Room for improvement	Room for improvement	Room for improvement
Zimbabwe	Adequate	Room for improvement	Inadequate	Adequate	Inadequate	Inadequate	Inadequate	Room for improvement	Inadequate	Room for improvement

GBV = gender-based violence; NSP = national strategic plan; PMTCT = prevention of mother-to-child transmission; VCT = voluntary counselling and testing.

Source: World Health Organization Regional Office for Africa, 2017 (334) based on Pascoe 2017 (333).

## 5.6 Case studies

In 2019 WHO opened a call to programmes and implementing partners for case studies describing interventions on the uptake of VMMC. WHO received 16 case studies. Each case study was evaluated by two reviewers based on pre-established criteria, and 11 cases were selected for inclusion in these guidelines. Table 5.3 references these case studies, which are presented in full in Annex 5.2. Most of these examples involve multiple interventions or strategies that address multiple barriers. The interventions in Table 5.3 include both those with effects demonstrated in comparative studies, which also informed the systematic reviews, and the cases that present programmatic evidence. The information is organized by the framework, shown in Fig. 5.1, on domains en route to health services: awareness, knowledge, intent and self-efficacy; availability and accessibility, and acceptability; however, it may not capture each component of all interventions.

**Table 5.3. Summary framework of interventions to address barriers along the pathway to uptake of VMMC among adult men in East and Southern Africa**

Note: a combination of the interventions listed below may have been used in one study or case.

Awareness, knowledge, intent and self-efficacy	
Individual-level barriers	<ul style="list-style-type: none"> <li>• lack of or inadequate information on VMMC benefits and the procedure</li> <li>• incorrect information or myths about VMMC</li> <li>• the fact that VMMC provides only partial protection</li> <li>• risk prioritization: limited perception of HIV risk, and HIV prevention not their priority concern</li> <li>• for older men, circumcision to reduce HIV risk not of value (103, 138)</li> <li>• unclear level of benefit for bisexual men</li> <li>• uncertainty or hesitance</li> </ul>
Community/household-level barriers	<ul style="list-style-type: none"> <li>• limited social cohesion, family support</li> <li>• limited partner support</li> </ul>
<b>Interventions addressing these barriers</b> <ul style="list-style-type: none"> <li>• Home visits by lay counsellors to HIV-negative men and support for clinic linkage (137, 301)</li> <li>• mHealth – SMS messages to HIV-negative men including follow-up after home visits and referrals (301, 335, 336)</li> <li>• dedicated and trained interpersonal communication agents (a component of multiple studies)</li> <li>• information provided on health and wellness (for example, general HIV prevention, improved hygiene, HPV reduction and cervical cancer risk reduction for female partners) (38, 298, 306) (Case 6)</li> <li>• offering VMMC onsite to clients at sexual health clinics (337)</li> <li>• education and mobilization through sporting groups and using educational games (124, 137) (Cases 1, 9)</li> <li>• peer promotion by circumcised men (124, 137, 302, 306) (Cases 1, 2, 4)</li> <li>• partner engagement in sexual and reproductive health education (302, 306)</li> <li>• engagement of partners, family members and peers (301) (Case 6)</li> <li>• engagement of religious leaders (338) (Case 6)</li> <li>• diverse multimedia and mass communication (302)</li> </ul>	

**Table 5.3. (continued)**

<b>Availability and accessibility</b>	
<b>Individual-level barriers</b>	<ul style="list-style-type: none"> <li>• co-location of HIV and non-HIV services with VMMC (for example, fear of HIV testing resulting in avoidance of service)</li> <li>• high costs of accessing services, including real cost such as transport costs</li> <li>• services too far away</li> </ul>
<b>Community/ household-level barrier</b>	<ul style="list-style-type: none"> <li>• limited community engagement</li> </ul>
<b>Systems- or policy-level barriers</b>	<ul style="list-style-type: none"> <li>• limited supply of outlets/facilities with VMMC services</li> <li>• limited supplies, including water and electricity</li> <li>• limited quantity of trained health care providers</li> <li>• limited service hours</li> </ul>
<p><b>Interventions addressing these barriers</b></p> <ul style="list-style-type: none"> <li>• service delivery changes as part of multiple interventions, enhanced outreach (302) (Case 3)</li> <li>• safer sex education with partner and enhanced provider capacity at facility (302, 306)</li> <li>• user-friendly opening hours, specifically evening hours and Saturdays (339)</li> <li>• site optimization using a site capacity tool (339) (Cases 5, 8)</li> <li>• developing strategic information systems to guide planning, service delivery and quality assurance (339) (Cases 5, 8); data to map coverage gaps; finding the underserved (305)</li> <li>• government support and leadership (340) including by traditional leaders (Case 6)</li> <li>• site-level training and monitoring of programme targets (339)</li> <li>• provider task sharing and task shifting (303)</li> <li>• task shifting, mobile VMMC units, providing VMMC at non-health care facilities including schools (303–305, 307)</li> <li>• offering VMMC onsite to clients at sexual health clinics (337)</li> <li>• integration of VMMC with community-based HIV testing services (Case 7)</li> <li>• mobile VMMC units (303, 304) (Cases 7, 9)</li> <li>• community engagement and ownership (341–343) (Case 11)</li> <li>• economic compensation – transport and transport vouchers – with engagement of community (317)</li> <li>• partnerships with employers to provide VMMC (343)</li> <li>• working with and medically training (303, 304) traditional circumcisers (Case 10)</li> <li>• intersectoral action for health in all policies, such as labour and transport (333)</li> </ul>	



**Table 5.3. (continued)**

<b>Acceptability and quality</b>	
<b>Individual-level barriers</b>	<ul style="list-style-type: none"> <li>• fear of pain</li> <li>• fear of healing period</li> <li>• fear of loss of sensitivity/sexual capacity</li> <li>• incompatible with social, cultural, religious identity</li> <li>• shame to go for VMMC (stigma)</li> <li>• opportunity costs – work loss</li> <li>• distrust of services</li> <li>• poor quality of interpersonal communication/health care worker–client relations</li> </ul>
<b>Community/ household-level barrier</b>	<ul style="list-style-type: none"> <li>• masculinity roles</li> <li>• fear of people’s reactions</li> <li>• social, cultural, religious influence               <ul style="list-style-type: none"> <li>– limited community engagement</li> <li>– limited engagement of traditional providers</li> </ul> </li> </ul>
<b>Systems- or policy-level barriers</b>	<ul style="list-style-type: none"> <li>• attitudes of health care workers make a huge difference – a lesson learnt from work with key populations that should be applied in VMMC services (334)</li> <li>• gender perspectives: for example, men not wanting female provider.</li> </ul>
<b>Interventions addressing these barriers</b> <ul style="list-style-type: none"> <li>• increasing privacy at facilities (344)</li> <li>• enhancing competency of health care workers and community mobilizers, including in interpersonal communications (306) (Case 2)</li> <li>• addressing issues affecting women (for example, cervical cancer screening) while also addressing their male partners (38, 306)</li> <li>• site-level training and monitoring of programme (339)</li> <li>• honestly discussing pain associated with the procedure and engaging satisfied clients to address fear with prospective clients (Case 4)</li> <li>• developing strategic information systems to guide planning, service delivery and quality assurance (Cases 5, 8)</li> <li>• working with and medically training traditional circumcisers (Case 10)</li> <li>• engaging religious leaders (338) (Case 6).</li> </ul>	

HPV = human papillomavirus; HTS = HIV testing services; VMMC = voluntary medical male circumcision.

### **Box 5.5. Research needs for enhancing uptake**

- Identify current barriers to VMMC uptake among men, including those who are at higher risk of HIV infection.
- Assess the effect of interventions to increase uptake among men, including using programme data.
- Determine other men’s services to add, including services for both younger and older men. Assess preferences, feasibility, cost and contribution to universal health coverage.
- Share the findings of service delivery research and lessons learnt.



# SUSTAINING VMMC SERVICES WITH A FOCUS ON ADOLESCENT BOYS: PROGRAMME AND IMPLEMENTATION CONSIDERATIONS

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# 6 SUSTAINING VMMC SERVICES WITH A FOCUS ON ADOLESCENT BOYS: PROGRAMME AND IMPLEMENTATION CONSIDERATIONS

## 6.1 Introduction and background

Prevention is a driving force for ending AIDS as a public health problem by 2030. As part of combination HIV prevention, VMMC is a proven-effective prevention intervention. To date, VMMC has been predominantly delivered through vertical service delivery approaches, with implementing partners supporting national programmes to scale up to higher coverage focusing on adolescents and adult men. Some countries have achieved or are near to achieving coverage targets for VMMC. While continuing to reach more adult men, programmes are now considering how to maintain high VMMC coverage levels and, thus, impact on HIV incidence. This chapter addresses the transition from the current donor-driven vertical service delivery approach to country-owned, sustainable services in countries with generalized HIV epidemics where VMMC services are part of the overall HIV prevention intervention.

VMMC uptake has been high among adolescents, reflecting a natural demand and the acceptability of VMMC during adolescence (8, 194). Reorienting services with a focus on adolescents is a next step in the progressive transition to sustaining high coverage.

Embedding VMMC services within overall health systems aligns with global efforts to strengthen health systems and achieve universal health coverage. Thus, the WHO health systems building blocks (345) can serve as a framework to consider issues and opportunities for sustaining VMMC services.

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

Building on existing WHO models and frameworks, the overarching principles of this guidance are that VMMC programming should be:

1. adolescent-focused
2. embedded in routine health services
3. high quality and people-centred
4. widely accessible
5. co-produced.

### Adolescent focus

Adolescents, particularly those over 15 years, will be an important group to reach so that high coverage levels will be maintained and the 2030 HIV incidence reduction goals achieved. Taking into account the considerations for adolescents (see Chapter 3),

sustaining VMMC should focus on adolescents ages 15 years and above, who usually are capable of giving oral or written informed consent. However, if informed consent is possible, VMMC also may be offered to boys in the 10–14 age group who are physically and cognitively mature. Countries that are planning to include infants (or a mix of age groups) as a strategy for achieving sustainable VMMC coverage are encouraged to carefully consider risks and benefits, acceptability issues and ethics and human rights, as well as what resources are available to safely deliver early infant male circumcision.

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.

Adolescence, defined as ages 10–19, spans a critical period of human development, with rapidly increasing physical, hormonal, neural, psychosocial, cognitive, emotional, sexual and reproductive development and maturation. Across adolescence an individual's understanding, needs and preferences change concerning sexual and reproductive health, including VMMC.

The meaningful engagement of adolescents is crucial, empowering them to have active roles in decisions regarding their own health rather than being passive recipients of services.

## 6.2 Framework for transition to sustainable services

### 6.2.1 What is sustainability?

There is no universally agreed definition of sustainability; its meaning depends on context, setting and situation. Key informant interviews with experts, however, revealed some key themes for defining sustainability in the context of VMMC:

- the capacity of VMMC services to continue to function effectively for the foreseeable future and maintain high VMMC coverage;
- the integration of VMMC services into the established health system's routine health services;
- strong country ownership and leadership through a co-produced approach, with community participation and subnational, national, regional and global support;
- resource mobilization, including domestic and external funding, coordinated through the government.

### 6.2.2 A health systems approach

Based on the World Health Report of 2000 (346), WHO has defined a number of "building blocks" that make up the health system (Fig. 6.1). In consultations on the writing of this chapter, national programme managers affirmed that this health systems approach would be applicable and useful.

**Fig. 6.1. The six building blocks of a health systems**

Good **health services** are those which deliver effective, safe, quality personal and non-personal health interventions to those that need them, when and where needed, with minimum waste of resources.

A well-performing **health workforce** is one that works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances (i.e., there are sufficient staff, fairly distributed; they are competent, responsive and productive).

A well-functioning **health information** system is one that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health system performance and health status.

A well-functioning health system ensures equitable access to essential **medical products, vaccines and technologies** of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use.

A good **health financing** system raises adequate funds for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them. It provides incentives for providers and users to be efficient.

**Leadership and governance** involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition building, regulation, attention to system-design and accountability.

Source: WHO, 2007 (345).







### 6.2.3 Conceptual framework and process towards sustainability

The health systems building blocks are the foundation of sustainable services, and they provide a framework for considering how to build sustainable VMMC services. In Table 6.1 each of the six health system building blocks is further divided into components that are relevant for sustaining VMMC services. In addition to the six building blocks, a seventh category, critical enablers, has been added because it encompasses important areas for countries to consider. The critical enablers support all the building blocks without necessarily fitting into a specific block.

Key informant interviews as well as, in particular, WHO's guidance, *Global accelerated action for the health of adolescents* (22), informed the identification of these components. Achieving sustainable VMMC services will need a systematic and phased approach that will differ from country to country. However, each country would need to assess and understand where they are in the transition to sustainability, recognizing that actions may differ from country to country.

Planning for sustainable VMMC services requires attention to each of the six WHO building blocks of health systems and critical enablers.

**Table 6.1. Health systems building blocks and components framework for sustainable VMMC services – six building blocks and critical enablers**

Building block	Component
 <b>Finance</b>	<ul style="list-style-type: none"> <li>• Resource allocation and mobilization</li> <li>• Purchasing of services</li> <li>• Financial risk protection</li> </ul>
 <b>Health workforce</b>	<ul style="list-style-type: none"> <li>• Health workforce planning</li> <li>• Pre-service and continuing education</li> <li>• Management, support and supervision</li> </ul>
 <b>Strategic information</b>	<ul style="list-style-type: none"> <li>• Data collection and management</li> <li>• Data quality</li> <li>• Data analysis and use</li> <li>• Safety monitoring</li> </ul>
 <b>Supplies and equipment</b>	<ul style="list-style-type: none"> <li>• Norms and standards</li> <li>• Procurement, supply and distribution</li> <li>• Quality of VMMC supplies and equipment</li> </ul>
 <b>Leadership and governance</b>	<ul style="list-style-type: none"> <li>• Programme leadership and coordination</li> <li>• Accountability, oversight and regulation</li> <li>• Inter-sectoral coordination</li> <li>• Health sector plans and policies</li> </ul>
 <b>Service delivery</b>	<ul style="list-style-type: none"> <li>• Access (strategic planning of health services)</li> <li>• Reorienting service delivery models</li> <li>• Empowering and engaging people</li> <li>• Safety and quality</li> </ul>
<b>Critical enablers</b>	
<ul style="list-style-type: none"> <li>• Adolescent leadership, co-produced health services, local ownership and participation</li> <li>• Community engagement and empowerment</li> <li>• Multisectoral partnerships</li> <li>• Enabling laws and policies</li> </ul>	

## 6.2.4 Building blocks, components, key issues and actions for sustainability

### Building block: finance



A good health financing system raises and budgets adequate funds for health care in ways that ensure that people can use needed services and are protected from financial catastrophe or impoverishment due to their cost (347). 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 (347, 348). Components of sustaining financing for VMMC service delivery include resource allocation and mobilization, purchasing and financial risk protection.

#### Resource allocation and mobilization.

Currently, VMMC services are heavily dependent on international donor assistance (349). A key step is to ensure that VMMC is part of national essential health service packages that form the basis of national and subnational financial planning, mobilization and allocation. Key considerations for resource allocation and mobilization are the following:

In a time of declining donor funding, countries should take a prominent role in the mobilization, allocation and administration of resources.

- incorporation of VMMC into the national essential health services package;
- adequate funding from domestic and regional sources, avoiding reliance solely on international donor funding, which can lead to insufficient and/or unpredictable financing for VMMC;
- resource estimation for VMMC undertaken as part of national health plans using integrated tools such as OneHealth (22);
- harmonization of donor-financed elements of the VMMC budget with the national ministry of health (MOH) budget;
- a diverse mix of mechanisms and strategies to fund VMMC, including through national health budgets, general taxation, earmarked tax, external multilateral funds, bilateral funds and voluntary contributions.

**Purchasing of services.** Purchasing refers to the arrangements and mechanisms to allocate pooled funds to provide health services (350). Providers use these funds to deliver defined benefits to the population. Purchasing is a core function of any health system. Moving from passive to strategic purchasing is the focus of health financing reforms in many countries and is key to sustainability (350). Key considerations for purchasing of services include:

- public financial management that is flexible enough to adjust to changes in demand for services;
- remuneration of health care workers for effective delivery of quality, safe and person-centred VMMC services;



- ready availability of information on VMMC services to meet clients' needs and demand. These should include clinical, administrative and financial information tailored as relevant to clients' age and income group, service location, level of care and sector (public or private). (See the strategic information building block for detail.)

**Financial risk protection.** To support sustainable VMMC services, financing approaches should ensure access to needed services while protecting people against severe financial consequences of paying for care. Cost should not be a barrier to services, particularly for adolescents, for whom cost is one of many substantial barriers to care (22). Therefore, a key consideration is:

- financial risk protection for all adolescents, especially coverage for the most vulnerable, such as out-of-school youth.

### Key actions for financing

- Resource allocation and mobilization
  - Promote VMMC as part of national essential service packages.
  - Estimate country-specific resource needs and resource availability and develop an investment case with VMMC as a key aspect of HIV prevention.
  - Include VMMC services in national health operational plans through integrated tools such as OneHealth.
  - Increase domestic resources for VMMC.
  - Harmonize donor-financed elements of VMMC services with national MOH budgets.
  - Promote transparency and accountability in health financing systems.
  - Advocate continued prioritized support for VMMC through local ownership, leadership and domestic resource mobilization.
  - Explore regional resource mobilization options through regional bodies (for example, the African Union, the East African Community and the Southern Africa Development Community) for funding regional activities and mechanisms to support the sustainability of VMMC.
- Purchasing of services
  - Consider remuneration of providers of health services based on approaches that encourage effectiveness and quality and that are risk- and income-adjusted.
  - Cover VMMC in health insurance and explore strategies to further integrate coverage of VMMC services into private and public health insurance schemes.
  - Consider the private sector as partners and explore new sources of financing from the private sector (351).
- Financial risk protection
  - Design and implement financial risk protection measures (for example, waivers, vouchers); improve or develop pre-payment and risk pooling initiatives for adolescents to mitigate indirect and opportunity costs (348).

## Building block: health workforce



For the health workforce building block, the overall goal is a readily available, competent, responsive and productive health workforce to provide VMMC services. Key components to ensure this include:

A major challenge for many countries is identifying and training the required quantity of personnel to competence.

**Health workforce planning.** Inadequate mobilization and distribution of the health workforce is an important obstacle to improving health systems and achieving key health objectives, particularly in low- and middle-income countries (350, 352). Key considerations for health workforce planning include:

- integration of VMMC into national health workforce planning, based on projections of VMMC demand;
- skill mix, distribution and retention of health workers who offer VMMC services, including such issues as workload, staff burnout and turnover, and coverage in rural areas;
- gender, ethics and the safety of health workers are considered in the selection, training and deployment of health workers providing VMMC services;
- health workers are trained more broadly and their skills optimized to provide VMMC and other health services to support the broader needs of the health system.

**Pre-service and continuing education.** Both national pre-service and continuing education should include VMMC content in their curricula for relevant cadres of the health workforce, especially those providing clinical and other VMMC support services (347, 350, 352). As a predominant health care cadre in many regions, nurses have a particularly important role in VMMC services (352, 353). Training curricula should be aligned with regulated scopes of practice but at a minimum should introduce VMMC and the service package to be provided (354). Key considerations for education include:

- including VMMC and other critical elements of adolescent-friendly service provision and person-centred care in national pre-service training and continuing education requirements across relevant cadres that might provide elements of VMMC services; this will involve both pre-service and continuing education institutions;
- establishing continuing education and competency requirements for all cadres of VMMC health care workers;
- developing national health education and training courses on adolescent health that address VMMC, including modules on interpersonal communication and patient safety in VMMC.

### Management, support and supervision.

Maintaining an efficient and effective health workforce requires a strong management system covering personnel, recruitment, working environment and conditions and performance management, including monitoring and evaluation,

Support and supervision should be person-centred, with a focus on enhancing adolescent-friendly, integrated services.

as well as providing support and supervision to all health cadres (355, 356). Key considerations for management, support and supervision include:

- supportive supervision for adolescent-friendly and responsive care by health care workers offering VMMC services;
- integration of VMMC into national, district and local structures for health-worker management, support and supervision;
- patient safety systems that enable learning from AEs and include quality improvement.

### Key actions

- Health workforce planning
  - Document and analyse the situation of health workers providing VMMC in light of VMMC strategic objectives.
  - Include projections of the number of clients, including adolescents, who will need VMMC services in the country-level health workforce plan.
  - Develop systems to address and monitor skills mix and the distribution and retention of health workers offering VMMC services, including, for example, broad incentive schemes to ensure sufficient staffing levels in facilities.
  - Consider ways to engage community health workers and non-health actors, such as educators and community members, in community sensitization, which may help to sustain community demand for VMMC services (357).
  - Plan and facilitate the involvement of community health volunteers.
- Pre-service and continuing education
  - Include VMMC in national pre-service training requirements (357).
  - Develop clear national mechanisms to involve health care workers in determining their VMMC training and education needs. Conduct competency-building activities at national and district levels that respond to reported needs, including as a part of recertification requirements.
  - Include VMMC modules in national adolescent health education and training courses (345).
  - Employ training methodologies that emphasize adolescent-friendly services and that are people- and health worker-centred, including blended learning approaches.
- Management, support and supervision
  - Develop and implement health care service delivery standards for assessing adolescent-responsive VMMC services, patient safety and infection prevention and control.
  - Align VMMC programmes with national systems of supportive supervision, as led by the MOH (358).

## Building block: strategic information



To ensure the sustainability of VMMC, country programmes will need to move from vertical and parallel strategic information structures to more integrated, country-owned and less donor-dependent structures and systems for data collection and use. Country-owned strategic information systems that routinely collect data and monitor systems from the facility level through the national level are key for sustainability (356). Key components for strategic information include:

**Data collection and management.** Methods of data collection, management and reporting are key to programmatic interventions that are well-designed, data-driven and dynamic. Key component for data collection and management include:

Strategic information interventions need to engage clinical staff more closely.

- developing efficient VMMC data collection methods that take advantage of electronic information systems and move away from paper-dependent data collection;
- data management and reporting systems that encourage country-level data ownership and reduce the number of parallel systems across various donor and implementing agencies.

**Data analysis and usage.** The effectiveness of VMMC programming reflects how data are analysed and used to contribute to programme planning and management, performance review and decision-making. A bottom-up approach to data analysis and use, starting at the facility and then moving to the programme level, is very important. Countries, donors and donor-supported implementing partners need to further harmonize processes for VMMC data use. Key considerations for data analysis and usage include:

- planning for data analysis and relevant disaggregation, especially by age and location;
- use of data for reporting, planning, logistics management, evaluation and quality assurance at the facility level and above.

**Data quality.** Countries need to apply to VMMC data the quality assurance policies, procedures, processes and tools that constitute the country's routine data quality systems. As well, continuous quality improvement systems – including data quality improvement – are needed at every level of the health system. A key consideration for data quality is:

- procedures for routine data quality checks, to reduce duplication of data entry and improve data flows.

**Safety monitoring.** Safety monitoring systems for VMMC are critical for detecting, reporting and responding to AEs related to circumcision procedures. AEs need to be clearly and consistently defined, and the systems, structures and resources required to detect, report, evaluate and respond to them need clear description. Key considerations for safety monitoring include:

- improvements in VMMC safety monitoring systems, including routinization within national systems;
- a multi-level surveillance system for monitoring AEs.

## Key actions

- Data collection and management
  - Embed VMMC strategic information in routine monitoring and evaluation (M&E) systems (347, 353).
  - Update and agree a minimum standard set of indicators for VMMC, a subset of which can report on district, national and global indicators for programme monitoring and management.
  - Transition progressively from paper-based to electronic patient information systems.
  - For countries with paper-based systems, simplify patient monitoring tools (cards, registers and reports) and standardize.
- Data analysis and usage
  - Prioritize indicators of VMMC provision to be disaggregated by 5-year age bands, especially adolescents ages 10–14 and 15–19 years.
  - Collect, analyse and use key national and facility-based indicators of quality of care.
- Data quality
  - Develop quality improvement plans at all levels that are both data-derived and data-driven.
  - Periodically review client monitoring systems to assess data quality.
- Safety monitoring
  - Make safety monitoring routine programme-wide.
  - Establish an effective, multi-level surveillance system for monitoring AEs. This system should monitor health care workers' safety as well as patients' safety.



## Building block: supplies and equipment



A well-functioning health system ensures equitable access to essential medical products and technologies of assured quality, safety and efficacy and their scientifically sound and cost-effective use (345). The implementation of sustainable VMMC services requires a durable logistics system, involving commodity procurement, supply chain management, human resources, waste management and proper storage, including storage of wastes as appropriate. Accurate forecasts of demand and timely ordering are crucial. Key components for sustainable supplies and equipment include:

**Norms, standards and policies.** National standards and guidelines are needed to ensure continuous supply of quality VMMC supplies and equipment (359). Countries should consider VMMC when developing a national plan for procuring surgical, obstetric and anaesthesia supplies and equipment. Key considerations for norms, standards and policies include:

- a national set of standards for the quality of VMMC supplies
- guidelines on prescribing and dispensing practices and strategies to support rational use of VMMC supplies and equipment.

**Procurement and distribution.** In some countries the implementation of VMMC programmes has involved creating a supply chain system that is managed by an implementing partner and operates parallel to the supply chain for national essential medicines (349). To build toward sustainability, however, national programmes must take responsibility for procurement and management of commodities required for VMMC, as well as for introducing new technologies, such as circumcision devices, as they become available. Key considerations for procurement and distribution include:

- national procurement systems for VMMC supplies and equipment
- national systems of supply and distribution for VMMC supplies and equipment.

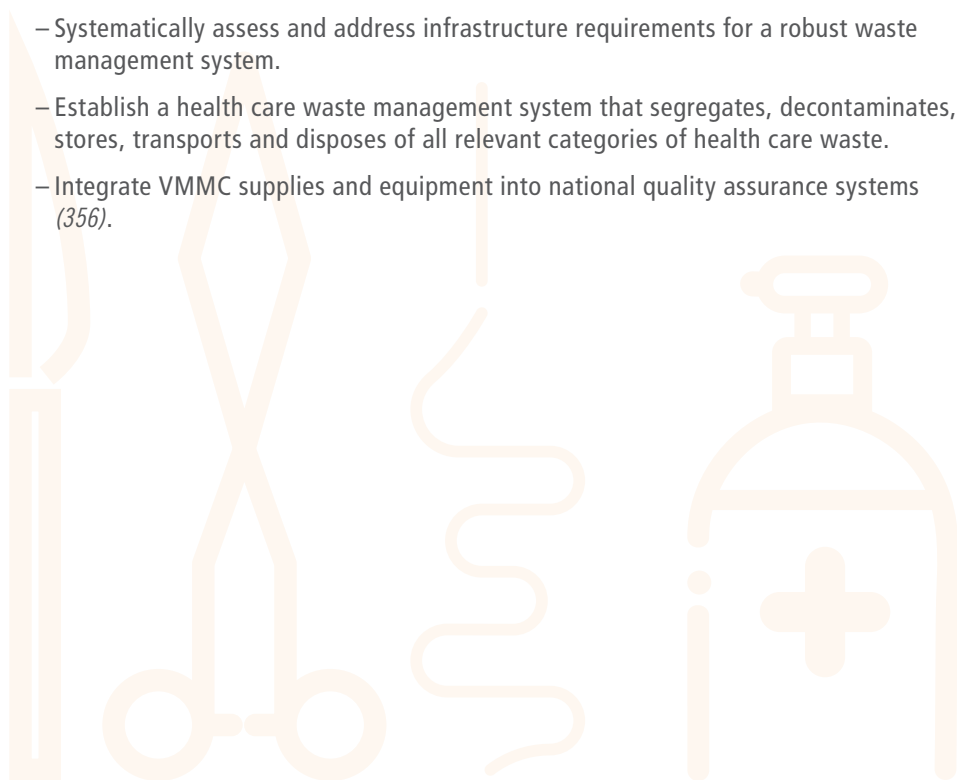
**Quality of VMMC supplies and equipment.** Quality assurance processes and mechanisms can maintain or strengthen the quality of VMMC supplies and equipment. This includes, where available, facilitating clients' access to safe, appropriate and affordable male circumcision devices of good quality in an equitable manner. Key considerations for supplies and equipment include:

- quality of VMMC equipment and supplies, including male circumcision devices
- waste management that addresses segregation, storage, transport, treatment and disposal of all relevant health care waste categories.

### Key actions

- Norms, standards and policies
  - Set national standards for the quality of VMMC supplies and assurance of continuous procurement without disruption (360, 361).
  - Develop and implement standard guidelines on prescribing and dispensing practices to support rational use of VMMC supplies and equipment (360).

- Develop a standard list of VMMC commodities, including for waste management, HIV counselling and testing and the treatment of STIs (349).
- Procurement and distribution
  - Include VMMC supplies and equipment in centralized national procurement, supply and distribution systems (360).
  - Consider supply chain costs when determining the resource needs of VMMC programmes (359).
  - Consider the use of specific VMMC technologies, such as pre-qualified devices, and develop and implement strategic plans for their introduction and roll-out, including quantification, procurement and disposal considerations (356).
  - To prevent expirations and stock-outs, build capacity at the facility level for proper stock management practices (first expiry–first out, forecasting, reporting and requisition, storage and tracking through electronic logistics management information systems).
- Quality
  - Develop the minimum requirements and the specifications for the equipment needed to perform safe VMMC.
  - To help service delivery points assure patients’ and health care workers’ safety, develop action plans that consider the quality of VMMC equipment and supplies, including removing expired stock from pharmacy shelves, adequate handling and proper conservation conditions (359).
  - Systematically assess and address infrastructure requirements for a robust waste management system.
  - Establish a health care waste management system that segregates, decontaminates, stores, transports and disposes of all relevant categories of health care waste.
  - Integrate VMMC supplies and equipment into national quality assurance systems (356).



## Building block: leadership and governance



Effective leadership and governance lie at the core of building a health system (345). Strong leadership by government ministries and at higher levels of the government should foster implementation of sustainable, adolescent-responsive policies and programmes (22) (see Annex 6.1, case example of linking the adolescent SRH and VMMC programmes and services to achieve similar objectives in Zimbabwe). Key components for sustainable leadership and governance include:

Country leadership, ownership and effective collaboration with partners are essential at all levels – national, district and local.

**Programme leadership and coordination.** Synergies and efficiencies are enhanced when relevant sections of the MOH collaborate closely with each other and with implementing partners, communities, civil society, young people and the private sector (22). A clear and agreed vision is needed to ensure that leadership and governance structures consider and address VMMC. Key considerations for programme leadership and coordination include:

- the ministry's leadership and coordination role that makes programme ownership paramount and prominent;
- programme engagement with subnational and local political and traditional leaders, including MOH-funded and supervised VMMC focal points at national, regional, district and local levels;
- a partnership structure for MOH-led VMMC delivery that ensures coordination, advocacy, implementation, reporting and quality assurance;
- engagement of relevant departments of the MOH and across and within other relevant line ministries in implementing, coordinating and overseeing VMMC activities.

**Accountability, oversight and regulation.** Countries need to develop mechanisms for accountability within the MOH and relevant health programmes to measure progress, identify challenges and improve results. National programmes should lead in coordinating, setting sustainability milestones and assessing and possibly revising regulations as needed (362). Key considerations for accountability, oversight and regulation include:

- systems for support and supervision of VMMC led by the MOH through the relevant health programme focal points;
- VMMC focal points or coordinator in the MOH and at different operational levels (national, district, local);
- a technical working group in the MOH for oversight and review of VMMC performance, including quality of services;
- key cadre-specific practice regulations, including those concerning scopes of practice, with consideration to providing clear authorization of each cadre's tasks.

**Intersectoral coordination.** Coordination across sectors is important to address coverage gaps and barriers (294, 363) (290, 361), particularly for health services addressing adolescents and youth (see Annex 6.1). Coordination is crucial with such



sectors as education, culture, civil society, traditional/community, youth, education, finance and the private sector (22). A key consideration for intersectoral coordination is:

- platforms to support effective intersectoral linkages, partnerships and coordination.

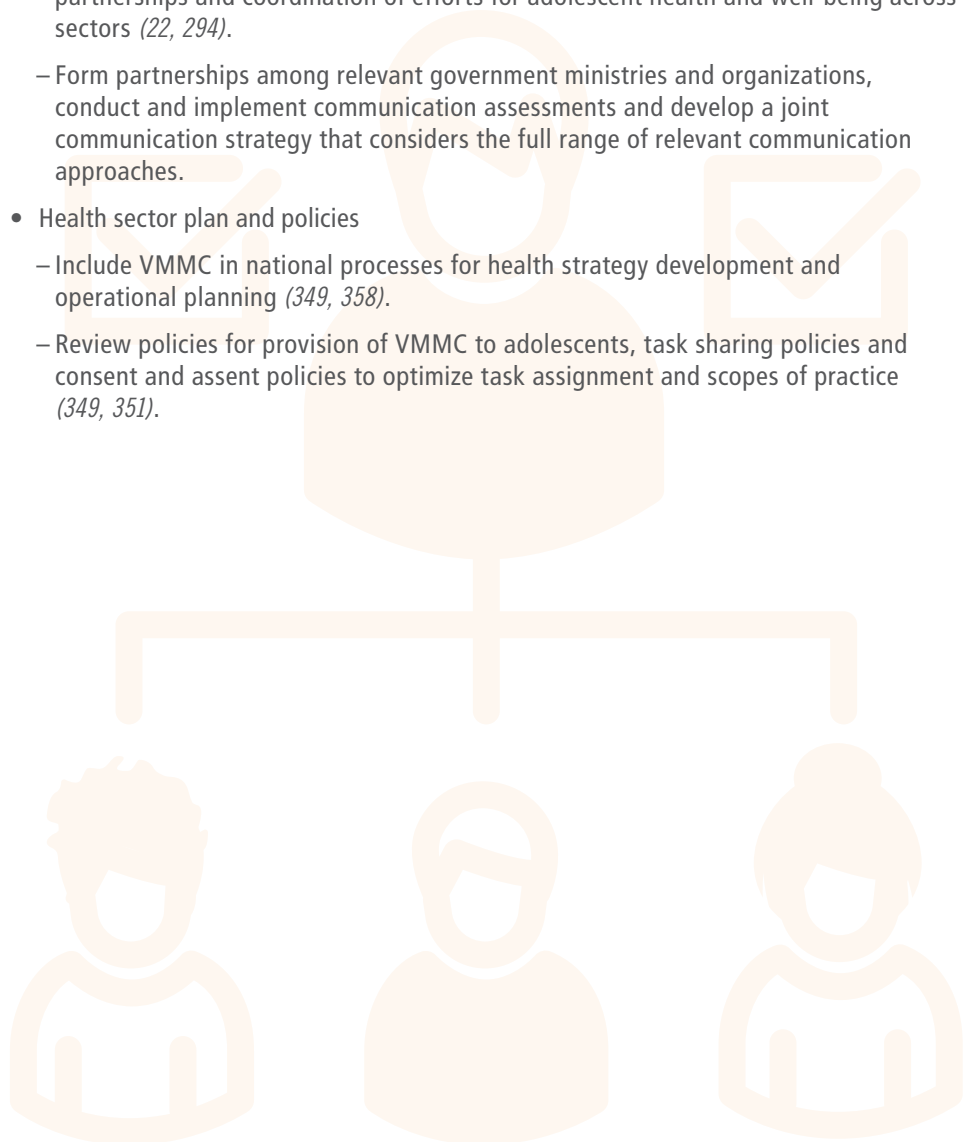
**Health sector plan and policies.** The integration of VMMC into national health sector plans and policies helps to assure that VMMC is addressed within the broader national health framework and integrated planning (294). Key considerations for health sector plans and policies include:

- integration of VMMC into the essential package of health services
- inclusion of VMMC in the national health strategy and operational plan
- assessing and planning for necessary regulation changes to reflect the task distribution in VMMC services.

### Key actions

- Programme leadership and coordination
  - Enhance the MOH’s leadership and coordination role for VMMC services (294).
  - Use existing national platforms to oversee and coordinate efforts for VMMC across sectors and government ministries.
  - Manage VMMC services as an integral part of the national essential package of health services.
  - Build national and subnational (for example, district-level) political and administrative capacity and leadership for VMMC in multiple areas. These areas include data use for decision-making, advocacy, negotiation, budgeting, building consensus, planning and programme management, coordination across sectors, mobilizing resources and ensuring accountability (22, 353).
  - Increase domestic funding for VMMC and assure better financial coordination between donors and the national government.
  - Encourage strong, visible support for VMMC by regional bodies – for example, the African Union, the East African Community and the Southern Africa Development Community.
- Accountability, oversight and regulation
  - Assign and support VMMC focal points or coordinators in the MOH at different operational levels (national, district, local).
  - Include VMMC in the mandate of focal persons for adolescent health and other relevant areas within the MOH (194).
  - Establish clear roles and responsibilities in leadership and coordination for support and supervision of VMMC, giving consideration to synergy and collaboration between VMMC focal points and adolescent health focal points based on clear roles, responsibilities and lines of communication (22).
  - Ensure that the MOH leads partnership structures for VMMC, with fully developed mechanisms for coordination, advocacy, implementation, reporting and quality assurance.

- Engage all relevant departments of the MOH in implementing, coordinating and overseeing VMMC activities. Such departments may include HIV, adolescent sexual and reproductive health, essential surgical services, maternal and child health, health promotion/behaviour change communication, infection prevention and control, and quality assurance.
- Enhance the VMMC technical working group within the MOH to conduct programmatic oversight and performance review.
- Promote VMMC as part of the agenda of broader adolescent health technical working groups.
- Intersectoral coordination
  - Include VMMC among the responsibilities of existing platforms that oversee partnerships and coordination of efforts for adolescent health and well-being across sectors (22, 294).
  - Form partnerships among relevant government ministries and organizations, conduct and implement communication assessments and develop a joint communication strategy that considers the full range of relevant communication approaches.
- Health sector plan and policies
  - Include VMMC in national processes for health strategy development and operational planning (349, 358).
  - Review policies for provision of VMMC to adolescents, task sharing policies and consent and assent policies to optimize task assignment and scopes of practice (349, 351).



## Building block: service delivery



Good health services are those that deliver effective, safe and high quality health interventions to those who need them, when and where needed, within the tenets of an integrated, people-centred framework (364). Delivering adolescent-friendly VMMC services is important in order to meet the different expectations and preferences of adolescents. The WHO quality of care framework working definition of adolescent-friendly health services calls for health services that are accessible, acceptable, equitable, appropriate and effective (365). Key components for sustainability of VMMC service delivery include:

**Access (strategic planning of health services).** The organization and management of services to ensure access, quality, safety and continuity of VMMC services require critical and strategic planning. Key considerations for planning access include:

- comprehensive assessment of VMMC service delivery to determine availability, accessibility, acceptability, contact with and use of services, and effectiveness;
- mapping existing service delivery infrastructure and resources that deliver VMMC in community-based and health-facility settings and identifying gaps in harder-to-reach areas;
- demand creation activities specific to context and intended audience. Outreach, community engagement and communications seek to increase uptake of VMMC. Informed by research and situational analyses, demand creation should address barriers to VMMC uptake (366, 367).

**Reorienting service delivery models.** Making VMMC services sustainable may entail reorienting current models of care to emphasize feasible care that is community-owned and that prioritizes the primary and community levels (see Annex 6.1). Demand creation to maintain coverage should complement such service delivery. Key considerations for reorienting service delivery models include:

- VMMC services made a part of routine primary care and delivered as part of an integrated or linked package of services, including with routine adolescent health services and essential minor surgical services;
- varied service delivery platforms for reaching adolescents with adolescent-friendly care (for example, in and out of school, community-based platforms, digital communication, faith-based platforms);
- clear referral systems from VMMC to other adolescent services (for example, mental health, sexual and reproductive health, non-communicable diseases, vaccinations);
- use of digital technology to support continuity of information and patient tracking.

**Empowering and engaging people.** The sustainability of VMMC will be further enhanced through the empowerment and engagement of people as clients for VMMC services and advocates for VMMC. Through this engagement men, their families and their communities can make effective decisions about their own health. A human rights-based approach is key. Importantly, underserved and marginalized groups, including adolescents, need to be empowered and reached by sustained service delivery that leaves no one behind. Key considerations include:

- individuals, families, communities and informal health care workers and traditional circumcisers who are affected by the services;
- the underserved and marginalized.

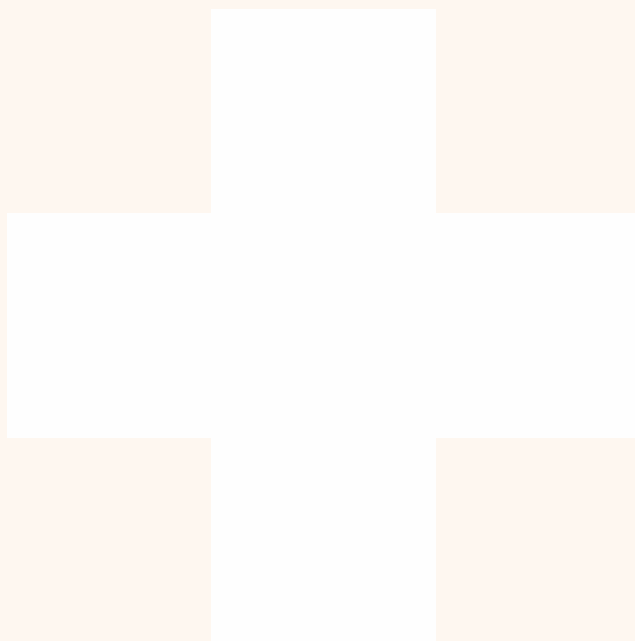
**Assuring safety and quality.** National standards for safety and quality of services are crucial to sustainable VMMC services. National ministries of health need to be at the forefront of setting the agenda and standards for quality improvement and safety. Key considerations for assuring safety and quality include:

- national quality standards and systems in line with WHO and UNAIDS global standards for quality health care services for adolescents;
- standardized surgical protocols focused on patient safety (that is, surgical systems strengthening);
- AE reporting in keeping with national systems.

### Key actions

- Access (strategic planning of health services)
  - Conduct comprehensive strategic planning for VMMC in the context of broader adolescent health planning and programming. Strategic planning processes should include comprehensive assessments and mapping of existing service delivery infrastructure and resources for VMMC.
  - Conduct research-based demand generation activities, including advocacy (with, for example, community leaders, school teachers) and communication with potential users, employing different communication channels (for example, television, radio, print media, interpersonal communication, social media, SMS reminders) and community engagement activities and mobilization (366).
  - Match demand creation with available service delivery to ensure optimal utilization.
- Reorienting service delivery models
  - Promote services in both health care facilities and outreach services, including in and out of school, community-based, faith-based, arts and sports platforms (353, 364).
  - Implement VMMC services as part of a comprehensive package of services defined through a participatory and transparent process, taking into consideration the diverse cultural and age-sensitive needs of adolescents (22, 345).
  - Identify and consider innovative entry points to reach adolescent boys and men, including services for preventing mother-to-child transmission (PMTCT) of HIV and family planning services, which are attended mainly by women and adolescent girls.
  - Consider family- and community-based approaches to making VMMC a routine part of primary care services.
- Empowering and engaging people
  - Reach vulnerable and higher-risk populations for greater impact (364).
  - Develop routine referral mechanisms for linkage to other adolescent health interventions.

- Use digital platforms and technology to engage adolescents, as appropriate.
- Support individuals, families and communities to make effective decisions about their own health.
- Engage informal health care workers and traditional circumcisers with education and training to enable them to support VMMC service delivery (357).
- Identify and address barriers facing underserved and disadvantaged populations, including key populations.
- Advocate review of policies that may limit access to services inappropriately – for example, age of consent laws (368).
- Facilitate an age-appropriate, meaningful and comprehensible informed consent process for all clients.
- Give private health care workers the necessary education and training to support VMMC service delivery.
- Safety and quality
  - Ensure that quality standards and systems are in place and implemented as part of routine national systems.
  - Include VMMC in national standardized guidance on patient surgical safety.
  - Establish an effective multi-level surveillance system for monitoring AEs. This system should include both health care workers' and patients' safety.



## Critical enablers

Making VMMC sustainable requires cross-cutting interventions that provide an enabling environment for the six health system building blocks. These critical enablers include:

**Adolescent leadership, co-produced health services, local ownership and participation.** A strong case needs to be made for investment in adolescents, based on a triple dividend of benefits: now, into future adult life and for the next generation (22). 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 includes meaningful involvement and engagement of adolescents and youths as leaders and key stakeholders in VMMC at national, district and community levels.

**Community engagement.** Community engagement is key to high quality integrated, resilient health services in general and to moving towards tailored, sustainable VMMC services specifically (369) (see Annex 6.1). Community engagement is a process of developing relationships that enable stakeholders to work together. There are multiple points of connection and linkages between health systems and communities that can be leveraged (370). Key considerations for community engagement include:

Partnering with community organizations and networks can increase access for adolescents.

- engagement and partnerships with community gate keepers (for example, women and girls, parents, community leaders);
- engagement with traditional male circumcisers.

**Multisectoral partnerships.** Partnerships and collaborations at multiple levels and with different sectors help to enable sustainable VMMC services. Sustaining VMMC services for adolescents requires multisectoral partnerships, with a broader adolescent health foundation, that are based on a clear vision, structure and defined mandates at the national level (22). Key considerations for multisectoral partnerships include:

- functional platforms for strategic and operational engagement and partnerships on VMMC with other sectors, such as education, family and social affairs, agriculture and nutrition;
- capacity for dialogue and participation.

**Enabling laws and policies.** To increase adolescents' access to and uptake of VMMC services, structural barriers must be removed. Reviewing policies and laws, seeking to uphold adolescents' rights to health choices and well-being, is very important. Adolescents' different levels of maturity and understanding must be considered. One important example is laws on age of consent for health care services. In most countries individuals under the age of 18 cannot give consent for their own health care, including sexual and reproductive health care (22). Consent to a surgical procedure may have different age requirements.

## Key actions

- Adolescent leadership, co-produced health services, local ownership and participation
  - Develop and promote platforms, forums and channels for meaningful adolescent and youth engagement at national, district and community levels (22).
  - Involve adolescents and youth throughout planning, implementation, monitoring and evaluation (22).
- Community engagement
  - Support grass-roots community mobilization, cultivate and support grass-roots champions for community mobilization for adolescent health and VMMC (22).
  - Identify and engage community gate keepers (for example, women and girls, parents, community leaders, religious leaders) as a core aspect of VMMC programmes.
  - Engage and partner with traditional male circumcisers and faith-based health care workers, through advocacy, education, training and support, and develop clear roles, reporting and monitoring (357, 358).
- Multisectoral partnerships
  - Establish formal engagement with nongovernmental and community organizations and strengthen community-based platforms for service delivery and for reaching underserved populations of adolescents.
  - Promote functional platforms for strategic and operational engagements with related sectors, including education, arts, sports, family and social affairs, agriculture and nutrition (362).
- Enabling laws and policies
  - As needed, revise age of consent policies with a view to upholding adolescents' rights to make choices about their own health and well-being and with consideration for different levels of maturity and understanding among adolescents of different ages (229, 368).

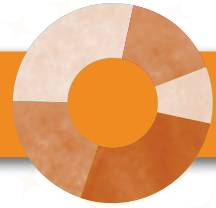
### **Box 6.1. Research needs for sustainability**

The transition to sustainability is a process that will evolve over time. Research needs include:

- implementation research and participatory learning approaches in diverse and country-specific settings on:
  - how to integrate and/or link VMMC into existing health and other relevant services (such as youth services) to meet other health needs such as sexual and reproductive health;
  - how to maintain safe VMMC service delivery approaches for older adolescents, and their effectiveness and cost;
  - the impact of unintended gaps or the consequences of less uptake by younger adolescents;
- assessing needs in each health systems building block to support sustainable VMMC services;
- identifying best practices and country experiences through use of programmatic data, with an eye to sustainability;
- share and transfer knowledge and experiences.



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



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