MINISTRY OF HEALTH

National Guidance on Tetanus Prevention in Voluntary Medical Male Circumcision Settings in Kenya

ATTRIBUTION OF SUPPORT

This material has been supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the US Centers for Disease Control and Prevention (CDC) under the terms of CDC Award Number GH001469.

Disclaimer

The findings and conclusions in this paper are those of the author(s) and do not necessarily represent the official position of the funding agencies.

SUGGESTED CITATION

National AIDS and STI Control program. National Guidance on Tetanus Prevention in Voluntary Medical Male Circumcision Settings in Kenya. Nairobi: Ministry of Health, Republic of Kenya; 2017

ACKNOWLEDGEMENT

The Ministry of Health through the National AIDS and STI Control Program (NASCOP) is pleased to publish and promulgate the *National Guidance on Prevention of Tetanus in Voluntary Medical Male Circumcision Settings in Kenya*. This guideline has been developed in line with the 2nd National Voluntary Medical Male Circumcision (VMMC) Strategic and Operational Plan for July 2014/15 – June 2018/19, which emphasizes on the need to focus on circumcision safety and prevention of tetanus in circumcision settings. The rigorous process of developing this document was initiated by the National Technical Working Group on VMMC in response to the recommendations by the World Health Organization (WHO) following its consultation with multiple levels in the Ministry of Health and other VMMC stakeholders on *tetanus and voluntary medical male circumcision in March 2015* (updated 3rd June 2016).

Development of this guidance involved consultations with several stakeholders, including key Ministry of Health staff at national and county levels, VMMC implementing partners, technical agencies, researchers, and donors. Key considerations included the current strategic objectives for the National VMMC program, the country's tetanus burden and risks, tetanus toxoid containing vaccine (TTCV) immunization schedule required for long-term protection, and current immunization service delivery practices and coverage in Kenya. We acknowledge with deep gratitude the financial and technical support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Centers for Disease Control and Prevention (CDC), Jhpiego and the United Nations family through WHO.

Special thanks go to former Head NASCOP Dr. Martin Sirengo, and former NASCOP VMMC Manager, Dr. Jacob Odhiambo, for providing day-to-day leadership. Special thanks also go to Head NASCOP, Dr. Kigen Bartilol, Head NVIP, Dr. Collins Tabu, Dr. Christine Kisia (WHO), Dr. Elijah Odoyo-June (CDC) and Catey Laube-Jhpiego for their technical support. We also acknowledge all members of the National VMMC Technical Working Group listed in Annex 1, who contributed significant time and effort to planning, drafting, editing, and reviewing this document.

Additionally, we acknowledge with thanks, the external reviewers listed below for their invaluable insights and time into this document:

1. Stephanie-Davis-CDC
2. Julie Samuelson-WHO
3. Renee Ridzon-CDC
4. Carlos Toledo-CDC
5. Heather Scobie-CDC

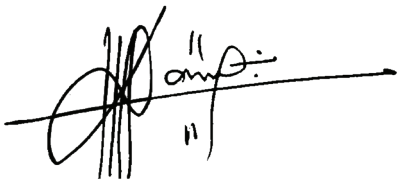
6. Elisabeth Krow-Lucal-CDC

7. Tejpratap Tiwari-CDC

I call upon all the service providers in public and private health sector and partners working in immunization and VMMC programs in Kenya to familiarize themselves with the contents of this guideline and use it in implementing their program activities.

Dr. Kigen B. Bartilol

Head of the National AIDS & STI Control Programme.



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FOREWORD

Since the recommendation by The World Health Organization (WHO) and the Joint United Nations Program on HIV/AIDS (UNAIDS) in March 2007 that male circumcision should be regarded as an additional method of HIV prevention, Voluntary Medical Male Circumcision (VMMC) programs have been implemented in 14 priority countries in east and southern Africa that have generalized HIV epidemics and low prevalence of male circumcision. By 2016, nearly 15 million circumcisions had been performed for HIV prevention in these countries. Of these, more than 95% were performed using forceps-guided or dorsal slit surgical procedures, with fewer than 200,000 performed using elastic collar compression device.

Voluntary medical male circumcision is safe with low numbers of related adverse events (AEs) occurring despite the large number of procedures performed. However, following the report of 16 cases of tetanus in four countries (including Kenya) by the WHO Technical Advisory Group on Innovations in Male Circumcision – consultative review of additional information, 12 August 2016, it has become imperative to prioritize efforts to mitigate the risks of tetanus in VMMC settings.

Tetanus is a rare but potentially fatal disease, yet easily preventable. The procedures used in performing circumcisions have different tetanus risks. Of these, circumcision with the elastic collar compression device has an inherently higher tetanus risk than circumcision methods that remove the foreskin at the time of the procedure. Risk for all circumcision methods is partially dependent on wound care and hygiene, but these may be mitigated through a dual approach of “clean” care and TTCV vaccine interventions.

The Ministry of Health has prioritized scaling up the proportion of males aged 15-49 years who are circumcised in Kenya from 92% to 95% by 2019, and maintain moderate and severe AEs below 2% of all VMMC performed. With more than 1.3 million male circumcisions performed in Kenya through 2016, the AE rate has remained lower than 1%. By 2016, 2 of 12 tetanus cases reported in eastern Africa (Kenya, Uganda, Tanzania and Rwanda) occurred in Kenya.[1] Reports of tetanus occurrence in VMMC settings reveal low immunity to tetanus for adolescent and adult males.[2, 3]This document provides guidelines on measures to mitigate risk of tetanus. However, the scope of this document does not include tetanus prevention in EIMC.

Vaccination has been one of the most successful and cost-effective public health interventions in history as exemplified by the eradication of smallpox, significant lowering the prevalence of poliomyelitis and the dramatic reduction in morbidity and mortality from several other illnesses. Indeed, The Kenya National Guidance on Tetanus Prevention in

1 WHO. 3 June 2016 - Technical consultation update to the WHO March 2015 meeting report

2 Scobie et al., (2017). Tetanus Immunity Gaps in Children 5 – 14 Years and Men ≥ 15 Years of Age Revealed by Integrated Disease Sero-surveillance in Kenya, Tanzania, and Mozambique. Am. J. Trop. Med. Hyg. 96(2); 415–420

3 Kyu et al., (2017). Mortality from tetanus between 1990 and 2015: findings from the global burden of disease study 2015. BMC Public Health. 17:179

Voluntary Medical Male circumcision in Kenya marks yet another milestone in the country's response to tetanus and adverse events related to VMMC in the wake of programmers and implementers desire to offer safe Male Circumcision services to the nation.

In developing the guideline for the countries response, The National Vaccines and Immunization Services (NVIP) unit has taken cognizance of the WHO guidelines which requires that we shift from the characterization of the AEs response from "Crisis Management" to strategic sustainable mode. NVIP understands the importance of engaging with other stakeholders in developing the guideline and in working together with our collaborators. The Government of Kenya through the constitution and the vison 2030 has created an enabling and secure environment that allows the country to build a fair and unified society by addressing some central factors that affect human capital including the health of its population.

Recognizing that unvaccinated individuals are more prone to the adverse outcomes of tetanus, the Ministry of Health has prioritized provision of booster tetanus immunizations to adolescent and adult males. Experience with the TT5 immunization for pregnant women has shown that, a complete primary series of immunizations in childhood and subsequent appropriately spaced scheduled booster doses to adolescents and adults confer consistent long-term protection against tetanus. As a result, provision of TTCV for adolescent and adult males and promotion of clean care (wound care education for individuals and communities) shall now be included as additional components to the VMMC package as key strategies for mitigation of risk for tetanus infection.

The Ministry of health shall progressively increase allocation of funds and other resources necessary to promote:

1. High coverage of adolescent and adult males, who are largely the VMMC target groups, with booster TTCV immunizations to ensure they have long-term protection against tetanus.

2. Interventions that improve risk perception and awareness and acceptability of tetanus prevention approaches.

3. Efforts that support ongoing adoption of tetanus prevention behaviors. The VMMC program shall coordinate with the Unit of Vaccines and Immunizations to leverage provision of supplemental TTCV immunization doses to adolescent and adult males as provided for in this guideline.

This document is a product of a rigorous consultative process at multiple levels by the Kenya Ministry of Health with key stakeholders (local actors plus international and other states agencies, including the Ministry's Unit of Vaccines and Immunization Services (NVIP), the World Health Organization (WHO), United Nations Children's Fund (UNICEF), U.S. Centers for Disease Control and Prevention (CDC) and Jhpiego. The initial phase of preparation involved consultative planning and technical meetings between the Kenya Ministry of Health and international-level technical advisors representing WHO/UNAIDS, CDC and, PEPFAR, VMMC TWG meetings to discuss WHO TAG reports on Tetanus and VMMC and Inter County-TWG meetings. The next phase involved a workshop for the VMMC technical working group and experts from WHO, CDC, partners implementing VMMC and Ministry of Health supported by a consultant.

Additionally, this document incorporates technical information synthesized from key international and local policy and technical documents on immunology, tetanus epidemiology and related risk mitigation strategies. Resulting drafts were duly reviewed and validated by a large group of stakeholders including experts from international collaborating agencies, key MOH agencies, VMMC implementing partners, partners supporting maternal and child health, and MOH representatives from VMMC priority counties. The process provided an opportunity to refine the document and incorporate different interests to enhance broad consensus on what is in the best interest of the whole country concerning provision of supplemental TTCV immunization to adolescent and adult males for long-term tetanus protection.

This document is divided into six sections:

1. **Section I**: Introduction: this section reviews the methodology used for National guidance preparation, male circumcision for HIV prevention in Kenya, male circumcision methods, policy context of national VMMC Program, epidemiology of tetanus and its implications for VMMC program.

2. **Section II**: Considerations for tetanus vaccination: this section reviews considerations for tetanus vaccination in the context of medical male circumcision and describes characteristics of tetanus-containing vaccines.

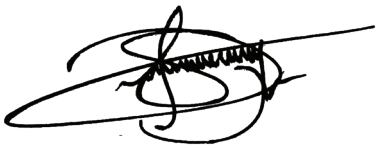
3. **Section III**: Implementation of tetanus risk mitigation activities: this section reviews operational issues regarding implementation of tetanus risk mitigation activities.

4. **Section IV**: Forecasting TTCV needs in VMMC settings

5. **Section V**: Collaboration and liaison with other agencies, areas of collaborations and roles of respective actors.

6. **Section VI**: Monitoring and evaluation: this section explains the monitoring and evaluation modalities and identifies specific M&E tools to accommodate TTCV reporting requirements and potential program areas for further research.

I encourage health care providers in both public and private sector as well as partners working in immunization and VMMC programs in Kenya to implement the guidelines articulated herein with utmost dedication.



Dr. Kioko Jackson K., OGW

Director of Medical Services,

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LIST OF ABBREVIATIONS AND ACRONYMS

AEs	Adverse Events
AIDS	Acquired Immune Deficiency Syndrome
ARVs	Antiretroviral (Drugs)
BCC	Behavior Change Communication
CDC	Center for Disease Control
DCAH	Division of Child and Adolescent Health
DVI	Division of Vaccines and Immunization
DHIS	District Health Information System Software
DPT	Diphtheria, Pertussis and Tetanus vaccine
DQA	Data Quality Assessment
EPI	Expanded Program on Immunization
HIV	Human Immunodeficiency Virus
HR	Human Resource
IEC	Information, Education, Communication
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package for Health
KEPI	Kenya Expanded Program on Immunization
M&E	Monitoring and Evaluation
MC	Male Circumcision
MoH	Ministry of Health
MTP	Medium Term Plan
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Program
KNHSSP	Kenya National Health sector strategic plan

NRAs	National Regulatory Authorities
NVIP	National Vaccine and Immunization program
OPD	Out-Patient Department
OVCs	Orphans and Vulnerable Children
PEPFAR	The United States President's Emergency Plan for AIDS Relief
QA	Quality Assurance
QC	Quality Control
SI Officers	Strategic Information Officers
SIMS	Site Improvement Through Monitoring System
SOPs	Standard Operation Procedures
SWAP	sector-wide approach
SYMMACS	Systematic Monitoring of Male Circumcision Scale-up
TA	Technical Assistance
TeNT	Tetanus Neurotoxin
TIG	Tetanus Immune Globulin
TT	Tetanus Toxoid
TTCV	Tetanus-Toxoid Containing Vaccine
TWG	Technical Working Group
IU/ml	International Units per milliliter
UNAIDS	Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
USA	United States of America
USAID	United States Agency for International Development
USG	United States Government
NVIP	Unit of Vaccines and Immunization Services
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

SECTION I: INTRODUCTION

1.1 BACKGROUND OF VMMC PROGRAM FOR HIV INTERVENTION

1.1.1 Global VMMC context.

Voluntary medical male circumcision (VMMC) decreases the risk for female-to-male HIV transmission by approximately 60%. Given this considerable capacity to lower rates of new HIV infections, it offers proven opportunities for HIV prevention for men. Currently, VMMC program is offered as an essential package of health services for boys and older men to prevent HIV and other sexually transmitted infections, and as a means to improve their opportunities to access other essential health services. It is a fast track strategy for achieving high coverage of target male population with effective preventive healthcare in priority countries with high HIV prevalence and concurrent low prevalence of male circumcision.[4,5] By end of 2016, over 14 million males had been circumcised in VMMC program priority countries in eastern and southern Africa since the launch of medical male circumcision in 2008. Whereas medical male circumcision is associated with very low adverse event rates, as an elective procedure chosen by often healthy men to reduce future HIV risk, ensuring safety of procedure is a priority. Consequently, infection prevention and control, and adverse event surveillance are critical.

As part of the ongoing safety reviews of voluntary medical male circumcision (VMMC) procedures, WHO performed an initial review of data from VMMC programs on serious and moderate adverse events that had occurred during 2013–2014. Over that period, nine cases of tetanus had been reported among a cumulative total of 9.1 million VMMCs at the end of 2014. Consequently, WHO convened a technical consultation forum on 9 – 10 March 2015 to assess the potential risk of tetanus associated with medical male circumcision and to advice on risk management strategies. By May 2016, an additional six cases of tetanus were reported since the previous consultation took place in March 2015.[6] Of these tetanus cases, eight patients died and only one patient had a known history of tetanus vaccination. The cases prompted a review of the evidence on tetanus vaccination coverage and case notifications in sub-Saharan Africa, which revealed a tetanus immunity gap for males. Subsequently recommendations for vaccination for boys and older men undergoing medical male circumcision were made to improve their protection against tetanus.

4 Smith, J. A., Anderson, S. J., Harris, K. L., et al., (2016). Maximising HIV prevention by balancing the opportunities of today with the promises of tomorrow: a modelling study. The Lancet HIV, 3(7), e289–e296.

5 UNAIDS. (2016). Fast-Track Commitments to end AIDS by 2030

6 World Health Organization (WHO), 2015. June 2016 - Technical consultation update to the WHO March 2015 meeting report. Geneva, Switzerland. Available at: www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/.

1.1.2 Male circumcision methods

The WHO recommended techniques used in performing medical male circumcision procedures and which Kenya has adopted are: i) conventional surgical methods (forceps-guided, dorsal slit and sleeve) as described in the national clinical manual for male circumcision under local anaesthesia; ii) WHO-prequalified devices (elastic collar compression device and collar clamp compression device). Compared to the conventional surgical methods, the devices do not require suturing to close the wound. Of all these methods, conventional surgical procedures (particularly forceps-guided surgery) have been the most popular approach to performing male circumcisions. The dorsal slit is currently being prioritized over forceps guided method. The devices however, provide males with important alternatives to surgery. Additionally, they simplify male circumcision procedures, thus providing potential for accelerating and expanding access to safe circumcision for HIV prevention. These devices have different mechanisms of action and risk profiles.

The collar clamp device causes compression and haemostasis, the foreskin is removed immediately after device placement, but device remains in place for about 7 days. This device has been evaluated in research studies and field studies in well-controlled environments, and has since been pre-qualified for use in males aged 13 years and above.

The elastic collar compression device, has also been prequalified by WHO for use in males aged ≥18 years. It works by slow compression of the foreskin resulting in occlusion of circulation, ischaemia and necrosis. The device and devitalized foreskin are removed after 7 days. Males circumcised using this device have increased risk of getting tetanus compared to those circumcised using other methods. This is because the remaining necrotic tissue, following device placement, offers anaerobic environment for germination of tetanus spores to toxins-releasing vegetative form. However, research is ongoing on a modified process for use of the elastic collar compression device, involving removal of the foreskin on the same day as device placement. This shall help in eliminating the environment conducive to germination of tetanus spores.

1.1.3 Male circumcision and risk for tetanus

Generally, in the genital area, unclean wounds are considered to be at high risk for infection due to the high concentration of commensal flora.[7] All unclean circumcision wounds are potentially at risk of tetanus infection, especially with delayed healing[8]. These risks tend to vary according to the methods used, based on the primary mechanism of action to remove fore-skin. The circumcision wound forms a portal of entry for tetanus bacteria which is ubiquitous in the environment and may be present in dirty skin. In addition, bacterial infection of the circumcision wound may precipitate necrosis. Inflammation and loss of immune system surveillance associated with necrosis presumably promote anaerobic growth which increases risk for tetanus occurrence. The tetanus cases observed to date in the context of VMMC suggest that tetanus risk after conventional surgical circumcision is predominantly linked to substances that potentially contain tetanus being applied to wounds. These substances may also encourage bacterial infections of the circumcision wound.

7 Prevaldi, C., Paolillo, C., Locatelli, C., Ricci, G., Catena, F., Ansaloni, L., et al. Management of traumatic wounds in the Emergency Department: position paper from the Academy of Emergency Medicine and Care (AcEMC) and the World Society of Emergency Surgery (WSES). World Journal of Emergency Surgery, 11(1), 30

8 WHO/UNICEF. Technical Advisory Group on innovations in male circumcision. 30 September – 2 October 2014Geneva, Switzerland

With regard to the collar compression device there is an observed increased risk compared to conventional circumcision procedures. The elastic device method requires leaving the foreskin in situ for some time before it is removed. The anaerobic environment and necrotic tissue associated with this method are believed to be the mechanisms for the observed increased risk.

Given that the circumcision methods each exhibit differential level of risk for tetanus, the world health organization (WHO) has recommended and Kenya has adopted, different tetanus immunization approaches based on these different levels of risk. In addition to tetanus immunization, observing strict hygiene practices at all stages of performing medical circumcision, taking standard precautions to prevent and control infection of circumcision wound as well as maintaining normal personal hygiene and good genital health play a critical role in tetanus control and prevention, regardless of the techniques used.

1.1.4 Kenya National VMMC program

The Kenya national VMMC program has made remarkable progress since its roll out in 2008. By end of 2015, nearly 1.3 million males had been circumcised across the country, with national MC coverage increasing from 84% to 92% over the period, while related complications have remained lower than 1%. The 2nd National VMMC strategy and operational plan, launched in 2015, was developed to guide implementation of VMMC in Kenya during 2015 – 2019 program period. By this strategic document, the country has prioritized provision of age-appropriate comprehensive VMMC services to young infants aged 0 – 60 days, adolescents (10 – 14 years) and older men 15 – 49 years. Of these, males aged 15 – 49 years are being particularly targeted to achieve a more rapid intervention impact from VMMC. Simultaneously, the document emphasizes service safety, accessibility, equity and program sustainability. As a further step to improving male protection against tetanus resulting from circumcision and other wounds, offering tetanus risk reduction education and TTCV immunization to all VMMC clients has been emphasized. This is in addition to the standard HIV prevention package comprising of: informed consent, HIV screening and testing, risk-reduction counselling, condom promotion and provision, and STI screening and management. By May 2016, 2 cases of tetanus had been reported in Kenya through the adverse events surveillance system[9] hence the need to intensify tetanus mitigation strategies. This current guideline has been developed to guide implementation of TTCV immunization for tetanus mitigation in the context of VMMC program.

1.1.5 TTCV and the Policy context of national VMMC Program

The promotion of TTCV immunization for males beyond infancy is a strategy that aims to provide a life-course vaccination for tetanus prevention. The additional booster doses after the three primary doses are expected to achieve long-term immunity from tetanus among older male children, adolescents, and adults. This is consistent with the global goal of universal coverage with essential health care. At the national level, this health goal is anchored in the Kenya Health Policy 2012 – 2030, whose theme is 'towards attaining the highest standard of health for all' through increased investment in health and implementation of planned interventions. It's also anchored in the 2nd National VMMC strategic plan which aims to promote effective target coverage, and provision

9 World Health Organization (WHO), 2015. June 2016 - Technical consultation update to the WHO March 2015 meeting report. Geneva, Switzerland. Available at: www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/.

of safe, efficient and equitable VMMC services as a comprehensive HIV intervention package through enhanced coordination, as well as evidence-based communication and interventions.

The Government's three-pillar Vision 2030 (comprising the economic pillar, social pillar and political pillar) and the Second Medium Term Plan (2014-2018) provide a framework for implementing intervention efforts to improve both access to and equity of essential health care services, and to ensure that the health sector plays its essential role in the realization of the Vision 2030 and the 2nd Medium Term Plan (MTP) 2014 - 2018. The social pillar specifically takes into account the respective functional responsibilities as well as accountability, reporting, and management lines of national and county governments.[10] The 2nd Medium Term Plan (MTP 2, 2014 – 2018) highlights multiple levels of partnership opportunities which shall synergize overall implementation of the guideline through resource investment, capacity strengthening and organizational inputs. Collaborative partnerships shall involve both local and international stakeholders.

The existing policy context and operational frameworks expressly provide the functional environment within which this guideline shall be implemented and coordinated. For example, while the DVI has the overall mandate to provide vaccines for vaccine-preventable diseases in Kenya,[11] the VMMC program shall provide a platform on which to leverage coverage of adolescent and adult males with TTCV and other tetanus mitigation strategies.

1.2 TETANUS EPIDEMIOLOGY, IMMUNITY GAP FOR MALES AND PREVENTION APPROACHES

1.2.1 Epidemiology of tetanus

Tetanus is an acute disease caused by tetanospasmin, a neurotoxin produced by Clostridium tetani (C. tetani). C. tetani is a gram-positive, spore-forming, anaerobic bacillus widely found in the environment, particularly soil. It also occurs in the gastrointestinal tract and feces of animals and humans.

C. tetani exists in two states: vegetative and spore. In a vegetative state, the bacterium is sensitive to heat and dies if exposed to oxygen. By contrast, the spore state is extremely hardy and can survive for years in nature. Spores can survive even extreme conditions such as 10–15 minutes in boiling water, as well as alcohol, phenol and formalin disinfectants. The spores can be killed by iodine, sodium hypochlorite (household bleach), hydrogen peroxide and extreme heat above 120°C for 15–20 minutes.[12]

Clostridium tetani usually enters the body through contamination of (severe, trivial or unapparent) wounds. Tetanus is not communicable. The incubation period is usually between 3 and 21 days (median 7 days). In a favorable environment with low oxygen availability (such as dead or injured tissue surrounding a wound), the spores germinate to the vegetative form that releases tetanus toxin (tetanospasmin), which is an

10 Vision 2030 Second Medium Term Plan 2013 - 2017
11 Kenya DVI Comprehensive Multi-Year Plan 2011-2015
12 Hinfey PB. http://emedicine.medscape.com/article/229594-overview#showal

extremely potent neurotoxin. When it binds to the nerve terminals, it blocks inhibitory neurotransmitters resulting to trismus, spasticity, respiratory compromise, muscle spasms, dysphagia and autonomic disturbances including changes in heart rate and blood pressure. Tetanus can affect any age group and may occur as either of two distinct epidemiological entities: i) neonatal tetanus, which occurs in new borns aged less than 28 days and; ii) tetanus in all other age groups (non-neonatal).

Immunization with recommended doses of tetanus toxoid containing vaccines (TTCV) is the most effective way of controlling Tetanus. The disease does not induce natural immunity and herd immunity does not play a role in protecting individuals against tetanus. Hence, all persons must be vaccinated in order to be protected against tetanus. People who are unvaccinated, are partially vaccinated, or have waning immunity have an increased risk for tetanus. Fully immunized individuals who nevertheless develop tetanus are less prone to the fatal outcomes of the disease.[13,14]

1.2.2 Evidence of TTCV immunization gaps for males

Globally, age-standardized mortality from tetanus is higher among males than females.[15] Whereas WHO recommends a schedule of 6 TTCV doses (primary infant series of 3 doses, and booster doses at 12–23 months, 4–7 years, and 9–15 years) to ensure life-course protection against tetanus, few countries in the Africa WHO-region provide booster doses beyond infancy, except for pregnant women. As a result of waning immunity from infant doses, immunity gaps in school-age children and adult men have been observed in countries not providing booster doses to both sexes. Booster doses with tetanus toxoid containing vaccine (TTCV) at prescribed intervals are necessary during childhood, adolescence and adulthood to ensure sufficient immunity against tetanus throughout an individual's life. Experience with the TT5 immunization for pregnant women in countries where maternal and neonatal tetanus is a public health issue, has shown that a complete primary series of immunizations in childhood and subsequent boosters to adolescents and adults confers consistent long-term protection against tetanus.[16] In these countries, tetanus toxoid-containing vaccines is provided through routine immunization of pregnant women and through campaign to women of reproductive age (WRA) living in high-risk areas. It is important to note that recovery from a clinical attack is not followed by a protective immunity against tetanus.

In Kenya the EPI recommended schedule for TTCV (Pentavalent vaccine) is administered at week 6 – 10 – 14 of an infant's life or at first contact. The current operational target population for the nine main vaccines given in Kenya is children aged 0-12 months. Supplemental TTCV is only recommended for pregnant women, trauma patients and special occupational risk groups. As shown in figure 1.1 below, Kenya has experienced challenges in sustaining sufficiently high DPT 3 and protection at birth (PAB) coverage thresholds since 1994.

13 Hopkins, J. P., Riddle, C., Hollidge, M., & Wilson, S. E. (2014). A systematic review of tetanus in individuals with previous tetanus toxoid immunization. Canada Communicable Disease Report, 40(17), 355.

14 Livorsi, Eaton, & Glass. (2010). Generalized Tetanus Despite Prior Vaccination and a Protective Level of Anti-Tetanus Antibodies. OI: http://dx.doi.org/10.1097/MAJ.0b013e3181c2f534

15 Kyu, HH., Mumford, JE., Stanaway, JD. et al., (2017). Mortality from tetanus between 1990 and 2015: findings from the global burden of disease study 2015. BMC Public Health (2017) 17:179. DOI 10.1186/s12889-017-4111-4

16 Systematic review of literature, WHO's Optimizing Immunization Schedules Project

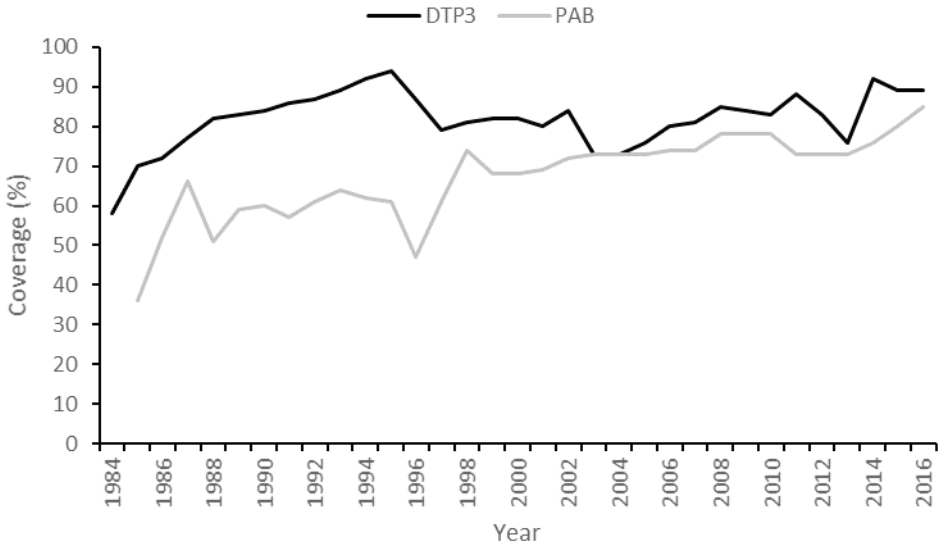


Figure 1.1: WHO-UNICEF estimates of coverage of infants aged <12 months with 3 doses of diphtheria-pertussis-tetanus (DPT3) containing vaccine and protection at birth (PAB) against tetanus in Kenya, 1984–2016[17]

The persistent low DPT3 coverage implies that considerable proportion of males born during this period may not be adequately protected against tetanus. Because of waning antitoxin titers, most individuals have suboptimal protective antitoxin titers 10 years after the last dose of TTCV.

By 2015, Kenya still had <50% of its sub-counties achieving at least 80% DTP3 coverage.[18] Recent evidence from a review of global, regional, and national levels and trends of mortality from neonatal and non-neonatal tetanus based on the results from the Global Burden of Disease Study 2015[19] showed that Kenya is one of three countries (the other two being Somalia and South Sudan) with the highest rates of mortality from tetanus after the neonatal period (more than 5 deaths per 100,000 population) with more males than females being at risk.

A recent study in Kenya has also demonstrated an instance of low tetanus immunity particularly among older children aged 5-14 years and males aged ≥15 years (Fig. 1.2).

17 http://apps.who.int/immunization_monitoring/globalsummary/

18 WHO Database as at 28 July 2016. Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization. 194 Member States.

19 Kyu, HH., Mumford, JE., Stanaway, JD. et al., (2017). Mortality from tetanus between 1990 and 2015 : findings from the global burden of disease study 2015. BMC Public Health (2017) 17:179. DOI 10.1186/s12889-017-4111-4

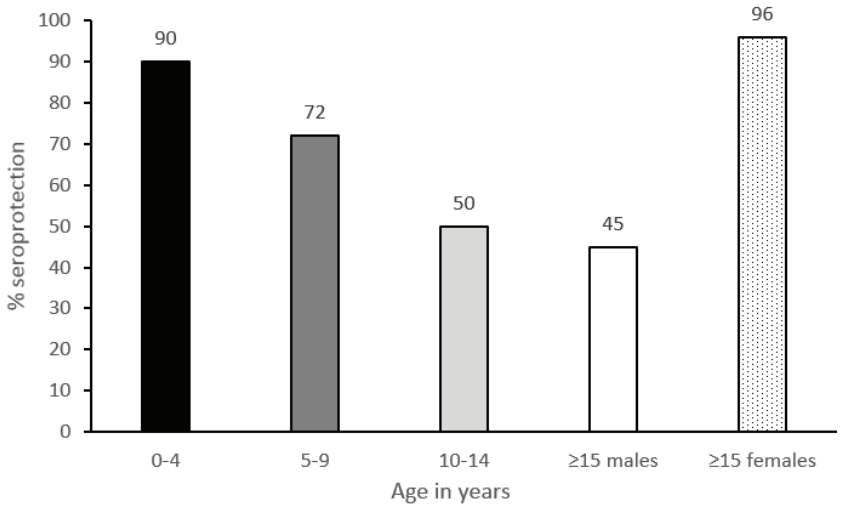


Figure 1.2: Tetanus seroprotection by age (and sex for ages ≥15 years) in the then Mbita district, Homa Bay, Kenya, 2012[20]

Existing immunity gap for tetanus among males in a region in Kenya as demonstrated in fig. 1.2 above indicates the likelihood that a majority of adolescent and adult males especially in areas with consistently less than 90% DPT3 coverage, similar to or lower than Mbita, and greater than 10% (DPT1 – DPT3) dropout rates have low acquired tetanus immunity and are therefore without protection to tetanus from all wounds.

Integrating tetanus booster vaccination services into circumcision program offers an important opportunity to increase tetanus vaccine coverage rate for the poorly served and tetanus prone adolescent and adult males who also are the main targets for the VMMC. Serological survey data suggest that appropriately spaced booster doses in adolescents and adults are critical in maintaining high antibody levels to assure long-lasting, possibly lifelong protection.[21] It is important to note that recovery from a clinical attack is not followed by a protective immunity against tetanus. Persons recovering from tetanus should begin or complete active immunization with a tetanus toxoid-containing vaccine during convalescence.[22]

1.2.3 Tetanus prevention measures

1.2.3.1 Basic concepts of infection prevention

Measures to prevent infection in male circumcision settings are broadly aimed at minimizing the risk of wound infections in clients as well as the risk of transmitting HIV and other infections to clients and health care workers. Health care providers should adhere to the standard infection prevention and control practices in their respective areas of operation in line with the WHO Manual for male circumcision under local anaesthesia. These include the following:[23]

20 Source: Scobie et al. (2017) AJTMH 96(2): 415–420

21 WHO. Tetanus vaccines: WHO position paper – February 2017. Available at: http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/.

22 Systematic review of literature, WHO's Optimizing Immunization Schedules Project

23 Male circumcision under local anaesthesia Version 3.1 (Dec09)

1. Hand washing and antisepsis (hand hygiene) to eliminate disease-causing microorganisms that may contaminate circumcision wounds. This should occur prior to initiating any of the services and at any point where there is contact with the wounds. Proper hand scrub with povidone iodine is recommended since Clostridium spores are resistant to alcohol- based antiseptics (ethyl and propyl alcohols).

   As a general recommendation for prevention of wound contamination, clean water should be available for hand hygiene in all health care settings providing services related to male circumcision (screening, surgery, and follow-up). If the tap water is contaminated, use either water that has been boiled for 20 minutes and filtered to remove particulate matter, or chlorinated water (water treated with a dilute solution of sodium hypochlorite (bleach) to give a final concentration of 0.001%).

2. Use of sterile equipment: Soiled working surfaces, instruments and other reusable items should be disinfected immediately after use and **MUST** be then cleaned to remove debris before sterilization. Autoclaving at 121°C for 15 minutes kills the C. tetani spores readily. Also, spores can be killed by high level disinfectants such as 2% aqueous glutaraldehyde within 3 hours, 8% formaldehyde, 20ppm sodium hypochlorite (%weight / volume)[24] Iodine (1% aqueous solution.) and Hydrogen peroxide (10 volume) kills spores within few hours. Sodium hypochlorite (bleach) should be used for cleaning surfaces. Items that have been sterilized need to be properly stored, to ensure that they do not become re-contaminated.
3. Cleaning of working environment: Routine cleaning is important to ensure a clean and dust-free clinic environment and to eliminate contaminating microorganisms. C. tetani spores are blown in dust and may contaminate working surfaces.
4. Appropriate handling of waste to prevent the spread of infection to health care workers and the local community.

1.2.3.2. Measures introduced specifically for tetanus risk mitigation

Specific tetanus risk mitigation measures in the context of VMMC service delivery shall entail dual care approach:

1. Provision of TTCV doses according to the recommended number and timing of TTCV doses to be given in the context of VMMC programs. This is to ensure that all VMMC clients are adequately protected against tetanus by vaccination before circumcision, and is discussed in detail in section II;
2. Clean care practices to ensure enhanced attention to standard protocols for skin preparation; cleanliness and proper wound care by individuals who undergo the circumcision procedure, irrespective of VMMC method. Skin preparation for all circumcision methods and post-operative wound care are principle components of clean care approach. Essential skin preparation responsibilities involve tasks expected of clients and service providers to ensure risks of infection are minimized throughout the circumcision process.

24 Centre for Biosecurity, Public Health Agency of Canada: available at https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/clostridium-tetani.html (accessed on 09-09-2017)

Service providers shall engage individual clients (at facility level) through interpersonal interactions, and whole communities through advocacy, health behavior change promotion and education on the benefits of hygiene and vaccination against tetanus. These activities shall be integrated within the essential health package components.

At facility level, service providers shall promote personal cleanliness before and after circumcision; educate clients to avoid application of potential contaminants to the circumcision wound; educate clients on hand washing before and after handling circumcision wounds and; instruct them on danger signs for infections and to return urgently if specific symptoms suggestive of tetanus are noted. These symptoms include locked jaw, muscle rigidity and muscle spasms.

The providers should encourage clients that while at home, before coming for circumcision, they should use soap and clean water to thoroughly wash the entire genital area, including the scrotum, penile shaft and area under the foreskin to remove all visible dirt and debris. They should encourage them to wear clean undergarments. If the genital area is not cleaned appropriately when the client presents for circumcision, the service provider should give cleaning instructions and offer reasonable assistance to enable him access soap, and clean water to wash himself in a nearby private space where feasible.[25]

Before circumcision procedure begins, the clinical team shall ensure strict adherence to standard protocol for skin preparation. The provider should use povidone iodine (since it is able to kill C. tetani spores) to wash the entire genital area, including the scrotum, penile shaft and area under the foreskin.Site level managers shall oversee all activities to ensure providers' adherence to the procedure protocols. Copies of the guide and related job aids shall be displayed in the procedure rooms for easy reference. To clean the glans and inner foreskin, the provider should hold the penis with a gauze swab, retract the foreskin then clean the glans and the retracted inner foreskin. Next allow the foreskin to return to its natural position over the glans, then clean the outer foreskin. Adhesions, if present may be separated by gently swiping the area with a clean gauze swab or forceps, depending on adhesion strength. To clean shaft and peripheral genital area, the provider should apply antiseptic solution to the penile shaft, then move out to the periphery, including the scrotum, the adjacent areas of the thighs and the lower part of the abdomen.

Meticulous skin preparation is essential because the genital region has high concentration of commensal flora which makes the circumcision wounds 'high risk' for bacterial infection. The area under the foreskin particularly has greater prevalence and abundance of anaerobic bacterial species.[26] In addition, because circumcision methods entail differential risks for tetanus, method specific standard operating procedure and job aids for providers plus "client's role" instructions on skin preparation, wound care instruction guides, tetanus prevention brochures and fact sheets for VMMC clients shall be availed at every health facility for distribution to circumcision clients/guardians.

25 http://project-iq-resources.jhpiego.org/resource/vmmc-skin-preparation-and-wound-care-to-reduce-the-risk-of-infections-and-tetanus/

26 Prevaldi, C., et al., Management of traumatic wounds in the Emergency Department: position paper from the Academy of Emergency Medicine and Care (AcEMC) and the World Society of Emergency Surgery

SECTION II: CONSIDERATIONS FOR TETANUS VACCINATION IN THE CONTEXT OF VMMC

2.1 TETANUS RISK ASSOCIATED WITH VMMC

Tetanus events are rare after VMMC, but unvaccinated individuals and those with sub-optimal protective immunity (under-vaccinated, or incapable of mounting a normal immune response to vaccination) are at an increased risk. Since adolescent boys and men do not routinely receive tetanus booster vaccines they have limited protection from tetanus exposure via any wounds due to waning tetanus immunity with age. Recommendations for TTCV provision in the context of VMMC program have been designed to ensure circumcision safety considering the level of risk for each of the circumcision methods in use.

2.2 ATTRIBUTES OF TETANUS TOXOID CONTAINING VACCINES

2.2.1 Efficacy and effectiveness

Tetanus toxoid is a protein-based vaccine derived from an inactivated tetanus toxin. It is highly efficacious, safe and of low-cost. When administered into the body, it induces the immune system to produce antibodies that neutralize the tetanus toxin. Several studies have reported that completion of the third dose TTCV induces protective immunity in nearly 100% of those vaccinated.

2.2.2 Safety and immunogenicity of TTCV in individuals with low immunity

TTCVs are considered suitable for use in HIV-infected and immunocompromised persons. However as with other vaccines, the antibody response to TTCVs may be lower than in fully immunocompetent persons. In children infected perinatally with HIV, satisfactory antibody responses to TTCV have been obtained during their first 2 years of life. Between 74%–90% of them have protective antibody levels following recommended booster immunization. In HIV-infected adults, the antibody response to TTCV may be less than that in non-infected individuals, especially as the disease progresses, but the concentration of antibody is substantial and represents a positive response to vaccination.[27] Booster doses ensures life-long protective antitoxin levels.

27 WHO. Tetanus vaccines: WHO position paper – February 2017. Available at: http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/. Accessed on 09-09-2017

2.3 PROTECTIVE IMMUNITY TO TETANUS WITH TTCV

2.3.1 Mechanisms and definition of protective immunity

Immunity to tetanus can be acquired by passive immunization either by trans-placental transfer of maternal antibodies (which lasts a few months) or administration of tetanus immunoglobulin, and by active immunization with TTCV following an appropriate schedule. Protective immunity is defined by the level of serum antibodies above which the probability of tetanus infection is low, which is 0.01IU/mL as measured by neutralization test or modified ELISAs, or 0.1 IU/ml for standard ELISAs (which have issues with non-specific binding in the low sero-protective range 0.01-0.2 IU/ml). However, as cases of tetanus have been documented in individuals with antibody concentrations above these thresholds, a normally protective antibody concentration may not be a guarantee of immunity in all circumstances. The aim of TTCV immunization should be to sustain high antibody concentrations throughout life.[28]

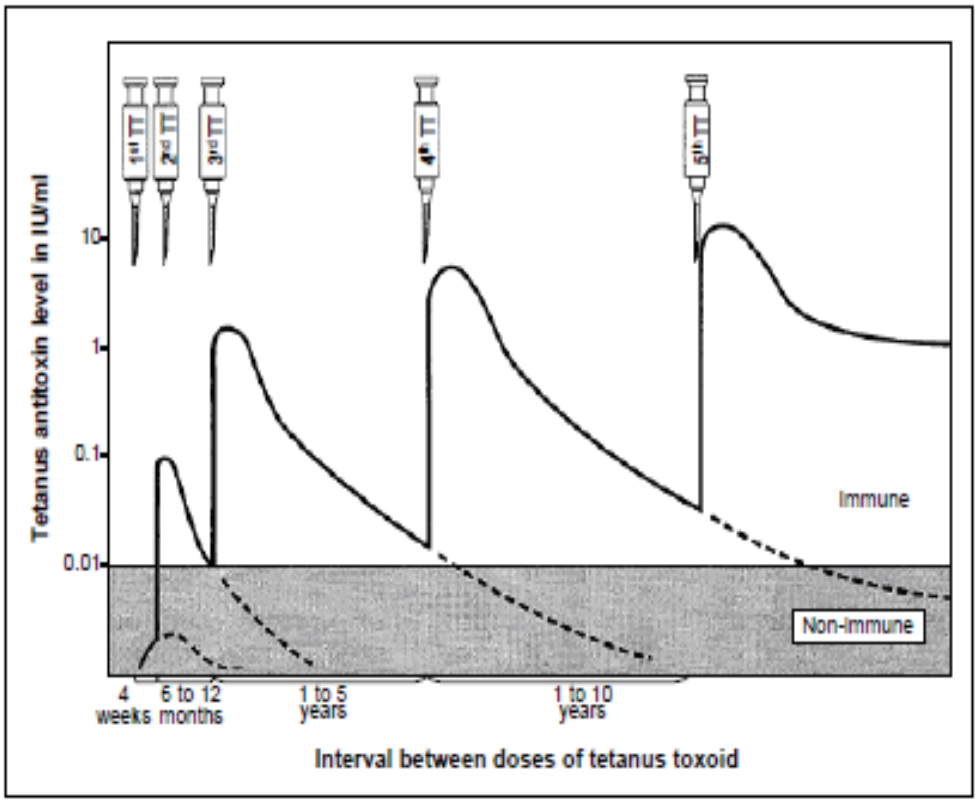
2.3.2 Relationship of protective immunity to dosing schedule for TTCV

The primary TTCV series (three properly-spaced doses of tetanus toxoid containing vaccine at infancy) provides the initial immunological stimulus that allows the body to mount a more robust immune response during subsequent booster doses. The first dose only primes the immune system and offers no protection against tetanus. A second TTCV dose given at least 4 weeks later provides protective immunity for up to 3 years. A third TTCV dose induces more durable protective immune response in almost 100% of vaccinated infants but declines rapidly to sub-optimal levels over approximately 5 years. After the third dose, each additional dose given at least at one-year interval increases the serum anti-tetanus antibody level and prolongs the duration of immunity. Immunity shall last for up to 10 years after the fourth dose, thus providing protection into adolescence. A fifth booster during adolescence shall induce immunity that lasts at least 20 years through much of adulthood.[29] However, the degree and duration of immunity subsequent to the primary doses depends on the dosing schedule, serum circulating antibody level and the time since last dose. Booster doses improve the robustness of protection against tetanus and duration of protection (figure 2 below).

28 WHO. Tetanus vaccines: WHO position paper – February 2017. Available at: http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/

29 WHO. Immunology basis for vaccination, module 3

Figure 2. Antibody response to tetanus toxoid (TT)



Source: Galazka, 1993

Following a booster dose, increase in antibody levels can be detected in a majority of recipients at 7-14 days post-booster, with response achieved by most recipients at 28 days. Thus administration of a tetanus booster as part of wound management shall not protect against an incubating tetanus infection if antitoxin levels are insufficient, but shall provide long-term protection against future tetanus episodes. In addition, at least 2 doses given 4 weeks apart are needed to have confidence in the level of antibody protection, and a third dose at least at one year interval is required for long-term protection.

2.3.3 Dosing schedule and duration of immunity for individuals not immunized in childhood

For previously non-immunized adolescents and adults, at least 2 doses given 4 weeks apart are needed to have confidence in the level of antibody protection, followed by a third dose administered at least 6 months after the second. Subsequent booster doses given at least at one year interval is required for long-term protection. For those who had not received all doses of the basic schedule (primary doses) the full vaccination schedule of appropriately spaced doses should be completed as soon as possible, in order to provide long-term protection against tetanus. Interruption of the recommended schedule or delay of subsequent doses however does not reduce the response to the vaccine when the series is finally completed. There is no need to restart a series regardless of the time elapsed between doses.

2.4 RECOMMENDED TTCV VACCINATION SCHEDULES

2.4.1 Recommended TTCV vaccination schedule for general population

WHO recommended vaccination schedule for long-term immunity includes three booster doses after completion of the infant primary series, for a total of six doses (booster dose between 4–7 years; a further dose in adolescence and; the sixth dose for young adults). Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only five appropriately spaced doses to obtain long-term protection. For previously non-immunized adolescents and adults, the recommended schedule is two doses administered at least four weeks apart followed by a third dose administered at least six months after the second, and two subsequent boosters at least one year apart.[30] Thus, individuals who begin vaccination in infancy require a total of 6 doses for lifetime protection, whereas those who begin in adolescence or adulthood require a total of 5 doses (table 2.1 below).

Table 2.1: Schedule for administration of tetanus toxoid (TT) vaccine to adolescents and adults in Kenya (i.e., for pregnant women and men undergoing VMMC)

	Administration schedule with minimal intervals between doses	**Duration of immunity conferred**
1st TT dose	At first contact	Nil (primes the immune system)
2nd TT dose	One month after 1st TT	3 years protection
3rd TT dose	Six months after 2nd TT	5 years protection
4th TT dose	One year after 3rd TT	10 years protection
5th TT dose	One year after 4th TT	20 years protection

Source: MoH National Policy Guidelines on Immunization 2013, p.34

Note that any type of TTCVs should be stored at 2–8 °C. They must not be frozen

2.4.2 Choice of combination vaccines for adolescents and adults

In 2006 the WHO recommended transition from the use of single-antigen TT to combinations containing diphtheria toxoid, i.e. DT or Td vaccines. To provide and sustain both tetanus and diphtheria immunity throughout the life course and for both sexes, age-appropriate combinations of tetanus and diphtheria toxoids should be used. The Ministry of Health is taking steps progressively to accelerate this shift to extend and strengthen adult protection against diphtheria, benefitting from tetanus immunization activities. Tetanus toxoid for school aged children and adults can be used as a: i) component of combined tetanus-diphtheria(Td) vaccine, which contains the equivalent amount of tetanus toxoid and a reduced amount of diphtheria toxoid compared to DT vaccines. It is preferred for use in adults and children 4 years or older, instead of monovalent tetanus toxoid; ii) component of a tetanus-diphtheria-acellular pertussis (TdaP) combination, for adolescents and adults primarily focused at better control of pertussis (whole cell pertussis vaccine is not recommended for persons ≥7 years of age due to safety concerns).[31, 32]

30 WHO. WHO informal Consultation on tetanus and voluntary medical male circumcision report of meeting convened in Geneva, Switzerland, 9-10 March 2015

31 WHO. Tetanus vaccines: WHO position paper – February 2017. Available at: http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/. Accessed on 09-09-2017

32 WHO. Immunology basis for vaccination, module 3

Note that where an individual is acutely unwell, immunization should be postponed until they have fully recovered. This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine.

Voluntary medical male circumcision services offer a platform for an opportunistic catch-up delivery of all recommended TTCV doses to adolescent and adult males. The standard dose of TTCV is 0.5 ml. This is administered intra-muscular (IM) in the deltoid muscle in older age groups.[33]

2.4.3 Recommended number and timing of TTCV doses in the context of VMMC programs

When an individual's tetanus vaccination status is known, his status should guide decisions on vaccination dose needs. The following guidelines are based on the Immunological kinetics of TTCV, biological and epidemiological evidence of risk for tetanus as well as the Kenya country context, in which adolescent and adult males do not routinely get TT booster and, the progress of DPT 3 coverage has nearly stalled at around 80% nationally but considerably lower in majority of the counties.

1. Tetanus vaccination for clients undergoing circumcision methods that involve immediate removal of the foreskin (conventional surgical methods of male circumcision):
    b. For clients with documented evidence of at least 5 appropriately-scheduled TTCV doses beginning in adolescence (these have long-term protection and need no additional 6th dose), offer circumcision.
    c. For clients with documented evidence of having received 5 appropriately-scheduled TTCV doses beginning with the 3-dose infant series and two boosters, offer circumcision and provide the 6thbooster dose at site where feasible, else advice to complete the dose as soon as possible where offered.
    d. For clients with documentation of three infant TTCV doses, or one dose during adolescence or adulthood, offer circumcision and provide the next due booster dose at site where feasible, else advice to complete the doses as soon as possible where offered to ensure long-term protection. (see decision flow chart in annex 1)
    e. For clients with no documentation, or known to have no previous immunization or to not have completed the primary series, administer one dose at the time of the circumcision and offer circumcision. Advise to complete the subsequent recommended dose. Where possible, the clients should receive the initial dose at least 2 weeks (14 days) before coming for circumcision, for example during community mobilization activities. Single TTCV dose is inadequate to induce protective antibody response hence, a second dose four weeks after the initial dose should be emphasized.

33 WHO. Tetanus vaccines: WHO position paper – February 2017. Available at: http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/. Accessed on 09-09-2017

2. Tetanus vaccination for clients undergoing circumcision with a device method where the foreskin is left in situ and removed several days after application.

    c. If the Individual has no documented evidence of having received the 5 or 6 appropriately scheduled TTCV dose series it is mandatory to administer the initial two doses at least 4 weeks apart, with the second dose at least 2 weeks before device placement. Where a client declines immunization, or where the facility is out of tetanus vaccine circumcision should be postponed, given that the risk for tetanus is high with any method in such cases. Appropriate counseling should help with consenting for TTCV vaccine use.

    d. If an individual has documented evidence of having received three infant TTCV doses, or one dose during adolescence or adulthood, give one TTCV booster dose at least 2 weeks before device placement. For long-term protection against tetanus, the client who has not completed 5 – 6 TTCV doses shall be advised to seek additional doses of TTCV at MOH approved facilities that provide vaccination services (refer to table 2.1 above). As above, where the client declines immunization or vaccine is not available, circumcision should be postponed.

3. Patients presenting with moderate to severe post-circumcision wound infection

    d. Persons with wounds that are neither clean nor minor, and who have had fewer than 3 prior doses of tetanus toxoid or have an unknown history of prior doses should receive 250 IU TIG IM and TTCV on separate arms. The equine TIG provides temporary immunity by directly providing antitoxin. This ensures that protective levels of antitoxin are achieved even if an immune response has not yet occurred.[34]

    Also perform standard surgical wound cleaning and debridement of necrotic tissue. Consideration should be to leave tetanus prone wounds open. Provide patient with summary report of management provided and instructions on wound care, immunization status and follow up schedule,

    e. For patients presenting with clinical manifestations of tetanus, treatment would involve:

        i. Patient admission

        ii. Management of seizures with muscle relaxants and sedation;

        iii. Management of autonomic nervous system manifestations;

        iv. Providing supportive therapy (airways, nutrition etc.)

        v. Administration of human tetanus immune globulin (TIG). This is critical because it prevents further progression of the disease by removing unbound tetanus toxin though it won't immediately relieve existing symptoms. Further, it is important that tetanus patients be admitted for emergency care in a facility capable of providing TIG as well as intensive care including respiratory support. A single intramuscular (IM) dose of 500 IU TIG is recommended as soon as possible. If human or equine TIG is not available, intravenous immune globulin (IVIG) may be used. Equine derived tetanus antitoxin is associated with serious allergic and should only be used in a single large dose after conducting hypersensitivity testing.

34 CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. The Pink Book. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/tetanus.pdf

vi. Removing the source of infectionthrough meticulous cleaning of the wound, surgically removing unhealthy tissue and killing the tetanus bacteria via antibiotics to prevent further toxin release.

vii. At discharge, patient should be started on TTCV series

SECTION III: RISK MITIGATION ACTIVITIES

This section reviews and provides guidance on operational issues on implementation of tetanus risk mitigation activities; forecasting TTCV needs in VMMC settings and; collaboration and liaison with other agencies in implementing TTCV interventions to mitigate the risk of tetanus.

3.1 SERVICE DELIVERY

Recognizing that tetanus vaccination in VMMC services would also benefit the implementation of the WHO vaccination recommendation for children, adolescents and adults to reduce the risk of tetanus from other wounds in unprotected adolescents and adults, the ministry has engaged with other stakeholders at both the national and county government levels and has put in place the necessary structures to fast-track the implementation of TTCV in VMMC settings. The TTCV-VMMC service delivery package shall be planned and coordinated in consultation with the Unit of Vaccines and Immunization services, NASCOP and Kenya Medical Supplies Agency (KEMSA). Planned activities shall be in line with the Kenya Essential Packages for Health (KEPH).Delivery for TTCV immunization for male circumcision shall be implemented within the overall framework of the goals, guidelines and standards[35] of the national policy on immunization with emphasis on improvement, expansion and intensification of immunization services in the country. Clinical staff shall undergo refresher course on immunization and vaccine management. Administration of vaccine shall be performed only by staff trained on giving injections in accordance to the national policy guidelines on immunization. Similarly, surveillance exercise for adverse events following immunization (AEFI) shall be conducted as per the national guidelines.

3.1.1 Mode of service delivery

Routine service delivery outlets (fixed stand-alone or integrated sites) as well as mobile and outreach service delivery models and various forms of campaigns hitherto being used in delivery of VMMC provide the ideal platforms for provision of TTCV immunization. Choice of specific strategies to deliver services may vary according to the needs and resource availability in each county. They shall be cost-effective, efficient, reliable and flexible to meet client access needs in addition to existing national and county level VMMC and immunization program goals.

There is evidence that task-shifting and service integration[36] are important efficiency elements to improve delivery of preventive services such immunization. Provision of TTCV immunization services in VMMC settings shall co-opt trained community health workers

35 MoH, 2013. National Policy Guidelines On Immunization 2013

36 WHO. (2008). Treat, Train, Retain: Task Shifting Global Recommendations and Guidelines. DOI: 10.1080/17441692.2011.552067

in performing non-clinical roles, including planning logistics, mobilizations of clients, counseling and follow-up/linkages as appropriate, while nurses and clinicians may focus on more technical clinical aspects. Immunization services shall be delivered alongside existing programs through a mix of both community- and facility-based approaches. It is recommended that at all times the community services such as mobile and outreach services should have functional linkages with adjacent health facilities for commodity supply, referrals, reporting and quality assurance.

Facility-Based (Static sites): The NVIP guideline provides for vaccination service delivery at accredited facilities only. These shall play a central role in coordinating immunization activities both at the site and through linkage with their respective satellite sites. They shall collaborate in providing logistical support and service delivery as well as advocacy and resource mobilization for immunization services.

To improve access and use at static facilities, specific TTCV service rooms or days for VMMC clients may be designated, but in ways that promote synergy of activities. Where additional resources are needed to strengthen capacity for service delivery, the respective program managers shall coordinate with the relevant county health in-charges as part of ongoing on-site service integration.

Outreach immunization activities: Outreach service delivery approaches are versatile service delivery models and allow programs to optimally adjust their resource inputs in response to variations in service demands, experience, and organizational functions.[37]The purpose of outreach immunization services is to increase access to clients in hard-to-reach areas and therefore it is not applicable in all places and at all times. They may be organized with the aim of providing TTCV to groups targeted with VMMC, based on the TTCV immunization needs. As far as possible, immunization outreach activities should be integrated with other adolescent / adult health activities. The frequency should be regular and consistent, and should be mounted in coordination with respective community leaders, and the sub-county health managers.

3.1.1.1. Infrastructure

Services should be spatially distributed in the participating facilities in a way that they increase accessibility to as many people as possible while guaranteeing privacy and confidentiality. Provision should be made for space in VMMC facilities to allow for integrated tetanus toxoid-containing vaccine service delivery for adolescent and adult males. Additional efforts to promote clean care for individuals and communities may be required. Development of materials for community sensitization and mobilization on mitigating risk for tetanus infection shall be required.

3.1.1.2 Cold chain and vaccine storage.

Cold chain is a process of maintaining vaccines in a potent state from the manufacturer to the recipient (children, adolescents and adults). It is used to maintain and distribute vaccines in optimal condition. Vaccines lose their potency when exposed to high temperature, sunlight or freezing conditions depending on type. Tetanus toxoid should be stored in the refrigerator as per national guidelines. Any type of TTCVs should be stored at 2–8 °C. They must not be frozen. Evidence has shown that Tetanus toxoid is stable,

37 Aduda DSO., Ouma C., Onyango R., Onyango M., Bertrand J. Voluntary Medical Male Circumcision Scale-Upin Nyanza, Kenya: Evaluating Technical Efficiency and Productivity of Service Delivery. PLoS ONE ·2015

and can withstand exposure to room temperature for a time without a significant loss of potency.[38]However, freezing tetanus toxoid containing vaccine results in substantial loss of vaccine potency and should be avoided. Frozen vaccine should be discarded. The national forecasting of overall demand and infrastructure for the cold chain, vaccine quality assurance and monitoring, dry storage, vaccine transport systems shall be enhanced to ensure adequacy and improved capacity to ensure compliance with requirements. In addition, the quality assurance standards shall incorporate parameters for monitoring TTCV vaccine vial monitors and reconstitution guidelines, preventing contamination of multi-dose vials (double-dipping) and use of multi-dose vials once opened.

Compliance with standard vaccine management procedures helps to ensure quality and safety in service delivery as well as minimizing losses, unnecessary costs for providing services and potential damage to public confidence. The vaccine management system shall be strengthened to enhance compliance with cold chain capacity requirements and to provide adequate dry storage for the additional injection materials such as syringes, and safety boxes that shall be needed for delivery of TTCV.

3.1.1.3 Planning and logistics:

Additional requirements that deserve attention during Programs planning shall include the following:

1. Implementing the WHO recommended transition from TT to Td vaccines
2. Implementing comprehensive community sensitization and mobilization activities
3. Advocacy activities with key stakeholders at national, county and sub-county levels
4. Revision and printing of standard immunization forms, such as vaccination cards, tally sheets, registers, monitoring forms, guidelines, etc.
5. Strengthening AE surveillance, reporting, and management
6. Refresher training: to enhance quality improvement standards, organizational as well as practice capacities role-appropriate competency refresher training on TTCV immunization services shall be conducted for all direct service providers and supervisors working at the facility, sub county and county levels .
7. Documentation: All documentation and reporting shall be done within the framework of the NVIP guidelines and standards for monitoring.

3.1.2 Advocacy and communication:

Recognizing the important role of advocacy and communication for vaccination services, providers shall consider integrating activities that focus on providing information, persuasion, and motivation to augment access to and use of TTCV for prevention of tetanus. Relevant materials appropriate to all stakeholders shall be adopted or new ones developed for community sensitization and mobilization. Depending on the model of service delivery, additional staff may be incorporated into the service delivery team for special initiatives such as community mobilization, immunization and quality assurance as needs evolve.

38 Immunological basis for immunization series ; module 3, WHO, 2006

Multi-level community awareness activities shall be designed and implemented through the existing structures. The target audience shall include managers of the facilities, community gate keepers, the local administration, religious leaders and key educational institutions on the relevance of TTCV and wound management as key strategies for tetanus risk reduction in male circumcision and general health settings. The process of sensitization shall be integrated within the current national behavior change communication framework. The National VMMC communication document shall be appropriately updated to cater for the new requirements for tetanus risk reduction in male circumcision settings.

3.2 CAPACITY BUILDING AND CERTIFICATION

3.2.1 Modalities of training service providers

Building capacity of the institution and service providers is key towards achieving the overall objective of obtaining tetanus-free male circumcisions. Using multiple modalities, capacity building shall involve personnel training to improve technical skills. It shall also involve systems strengthening to enhance institutional capacities through practical ways that improve overall outputs, efficiency and quality of service delivery. Capacity building trainings shall be conducted for health care providers at multiple levels.

New program updates on VMMC and tetanus mitigation in VMMC settings shall be emphasized, including additional VMMC package components related to tetanus risk reduction, updated procedures, program protocols and M&E tools as well as NVIP requirements for vaccine handling, cold chain management and logistics. Clinical service providers and other relevant staff shall be updated on quality improvement strategies to enhance safety of clients. Different modalities and approaches exist for implementing this TTCV program dimension. Innovative implementation approaches that evolve with time shall be continually evaluated for adoption.

Using current field or in-house procedures, all service providers, supervisors, policy makers, training institutions and key community leaders shall be progressively provided with role-appropriate competency refresher courses or new updates and specific variations in standard protocols on dual approach to tetanus mitigation, TTCV immunization and clean care, the signs and symptoms of tetanus, the need for a rapid response and recommended care including indications using the elastic collar compression device, providers shall ensure immunization against tetanus as recommended by Kenya ministry of health. Training shall also emphasize importance and process of monitoring all AEs (related to VMMC and TTCV) through post-surgical follow-up and regular review of AEs by the National VMMC TWG.

After the initial refresher training, service providers shall undergo continuing annual refresher training to be updated on the latest information on tetanus disease management and TTCV. In addition, community mobilizers, infection prevention officers, health information management officers and the county/sub-county health management teams shall continually be provided with role-appropriate information updates as per program requirements. The required training curriculums and competency assessment criteria shall be coordinated by NASCOP. Facilities providing VMMC and TTCV shall require periodic assessments by NASCOP and NVIPas part of program quality assurance process.

3.2.2 Updates for training materials

The NVIP policy guideline on immunization shall be adopted for developing training and operational toolkits. Relevant aspects of both program manuals shall be integrated within their operational frameworks. This shall be done through consultations between relevant NASCOP and NVIP technical working groups.

The current training curriculum for VMMC service provision and quality assurance (QA) training guidelines shall be updated to include information on the clinical management of tetanus disease and knowledge on TTCV administration including NVIP cold chain management system. The tetanus information needs shall also be incorporated into the National communication strategy document.

The NVIP TTCV training manual shall be reviewed and updated to integrate the recommended dual approach to tetanus mitigation for all wounds and in circumcision settings. Resource needs for all training curriculum revisions shall be assessed and estimates consolidated with others. This shall be done through consultations between relevant NASCOP and UVI/NVIP technical working groups.

3.3 OPPORTUNITIES AND POTENTIAL CHALLENGES OF TTCV IMMUNIZATION PROGRAMS

The introduction of TTCV vaccine into the national immunization programs is unique sand likely to present new opportunities as well as certain challenges.

Opportunities:

1. The country has an opportunity to champion commitment and progress on Global Immunization Action Plans -- such as eliminating risks of infection by vaccine preventable diseases and demonstrate feasibility of implementing TTCV in the context of VMMC.
2. Integration of TTCV for adolescent and adult males with the delivery of other health services provides opportunities to increase coverage of males and bridge the male female TTCV gap and health system strengthening.
3. Broadening of stakeholders and partners for immunization, including those from reproductive health, adolescent health, school health, non-communicable disease control, cancer control, HIV prevention, and women's health.
4. Synergies from various collaborators shall invigorate advocacy and other program plans, inject innovative ways of working, provide new linkages, broader access, and additional resource mobilization and support for immunization.

All these shall require a commitment to continuous quality improvement processes.

On the other hand, while VMMC service delivery platform provides a good opportunity to reach the adolescent and adult males, anticipated challenges may include: uncertainties on demand and supply for services which has overall implications on resource planning and management; people's perceptions around the vaccine, recurrent religious concerns

about Adverse Events Following Immunization (AEFIs) and vaccine safety may pose initial access challenge; additional resource needs; complex coordination; communication among many stakeholders (to make decisions, plan, and implement).

Appropriate mechanisms and structures shall be put in place to make sure the intervention plans are inclusive and effective. Technical experts may be co-opted from time to time to provide support as program needs evolve.

SECTION IV: VMMC SETTINGS

4.1 IMPLICATIONS AND RECOMMENDATIONS

The guidelines shall be implemented in line with the existing KEPI framework. Therefore, the current policy and implementation framework on immunization shall be reviewed to include logistical considerations and forecasting for the scale up of TTCV immunization schedule for adolescent and adult males. Additional commodity (cold boxes, KEPI fridges, icepacks, thermometers, TTCV) as well as other resource and logistical requirements shall be considered in subsequent TTCV and VMMC program activities forecasting and estimates plans. Procurement and distribution shall be coordinated centrally through the county and national coordinating health teams. To ensure commodity security, careful consideration shall be made to ensure the systems respond to the new requirements introduced by these guidelines.

Mapping for the VMMC sites and TTCV vaccination infrastructure shall be implemented in due course. This shall be integrated within the commodity management structures that already exist for distribution and delivery of Expanded Program of Immunization, taking into account the national and county governments' lines of operation.

Assessment of staff training needs in VMMC program updates, including vaccine management and administration shall be conducted to provide information to facilitate budgeting and operational management.

4.2 COMMODITY SECURITY CONSIDERATIONS

Forecasting and quantification of consumables and antigens, shall be done jointly with stakeholders to identify additional commodities required to support the extra demand during the scale-up phase and subsequent maintenance phase. Consideration shall be given to seasonal variations in demand for VMMC in both traditionally circumcising regions and the traditionally non-circumcising regions.

Vaccine related procurement, logistics management and inventory management shall be conducted and coordinated according to the existing systems under the management of NVIP in collaboration with NASCOP. Modalities and guidelines for resource sharing shall be developed at national level and cascaded down to the counties and sub-counties.

Estimates of the national capacity needs for transitioning to providing routine 5TTCV immunization doses to everyone as recommended by the WHO[39] shall be consolidated and coordinated by the central and county governments based on their respective lines of functions.

39 World Health Organization. Tetanus vaccine – WHO position paper. Weekly Epidemiological Record. 2006; 81: 197–208.

SECTION V: COLLABORATION AND LIAISON WITH OTHER AGENCIES

The Ministry of Health coordinates all related activities and actors in the Health sector under the sector-wide approach (SWAP). The successful implementation of measures to mitigate risk of tetanus among clients accessing VMMC services requires broad engagement and collaboration with stakeholders who implement aspects of health policy and service provision. The collaborating agencies include divisions and departments within the Ministry of health, Ministry of Education, County governments, donor agencies and other implementing partners.

5.1 APPROACHES TO STAKEHOLDER ENGAGEMENTS

The Ministry of Health shall expand the VMMC National Technical working group, including relevant subcommittees to include relevant key stakeholders. This will ensure on-going consultation and participation in decision making. Regular updates through stakeholder meetings shall be planned including ad hoc sessions to address emerging issues.

5.2 OUTPUTS OF COLLABORATIVE ACTIVITIES

The outputs of the specific collaborative activities shall be considered in relation to the required collaboration inputs, process and outcomes. These shall be identified and aligned to the existing NASCOP objectives for VMMC and NVIP objectives on immunization. They shall form the basis for monitoring and evaluation.

The main outcome is an all-inclusive comprehensive and consultative adoption and implementation of the tetanus mitigation guidelines to ensure that all clients consistently receive high quality VMMC services in an environment safe from tetanus infections.

Table 5.1: Matrix for stakeholder engagements for TTCV immunization Programs: Agency roles and expected outputs

No.	Name of Institution/ Partner	Area of operation	Role	Outputs
Ministry of Health				
1	NACC	Advocacy	Advocacy and Resource mobilization Multi-Sectoral collaboration Strategic planning	Stakeholder buy-in High level advocacy for the new policy directions Resources are mobilized for aspects of implementation.
2	NASCOP	Health Policy	Guideline development and dissemination Capacity development M&E and surveillance Operations research HIV stakeholder coordination	Relevant guidelines developed and dissemination Capacity of Counties/partners to implement guidelines developed Strategic information generated and utilized
	Health Promotion Unit	Behavior Change Communication Health Promotion	BCC strategies and policy guidelines Dissemination of BCC guidelines Capacity development for Health promotion BCC stakeholder coordination BCC message development	BCC Guidelines and policies in place and disseminated Adequate Capacity for BCC is built

3	NVIP	Vaccine commodity management, Policy guidelines	Immunization policy development and dissemination Vaccine Procurement & distribution Immunization Commodity security (KEMSA) Vaccine Quality assurance	Adoption of TTCV policies and guidelines for the new target population Adequate TTCV commodity security strategies implemented
4	DCAH	Adolescent health policy guidelines	Adopt and disseminate policies on adolescent vaccination and circumcision Guidelines for adolescent friendly policies and service delivery models.	policies on adolescent vaccination and circumcision disseminated and implemented Adolescent friendly services implemented
5	KEMSA	Commodity security	Commodity security(NVIP)	Implement TTCV & VMMC commodity security strategies
Ministry of Education		Education sector coordination	Adopt TT immunization policies into school health Programs and guidelines Champion demand creation for TT immunization and male circumcision in schools	TTCV immunization policies disseminated and implemented in schools Demand for VMMC/TTCV interventions created in schools
	Departments of Health	Service delivery	Disseminate and implement TT/VMMC policies and guidelines Adopt integrated models of implementation of TT/ VMMC policies Develop capacity for service diversity at all sites	Policies and guidelines disseminates Immunization and integration of HIV prevention services into routine health services Capacity of health providers to provide integrated and high quality VMMC services
	Department of Education	HR & Quality management	Adopt TT immunization policies into school health Programs and guidelines Champion demand creation for TT immunization and male circumcision in schools	Policies for TT immunization and demand creation for TTCV is developed and implemented.

	Department of social services	Provision of social services	Advocates for disadvantaged and marginalized Groups like the OVCs, disabled, economically disadvantaged Lobby youth, religious and civil society and women groups to support adoption of services	Equity in service provision for marginalized groups is realized
	Department of Health Promotion		Implement BCC and other health promotion activities that support VMMC/TT immunization among target populations	BCC and health promotion activities implemented for target populations
Donor Agencies				
	UN Family (WHO,UN agencies)	Technical & Financial support	Resource mobilization and allocation Technical and financial support for country guideline development and dissemination	Country guidelines appraised Resources and successful dissemination of TTCV guidelines
	USG (CDC, USAID, KDOD, US Peace corps	TA & Financial support	Technical and financial support for Programs guidelines and implementation activities Resource mobilization	Implementing partners' capacity built to implement guidelines Resources made available to support implementation and monitoring of TTCV guidelines
Implementing partners		Technical support and service delivery	Technical support to County and National teams Implementation of policies in collaboration with County teams	Counties provided with technical assistance to implement guidelines Implementation of TTCV guidelines as part of quality VMMC services
Faith based organizations			Demand creation Buy in of religious groups through discussion of religious sensitive aspects Implementation of BCC activities and demand creation	Demand creation

SECTION VI: MONITORING & EVALUATION AND QUALITY ASSURANCE

6.1 REVISIONS AND UPDATES OF M&E TOOLS

The frameworks and plans for VMMC and TTCV program monitoring and evaluation shall be reviewed to accommodate multiple changes that have been occasioned by new program requirements. The changes shall have direct implications for reporting program activities as well as value of program information for planning. Specifically, the following aspects have been identified for review and updates:

1. Baseline data/information: the data required for initial planning of TTCV program requirements and designing initial operational targets shall be derived from the available studies and other data sources e.g., DHIS, Facility needs assessment reports, among others.
2. Indicators: these shall include the following:
    a. Number of males given TTCV booster doses, disaggregated by number of doses
    b. Proportion of males given at least one TTCV booster and circumcised, disaggregated by type of VMMC procedure
    c. Percent of health facilities reporting TTCV stock-outs in the last 3 months
    d. Percent of health facilities that experienced stock-outs within the last 3 months and as a result had some clients missing the TTCV.
3. Data capture tools: existing data capturing tools shall be reviewed to update them as appropriate. The table below indicates the specific tools which shall be revised as a priority, revisions to be made and the responsible agency:

Table 6.1: Revisions for specific VMMC M&E tools

Tool	Revisions to be included	Responsible entity
Vaccine Monitoring Chart (Tally sheet)	1. An additional check box for reporting on males shall be included in this tool to facilitate capturing data for VMMC clients	NVIP
VMMC Client form	2. An additional variable on TTCV status of client based on previous vaccination in the medical history and screening section (B) 3. In the screening checklist: • 3 dose primary series, add check boxes; • one up to three TTCV boosters; • dates and facilities where these were administered in the medical history and screening section (B) 4. In the eligibility summary section (C) include a summary question on whether the client is eligible for VMMC based on the TTCV vaccination status.	NASCOP and Male Circumcision TWG
VMMC Client appointment Card	5. Additional space for TTCV information (appointment dates, return dates) 6. Facility information (facility of TTCV administration and that of VMMC procedure)	NASCOP and VMMC Implementing Partners
Severe Adverse Events Notification form	7. Additional space for information on administration of TTCV and TIG before and after the adverse event	NASCOP and VMMC TWG
MoH 710 Vaccines and Immunization Report	8. Provision for capturing data on males as well as females (disaggregate F/M)	NASCOP/NVIP
MoH 705 B OPD Summary >5 yrs	9. Disaggregate F/M	NASCOP/NVIP
Electronic client-level databases	10. The Implementing partners shall update their client-level electronic databases to include all the effected changes in the VMMC client form	Implementing Partners
PEPFAR SIMS tool	11. Information on TTCV for VMMC	PEPFAR

6.1.1 Refresher training on the M&E tools

Refresher training on the M&E tools shall be consolidated with the others. Specifically, the following cadres shall be targeted:

1. Health Records and Information Officers (HRIO);
2. Strategic Information Officers;
3. Data managers;
4. Clinical teams: medical officers, registered clinical officers and nursing officers;
5. Program managers;
6. County and Sub County health managers;

6.1.2 Program evaluation

Program evaluation and operations research shall be conducted periodically to determine the program trends and emerging spatial-temporal disease patterns in relation to program coverage. These shall inform overall and specific program level decisions on TTCV immunization in VMMC context.

6.2 QUALITY ASSURANCE AND QUALITY IMPROVEMENT

The existing national toolkit for QA shall be reviewed and updated to incorporate the necessary information on TTCV immunization program. The toolkit is used by program and facility managers to guide the set-up of services and to improve ongoing service provision. In addition, it helps to measure progress towards meeting standards for service delivery and can be used by external assessors to certify or accredit facilities or as a reference point for comparison. These shall include the following aspects:

1. Storage
2. Administration
3. Cold chain and
4. Provider skills

The VMMC training package on QA shall be reviewed and updated to align with the other strategic documents and program objectives relating to the additional program requirements and objectives. Refresher training shall be prioritized and provided periodically at all levels to service providers and managers, through different approaches as may be appropriate and cost-effective. Training shall enable service providers and program managers to locally use QA information to inform their service improvement decisions to conform to the set standards.

Data quality assessment (DQAs)activities shall be conducted quarterly, semi-annually or annually depending on resource availability and program needs. However, a minimum of two DQAs (or more frequently as warranted) should be performed using the revised National Male Circumcision Services Quality Assessment Toolkit, to determine the site/region level status of the standards. DQA semi-annual and annual reports should be compiled and submitted to the NASCOP head office through the relevant MOH health information and records officers.

DQA shall focus on the following key data tools:

1. Client forms/folders
2. Vaccine monitoring charts
3. MoH 204A
4. MoH 710
5. MoH 731
6. DHIS
7. Client appointment cards

8. Severe AE notification form
9. Minor theater register

Periodic evaluation shall be conducted to assess whether the implementation is on track, and to identify useful lessons to be incorporated into program process.

Operations research

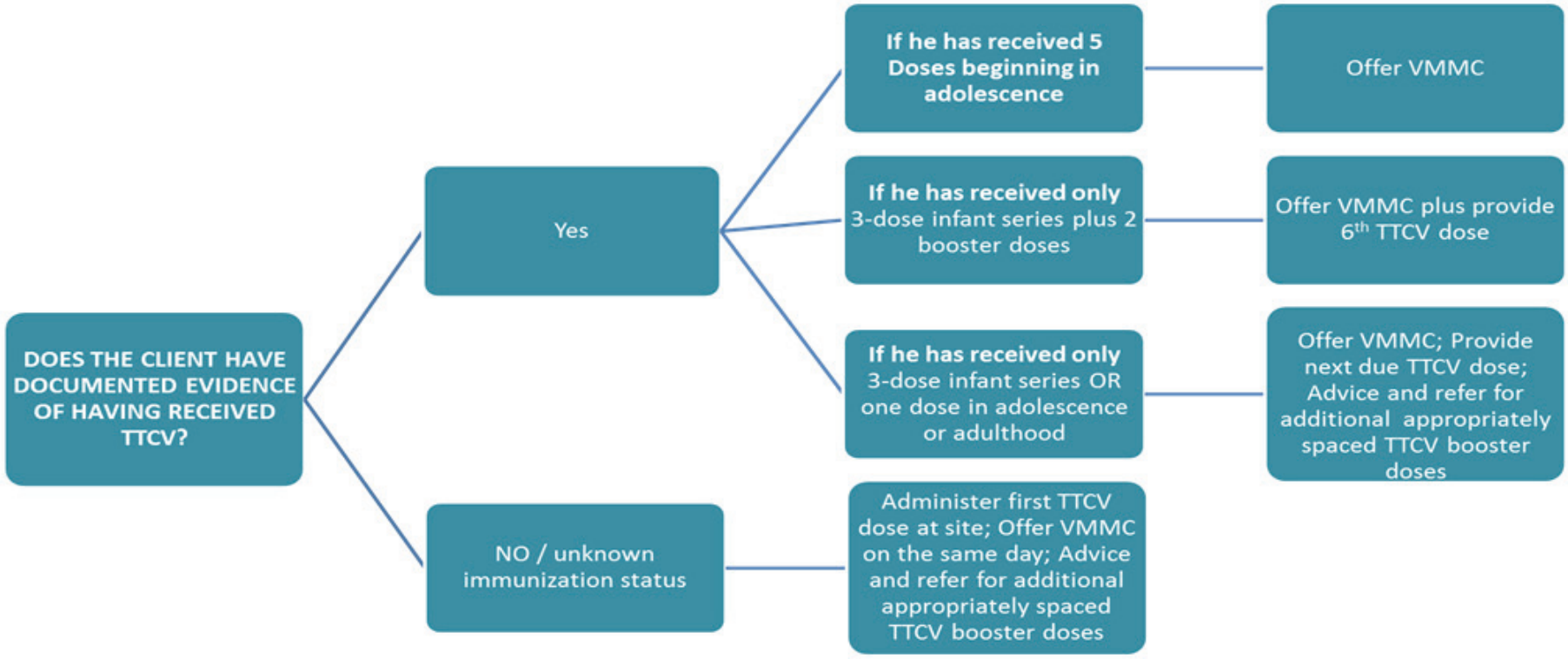
NASCOP shall, in coordination with research units identify key operational research problems, mobilize and allocate resources for operational research.

Information gaps

1. Acceptability of immunization in adolescents and adult males and specific platforms to increase vaccine uptake by adolescent / adult males.
2. Effective strategies for expanding the recommended TTCV immunization for adolescent and adult males.
3. Prevalence and characteristics of Vaccine “hesitancy” (vaccine decision-making and determinants of vaccine acceptance. It recognizes a continuum between the domains of vaccine acceptance and vaccine refusal).

TIMING OF ANNEX 1: TTCV DOSES

Algorithm for recommended number and timing of TTCV doses for clients undergoing male circumcision using conventional surgical or collar clamp procedures



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