

Technical Implementation Considerations for Early Infant Male Circumcision Programs

A Resource Guide for Optimizing Quality



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Introduction

Early infant male circumcision (EIMC), as described in this document, is a public health intervention to reduce a male's susceptibility to HIV acquisition from heterosexual intercourse once he becomes sexually active. EIMC involves the full removal of the foreskin within the first 60 days of life by a trained health care provider (WHO 2010).

There is a need for guidance on quality standards for EIMC. The World Health Organization (WHO) published an EIMC clinical reference manual in 2010 (WHO 2010) and a training package in 2014,¹ both intended to inform safe, quality practice of EIMC for HIV prevention. However, subsequent experiences in select countries in East and Southern Africa in implementing EIMC pilots have identified gaps in existing quality standards and technical guidance to optimize EIMC implementation. In addition, the WHO published a quality assurance (QA) guide in 2008 for voluntary medical male circumcision (VMMC) in males aged 15–49 years (*Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services*, henceforth referred to as the “WHO VMMC QA guide” (WHO 2008), but no analog exists for EIMC. This resource guide is intended to address these gaps.

Purpose, Structure, and Scope of This Resource Guide

Drawing from available scientific evidence and implementation experience with EIMC, VMMC, and reproductive, maternal, newborn, child, and adolescent health (RMNCAH) programs, this document offers considerations for national decision-makers and EIMC program planners for filling identified gaps in EIMC quality standards and making the associated technical or program policy decisions. It focuses on EIMC for HIV prevention, though EIMC confers other benefits, as well as opportunities to provide other RMNCAH services.

This document is structured the same way as the 2008 WHO VMMC QA guide, but is adapted for the scope and implementation approach of EIMC. Key differences from VMMC addressed here include the service delivery setting (EIMC is often integrated with RMNCAH services); screening considerations for infant physiology and immune systems; circumcision method; and role of parents or guardians, which by nature is more intensive in EIMC. Some important themes detailed in one section are also briefly discussed in others because their relevance is cross-cutting. In these cases, the reader is also referred back to the detailed section for more information.

¹ <https://www.malecircumcision.org/resource-bundle/training-package-early-infant-male-circumcision-under-local-anaesthesia>.

This document does not include detailed QA and quality improvement (QI) tools; countries may consider developing such tools in alignment with the core standards put forth in this document to enable concrete assessment of core standards at the program and site levels. **Finally, this guide attempts to fill gaps but does not duplicate key clinical information contained in the 2010 EIMC manual, which remains crucial for EIMC program implementation.**

Important: This document addresses only medical EIMC; it does not address male circumcision practiced on infants as a cultural custom.

Core EIMC Service Standards

Following is a proposed list of uniform quality standards for EIMC service delivery. They follow the format used in the WHO VMMC QA guide, but have been adapted where necessary to address the specific context of EIMC. They may be further adapted for applicability in the country and communities concerned, based on cultural, legal, and other considerations, but could also be adopted as written.

One standard included in the WHO VMMC QA guide is not duplicated here: it describes a “minimum package” of HIV prevention and other sexual and reproductive health services to accompany the male circumcision procedure. An analogous minimum package for EIMC has not been defined. However, **a key theme of this guide is that EIMC represents an additional health system encounter with infants in perhaps the most vulnerable, high-mortality period of their lives (unrelated to circumcision), and is an important opportunity to identify common acute serious illnesses and prevent poor outcomes.** Thus this document offers a set of tasks somewhat analogous to a minimum package, designed to ensure providers **leverage EIMC services as an opportunity to screen and diligently refer clients and mothers to needed services.**

The remaining core standards are:

1. There is an effective management system that includes planning, policy, standard operating procedures (SOPs), and guidelines to oversee the provision of EIMC services
2. Each facility has all the required space, medicines, supplies, and equipment (including emergency equipment) for providing safe, high-quality EIMC services
3. EIMC providers are properly trained, qualified, and competent
4. Parents/guardians receive the necessary information and education about the potential risks and benefits of EIMC to enable them to provide informed consent if they choose to do so
5. Assessments are performed to evaluate the condition of infants and determine their eligibility for EIMC and any other necessary health interventions
6. The EIMC procedure is always performed according to stipulated clinical and service standards
7. Infection prevention and control measures are practiced throughout and following the EIMC procedure
8. Continuity of care, including referral to other services, is provided as needed for all infants who visit EIMC services
9. There is a proper monitoring and evaluation (M&E) system for the EIMC programs

Subsequent sections offer detailed descriptions of each core standard, with technical considerations and possible variations as observed in different countries.

Core Standard 1: There is an effective management system that includes planning, policy, SOPs, and guidelines to oversee the provision of EIMC services

Intent

Assure government leadership and acceptability of quality EIMC services as a public health priority

Criteria

1. EIMC-specific policies and guidelines

2. Clear SOPs for linkage between EIMC and other RMNCAH services
3. Long-term sustainability, including financial support

Relevant Content from the 2010 EIMC Clinical Reference Manual and WHO VMMC QA Guide

The 2010 manual emphasizes strong planning and management at above-site and site levels (WHO 2010). It identifies human capacity development, equipment and supply management, community involvement, assessment and monitoring, organization of services, and high-quality services as key elements of planning and management. See Chapter 13 of the manual for details.

The WHO VMMC QA guide provides extensive recommendations concerning the role of government in leading strategic technical, programmatic, and financial planning for VMMC services (WHO 2008). Those principles apply with even greater emphasis for EIMC, as a country-led response is vital to sustainability of EIMC as a fully funded, integrated health program. EIMC programs will benefit from reviewing pp. 14–20 of that document. Key issues discussed include:

- Establishing implementation policy and strategy, with clearly defined oversight and decision-making roles and responsibilities, as well as linkages to and integration within existing services and platforms, at national and subnational levels
- Workforce planning to support programmatic needs
- Supply chain management
- Budgeting and financing of services
- Strategic planning processes, structures, and the importance of community engagement
- Developing clinical and programmatic quality standards
- Applying a sustainability lens to all of the above, from the outset

In addition to this existing content, EIMC-specific policy and planning issues to consider include:

1.1 EIMC-specific policies and guidelines

A crucial initial decision is which stakeholders will be involved in development of EIMC policies and guidelines. Considerations include:

- Involvement of EIMC experts, rather than only VMMC experts, can ensure that the many important differences between EIMC and VMMC are reflected in policies and guidelines.
- At the Ministry level, planners will need to consider whether EIMC will be primarily overseen by, led by, and draw expertise from:
 - Pediatricians
 - Obstetricians
 - Surgeons
 - Nurses
 - Another or multiple cadres
 - Leaders selected based primarily on Ministry departmental role rather than cadre
- The appropriate stakeholders can then be involved. See **Box 1** for two examples.
- More broadly, early involvement of the leaders of the existing governance structures of the overall health care system—referred to here as RMNCAH governance structures—is crucial. This is because these structures will play an essential role in ensuring the pre-service training, management, logistics (including supply chain), and staffing of EIMC programs.

With participating stakeholders identified, the format of EIMC policies can be selected. A key consideration is that the policy and technical (i.e., provider) audiences for EIMC and VMMC may be entirely distinct, with unique considerations for services geared toward infants versus adolescents and adults. Creating an EIMC addendum to local VMMC policies and guidelines, as opposed to incorporating EIMC policy considerations throughout VMMC policy documents, may increase accessibility, comprehensibility, and applicability for those whose involvement in circumcision is limited to EIMC.

The remainder of this resource guide addresses the potential technical contents of these EIMC policies.

1.2 Clear SOPs for linkage between and/or integration of EIMC and other RMNCAH services

SOPs, memoranda of understanding, or similar clear parameters for the relationship between EIMC and general health (RMNCAH) services are needed. Important elements of these include:

- Defining the extent of integration of EIMC services within existing RMNCAH services, including to what extent EIMC service providers will also provide other maternal and infant services. Though experience with the best way to approach this is still developing, pilot programs to date have primarily integrated EIMC fully within RMNCAH. This may have advantages compared with the vertical programs often used in VMMC scale-up, including enhanced parent recruitment, better assurance that infants receive appropriate infant and child survival interventions, and more financial sustainability.
- Ensuring ownership and cooperation between the services for purposes of information-sharing, provider education, and referral (see more on continuity of care in Core Standard 8), with the aim of providing comprehensive health care to infants.
- Planning for EIMC providers' skill retention. If consideration is given at the Ministry and facility levels to working out assignment rotation systems that support skill retention, providers may require less in the way of refresher training and be more productive in EIMC.

1.3 Long-term financial support

As countries adopt EIMC as part of the national HIV prevention strategy, the program's budgetary support and allocation method within the broader frame of the national health budget need to be determined. Ideally, this would be a specific line item within HIV or RMNCAH budgets.

Box 1. EIMC leadership approaches in Botswana and Tanzania

Implementers of EIMC pilots in Botswana and Tanzania shared summaries of how EIMC leadership and coordination occur in their countries.

National oversight and coordination—Botswana

As services were beginning, Botswana created an EIMC-specific technical working group (TWG) with its own terms of reference and membership. Over time, as the country addressed initial operational considerations and required less time to discuss EIMC-specific issues, the government determined it would be most efficient to address EIMC and VMMC in a single, merged TWG, which is how the structure remains today. Countries may see benefit to following a similar approach, or to appointing an EIMC task force within the VMMC TWG or a similar RMNCAH governance structure, particularly during the initial stages of program start-up, with an expectation that the task force would be absorbed into the broader TWG as EIMC becomes routine.

Guidelines and scale-up—Tanzania

Existing national VMMC guidelines were revised to include EIMC guidelines and SOPs; VMMC and EIMC are addressed in tandem across guideline categories, with boxes highlighting areas where standards and practices diverge between the two programs. Countries may wish to take this approach, or to develop guidelines integrated with RMNCAH programs; the latter may work best in countries where EIMC will be led by and fully integrated into RMNCAH departments.

Tanzania used a phased EIMC introduction approach adapted from the WHO framework for clinical evaluation of adult MC devices (WHO 2012). After an initial pilot involving 16 sites in Iringa, Tanzania transitioned to a period of “active surveillance” (1,000 procedures) with seven additional sites in Njombe. Under active surveillance, all clients were followed up with, by home visits if necessary, to ensure that all adverse events (AE) were captured so overall program safety could be assessed. This was followed by a data review and the decision to proceed to passive AE surveillance (an additional 1,000 procedures), in which routine service delivery and follow-up protocols were employed, and program data documented to inform further policy decisions. Based on results from these phases, the Ministry of Health now recommends establishing EIMC in all priority regions as funding and human resources allow. To date, much of EIMC in the country has been donor funded.

Core Standard 2: Each facility has all the required space, medicines, supplies, and equipment (including emergency equipment) for providing safe, high-quality EIMC services

Intent

Provision of safe and high-quality EIMC services requires availability of all the necessary EIMC equipment, medicines, and other supplies. In addition, each site should have emergency equipment and medicines to provide initial management of any medical emergencies that may happen there.

Criteria

1. The room/space is adequate for provision of EIMC services
2. All the required equipment, instruments, and medications for safe provision of EIMC are available
3. Minimum emergency equipment is available on site

Relevant Content from the 2010 EIMC Clinical Reference Manual

Facility requirements mentioned include but are not limited to: a clean room with good lighting, proximity to (or co-location with) RMNCAH services, resources for contaminated waste disposal, and access to routine follow-up care. Also, the 2010 manual lists equipment, supplies, and instruments that must be “immediately available and routinely checked” before beginning any case (WHO 2010). They include, but are not limited to, handwashing/cleaning facilities, sterile gloves, instrument tray with sterile drape, and 1% lidocaine. The manual also suggests the EIMC supply chain should be integrated with the national health supply chain (as part of HIV/AIDS or RMNCAH), and that facility-level management should incorporate the required equipment, supplies, and drugs into the routine logistics and procurement systems. See Chapters 2 and 13 of the manual for details.

Note that this section speaks to criteria for safe facility-based EIMC. Pilot studies have been conducted on community-based EIMC (EIMC performed in the infant’s home). A recent prospective comparison of facility- and community-based EIMC, with EIMC typically delivered using a rigid restraining board on a home table or bed surface in a room with good natural light, found safety to be comparable between the two models (Bailey et al. 2017). However, there is still insufficient programmatic experience to define the safety and environmental requirements for community-based EIMC.

2.1 The room/space is adequate for provision of EIMC services

The first decision that will affect programs’ approaches to meeting this standard is exactly where EIMC service delivery will be situated. This is a separate question from the extent of operational integration with RMNCAH services, though related. Several considerations may be important. Large tertiary care institutions or existing VMMC facilities will already have stocks of and supply chains for many of the necessary supplies and equipment. However, even in larger institutions, maternity and pediatric wards may not have sufficient space, tables, commodities, and other essentials for EIMC, while using current VMMC facilities would result in fragmentation of EIMC from other infant care services. As of 2017, EIMC programs are often initially nested in large hospitals, which allows for developing national EIMC experience in a setting with more available support. But countries may also consider involving small health centers and dispensaries from the beginning, as ultimately offering EIMC services in the lowest-level facilities where safe and comprehensive services can be provided will maximize coverage.

Within facilities, programs will need to determine whether EIMC should be placed within maternity and/or RMNCAH. Pediatrics departments tend to serve clients above the age of 60 days and may not have the necessary focus and familiarity with infant care to support EIMC.

2.2 All the required equipment, instruments, and medications for safe provision of EIMC are available

Programs can easily track emergency equipment, medicines, and supplies with a regularly verified paper or digital inventory. Storage specifications differ by item—some require secure storage only, while others have specific temperature or other requirements. Surgical instruments and EIMC devices require storage that preserves their sterility. Medications typically require storage away from heat or sunlight, and some require refrigeration. A complete list of all routine EIMC equipment, instruments, and commodities is provided in **Appendix A**, building on the minimum necessary equipment listed in the 2010 EIMC manual (WHO 2010). As with VMMC, EIMC services also require a procedure area with adequate space, light, temperature control, and ventilation to accommodate providers and clients. The entire process has been successfully done using a single room for education and counseling, procedure and recovery, and postoperative instructions, but determining the ideal use of space for higher-volume programs will require more experience.

Reusable devices (e.g., Mogen and Gomco clamps) require regular quality checks and maintenance to ensure that they can still be effectively and safely used for the procedure—see **Box 2** on device/instrument quality. Given that some devices contain parts that come in multiple sizes, confirming size match of all parts is also essential prior to performing device-based EIMC. Standardizing this process with a formal SOP and onsite recordkeeping of each quality check can improve safety.

Box 2. Signs of wear or need for repair in EIMC devices

Hinge—stiffness opening/closing, cracks in hinge parts, loose screws

Ratchet—fails to hold

Clamp—fails to hold tissue/visible gap between edges when closed

Surface—rust/corrosion, spots and stains that do not come off after sterilization, difficulty cleaning/visibly unclean

Blade—dull spots or chips on blade edge; there are tissue-simulating products that can be used to test blades for sharpness

Reusable EIMC devices are sterilized between uses, so EIMC services using them are reliant upon access to a functioning autoclave. Autoclave availability may be a determining factor as programs decide where to locate EIMC services. If not directly available on site at the health facility, an offsite autoclave can address instrument sterilization needs so long as reliable transport is in place. Programs using offsite autoclaves may wish to maintain a greater device stock to reduce the likelihood of service interruption in cases of transport failure. See the Project IQ *Introduction and Use of Reusable Instruments in Voluntary Medical Male Circumcision Programs* guide and tools package² for information on autoclave specifications, procurement, operation, and QA.

2.3 Minimum emergency equipment is available on site

Although EIMC is a minor surgical procedure, emergencies may occur and can result in catastrophic outcomes if appropriate supplies for management are not available. Minimum emergency preparedness components include appropriate medications (e.g., adrenaline and vitamin K) and equipment and a pre-existing plan for referral and transport to specialized centers or expertise. A list of such supplies is provided in **Appendix B**. Training all providers on emergency management skills including emergency resuscitation and use of emergency equipment is also crucial, as covered in Core Standard 3.

Note: Appendix B list only contains equipment for emergencies directly resulting from EIMC, though many listed items are also important in management of other common infant emergencies.

Core Standard 3: EIMC providers are properly trained, qualified, and competent

Intent

The EIMC providers are trained in accordance with an accredited curriculum and assessed to determine whether they are competent and qualified to provide EIMC services.

Criteria

1. Staff cadre requirements and other staffing considerations for safe provision of EIMC are clearly outlined
2. Training takes into account all essential considerations for the provider to be able to perform EIMC safely and efficiently and to address emergency situations appropriately

Relevant Content from the 2010 EIMC Clinical Reference Manual

The 2010 manual (WHO 2010) does not address training; however, the 2014 EIMC training package³ describes the necessary knowledge and skills to be a competent EIMC service provider. Specifically, it addresses education and counseling, screening, competency with a surgical device, postoperative care, infection prevention, and M&E.

² <https://project-iq-resources.jhpiego.org/resource/introduction-use-reusable-instruments-voluntary-medical-male-circumcision-programs/>

³ <https://www.malecircumcision.org/resource-bundle/training-package-early-infant-male-circumcision-under-local-anaesthesia>

3.1 Staff cadre requirements and other staffing considerations for safe provision of EIMC are clearly outlined

In pilot programs in Botswana, Kenya, Lesotho, and Tanzania, EIMC services tended to be integrated within RMNCAH (or equivalent) services, with the majority of providers being nurses or nurse-midwives. However, other cadres, including medical officers and non-physician clinicians such as clinical officers, also serve as EIMC providers. Health professionals' councils may need to be engaged to review and expand scopes of practice so that the desired provider cadre(s) can perform EIMC.

When selecting staff to be trained, prioritizing individuals who can commence EIMC service delivery immediately will help with skill retention and maximize training efficiency. In contrast, individuals who will return to other services exclusively after their training will not immediately increase the EIMC workforce, and may lose their proficiency. Previously trained individuals who perform few circumcisions or who have rotated out of EIMC service delivery for an extended period may require performance reassessment and/or refresher training before they are allowed to perform EIMC again. (See **Section 1.1** on policies that can mitigate this challenge.)

In addition to identifying which cadres will serve as basic EIMC providers, it is also essential to ensure that a pool of physicians trained in EIMC and pediatric emergency care is available in a timely manner for consult or referral, to address cases requiring advanced surgical or emergency skills beyond the typical EIMC provider's scope of practice. Beginning national EIMC scale-up initially in larger facilities can offer the additional advantage of facilitating swift consultation and referral. Over time, national experience with and systems for managing complex cases will develop, so that systems are already in place when EIMC services scale up to lower-level facilities.

3.2 Training takes into account all essential considerations for the provider to be able to perform EIMC safely and efficiently

All providers undergo a specific competency-based EIMC training in order to safely perform EIMC; prior experience in adult and adolescent VMMC is not adequate because the procedures differ in several important ways. This means that every provider will need to go through standardized device-specific competency-based training for EIMC in accordance with an accredited curriculum as defined by the national government. Competencies include:

- Education and counseling of families/parents/caregivers
- Screening based on national eligibility criteria
- Performance of the physical exam and recognition of serious conditions necessitating deferral of EIMC and referral to urgent medical attention
- National protocols on HIV screening in pregnancy and follow-up of HIV-exposed infants
- Infection prevention and control (including instrument processing)
- Administering anesthesia
- Preprocedure marking and glandular adhesion removal
- Device-based procedure, in line with manufacturer instructions for use
- Wound dressing
- Postoperative observation
- Management of typical adverse events (AEs) of EIMC (see list of AEs in Core Standard 6)

- Emergency management, including for neurologic complications of anesthesia reactions and infant resuscitation (see **Box 3**)
- M&E and reporting
- Proper waste management
- Home care, including key steps for mitigating tetanus risk and warning signs for which parents should contact health care providers (fever, lethargy, poor feeding, inconsolability, ongoing bleeding, etc.)
- Care at follow-up visits

Box 3. Emergency preparedness

Emergency procedures are a key to avoiding preventable injury and mortality in EIMC. Procedures suitable for infants may not already be in place in all settings that will practice EIMC for HIV prevention. Therefore, it is incumbent upon EIMC services to ensure the following are developed/identified:

- Detailed infant emergency care SOPs, including clear roles and contact details for after-hours emergencies
- Training on these SOPs for staff at the service delivery site
- Designated emergency transport from the client’s home to the service delivery point, and from there to appropriate referral centers for emergencies that cannot be managed on site
- Designated specialists to address acute injury and other complications (e.g., pediatric surgeon and pediatric intensive care unit/emergency specialty care), even if not located near the service delivery point

- How, and to whom or where, to refer an infant in cases of:
 - Identification of unrelated serious conditions (see **Section 8.1** for detailed provider competencies on this subject)
 - An EIMC-related emergency or a procedure requiring a higher level of care, including suspected tetanus cases (which may require referral to a different facility than other emergencies, given the need for tetanus immune globulin).

In most pilot programs, when a sufficient number of infants have been available, EIMC training took about 5 days (half used for theory and practice on anatomic models, and half for practicum; most practitioners performed on average 10–20 procedures before competency was achieved). However, the number of infants available for EIMC during a training event may not always be sufficient. Based on program experience in Tanzania, five procedures under trainer supervision was sufficient for an initial skills transfer during formal training. This is followed by a 2-week period of post-training mentorship after which providers are certified to work independently, if applicable, or continue to receive support until they meet competency requirements. In comparison, a program in Kenya required that at least 10 procedures be performed under supervision before the trainee was certified, followed by a period of oversight by a regional coordinator.

Such approaches may be useful in or adapted for other countries. Regardless, post-training mentorship by an authorized trainer is an important component of the training process, to inform final certification by that trainer of the provider’s competency to undertake EIMC in a typical service delivery (rather than a dedicated training) setting.

Core Standard 4: Parents/guardians receive the necessary information and education about the potential risks and benefits of EIMC to enable them to provide informed consent if they choose to do so

Intent

The EIMC providers and staff are able to serve as knowledgeable resources on safe, high-quality EIMC. The EIMC program has a lead role in and responsibility for developing channels for sharing information and materials about EIMC and HIV.

Criteria

1. Information is provided to expectant parents and parents/guardians on male circumcision, including potential future sexually transmitted infection (STI) and HIV prevention benefits
2. Informed consent is obtained from client's parents or guardians

Relevant Content from the 2010 EIMC Clinical Reference Manual

The 2010 manual identifies many settings, in addition to the EIMC delivery point, where group education and individual counseling can be held (WHO 2010). These include antenatal care (ANC) clinics as well as postpartum, well-child, and immunization services and home-based services. It also describes the core content of a group education session and the skills needed to conduct successful group and individual education counseling sessions. The manual goes on to describe the necessary elements of proper informed consent. See Chapter 3 of manual for details.

4.1 Information is provided to expectant parents and parents/guardians on male circumcision, including potential future STI and HIV prevention benefits

Provision of information refers not only to laying the foundation for informed consent, but to creating a purposeful strategy for demand creation. This document does not address quality standards for EIMC demand creation. But two key principles are that demand creation strategies can address both facility-based and home births, and that providing EIMC information beginning before delivery offers the important advantage of giving pregnant women time to make thoughtful decisions, involving partners and others as necessary, so that EIMC is not delayed after birth. Specific activities can include:

- Broad community sensitization activities, to increase EIMC awareness and knowledge prior to and throughout pregnancy and childbirth.
- One-on-one community mobilization, which may include or even rely primarily on ANC and perinatal care visits by community health workers. For parents who plan or had home births, the community health worker may be the only contact with the health system during the infant's eligibility period for EIMC.
- Incorporating promotion into service routines at facility-based contact points, including ANC, maternity immediately after delivery, the RMNCAH clinic, immunization, and other hospital services. Many parents will access ANC clinics before delivery or postnatal services afterward, regardless of where the infant is born. Providers can promote EIMC at these visits, clinics can display posters for facility-based EIMC services following both home and facility-based delivery, and so forth.
- Outreach about EIMC to men who may be or soon become fathers in adult outpatient and VMMC services.

Education and Counseling

For parents/guardians who have a male infant who may be eligible for EIMC, the first step is for the health care provider to educate the parents to ensure that they are aware of the available EIMC services and understand the potential benefits and risks associated with this procedure. For efficiency, this can be done in a group setting for receptive parents/guardians, followed by individual counseling where each parent/guardian discusses specific questions and concerns on a one-to-one basis with the provider. Or, in settings where client volume is low and only one infant's parent/guardian is seeking services at a time, the provider can provide both the basic education messages and the individual counseling in a single session.

However education and counseling sessions are delivered, essential topics to cover in them include:

- Definitions of male circumcision in general and EIMC in particular
- Differences between adolescent and adult VMMC and EIMC
- Potential risks and benefits of EIMC
- Relationship between male circumcision and HIV and other STIs
- How circumcision is performed, including:
 - Eligibility criteria
 - Information about the specific EIMC device(s) used at the site
 - Pre- and postoperative procedures
 - Pain control measures
 - Strong emphasis on importance of wound care to prevent both infections and adhesions
 - Postoperative follow-up visits
 - Signs and symptoms requiring return for assessment and further management
 - How to contact a provider in case of questions or emergencies (e.g., hotline phone number)
- Parent/guardian feelings about circumcision**
- Partner/spouse feelings about circumcision**
- Parent/guardian questions**
- Completing client record forms**

Items starred with asterisks (**) may involve discussion of confidential client information and are thus suited to individual counseling sessions only.

When possible, use of pre-tested visual aids can improve comprehension and retention of counseling information.

Home Care Instructions

Providing correct information is also crucial immediately after the EIMC procedure. Reviewing postoperative care instructions in detail with the infant's parents/guardians before discharge will minimize the chance of complications. A postoperative information sheet can be provided as a handout. See Core Standard 8 for more detail on postprocedure care.

4.2 Informed consent is obtained from client's parents or guardians

Chapter 3 of the 2010 EIMC Clinical Reference Manual outlines considerations for informed consent, namely the need for assessing the comprehension and capacity for decision-making in parents and guardians with legal authority to consent on an infant's behalf, and to document consent in writing (WHO 2010). Annex 7 of the manual contains a sample EIMC consent form.

Core Standard 5: Assessments are performed to evaluate the condition of infants and determine their eligibility for EIMC and any other necessary health interventions

Intent

An initial assessment is performed to evaluate the suitability of clients for the circumcision procedure. Ongoing assessments are performed to evaluate the status of clients in relation to the surgical procedure.

Criteria

1. Initial client history and physical examination
2. Special considerations for EIMC eligibility
3. Contraindications for EIMC procedure
4. Assessment of infant HIV exposure
5. Appropriate referral/linkage for other conditions

Relevant Content from the 2010 EIMC Clinical Reference Manual

The 2010 manual briefly describes some screening procedures for infants to ensure eligibility (WHO 2010). A history and physical assessment are recommended as part of the evaluation, citing good health, full-term gestation, and weight above 2,500 g as the primary eligibility criteria at the time (see modified weight-for-age [WFA] criteria in this section). The manual briefly discusses some contraindications and includes photos of contraindicated congenital abnormalities. See Chapter 4 of manual for details.

Programs will need clear, consistent, universal contraindications for EIMC eligibility. Many of these are provided in the EIMC manual (WHO 2010). Others, described in this document, are more recent considerations for which less experience exists and which different countries may approach differently.

5.1 Initial client history and physical examination

Taking a thorough medical history and performing a physical examination informs the health care worker whether a client has any condition(s) that would be contraindications to EIMC (see **Figure 1** following **Section 5.5**). This involves taking a proper birth and medical history and performing both a brief general examination to assess the general condition of the infant and a genital examination to rule out any anomalies that may preclude EIMC.

If there is any doubt about eligibility based on the history and physical examination, then the client should be referred for a higher level of consultation before EIMC. **Experience with EIMC pilots has shown that for many unrelated deaths which follow EIMC, strict adherence to screening criteria would have excluded the infant. Appropriate, timely referral may also be able to prevent many of these deaths.**

Medical History

The medical history for EIMC should be focused and include an assessment of the items in the following list, some of which may be available from the infant's health card. Some of this information may not usually be known, particularly if the mother received little ANC or delivered at home. This missing information can be assumed to be normal unless there is evidence to the contrary:

- Whether the pregnancy and delivery were normal
- Gestational age of infant at birth
- Weight of infant at birth
- Feeding, urination, and bowel habits: Newborns should have one wet diaper every 24 hours for each day of life (one on day 1, two on day 2, etc.) until mother's milk comes in (if breastfeeding), and then five or six every 24 hours thereafter
- General well-being of the child
- Current fever, cough, skin infection, or diarrhea
- History of illness or any previous hospitalizations (these are not contraindications if fully resolved, but if the provider is not confident the issues have been resolved, the provider can suggest that specialist guidance be sought)
- History of convulsions/seizures
- Any family history of bleeding disorders (i.e., ask about excessive bleeding with surgery, minor injury, and tooth extractions)
- Maternal vaccination history against tetanus, to determine infant's protection at birth (PAB) (more in **Section 5.2**)

Physical Examination

A focused physical examination is completed on all infants prior to performing EIMC. When performing physical examination for an infant, wash hands with soap and water and dry with a clean, dry towel, then put examination gloves on both hands. Physical exam should include:

- Vital signs: temperature, pulse, respiratory rate, and oxygen saturation if available
- Current weight
- Assessment of the overall health status of the infant, including general appearance (activity, quality of cry, tone, color of skin, hydration status)—**Section 8.1** provides detailed provider competencies for identifying and referring acute illness
- Exam of skin from head to toe: ensure there is no cord or other skin infection, jaundice or scleral icterus (yellowing of the white part of the eyes), pallor, or bruising or bleeding (particularly around the umbilical cord) that would suggest vitamin K deficiency bleeding
- Exam of chest to include auscultation of lungs for crackles or wheezing and heart for abnormally loud murmurs
- Examination of the genitals to rule out penile torsion, penile length < 1 cm, hypospadias, hydrocele, buried penis, dorsal hood, swelling of scrotum, raphe not in midline, abnormal urethra or mega meatus, abnormal scrotal rugae, penile-scrotal web, abnormal ventral foreskin, ambiguous genitalia, or any other finding that the provider thinks is outside the normal appearance or may require

consultation with a urologist (photos of some of these conditions are available in the 2010 EIMC Clinical Reference Manual [WHO 2010])

Parents and guardians can be encouraged to bring the infant's health card to the EIMC service point as an additional data source to confirm no acute health issues have been identified. If unsure of an infant's general health, EIMC providers can refer clients for further screening.

5.2 Special considerations for EIMC eligibility

Following are several nuances related to EIMC eligibility that are not discussed in the 2010 clinical manual (WHO 2010). These considerations may assist countries in setting clear EIMC eligibility policy.

Weight-for-Age (WFA)

The EIMC manual provides guidance for EIMC eligibility based on a minimum birthweight of 2,500 g (WHO 2010). However, some infants may be born below this weight but gain weight well. Others may be born above this weight but gain weight poorly or even lose excessive weight (beyond the small normal weight loss in the first 1-2 weeks of life), suggesting underlying illness. Establishing what should be the minimum WFA at the time of screening for EIMC can account for many of these factors. Consider requiring that every infant be in at least the third percentile (2,500 g for males at birth) for WFA on the WHO standard growth curve⁴ immediately prior to EIMC. (If not already on the infant health card, the appropriate WHO WFA chart is available on the WHO site.⁵) Beyond this, additional criteria programs could require as a further safeguard are that the infant:

- If < 2 weeks of age, weigh at least 90% of his birthweight (if known)
- If 2 weeks of age or older, not have lost weight since his last weight check (if last weight is available)

With the WFA approach, having had low birthweight will not exclude a healthy infant if he is several weeks old and his WFA percentile has increased sufficiently. Thus, parents/guardians of an infant born at under 2,500 g could be asked to return for reassessment for EIMC in 2 weeks or a month, and he may become eligible based on his WFA at that time.

With the further addition of the birthweight/weight check criteria, infants who are not gaining weight properly even if above the 3rd percentile for age (e.g., an infant born in the 90th percentile who falls to the 10th percentile) will not receive immediate EIMC. Instead, providers should refer for further evaluation and growth monitoring, or refer to national guidelines for next steps. If this practice can be achieved, the program can avoid circumcising infants who are at high risk for serious short-term health problems regardless of the EIMC procedure, and instead refer them for potentially life-saving interventions. This can also prevent EIMC from being incorrectly blamed for health problems in these infants.

Individual programs will need to determine what level of complexity is feasible to use in weight criteria. At a minimum, using WFA at the time of EIMC as a criterion should be possible for almost all infants, except those for whom even the approximate birth date is unknown, since a scale is a necessary equipment item for EIMC. Existing experience is primarily with using the WFA criterion alone. Use of the additional criteria based on birthweight and last weight check may not be feasible in all programs. In some cases, infants will present without reliable birth weights and past weight checks, due to home births, broken scales, or other causes. In other cases, program leaders may feel that the complexity of the additional criteria will introduce error. For these reasons, programs will need to determine whether

⁴ http://www.who.int/childgrowth/standards/weight_for_age/en/

⁵ http://www.who.int/childgrowth/standards/cht_wfa_boys_p_0_6.pdf?ua=1

these additional criteria can be practically used. Further experience could demonstrate whether they would effectively identify a significant percentage of infants at high risk. A job aid for determining infant weight eligibility using all criteria is available as **Appendix C**, and can be modified to use only the WFA criteria.

HIV-exposed or HIV-infected infants may be at increased risk of failing to meet WFA criteria. See **Section 5.4** for considerations regarding assessment and management of HIV exposure.

Gestational Age

Infants who were born before 37 weeks gestational age but meet the other eligibility criteria can be circumcised after they reach 37 weeks “corrected gestational age” (gestational age at birth plus time elapsed since birth), as long as this occurs before the 61st day of life: i.e., if the infant was born at more than approximately 28.5 weeks gestational age. Infants who are more premature can be referred for specialist assessment. Many infants may have unknown gestational dates; in this case, WFA and the other contraindications can be used to determine eligibility.

HIV-exposed infants may be disproportionately represented in the population of clients born at less than 27 weeks gestational age. See **Section 5.4** for considerations regarding assessment and management of HIV exposure.

Maternal Tetanus Immunity Status

Neonatal tetanus can occur if tetanus spores contaminate any wound in a susceptible infant, but can be prevented when pregnant women are immunized to meet the criteria to confer PAB and clean practices are used during delivery and in the care of the infant’s umbilical cord. Specific considerations:

- The forthcoming WHO document “Protecting All People Against Tetanus: Implementation Guide for Sustaining Maternal and Neonatal Tetanus Elimination” (working title) states: “An infant is [protected at birth] if the mother received: (i) two TT [tetanus toxoid] doses while pregnant with the child, OR (ii) one TT dose while pregnant with the child and one or more doses at any time before that pregnancy, OR (iii) no dose while pregnant with the child and three or more doses at any time before that pregnancy.”
- Verifying the infant’s PAB status by reviewing complete documentation of the mother’s immunization status is ideal, if such documentation is available. However, if it is not, the mother’s self-report of her vaccination status will suffice, according to the forthcoming WHO document.
- If PAB cannot be ascertained or is not evident, there is no known intervention to produce sufficient immunity to protect against tetanus before 60 days of age. The first tetanus toxoid-containing vaccine, administered in the first 2 months of life, will not confer sufficient immunity; additional booster doses are needed, at which point the child is older than the recommended age parameters for EIMC and may have to wait for VMMC as an adolescent or adult.
- In the absence of global guidance, countries/programs are left to develop a policy on whether infants who do not have PAB can receive EIMC. The safest option in the absence of confirmed PAB may be to defer circumcision until adolescence.
- Regardless of the approach to maternal vaccination requirements, clean care practices should be followed at the facility and included in instructions for home care (see **Box 4**).

Box 4. Skin preparation

WHO and PEPFAR recently developed an SOP and job aid for skin preparation prior to VMMC. While similar guidance has not yet been provided for EIMC, programs can consider adopting a similar approach. The materials⁶ recommend the following simple steps:

1. Apply an aqueous antiseptic solution of either povidone-iodine (7.5%–10%) or chlorhexidine gluconate (2%–4%) (WHO Essential Medicine List⁷) three times
2. Allow antiseptic to dry completely after the third application—approximately 2 minutes
3. Practice hand hygiene and maintain sterile field throughout skin preparation and procedure
4. Leave antiseptic in place until client bathes at home

Vitamin K

The *WHO 2005 Pocket Book of Hospital Care for Children* (WHO 2005) recommends vitamin K for all newborns, and the 2010 WHO EIMC manual (WHO 2010) recommends routine administration of vitamin K be considered. Vitamin K deficiency bleeding can occur in infants up to 6 months of age, although it most commonly occurs either in the first week of life (classical) or at 3 to 8 weeks (late). The risk of uncontrolled bleeding is substantially higher in infants under 8 days of age than in older infants (about 1 in 60 versus 1 in 250⁸) in settings where vitamin K is routinely given at birth, and is over 80 times more common in infants who have not received vitamin K than in those who have. Breastfed infants are at greater risk than those who are formula-fed because there are lower levels of vitamin K in breast milk than in formula. Early studies of vitamin K administration prior to EIMC found that among infants given intramuscular vitamin K, 0%–3% experienced postcircumcision bleeding, while among those not given prophylaxis, 14%–36% experienced some bleeding (Zipursky 1999; Sutor et al. 1999; American Academy of Pediatrics Vitamin K Ad Hoc Task Force 1993; Vietti et al. 1960, 1961). Side effects of intramuscular (as opposed to intravenous) vitamin K are extremely rare, but all intramuscular injections carry risk of temporary bruising and soreness at the site, and a very small risk of infection which sterile technique is used to minimize.

In the absence of global guidance, the onus is on national governments and programs to develop policies around vitamin K provision for EIMC. Options to consider include:

- Recommending or requiring vitamin K before or at the time of EIMC (and providing it where necessary), either for all infants or for those circumcised before 8 days of age
- Making vitamin K available at all EIMC delivery sites for emergency administration in case of bleeding
- Working with RMNCAH leadership to initiate a simultaneous policy of vitamin K administration to all newborns (although EIMC-specific policies would still be needed for infants not born in a facility)

A final note: In areas where home births and/or incomplete prenatal care are common, providers may find that regardless of national ANC protocols, infants presenting for EIMC have not received vitamin K and their mothers have not received HIV testing to determine infant HIV exposure. Local EIMC services may need to be structured to address these issues efficiently. Furthermore, in such areas, many infants may be ineligible for EIMC due to lack of maternal tetanus vaccination or documentation thereof, depending on EIMC program policy.

⁶ <http://project-ig-resources.jhpiego.org/resource/vmmc-skin-preparation-and-wound-care-to-reduce-the-risk-of-infections-and-tetanus/>

⁷ <http://www.who.int/medicines/publications/essentialmedicines/en/>

⁸ <https://www.cdc.gov/ncbddd/vitamink/facts.html>

5.3 Contraindications for EIMC

A standardized set of contraindications for EIMC will allow providers to confidently screen clients. Below is a list of appropriate contraindications, incorporating the considerations discussed in this section:

- Family or personal history of bleeding disorders: Refer as appropriate for a positive screen and do not circumcise without consultation with a specialist
- Age < 12–24 hours (to be determined locally) or > 60 days
- Corrected gestational age < 37 weeks
- Newborn has not yet voided (circumcising an infant who is later found to have urethral obstruction can lead to confusion about the cause of the obstruction)
- History of convulsions, or history or evidence of hematological disorders
- Any deviation from national policy on vitamin K and maternal tetanus immunization requirements
- Weight below the program's chosen eligibility cutoff (see section 5.2), including the minimum weight for age
- Active/current neonatal sepsis or suspicion of infection, jaundice, or severe illness requiring hospitalization of the infant
- Acutely ill (abnormal vital signs when quiet, respiratory distress or impairment, or poor responsiveness or tone), but note that infants with prior illness now resolved or with minor upper respiratory symptoms (drainage and congestion) that are not causing respiratory distress can be circumcised (see **Section 8.1** for detailed provider competencies for identifying acute serious illness)
- Yellow sclerae or purpuric skin lesions
- Loud heart murmur or other abnormal heart sounds, crackles or other abnormal lung sounds, or other obvious physical abnormalities
- Penile length < 1 cm
- Any genital abnormality, as foreskin may be required for repair, including but not limited to:
 - Penile torsion/median raphe not in midline
 - Hypospadias/blind urethral pit
 - Buried penis
 - Penile-scrotal web
 - Hydrocele
 - Dorsal hood/ventral foreskin missing
 - Mega meatus
 - Ambiguous genitalia
 - Any other abnormality that may require consultation with a urologist

5.4 Assessment and management of HIV exposure

While HIV exposure and confirmed HIV infection are **not** contraindications for EIMC, it is important for every client evaluation to ensure that:

- All **HIV-exposed infants** are receiving the recommended care (including infant testing, co-trimoxazole prophylaxis, and antiretroviral prophylaxis per national guidelines, as appropriate) and comprehensive general health care.
- **HIV-infected infants** are identified early and provided with antiretroviral therapy services, ideally at the point of EIMC service.

Parents need to understand that if they choose EIMC for their HIV-exposed young infants, the procedure will not protect the infant from perinatal HIV acquisition, including HIV acquisition through breastfeeding. However, with timely intervention, the majority of HIV-exposed infants will not become HIV-infected perinatally and EIMC still has the potential to reduce their risk of acquiring HIV later in life. Additionally, circumcision confers non-HIV-related benefits including reduced risk of several other STIs, and in infants it reduces the risk of urinary tract infections.

HIV exposure can be assessed by:

- Verifying maternal HIV status during ANC visits by reviewing antenatal records, including a test within the last 3 months, or at the interval prescribed in national retesting guidelines for pregnant and breastfeeding women
- For newborn infants whose mother's HIV serostatus is unknown (not tested according to national guidelines in pregnancy): arranging or performing rapid antibody testing for the mother after appropriate counseling
- For infants whose mother is not available for testing: verifying HIV exposure status using a rapid test (valid through 4 months of age); if the infant's rapid test is positive, the infant is HIV-exposed (maternal antibodies)—nucleic acid testing is then needed to determine if the infant is HIV-infected
- For providers familiar with HIV care: reviewing maternal viral load and/or history of antiretroviral therapy to identify high-risk infants—those whose mothers did not receive the antenatal and postnatal antiretroviral regimen prescribed by national guidelines for prevention of mother-to-child transmission

EIMC providers will be able to better serve families if they are familiar with national maternal HIV screening and HIV-exposed infant care guidelines, including recommendations for infant HIV testing and diagnosis, co-trimoxazole prophylaxis, and antiretroviral prophylaxis regimens. Infants who are first diagnosed as HIV-exposed in the EIMC setting or are found to not be receiving appropriate follow-up need to be referred or re-referred for HIV virologic testing and/or care as appropriate. When possible, offering treatment initiation to confirmed infected infants at the EIMC point of care is consistent with global efforts to eliminate barriers to initiation by starting as soon as possible after diagnosis.

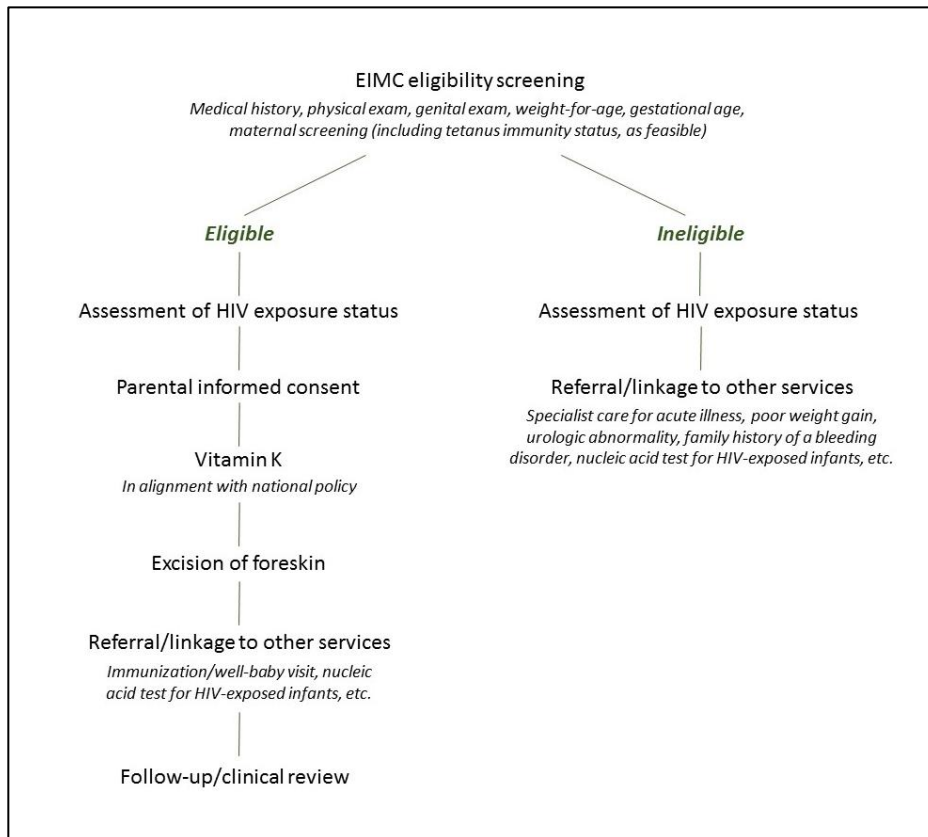
5.5 Appropriate referral/linkage for other conditions

Infants coming for EIMC may present with other conditions that may need referral for further management. **Infants meeting any of the above listed contraindications need appropriate referral for these conditions**, which are further described in **Core Standard 8** (except for age, a newborn < 24 hours old who has not yet voided, or not meeting any national tetanus/vitamin K criteria). Core Standard 8 includes referral of those with acute illnesses, diagnosed either by exam (fever) or by history (e.g., poor feeding or insufficient urination), for urgent treatment or specialized care. Those who do not meet weight criteria

should be referred for further evaluation and support. Those who are HIV-exposed should be referred to appropriate testing and care. Those with congenital anomalies should be further evaluated and managed by the appropriate specialist.

Finally, if programs choose to deepen the integration of EIMC within RMNCAH services, the initial and even follow-up EIMC visits could be used to expand beyond the basic checks for acute and severe illness already described, to include a broader wellness check. This might include assessment and counseling on such issues as breastfeeding, cord care, family planning, and birth registration—always including making the necessary linkages and referrals if issues are found.

Figure 1. Overview of early infant male circumcision (EIMC) screening and services based on client eligibility



Core Standard 6: The EIMC procedure is always performed according to stipulated clinical and service standards

Intent

The provision of safe, good quality clinical care is at the heart of the delivery of male circumcision services, regardless of the client’s age. These activities require an interdisciplinary approach. Each practitioner is assigned a role and responsibilities according to his or her professional competence and credentials, as well as the program’s policies. Procedures and care are provided according to evidence-based guidelines.

Criteria

1. Infant male circumcision procedures are performed according to standard guidelines
2. Standard procedures are followed for the assessment and management of emergencies and complications
3. Immediate postoperative care is provided according to the standard protocol

Core Standard 6 encompasses the provision of the circumcision service itself, including ensuring quality and safety through the use of evidence-based guidelines. It can be subdivided into the circumcision procedure, the assessment and management of emergencies and complications, and the postoperative care provided prior to discharge.

Relevant Content from the 2010 EIMC Clinical Reference Manual

The 2010 manual provides step-by-step directions on how to properly apply wound dressings, illustrates normal wound healing, and enumerates general guidance for when to return to the clinic or hospital with complications (WHO 2010). Chapter 10 discusses the most common postoperative complications (bleeding, injury to penis, infection, etc.) and offers basic suggestions for management. See Chapters 9 and 10 of the manual for details.

6.1 Infant male circumcision procedures are performed according to standard guidelines

With respect to the surgical procedure, standard guidelines for the use of three major EIMC methods with extensive international experience of use are provided in the 2010 EIMC manual (WHO 2010). All use specific, correctly sized devices. Devices more recently introduced, such as AccuCirc, are under evaluation in countries like Kenya and Botswana. The latest information as of 2017 on WHO's review of AccuCirc data is available in a 2015 WHO technical advisory group on innovations in male circumcision report (WHO 2015).

6.2 Standard procedures are followed for the assessment and management of emergencies and complications

Emergencies

Considerations for emergency preparedness include:

- The necessary equipment (see **Core Standard 2**)
- The necessary provider training (see **Core Standard 3**), including infant resuscitation (adult resuscitation differs from infant procedures and cannot be used as a substitute) with refresher trainings offered at a predetermined appropriate interval (e.g., every 2 years)
- A plan and the necessary resources for immediate transfer and transport to the appropriate level of care for any infant who requires emergency care
- Assurance that quality pediatric emergency care capacity is available with a pediatric intensive care unit

Complications (AEs)

Programs need a nationally standardized set of definitions for EIMC AEs. The 2010 WHO EIMC manual provides descriptions, pictures, and management guidance for the following types of EIMC AEs (WHO 2010):

- Bleeding
- Too little skin is removed
- Too much skin is removed (including degloving)

- Injury to the penis or surrounding structures
- Thin mucosal layer not excised
- Reactions to anesthetic agent
- Pain
- Infection
- Urinary obstruction
- Adhesions
- Preputial glandular fusion
- Trapped penis
- Glans covered with penile skin due to preputial fat pad (not a true AE, but a common cause of family concern that must be differentiated from insufficient skin removal)
- Meatal stenosis
- Skin bridge

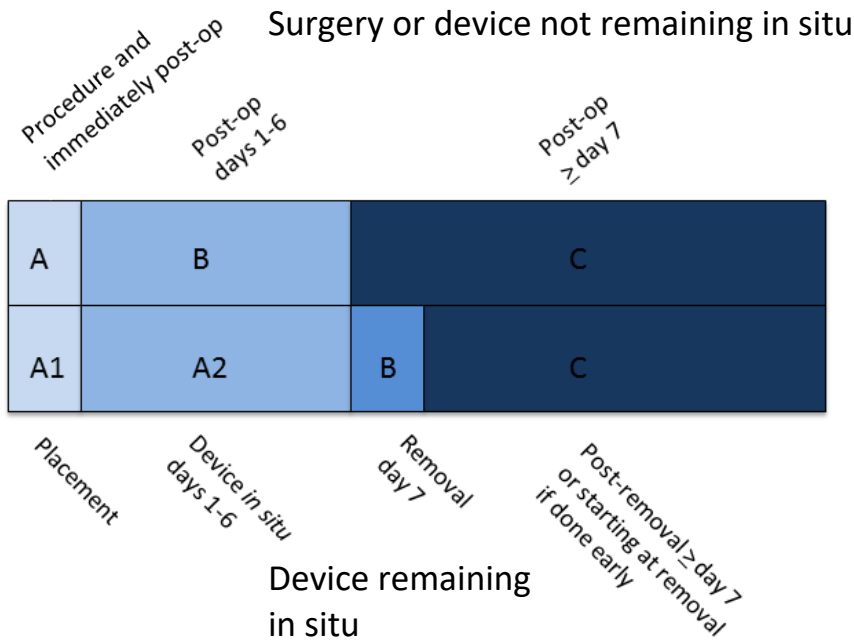
Additionally, there are other complications specific to the Plastibell method (retained ring, incomplete ring separation, bleeding beneath the device, etc.). Other complications may arise that are specific to other EIMC methods if those methods are prequalified and adopted (e.g., AccuCirc and PrePex for infants).

In VMMC, AEs are typically subclassified by severity and, potentially, by timing; these classifications may also be helpful in EIMC, particularly in national AE monitoring. Some EIMC AEs (e.g., bleeding) are essentially identical to those seen in VMMC. Other EIMC AEs (e.g., preputial glandular fusion) are unique to infants and do not have widely used severity classifications. Still others, such as pain or urinary obstruction, are similar to those seen in VMMC but cannot be classified using the same severity criteria (e.g., disability or a Likert pain scale) because they manifest differently in infants.

A potential approach to severity classification is in **Appendix D**, which is adapted from definitions used in a Jhpiego EIMC pilot. Some national EIMC programs may take a different approach, or might continue to use classifications already used in pilot studies conducted in their territories. In each country, the usefulness of its AE definition and management algorithms is best measured by the provider capacity to identify, classify, manage, and refer AEs. Programmatic experience indicates providers are more confident and effective in addressing AEs when they have detailed SOPs and established referral mechanisms for cases requiring specialist care.

Programs planning to also classify AEs by timing could consider using the Adverse Event Action Guide's timing classifications (shown in **Figure 2**) for surgical VMMC (for programs using devices which do not remain in situ) or device EIMC (for any programs using devices which do remain in situ).

Figure 2. Adverse event (AE) timing



For circumcisions performed surgically or with devices not remaining in situ, AEs are classified as follows:

- A = intraoperative (occurs during surgery or prior to discharge from facility)
- B = postoperative (occurs 1–6 days after surgery and discharge)
- C = postoperative (occurs ≥ 7 days after surgery and discharge)

For circumcisions performed using devices that remain in situ, AEs are classified as follows:

- A1 = during placement of device
- A2 = after device placement and before removal (typically occurring 1–6 days postplacement)
- B = during device removal
- C = after device removal (typically after day 7)

Adapted from Adverse Event Action Guide for Voluntary Medical Male Circumcision (VMMC) by Surgery or Device, 2nd ed., 2016. <https://www.malecircumcision.org/resource/adverse-event-action-guide-voluntary-medical-male-circumcision-surgery-or-device-2nd>

6.3 Immediate postoperative care is provided according to the standard protocol

The WHO EIMC manual provides instructions for immediate postoperative wound dressing and home care (WHO 2010). An additional consideration for programs is what procedure to use for postoperative observation and vitals monitoring. One possibility is to take the same approach recommended in the WHO manual for VMMC (WHO 2009): check vitals immediately postoperatively, and then again 20 minutes later to ensure they are stable and normal before discharging the patient. A dressing check could be done at the time of discharge to rule out continued bleeding. Much of this observation can take place during the time taken to explain home care instructions. Instructions should include avoiding the use of home remedies on the wound. See more on home care instructions in **Core Standard 8**.

Core Standard 7: Infection prevention and control measures are practiced throughout and following the EIMC procedure

Intent

The facility effectively implements infection prevention and control processes by involving staff and clients in observing standard precautions. Infection control surveillance, data collection, and corrective measures are conducted to reduce the likelihood of surgical site infections.

Criteria

1. Infection prevention and control policies and procedures are available.
2. Infection prevention and control measures are practiced according to policy and procedures.

Infection prevention and control standards are the same for EIMC as for surgical VMMC procedures, though EIMC also serves as an opportunity to examine and reinforce umbilical cord stump care. See home care instructions under **Core Standard 8**, pp. 48–49 of the WHO VMMC QA guide (WHO 2008), and the following resources:

- Project IQ, VMMC skin preparation and wound care to reduce the risk of infections and tetanus (provider and client resources), <https://project-iq-resources.jhpiego.org/resource/vmmc-skin-preparation-and-wound-care-to-reduce-the-risk-of-infections-and-tetanus/>
- CDC, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf>
- WHO: *Prevention of Hospital-Acquired Infections: A Practical Guide*, <http://www.who.int/csr/resources/publications/whocdscsreph200212.pdf>

Core Standard 8: Continuity of care, including referral to other services, is provided as needed for all infants who visit EIMC services

Intent

Systems and procedures are in place to promote effective follow-up care.

Criteria

1. An effective referral system is in place
2. The parent/guardian is given discharge instructions
3. A follow-up schedule is confirmed

Relevant Content from the 2010 EIMC Clinical Reference Manual

The 2010 manual recommends referral and feedback arrangements be in place to respond to emergencies and refer as necessary for contraindications, including care and support for HIV-exposed infants (WHO 2010). The manual also recommends information about family planning and infant feeding as well as referrals as needed for parents/guardians. See p. 108 of the manual for information on referrals. The manual also addresses discharge instructions and post-procedure home care instructions. See p. 79 and Annex 10 for details.

Meeting Core Standard 8 involves having effective systems for referring clients to any needed medical services outside the EIMC service; providing home care instructions for families of newly circumcised infants; and having effective systems in place for routine follow-up care.

8.1 An effective referral system is in place

EIMC providers make contact with infants during a stage of life when any illness can be serious, congenital diseases may not yet be diagnosed, and early intervention for health problems can substantially improve long-term outcomes. The EIMC visit can therefore be an important opportunity to make necessary referrals to care. The WHO EIMC manual recommends in particular that infants with evidence of illness, any urologic abnormality, or family history of a bleeding disorder be referred as appropriate (WHO 2010). More generally, when programs develop criteria for referral, most of the same concerns which exclude infants from EIMC are also appropriate reasons for referral, depending on which infant interventions are available in the health care system.

One unique aspect of EIMC service, as compared to VMMC, is that it may often be provided by the same health care staff member (e.g., a midwife or Expanded Program on Immunization nurse) who would also care for the infant's referable medical condition. In these cases, "referral" may consist of entry into a defined program or protocol rather than referral to another health care provider. However referral is accomplished, ensuring that provider competencies and EIMC program policies include the basics of recognizing and referring for serious conditions will help providers avoid missed opportunities to connect infants who have urgent medical needs to appropriate care. This might include:

- **For infants with acute illnesses:** In many countries where VMMC and EIMC are provided, the first few months of life carry high risk for morbidity and mortality. Every clinical encounter with an infant under 2 months of age is potentially a life-saving opportunity to recognize and refer an illness that could become life-threatening or seriously impact early development. Such illnesses are usually the result of infectious diseases, including pneumonia, diarrhea, or malaria. Preparing providers to recognize and refer for dangerous illnesses may include ensuring that they:
 - Are familiar with concerns raised by caregivers that can indicate serious illness, including poor feeding (can be an early sign of many serious diseases, including neonatal tetanus), inconsolable crying (often defined as crying longer than 3 hours), decreased responsiveness or activity, decreased numbers of wet diapers, and difficulty breathing or very rapid breathing.
 - Are familiar with normal vital signs and concerning physical exam findings for infants up to 2 months of age (e.g., recognize abnormally rapid breathing at rest and respiratory distress evidenced by intercostal retractions with inspiration; these are concerning signs for possible severe pneumonia or other respiratory emergencies of infancy). A set of ranges for normal vital signs that can be used is:
 - Temperature: 36.5°–37.5°C
 - Respiratory rate: 30–60 breaths per minute
 - Heart rate: 120–160 beats per minute
 - Recognize that a fever above 38.0°C is a medical emergency in any infant of EIMC-eligible age, regardless of whether or not he has undergone EIMC and regardless of the presence or absence of other signs.
 - Recognize normal muscle tone and responsiveness for young infants so that they will note if an infant is floppy, has abnormally high tone or spasms (a potential sign of tetanus), or is poorly

responsive and difficult to arouse. These are indications of serious illness that needs emergency care.

- If the EIMC provider will be the initial provider responsible for stabilizing a seriously ill child, are familiar with up-to-date Integrated Management of Childhood Illness (or the nationally favored equivalent) protocols for child assessment and disease severity classification at minimum, and management.
- In all these cases, are familiar with the local process for quickly obtaining appropriate emergency room or hospital care, keeping in mind that infants with tetanus may need referral to centers able to provide tetanus immune globulin.
- **For infants who do not meet the program's weight eligibility criteria** including weight-for-age (see section 5.2), or who otherwise meet national referral standards for poor weight gain: Providers should be familiar with referral in accordance with national protocols for failure to thrive, possibly including parental education, assessment for supplementary food programs, more frequent returns for weight check, and—ultimately—referral to a higher level of care.
- **For all infants:** Assessment of HIV exposure and appropriate referral (see **Section 5.2** for details on the below elements):
 - **For infants who are HIV-exposed:** Providers should be sufficiently familiar with national guidelines and practices around infant HIV to recognize whether an HIV-exposed infant is receiving appropriate follow-up care and treatment (such as diagnosis by nucleic acid testing and prophylactic co-trimoxazole) and know how to arrange referral to appropriate services if needed.
 - **For infants whose HIV exposure status is unknown:** Providers should be familiar with national guidelines for establishing an infant's HIV exposure status by maternal HIV testing during pregnancy and the postpartum period and how to establish HIV exposure status of the infant when the mother is not available. The WHO recommends periodic maternal testing during breastfeeding, but the precise interval should be specified in national policy (WHO 2016). The WHO recommendations also state that when the mother is not available, rapid diagnostic tests for HIV serology can be used to assess HIV exposure only in infants less than 4 months of age (WHO 2016). Providers should determine whether the mother and infant have received the recommended testing, and refer to, or perform, indicated testing.
- **For infants who develop an AE after EIMC:** Facilities should have a prearranged referral and transport plan for any AEs that require specialist care. All EIMC providers and staff at facilities who might be called upon to assist in implementation should be familiar with this plan.
- **For infants with urologic abnormalities:** These should be referred prior to EIMC to appropriate pediatric or surgical services to determine whether they would benefit from interventions for correction.
- **Other considerations:** Providers may encounter infants with birth defects that are treatable if caught early (e.g., clubfoot), behavior abnormalities that suggest disabilities (e.g., deafness), social situations that may warrant supportive interventions, and other similar issues. Programs will need to strike a balance between delivering efficient care and remaining alert for the many treatable health issues that first appear in the first months of life.

8.2 The parent/guardian is given discharge instructions

Reviewing postoperative care instructions in detail with the family of the infant before discharge from the clinic or hospital is integral to quality of care and will minimize chances of complications. A postoperative

information sheet is essential for reinforcing key information and can be used as a tool to answer the family's questions and assure comprehension of key steps.

Basic instructions include:

- Management of dressing/bandage (will probably fall off within 24 hours)
- Cleaning and caring for wound (including access to clean water); **these instructions should be strongly emphasized**, as experience in EIMC pilots has demonstrated the crucial nature of preventing adhesions and infection
- Avoiding use of home remedies, including ash or dung
- Appearance during healing (expect some redness, typically worst 2–3 days after EIMC)
- Warning signs for AEs
- Emergency contact information for on-call health care provider(s) who can assist in the event of AEs or wound care/healing questions, and facilities that can provide emergency care

8.3 A follow-up schedule is confirmed

Including a routine follow-up visit at a defined time period is recommended in the WHO EIMC manual as a component of comprehensive care, though no optimal timing is specified (WHO 2010). The follow-up visit has several benefits, which if communicated effectively can encourage parents' compliance with the follow-up schedule:

- It creates an opportunity to check on the home care the infant is receiving, to ensure no practices are being used that could increase risk for AEs.
- It gives the provider the opportunity to identify and treat AEs early, preventing or minimizing long-term consequences, such as adhesions or trapped penis.
- It allows programs to assess their AE frequencies, including trends over time and clusters associated with specific areas or providers that may suggest a problem that needs intervention.
- More generally, a follow-up visit represents an important opportunity to ensure the infant is well during the period of life in which he is at highest risk for mortality and also gives caregivers an opportunity to ask questions or raise concerns about the infant and his care, whether related to the EIMC procedure or not. In fact, caregivers may erroneously attribute problems like diarrhea or rash to EIMC; it is important to educate families and communities about the true potential risks associated with EIMC so that EIMC programs are not hampered by false concerns.

Considerations for programs planning routine return visits include:

- **Schedule:** Determine a number or range of days after the procedure when follow-up will take place. Because the bandage usually falls off within 24 hours, it should be possible to easily inspect the wound at any time afterward. One consideration is that circumcision wounds typically have their worst appearance on day 2 or 3 after the procedure; at visits after this period, any worsening in the appearance of the wound provides an important clue to the possibility of infection. Globally, there is not a single consistent practice for circumcision follow-up; many infants discharged at one day of life are seen on the second day for a general health follow-up that includes examination of the circumcision wound, but this may not be the optimal timing specifically for observing the wound.
- **Content:** As with referral, collecting specific data from the assessment on an EIMC client form (or equivalent) can guide the provider's attention to important aspects of the visit. These could include:

- The infant’s vital signs and overall appearance, encompassing the same aspects assessed at the initial visit
- The family member’s report on whether the infant is feeding poorly, fussy, or urinating less than usual, measured in number of wet diapers daily. This provides important information about hydration status and ability to urinate. Newborns should have one wet diaper every 24 hours for each day of life (one on day 1, two on day 2, etc.) until the mother’s milk comes in, and then five or six every 24 hours.
- The family member’s report on the appearance of the wound and whether it is improving or the family member has any concerns
- The family member’s report on the care being given to the wound, and reinforcement of instructions on appropriate wound care to prevent infection and adhesions
- Results of physical examination of the wound
- Any necessary referrals for either AEs or EIMC-unrelated health concerns
- Scheduling of any necessary follow-up visits (typically only if there is an AE that requires management and follow-up)
- **Active follow-up in the case of a missed visit:** While not all adolescent and adult VMMC programs perform active follow-up for clients missing their routine return visits, infants’ vulnerability and lack of control over return visits may lead program planners to create protocols for following up infants who miss routine return visits. Protocols would require a practice of routinely reviewing client files from the appropriate date to determine whether visits are missed. Follow-up methods could include calls or texts to a contact phone number provided at intake, home visits by community health workers affiliated with the EIMC site, other methods, or a combination of approaches.
- **If programs do not stipulate a follow-up visit or active follow-up of a missed visit:** Parents/guardians will benefit from providers reinforcing care and emergency instructions, to contact the program should any questions or problems arise; there should be a hotline that is staffed 24 hours per day. An alternative approach is to routinely have a provider call the parent 3–7 days after the procedure to check on progress and check for comprehension of post-EIMC care instructions.

Core Standard 9: There is a proper M&E system for the EIMC programs

Intent

A process is in place to monitor and evaluate the quality and safety of services. The process includes data collection and analysis, actions taken to improve quality of care and services, and the monitoring of the effect of these actions.

Criteria

1. Service delivery data are completely and accurately collected and timely reported
2. Evaluation data are used for the planning and improvement of service delivery
3. There is a system for prompt reporting and review of AEs

Relevant Content from the 2010 EIMC Clinical Reference Manual

The 2010 manual envisions EIMC as being integrated into countries’ RMNCAH service delivery models, including their M&E frameworks (WHO 2010). Aligned with general program M&E principles, the manual provides specific guidance on how programs should devise their goals and objectives to be clear and quantifiable. The manual also lists examples of global-

national- and facility-indicators and offers advice on how to choose specific indicators, and Annex 14 of the manual provides a sample monthly site-level summary reporting form. See Chapter 12 and relevant annexes of the manual for details.

9.1 Service delivery data are thoroughly and accurately collected on the services provided

A detailed SOP can direct data collection to support routine program monitoring and reporting, including:

- A complete set of data collection and reporting tools:
 - Client forms with consistent data elements across sites/programs
 - Facility registers
 - Local and central secure electronic databases
- Clear expectations on periodicity of data collection, verification, QA, and reporting.
- Indication of roles and responsibilities for all program data management. Particularly for EIMC programs fully integrated in RMNCAH services and governance, M&E in EIMC may be integrated into the general M&E processes used by the health system and performed by the same staff.
- Coordination with other reporting structures (e.g., HIV- or RMNCAH-specific structures) as needed, based on national and donor reporting needs. This is essential to ensure all stakeholders have access to program data without double counting. At the same time, it may be possible to reduce caregiver paperwork burden and streamline integration into existing M&E systems by integrating routine EIMC aggregate reporting into existing facility-level routine reporting forms (e.g., monthly district health information system reports).

A sample EIMC client form is in **Appendix E**. This form can be used as is, or with data elements adapted/integrated within existing newborn client forms.

9.2 Evaluation data are used for the planning and improvement of service delivery

Patient safety and program quality are perennial priorities in any medical service. QA and QI processes can be applied in various ways, and several organizations have detailed guides outlining the steps and process. Most follow a similar pattern:

1. Set clear performance standards for a technical area
2. Support implementation according to those standards in an efficient way
3. Routinely track progress in achieving these standards
4. Reward achievement of standards and provide support for filling gaps in unmet standards

Given the robust QA and QI processes and tools in use in HIV programs in general and VMMC programs in particular, VMMC program managers have an opportunity to support EIMC providers, including RMNCAH colleagues, drawing lessons from the VMMC experience. This EIMC considerations document can serve as a first step toward establishing standards from which more intricate QA/QI tools can be developed. Routine QA/QI can identify areas for program strengthening and also identify vulnerabilities in EIMC service delivery approaches to inform policy and practice.

HIV and RMNCAH quality resources:

- Operations Manual for Delivery of HIV Prevention, Care and Treatment at Primary Health Centres in High-Prevalence, Resource-Constrained Settings: Edition 1 for Field-Testing and Country Adaptation, chapter 10, <https://www.ncbi.nlm.nih.gov/books/NBK310911/>

- Standards for improving quality of maternal and newborn care in health facilities: http://www.who.int/maternal_child_adolescent/documents/improving-maternal-newborn-care-quality/en/
- Standards-Based Management and Recognition: a process for improving the quality of health services: <http://reprolineplus.org/resources/standards-based-management-and-recognition-process-improving-quality-health-services>

9.3 There is a system for prompt reporting and review of AEs

As with VMMC, AE surveillance and management in EIMC must be prioritized to ensure that clients experiencing complications are promptly referred to qualified providers, and that AEs inform future QA/QI processes. It will also be helpful to have clear standards for determining what AE types require in-depth investigation (e.g., all those leading to death or hospitalization) and where responsibility for investigation lies, and to routinely include in investigations an assessment of the relatedness of the AE to the circumcision.

Given the high infant mortality rates (IMRs) in some EIMC settings, deaths and other AEs following but unrelated to EIMC will sometimes occur, and may be more common than in adolescent or adult VMMC. Although deaths and serious AEs can be minimized by careful adherence to EIMC eligibility screening and referral to necessary care, they will not be eliminated. Furthermore, as the programs scale up in locations that are not familiar with EIMC, AEs following EIMC may be erroneously interpreted by family and community members as resulting from EIMC. It is important to evaluate and appropriately reassure and educate families with any complaints or concerns. Reporting and investigative structures can anticipate a caseload proportionate to the existing IMR in the country. The latest IMR and other child mortality data are available in the WHO Global Health Observatory data repository.⁹

For more information on M&E, see the following WHO resources:

- Maternal, Newborn, Child, and Adolescent Health, http://www.who.int/maternal_child_adolescent/documents/monitoring/en/
- HIV/AIDS, <http://www.who.int/hiv/strategic/me/en/#tools>

⁹ <http://apps.who.int/gho/data/view.main.CM1320N>

Appendix A: Routine Equipment and Commodities for EIMC

Item	Specification	Quantity per procedure (if applicable)
Equipment		
Examination table	Minimum size 183 cm L x 60 cm W	1
Restraining board		1
Handwashing buckets		1
Examination light		1
Mayo table		1
Thermometer		1
Wall clock		1
Stopwatch		1
Neonatal weighing scale		1
Autoclave		1
Supplies		
Towels		1
Infant blanket		1
Baby diapers		1 pack
Baby wipes		1 pack
O drape	45x50cm, 2.5 inch hole	1
Solid drape	50x50cm	1
Sterile gauze		?
Vaseline gauze and/or Vaseline		?
Plaster	Transparent, micro pore, 7.6cm x 9.1m	1 unit/container
Sterile gloves size	Latex, powder free, sizes 7.5 and 8	2 of each
Examination gloves	Latex, powder free, size medium	4
Utility gloves		2
1 mL sterile syringe	27G	1
Color-coded trash cans (assorted colors)		
5-0 chromic catgut (for suturing in case of excessive skin removal)	75 cm	1
Sterile marker pen (optional)		1
Sterilization tape		1
Plastic apron		2
Surgical caps		2
Face masks		2
Liquid soap		1 or access to communal soap/sink
Soft brush for cleaning instruments		1
Hard brush for cleaning instruments		1
EIMC M&E tools		N/A
EIMC demand creation materials		N/A
Instruments		
Appropriate EIMC device		1
Instrument tray		1
Kidney dish		1

Gallipot		1
BP handle		1
Surgical blade	Size 20-24	1
Flexible probe (optional)	7.5 cm	1
Mosquito artery forceps—curved	Stainless steel, reusable 12.5 cm	2
Mosquito artery forceps—straight	Stainless steel, 12.5 cm	1
Dissecting scissors, Metzenbaum	Stainless steel, 14 cm	1
Adson forceps, serrated		1
Needle holder		1
Sponge holding forceps		1
Pharmaceuticals		
1% lidocaine without epinephrine		10ml
EMLA cream		30g
Paracetamol syrup	125 mg/5ml	100ml
Amoxicillin syrup	125 mg/5ml	100ml
Dextrose 10% (for pacifying the infant during the procedure)		50ml
Postoperative instructions on wound care and contact information		Multiple
Wall charts of WFA		1
Wall chart for lidocaine dosage by weight		1

Appendix B: Emergency Equipment and Commodities for EIMC

Item	Specification	Quantity per procedure (if applicable)
Emergency equipment		
Neonatal resuscitation kit with suction	Oxygen mask sizes 0, 1, and 2	1
Oxygen—cylinder and regulator		1
Sphygmomanometer (with infant cuff)		1
Pediatric stethoscope	Mono, with chest piece	1
Oropharyngeal airways	Sizes 00 (40mm), 0 (50mm), 1 (60mm)	Multiple
Thermometer		1
Pulse oximeter with infant probe		1
IV cannulas, assorted sizes	19G, 23G, 24G, 25G	
Needles, assorted sizes	19G, 23G, 24G, 25G	
IV giving set, graduate	Infant type, 200ml	1
Glucometer		1
Glucometer strips		1 pack
Emergency medicines		
Adrenaline	1mg/ml	1 ampoule
Vitamin K	1mg/0.5ml	1 ampoule
Topical epinephrine (to control bleeding)		1
Gel foam (to control bleeding)		1
Other		
Access to a working vehicle/ambulance with fuel for emergency transport		
Emergency referral contact information and plan (to involve appropriate referral centers for emergencies which cannot be managed on site)		

Appendix C: Job Aid for Determining Infant Weight Eligibility for EIMC

See following page.

Job Aid: Does this baby weigh enough for circumcision?

1. All babies: Is weight today at or above the weight-for-age in the table?

Age	Is weight at least (kg):
0	2.5
1 week (7 days)	2.6
2 weeks (14 days)	2.8
3 weeks (21 days)	3.1
4 weeks (28 days)	3.4
5 weeks (35 days)	3.6
6 weeks (42 days)	3.8
7 weeks (49 days)	4.1
8 weeks (56 days)	4.3

Adapted from: WHO
Weight-for-age
BOYS: Birth to 13
weeks (percentiles).

Note to program planners:
elements below this table
can be deleted if program
will not use birth weight/
last weight check criteria

2. For babies under 2 weeks:

Is weight today also at least 90% of birth weight?

Birth weight (kg)	Weight today should be at least (kg)
2.5-2.8	2.5
2.9	2.6
3.0	2.7
3.1	2.8
3.2	2.9
3.3	3.0
3.4	3.1
3.5	3.2
3.6	3.2
3.7	3.3
3.8	3.4
3.9	3.5
4.0	3.6
4.1	3.7
4.2	3.8
4.3	3.9
4.4	4.0

For babies 2 weeks or over:

Is weight today increased from his last weight check, if available and reliable? (May be his birth weight.)

If yes to both 1 AND 2, infant meets weight criteria for circumcision. If yes to 1 but information for 2 (birth weight or last weight check) is not available and reliable, infant meets weight criteria for circumcision.

If no to either, do not circumcise today. Assess for acute illness and refer appropriately. If not acutely ill, refer for diagnosis of causes of poor weight gain and appropriate care.

Appendix D: Potential Approach to EIMC Adverse Event Severity Classification

Adverse Event	Description	Severity
Intraoperative or immediate postoperative		
Pain	Evidence of pain or discomfort (crying, fussiness, grimacing, and stiffness or squirming), but easily soothed	Mild
	Evidence of pain persists, requiring additional local anaesthesia intraoperatively; or postoperatively, requires frequent soothing but responds to soothing	Moderate
	Evidence of pain that does not respond to additional local anesthesia intraoperatively, or postoperatively cannot be soothed	Severe
Bleeding	More bleeding than usual, but easily controlled with compression	Mild
	Requires sutures or a firm dressing to control	Moderate
	Requires surgical exploration, blood transfusion or transfer to another facility	Severe
Anaesthetic reaction	Mild localised allergic or irritant reaction at site, without swelling or systemic reaction	Mild
	Systemic reaction to anaesthetic that resolves spontaneously, requiring physician consult and extended monitoring in a facility, but not emergency medications or transfer to a high-level facility	Moderate
	Convulsions, coma, loss of consciousness, bradycardia, anaphylaxis or other reaction, requiring emergency medications and transfer to another facility	Severe
Excess skin removal	Noted at time of procedure, but not expected to result in any discernible adverse condition	Mild
	Requires sutures or left open to heal, with some scarring expected, but additional surgery not necessary	Moderate
	Degloving wound requiring re-operation or transfer to another facility	Severe
Injury to the penis	Mild bruising or abrasion, not requiring treatment	Mild
	Laceration of the glans or shaft requiring compression to control bleeding	Moderate
	Part or all of the glans or shaft is severed, requiring additional surgery or referral to another facility	Severe
Insufficient skin removal	Severity can only be assessed once healing is complete and swelling is gone.	Cannot classify

Postoperative		
Swelling	Mild swelling not causing distortion of the anatomy	Mild
	Moderate swelling causing distortion of the anatomy, but urination is normal and no surgical exploration required	Moderate
	Swelling that impedes urination or requires surgical intervention	Severe
Wound infection	Uncommon, and often requires an experienced provider to distinguish from normal healing. Redness and swelling still worsening after 48-72 hours or substantially worse than normal; or purulent discharge (which, unlike the film formed during normal healing, can be easily wiped away and may smell foul). Requires urgent intravenous antibiotics and transfer to high-level facility, whether or not fever or other signs of systemic infection are present.	Always severe in young infants
Bleeding	Dressing soaked with blood but no active bleeding on exam	Mild
	Bleeding that stops with compression, sutures or a firm dressing	Moderate
	Bleeding that requires surgical exploration, blood transfusion or transfer to another facility	Severe
Undesired cosmetic outcome	Parent/Guardian concerned but no discernible abnormality; only reassurance needed	Mild
	Visible abnormality, not requiring surgical correction; expected to resolve with time; only reassurance needed	Moderate
	Significant abnormality; requires re-operation or may require repair in future	Severe
Insufficient Skin removal	Foreskin covers less than 1/3 of the glans in resting position; reoperation may be considered when fully healed	Mild
	Foreskin covers more than 1/3 but less than 1/2 of the glans in resting position; reoperation may be considered when fully healed	Moderate
	Foreskin covers more than 1/2 the glans in resting position; reoperation may be considered when fully healed	Severe
Difficulty urinating	Urination possible but with discomfort or irritability (crying at the time of passing urine)	Mild
	Urination possible but only with dribbling	Moderate
	Complete obstruction of urine (8 hours with no wet nappy)	Severe
Post-operative adhesions	Parent/guardian concerned, but no significant adhesions visible on provider inspection	Mild
	Foreskin can be fully retracted by gentle hand retraction; requires daily application of petrolatum jelly with retraction at home	Moderate
	Foreskin cannot be fully retracted by gentle hand retraction; requires surgical intervention	Severe
Other	Includes: failure to remove thin mucosal layer of foreskin, preputial glandular fusion, skin bridge, trapped or buried penis, meatitis, meatal stenosis due to scarring	Severe by definition

Appendix E: Potential EIMC Client Form

SOCIO-DEMOGRAPHIC INFORMATION		
1. Client name (first, middle, last) _____		2. Client Number:
3. Birth date (DD/MM/YYYY) __/__/____	4. Date today (DD/MM/YYYY) __/__/____	5. Infant's age today (days)
6. Facility Name (Name in full):		
7. Sub-County of residence:		
8. Place of birth:	<input type="checkbox"/> Home <input type="checkbox"/> Health facility <input type="checkbox"/> Other (specify):	
9. Referred from (<i>tick one</i>):	<input type="checkbox"/> Self-referral <input type="checkbox"/> ANC <input type="checkbox"/> Maternity <input type="checkbox"/> Delivery <input type="checkbox"/> Pediatric ward <input type="checkbox"/> Pediatric outpatient <input type="checkbox"/> Other (specify):	
10. Parent/guardian name: (<i>tick all that apply</i>)	<input type="checkbox"/> Mother:	
	<input type="checkbox"/> Father:	
	<input type="checkbox"/> Guardian:	
11. Telephone number:		
CONSENT STATUS		
12. Written informed consent obtained? (<i>tick one</i>)	<input type="checkbox"/> YES <input type="checkbox"/> NO (<i>MC should not be performed</i>)	
13. Written Consent obtained from (<i>mandatory</i>)	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Guardian	
MEDICAL HISTORY		
14. Mother's HIV status : (<i>If unknown, offer testing or refer mother and infant as appropriate. Document referrals on final page. Do not delay circumcision due to mother's HIV + or unknown status.</i>)	HIV test date (DD/MM/YYYY): _____	
	Result (tick one): <input type="checkbox"/> Negative <input type="checkbox"/> New positive <input type="checkbox"/> Unknown <input type="checkbox"/> Known positive; in care <i>Negative HIV test must be documented. If obtained more than 3 months ago, repeat as per national guidelines.</i>	
15. Vitamin K administered? (<i>tick one</i>) (<i>Do not circumcise infant <8 days without 1 dose Vitamin K today or earlier</i>)	<input type="checkbox"/> YES (Administered today) <input type="checkbox"/> YES (Administered at birth) <input type="checkbox"/> NO	
16. Has the baby passed urine? (<i>tick one</i>) (<i>Do not circumcise if urination not reported</i>)	<input type="checkbox"/> YES <input type="checkbox"/> NO	
17. Mother has documentation of or reports: two prior TT doses of which at least one was this pregnancy, OR three prior TT doses with none this pregnancy	<input type="checkbox"/> YES <input type="checkbox"/> NO	

Note: <i>If any answer below is yes, do not circumcise</i>		
18. Family or infant history of bleeding disorder (<i>excessive bleeding with surgery, minor injury, tooth extractions</i>)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
19. Infant history of convulsion	<input type="checkbox"/> YES	<input type="checkbox"/> NO
20. Other serious medical condition (<i>a previous health issue is not a problem if infant is well</i>)	<input type="checkbox"/> YES	<input type="checkbox"/> NO

Note: <i>If any answer below is yes, do not circumcise and refer as appropriate and document referral on final page</i>		
PHYSICAL EXAM/ELIGIBILITY		Check one
		Yes No
22. Current weight _____ kg Too low for age per job aid? (WHO child growth standards)		
23. Less than 37 weeks corrected gestational age (<i>if unknown, use other criteria</i>)		
24. Infant <12 hours or > 60 days old		
25. Any vital signs outside normal ranges when baby is calm	Temperature (C): _____ (36.5° – 37.5°C)	
	Respiratory rate (b/min): _____ (30-60 b/min)	
	Heart rate (bpm): _____ (120 – 160 bpm)	
26. Unwell-appearing or poorly responsive		
27. Medical contraindication (<i>specify</i>): (<i>includes jaundice or icterus, loud heart murmur or other abnormal heart sounds, petechiae or multiple bruises, crackles or other abnormal lung sounds</i>)		
28. Anatomic abnormality (<i>specify</i>): (<i>includes penile torsion, median raphe not midline, hypospadias or epispadias, abnormal urethra, buried penis, penile length < 1 cm, penile scrotal web, hydrocele, dorsal hood, abnormal scrotal rugae, foreskin abnormality, other genital abnormality</i>)		

EIMC PROCEDURE	
29. Date of procedure: _____	
30. Start Time:	Procedure started at: ____:____ (in 24 hrs)
31. End Time:	Procedure ended at: ____:____ (in 24 hrs)
32. Pre-operative medication:	Medication: <input type="checkbox"/> Paracetamol (give 15mg/kg body weight) <input type="checkbox"/> other: _____ Dose: _____ (refer to job aid for dosage)
33. Anesthesia:	Concentration and dose (tick one and fill in dose): <input type="checkbox"/> Lidocaine 1% _____ mL (maximum safe dose 0.3mL/kg) <input type="checkbox"/> Lidocaine 2% _____ mL (maximum safe dose 0.15mL/kg) diluted to total volume of 1 mL using sterile water for injection
34. Procedure	Technique (tick one): <input type="checkbox"/> dorsal penile nerve block <input type="checkbox"/> Other (specify _____)
	Device (tick one): <input type="checkbox"/> Mogen Clamp <input type="checkbox"/> Other (specify _____)
35. Intraoperative Adverse Events	Intraoperative adverse events: <input type="checkbox"/> Yes <input type="checkbox"/> No
	Adverse Event Type: _____
	Adverse Event Severity: <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe (document management of all AEs and referrals on the clinical notes page)
36. Name of Surgeon: Last Name _____ Other Names _____	
37. Cadre: <input type="checkbox"/> MO <input type="checkbox"/> CO <input type="checkbox"/> NO 38. Surgeon Signature: _____	
39. Name of Assistant Surgeon: Last Name _____ Other Names _____	
40. Cadre: <input type="checkbox"/> MO <input type="checkbox"/> CO <input type="checkbox"/> NO 41. Assistant Surgeon Signature: _____	
POST-OPERATIVE FOLLOW UP	
42. Date of Review: _____	
43. Type of Follow-Up	<input type="checkbox"/> Day 3 <input type="checkbox"/> Other (specify _____)
44. Vital Signs:	Temp. ____ Heart rate ____ bpm Respiratory rate: ____ b/min
46. Infant well-being	Has infant had poor feeding, fussiness or diminished urination? <input type="checkbox"/> YES <input type="checkbox"/> NO
45. Adverse Event reported:	Adverse event or abnormality in wound appearance? <input type="checkbox"/> YES <input type="checkbox"/> NO
	Adverse Event Type (enter AE Code): _____ (refer to the AE description form)
	Adverse Event Severity: <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe (Document management of all AEs and referrals on the clinical notes page)
46. Name of Reviewing Officer: Last Name _____ Other Names _____	
47. Cadre: <input type="checkbox"/> M.O. <input type="checkbox"/> C.O. <input type="checkbox"/> N.O. Reviewing Officer Signature: _____	
48. Return visit needed? <input type="checkbox"/> NO <input type="checkbox"/> YES, if yes when? Date _____	

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